MAYOR DE SAN ANDRES UNIVERSITY

HUMANITIES AND EDUCATIONAL SCIENCES SCHOOL

LINGUISTICS AND LANGUAGES DEPARTMENT

TRANSLATION OF DOSSIERS OF DRUG PRODUCT FROM ENGLISH INTO SPANISH AT FARMEDICAL SRL

Supervised Work submitted to obtain the Degree in Linguistic and Languages

By:

- **ARANA ALCAZAR INES NOEMI**
- **COPA CRIALES ALEJANDRA**
- **FLORES MIRANDA LARRY FERNANDO**

TUTOR:

- **LIC.: VIRGINIA CORONADO CONDE**

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By:

- Univ. Arana Alcazar Ines Noemi
- Univ. Copa Criales Alejandra
- Univ. Flores Miranda Larry Fernando

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Numeral note: _____

Literal note: _____

It was _____

Interim Director ……..

PhD.: Maria Teresa Terán Zubileta

Tutor: .....

Lic.: Virginia Coronado Conde

Tribunal: .....

Mg. Sc.: Eugenia Quispe Choque

Tribunal: ……..

Lic.: Virginia Ferrufino Loza

DEDICATION

This guided work is dedicated to my parents Claudio and Carmen, for their constant love, support and encouragement, to my sister Lorena and my brother Fabricio for their whole-hearted support

Alejandra

I would like to dedicate this supervised work to my father, Hector Flores, for his good solid advice, to my mother, Martha Miranda, for her support during my life, and to my brothers, Favio and Andy, for their unfailing support.

Fernando

For all the amazing people

I've me, who encouraged me

to fly towards my dreams.

To those who inspired me,

For loving an imperfect person perfectly.

Ines

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SUMMARY

This supervised work was carried out at FARMEDICAL SRL. It contains a Scientific Technical Translation (STT) of six dossiers from English into Spanish, which contain pharmacological information. The objective is to permit FARMEDICAL SRL obtain the license for preparing, distributing, importing, and marketing drug products throughout translation of dossiers. This supervised work allows to FARMEDICAL SRL fulfilled the sanitary register. The translation method used to translate the dossiers was "Direct Translation Method" and the translation procedure used to translate the dossiers was "Literal Translation". At the end of the process will be presented a glossary related to pharmacological and medical field.

Key words: dossiers, Scientific Technical Translation (STT), direct translation method, literal translation, pharmacological field, and medical field.

RESUMEN

Este trabajo dirigido fue realizado en FARMEDICAL SRL. En este trabajo se presenta una Traducción Técnico Científica (TTC) de seis dossiers del inglés al castellano, los mismos que contienen información farmacológica. El objetivo es permitir a FARMEDICAL SRL obtener el permiso de preparación, distribución, importación, y comercialización de productos farmacológicos a través de la traducción de dichos dossiers. Mediante este trabajo dirigido FARMEDICAL SRL podrá llenar el registro sanitario. El método de traducción usado para traducir dichos dossiers fue el "Método de Traducción Directa" y el procedimiento de traducción usado fue la "Traducción Literal". Al finalizar todo el proceso se presentará un glosario de términos relacionado con el área farmacológica y médica.

Palabras clave: dossiers, traducción técnica científica (TTC), método de traducción directa, traducción literal, área farmacológica, y área médica.

INTRODUCTION

A contribution to the society from students of "Mayor de San Andres University" (UMSA) is the development of pre-professional assignments in Public and Private Institutions. This contribution was realized through the implementation of projects where students apply all they have learned at the University. The Department of Linguistics and Languages has signed agreements with Public and Private Institutions in order to carry out projects on translation, perform researches or languages teaching. The Department of Linguistics and Languages offers "the Supervised Work" as a modality to obtain a degree. Therefore, students have the opportunity to put into practice their knowledge and skills to solve a problem or respond a need related to Applied Linguistics, Language Teaching, Translation or Researches in Public or Private Institutions.

In this case, we address translation matters along this work. First, we can assert that therefore of globalization, translation has become a global business and that the demand from consumers for translation of products, software information, or user manuals in their own language has increased. Such is the case of Scientific and Technical Translation (STT), which plays an important role in the exchange and transfer of information of science and technology internationally. The greater sophistication of industrial products has led to a growth in translation needs; such as pharmaceutical industries, which requires accurate and up-to-date technical knowledge.

In this way, FARMEDICAL SRL and the Department of Linguistics and Languages at "Mayor de San Andres University" signed an agreement, which aimed at developing translation activities in order to allow students to perform practices to establish an institutional strengthening and cooperative framework between both institutions. Therefore, undergraduate university students have the opportunity to respond needs related to translation in the institution and gain experience on the working field.

This supervised work was carried out at FARMEDICAL SRL in La Paz city from December 5th, 2018 to June 5th, 2019. FARMEDICAL SRL is a company in charge of

importing, marketing and developing pharmaceutical products. This work is focused on the translation of six dossiers that contain valuable written information, which need to be translated from English into Spanish. The information of drug products is presented in PDF format. Dossier´s content not only guides health personnel, doctors and patients to access and understanding the information, but also to obtain the Sanitary Certificate of Product Registration. Hence, translation process seems not an easy task, because the present work deals with Scientific and Technical Translation, in which the students address the translation process i.e. methods and techniques of translation, including the text analysis. The stages followed during the process were: recognition of the information and the technical terminology of the source text; selection of the appropriate translation method; the first draft, the revision and correction of the translation; and the proof reading.

Finally, this report is made up of five chapters: institutional framework, work proposal, development of the proposal, results, and conclusions and recommendations. The first chapter describes the information, function, history, mission, vision, organization, and localization of FARMEDICAL SRL and also deals with the needs analysis (SWOT analysis and Identification of the problem). The second chapter submits the work proposal, it involves the conceptual references, justification, objectives, fulfillment indicators, action strategies, and action plan. The third chapter involves the development of the proposal that gathers the main aspects about the work schedule, sequence of activities, initial achievements, and experiences. The fourth chapter focuses on the results obtained throughout the development of the proposal. Finally, the fifth chapter includes the conclusions and recommendations that come from the whole process.

CHAPTER I

IDENTITY OF THE INSTITUTION

This chapter is divided in two sections. The first part describes the institution and the second part develops the SWOT analysis.

The complete information about the history, mission, vision, organization and localization of FARMEDICAL SRL was taken from Farmedical's the web page[1].

1.1 INSTITUTIONAL FRAMEWORK

FARMEDICAL SRL is a company legally established by shareholders with a vast professional experience in the importation, marketing and development of products within the pharmaceutical and cosmetic industry. As a private company, managers and workers of FARMEDICAL SRL are really engaged with public and private health of our country.

Through an efficient management of its resources detailed planning of its decisions and the continuous improvement of their processes, FARMEDICAL SRL achieves a higher effectiveness reaching its objectives, giving egalitarian access of pharmaceutical products to the society at reasonable prices.

FARMEDICAL SRL does its best efforts in order to contact foreign suppliers whose quality has been certified. Laboratories that fulfill the international regulations and can guarantee the origin of raw materials and prove ideal manufacturing procedures.

FARMEDICAL SRL facilities are certified by the local Health authorities to ensure a proper handling and storage in order to meet the international regulations.

FARMEDICAL SRL is part of the proposed initiatives by authorities regarding pharmacovigilance. FARMEDICAL SRL establishes complaints transmission channels

[1] http://farmedicalcorp.net/farmedical/FarmaPreCorporativa/index.php

of its users and intermediaries, backing the technical and therapeutic quality of its products.

FARMEDICAL SRL takes part in the Public Tenders and Direct Sales of all the Bolivian health institutions i.e. “Caja Nacional de Salud, Cossmil, Banca Privada, Caja Petrolera de Salud, Caja de Salud de la Banca Privada, Seguro Social Universitario, Caja Cordes” and others.

These tenders are formal contests that require a strict compliance of the international regulations in the purchasing processes as well as in the presentation and the therapeutic response of the products.

1.1.1 Background and History

FARMEDICAL SRL was established in November 2002 as a private initiative. In order to consolidate the prestige, reliability and competitiveness of the company and to establish an important presence in the market FARMEDICAL SRL committed only with guaranteed and certified commercial partnerships by the regulatory agencies of their countries.

During the years 2003 and 2004 FARMEDICAL SRL arranged all the procedures needed for its establishment. FARMEDICAL SRL carries out a market study and entered into some strategic partnerships regarding manufacturing and commercialization. FARMEDICAL SRL started the registration and the sanitary registers of its first products.

Then, in 2005 FARMEDICAL SRL officially started its activities introducing gradually hemoderivative, bio technologic, anesthetics, antibiotics and anti-inflammatory products. Some formulas were considered as new molecules in the country.

Between 2006 and 2008 the company entered totally to compete in the private market at a national level, FARMEDICAL SRL opened subsidiary offices in other Bolivian major cities such as Cochabamba and Santa Cruz, increasing considerably the commercial and administrative support team.

In 2010, the company already had built its own offices in other major cities such as Beni and Sucre and had designed qualified staff in charge and with total residence in Oruro, Potosi and Tarija.

During 2013, Farmedical's structure had consolidated by the opening of its new national headquarters in La Paz. During the same year, the company completed its national coverage with the opening of its own offices in El Alto, other important Bolivian city.

During the last four fiscal years, FARMEDICAL SRL has shown a lineal and sustainable growth, consistent with a pharmaceutical company in a development phase. The company has even outperformed the growth of the pharmaceutical market of the country as a whole.

The teamwork contributes to the growing of the company day by day, performing its diverse tasks, backed by the implementation of a quality guarantee system in accordance to the norms and that promotes the development and active participation in the continuous improvement of the company processes, obtaining a better client service and more accessibility to pharmaceuticals by the general population.

"We are proud of our understanding about the problems and opportunities in the pharmaceutical market; we are compromised with excellence under the umbrella of our certifications that backed our quality".

1.1.2 Mission

The mission of FARMEDICAL SRL is to provide health to the public with the marketing of pharmaceutical products with high standards of quality, safety and accessibility in terms of cost-treatment.

1.1.3 Vision

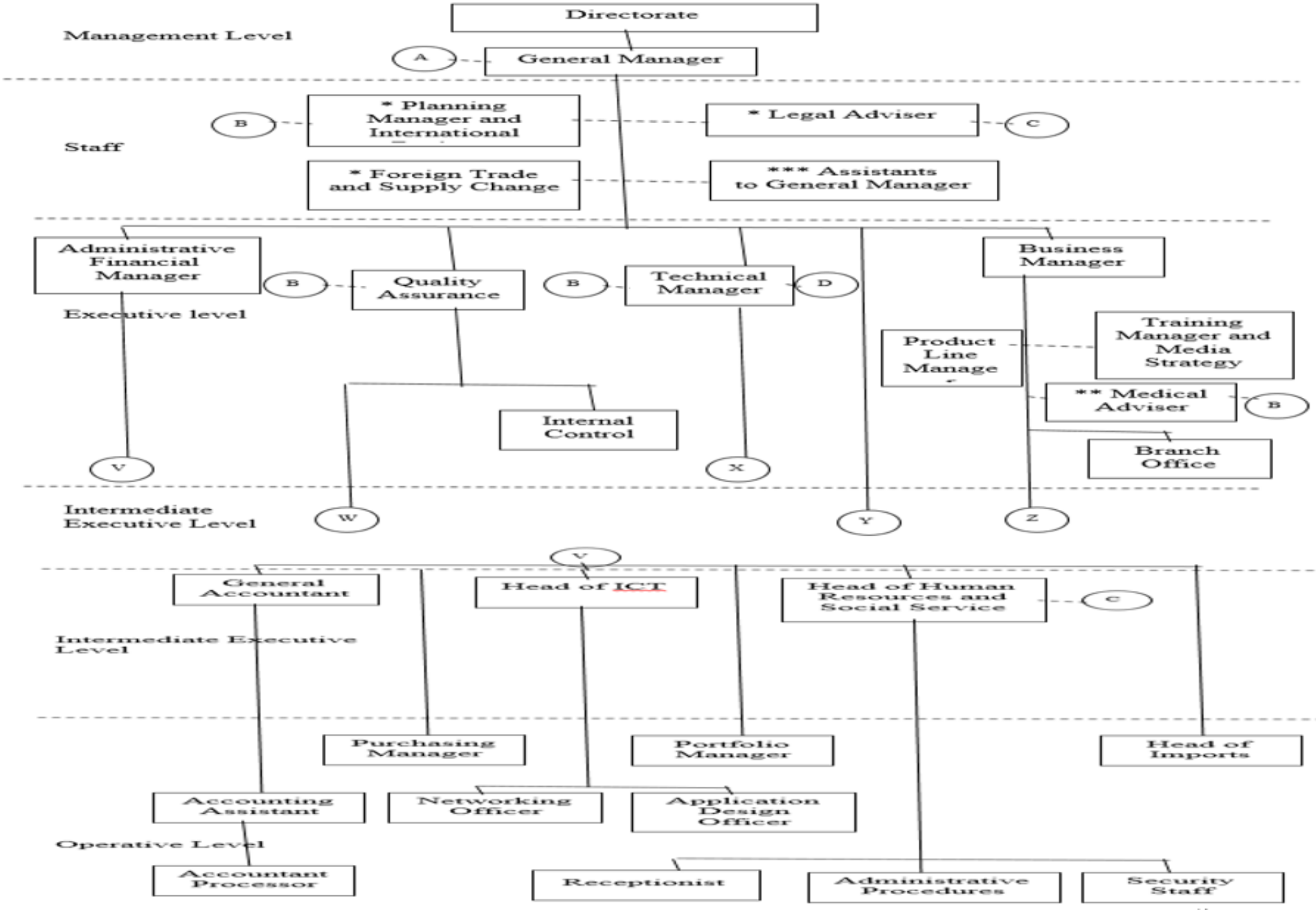
The vision of FARMEDICAL SRL is to become a leader company in the pharmaceutical market at an international level. Take part in all the supply chain processes

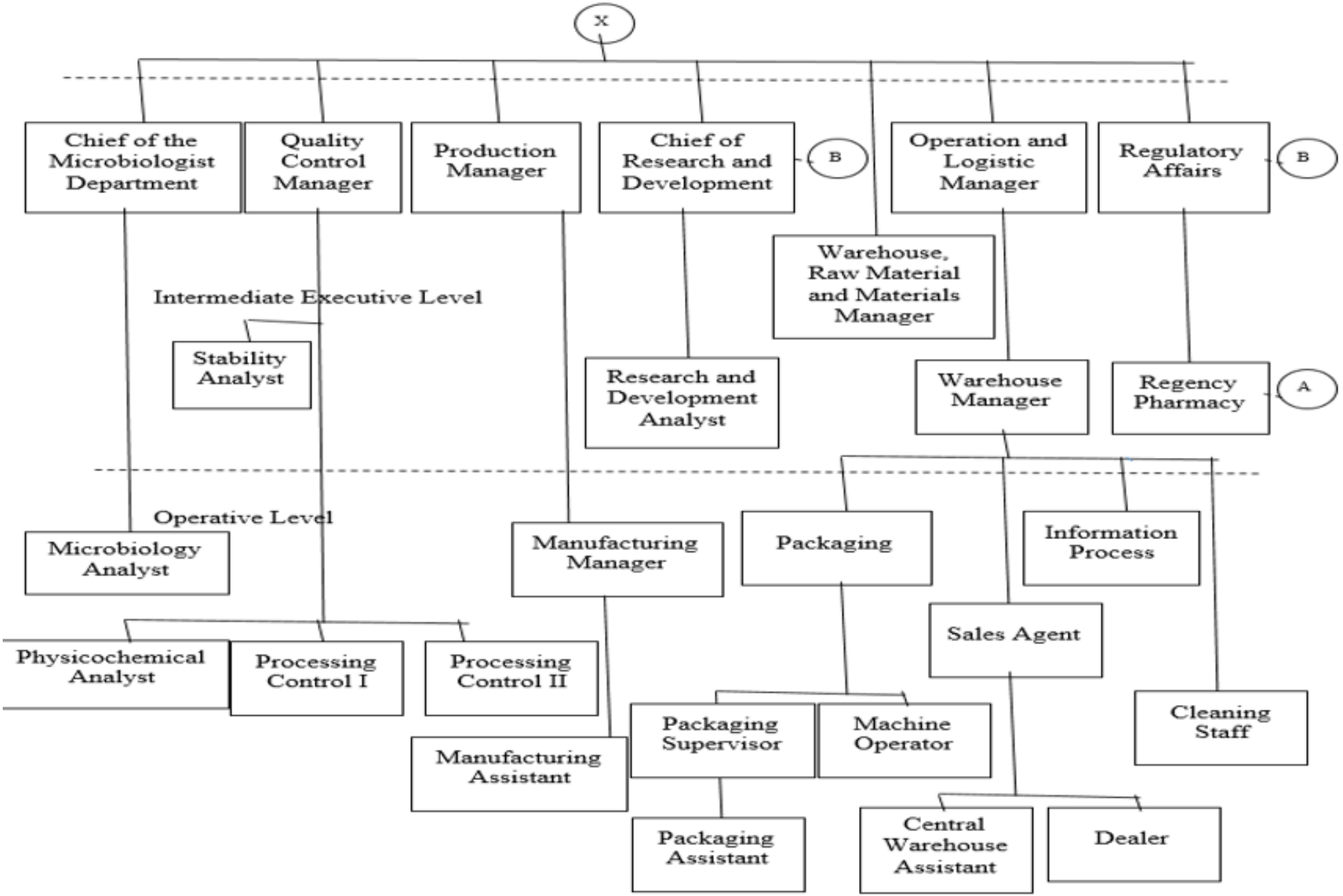
going from research and development to the final consumer and providing a good impression to the national pharmaceutical industry contributing to its global projection.

1.1.4 Organization

Chart 1 Organic Stricter of FARMEDICAL SRL

This chart describes the organic structure of Farmedical’s staff.


Management Level
Directorate
A
General Manager
Staff
B
* Planning Manager and International
* Legal Adviser
C
* Foreign Trade and Supply Change
*** Assistants to General Manager
Executive level
Administrative Financial Manager
B
Quality Assurance
B
Technical Manager
D
Business Manager
Product Line Manage
Training Manager and Media Strategy
** Medical Adviser
B
Internal Control
Branch Office
V
X
Intermediate Executive Level
W
Y
Z
V
Intermediate Executive Level
General Accountant
Head of ICT
Head of Human Resources and Social Service
C
Purchasing Manager
Portfolio Manager
Head of Imports
Accounting Assistant
Networking Officer
Application Design Officer
Operative Level
Accountant Processor
Receptionist
Administrative Procedures
Security Staff



(Source FARMEDICAL SRL)

1.1.5 Location

Chart 2 Companies' Headquarter

The company´s main headquarter is located in La Paz city.

(Source FARMEDICAL SRL)

1.2 NEEDS ANALYSIS

The purpose of these analysis is to identify the main needs of FARMEDICAL SRL, and based on these needs elaborate a working plan for responding the institutional problems.

1.2.1 SWOT ANALYSIS

> The SWOT analysis is a business analysis technique that any organization can perform for each of its products, services, and markets when deciding on the best way to achieve future growth (team FME, 2013).
>
> There is no such thing as a definitive SWOT for any particular organization because the strengths, weaknesses, opportunities, and threats depend on a large extent on the business objective under consideration (team FME, 2013).

According to these definitions, the SWOT analysis would help business in both; first to analyze and plan the best way to keep track of growth, strengths and weaknesses of any enterprise. And, in a decision-making process to examine and execute strategies in a more balanced, in-depth way.

Therefore, this technique is considered efficient when the weaknesses are reduced, the strengths are increased and the opportunities reinforce the achievement of the objectives in accordance to the mission and the vision of the institution.

It is important to mention that, the following SWOT analysis is based on the documentation from FARMEDICAL SRL, from a questionnaire, and from observation to the institution. First, FARMEDICAL SRL provided their written documents (institutional SWOT), then a questionnaire was supplied to the staff of Pharmacy and Biochemistry Department, and finally additional information was taken through observation.

The SWOT analysis was made from September to October 2018. The population consists of seven people in charge of Pharmacy and Biochemistry Department at FARMEDICAL SRL.

The process of data collection started by: first, sending a letter to the general manager of the institution; second, asking for permission to access the documentation and to apply a questionnaire; then, elaborating a questionnaire to determine the needs of the

institution; after that, coordinating the date of questionnaire supply with the institutional coordinator and people who would answer the questionnaire; and finally, providing the questionnaire.

The analysis of data is divided in two parts. The first part determines the internal factors and the second part determines the external factor. As follows:

Chart 3 SWOT Analysis

To determine the list of internal factors identifying strengths and weaknesses

STRENGTHS	**WEAKNESSES**
• Acquisition of manufacturing certificates • Years of experience • Importation of High-quality products • High-quality service • Highly qualified staff • Effective communication between leader to the staff • Continuous evaluation of the performance • Adequate equipment and tools	• Lack of product's promotion • Lack of training to the new staff • Reduction of the portfolio • Less financial support

To determine the list of external factors identifying threats and opportunities.

OPPORTUNITIES	**THREATS**
• Growth at national level • Diversity of products to expand the portfolio	• Investment expenditure • Increasing competition

• Regulations for obtaining the sanitary registration of medication. • Documents approved by the Ministry of Health to market Farmedical's products. • Participation in tenders by presenting dossiers	• Due date for the presentation of the dossiers to the Ministry of Health. • Failing in the date of document's presentation affects economically to the company • Rigorous control of the Ministry of Health.

1.2.2 IDENTIFICATION OF THE NEEDS

SWOT analysis results reflected that the presentation of the documentation to the Ministry of Health is relevant. According the Ministry of Health requirement all documentation must be presented in Spanish, but as FARMEDICAL SRL imports its products from different countries, all documents sent by the manufactures to FARMEDICAL SRL are written in English, for that reason, these documents need to be translated into Spanish.

The drug regulation No. 25235 states that the Dossiers for preparation, manufacture, distribution, importation, exportation, sale and market of drug products should be presented in Spanish. For that reason, FARMEDICAL SRL requires to translate their documents (Dossiers) in order to submit these documents for obtaining health records. In the case of not presenting the information on the due date, the company has to wait for the next date, which delays the marketing of their products, consequently affecting economically FARMEDICAL SRL.

Therefore, the purpose of this Supervised Work is to contribute to FARMEDICAL SRL through the translation of dossiers from English into Spanish that allows FARMEDICAL SRL to fulfill the Sanitary Register to obtain the license for preparing, distributing, importing, and marketing drug products.

CHAPTER II

WORK PROPOSAL

2.1 FOUNDATIONS

In this section, we develop the theoretical, epistemological and social basis of the proposal.

2.1.1 THEORETICAL BASIS

The present supervised work takes into account the theoretical basis of the following authors: *Peter Newmark, Eugene Nida* and *Vinay & Darbelnet*. This theoretical description would have been incomplete without reference to *Peter Newmark*, one of the founders of the Institute of Linguists and a fervent advocate for the professionalization of translators. Newmark's *Approaches to Translation (1981)* and A *Textbook of Translation (1988)* do not aim to promote any monolithic translation theory, but rather attempt to describe a basis for dealing with problems encountered during the translation process.

The contribution of *Eugene Nida* in the field of translation studies cannot be overstressed, with his two famous books in the 1960s: *Toward a Science of Translating (1964)* and the co-authored *The Theory and Practice of Translation (Nida and Taber, 1969),* attempting to give a more "scientific" sense to translation. Borrowing theoretical concepts from semantics and pragmatics, and being influenced by Chomsky's generative-transformational grammar (1965), Nida adopts a more systematic approach to exploring the field of translation studies. And finally *Jean-Paul Vinay and Jean Darbelnet* produced their "*Stylistique Comparée du Françaiset de l' Anglais (1958)*" which is a comparative stylistic analysis of the different translation strategies and procedures used in French and English.

2.1.2 TRANSLATION

Analyzing the term translation will ease our understanding of the theory, since the definition of translation will serve as the basis and starting point for this supervised work.

In words of **Peter Newmark** translation:

> Is a *craft* consisting in the attempt to replace a written message and/or statement in one language by the same message and/or statement in another language (Newmark 1981:7).

The noun craft doesn't just imply the act of crafting, as a matter of fact, it has connotative meaning, as Newmark assumes in his book "A textbook of Translation- a translator" a translator:

> A translator works on four levels: translation is first a *science*, which entails the knowledge and verification of the facts and the language that describes them- here, what is wrong, mistakes of truth, can be identified; secondly, it is a *skill*, which calls for appropriate language and acceptable usage; thirdly, an *art*, which distinguishes good from undistinguished writing and is the creative, the intuitive, sometimes the inspired, level of the translation; lastly, *a matter of taste*, where argument ceases, preferences are expressed, and the variety of meritorious translations is the reflection of individual differences (Newmark 1981).

Whilst for **Nida & Taber** the term translation

> Translation is the reproduction of the *closest natural equivalent* of the source language in target language firstly *in terms of meaning*, secondly *in terms of style*. Translating can be simply defined as transferring the message from the source language (SL) into the target language (TL), both in terms of meaning and style. So the ideal translation should make sense and be easily understood by the target readers. However, the message in the

> TL should be equivalent with that in the SL. The structure of a given language determines the way in which the speakers of that language view the world. (Nida, 1975:79)

As it can be observed, Nida's definition includes three main terms: 1) *equivalence*, which points to the original language; 2) *natural*, it points to the receptor language; 3) *closest*, it linked together on an extremely similar basis.

Meanwhile**, Vinay and Darbelnet** consider:

> Translation is *art* because it is possible to accept or reject several translation works throughout comparison to their fidelity and natural flow with original, it is also a *discipline* that has its own methods, particular problems and its perspective (Vinay and Darbelnet 1958).

From Vinay and Dabelnet's perspective, we rescued that: first, translation is a science because, it is necessary to use the appropriate methods or techniques. Second, it is art: for that reason, it is important to be cautious with the correct equivalence to the target language flows naturally.

To sum up, the term translation encompasses several distinct perspectives: it can refer to the process, the product or the abstract concept of translation. The sense of process centers on what a translator does in turning the source text (ST) into a target text (TT) in another language. The sense of product focuses on the text that is produced in the translating process. The sense of abstract concept of the general phenomenon can be said to be the general subject field.

2.1.3 TEXT ANALYSIS

Before conducting any translation, it is important for the translator to know the intention of the text or the type of text or its function. It is necessary a carefully and complete reading of the source text. P. Newmark indicates that before choosing a translation method for a text, it is necessary both to understand what it is about and to

analyze it from a translator's point of view. It means that the translator must perform *general* and *close* reading; the first one is to understand the subject and the concepts of the text and the second one brings a reader nearer to the text, i.e. as translators we have to know all the words both out of and in context.

Starting from the aforementioned, the result of those readings must therefore be the recognition of:

I) Criteria for analyzing a text

A translator has to make some generalizations about the text before taking the task of translation. Newmark suggest four criteria for analyzing a text:

a) The intention of the text

The understanding of a text involves a search for the intention of the text (by intention we mean the point of view of the text). The intention of a text is shown by the language used in the text, the ways of describing a text, and the *style*; all together represent the writer's attitude to the subject matter. If apiece is redundant or confusing, we can simplify, rearrange, clarify, and detail the text maintaining the *tone* and point of view displayed in the original.

In words of Nida the *style* refers to the way a text is written, a person's method of expressing himself through the written word. He subdivides the style in four text types:

- **Narrative:** A dynamic sequence of events, where the emphasis is on the verbs or for English 'dummy'; or 'empty' verbs plus verb-nouns or phrasal verbs.
- **Description:** This is static, with emphasis on linking verbs, adjectives, adjectival nouns.
- **Discussion:** A treatment of ideas, with emphasis on abstract nouns (concepts), verbs of thought, mental activity, logical argument and connectives.
- **Dialogue:** It emphasizes on colloquialisms and phaticisms.

To Nida the *Tone* is related with the use of words which changes the meaning of the text: There are four types:

- **Hot or strong**: Excessive use of intensifiers.
- **Warm:** The author's feelings are expressed in the text.
- **Neutral or objective:** There are no emotional expressions.
- **Cold:** It is based on facts.

b) Intention of the translator (readership)

In principle translator's intention is identical to that of the author of the SL text, says Newmark, but there may be certain instances where a translator may differ. Take for example a case of translation of advertisements where the translators need not always match the intention of the copy-writer. If a translator is translating such a text to persuade TL consumers to buy a certain product then he may have to change the style and the way of presentation in his translation. However, such instances are rare and mostly translators are expected to follow the original closely.

c) The reader and the setting of the text

Any translation is ultimately meant for a readership. Therefore, it is important to characterize the readership of the translation in terms of expert, informed or ignorant, age or young, etc. the likely setting of a text is that by which we indicate where the translation would be published? This is another point to be considered by the translator. Keeping both nature of the readership and setting of translation in view, a translator has to design his translation, *register* and style of presentation according to the requirements of his readership.

According to Nida, the *register* helps the translator to identify the type of readers the text would be addressed to, as well as the vocabulary that would be needed in the translation. It is divided into four:

- **Formal**: It has a grammar structure more elaborated and also a conservative vocabulary.

- **Technical:** It uses specific terms from a specific field.
- **Neutral:** It uses a basic vocabulary.
- **Informal:** The grammatical structure, vocabulary and idioms used every day.

d) The quality of writing

Lastly, a translator has to consider the quality of writing and the authority of the original text. Quality of a text derives from the intention of the text, subject-matter and the *style of writing*. If a writing efficiently fulfills the requirements of its subject matter and intention of the author, it is a good writing.

In a well-written text, every nuance of meaning should be regarded as important by the translator. Translators must follow and must make our best efforts to retain them in translation. Good syntax, use of fresh words that are rich in connotative meaning etc. attract us immediately for they are the qualities of a high-quality writing. A bad text would not only use stereotyped language phrases and ideas but also words and jargons of the contemporary fashion. Authority of text essentially derives from two things: from the quality of writing and from the status of the author. A sensitive translator would grasp both quality of writing and authority of the text and take his own decisions regarding translation in creative writing it is advisable to follow the style and every nuance of words used and in informative texts 'truth' should be given prime consideration.

II) Language function, Text categories and text types

Text categories and text types can be made either on the basis of subject matter, focus or on consideration of the function of language in a given text. Newmark and others distinguish text-types on the basis of language functions.

Language function: Since we make certain demands on language while using it, language has to serve certain functions both in our day to day speech and writing.

> (…) The main three functions of language are the *expressive* (the subjective “I form”), the *descriptive or informative* (the “it form”) and the

vocative or directive or persuasive (the "you form") and the minor functions being the *phatic*, the *metalingual* and the *aesthetic* (as quoted in Newmark 1981:21).

It is important to realize that, this division is an attempt to generalize language function; these generalizations are helpful only to the extent of understanding the main focus of a particular text which will help translators to choose an appropriate translation method.

- **Informative function** it focuses on the message of the text, external situations, facts, ideas or theories. Informative text is concerned with any topic of knowledge, for instance: manuals, technical reports, scientific reports, thesis, newspaper, etc.
- **Expressive function** it focuses on the mind and feelings of the author; he uses the utterance to express his feelings irrespective of any response. Some text considered expressive are literature text, autobiographies, and authoritative statements.
- **Vocative function** the core of this function is the readership or addressee. The term Vocative is used in sense of "calling upon" the readership to act, think or feel, in fact to react in the way intended by the text. Publicity, instructions, persuasive writings and sings are considered vocatives text.

Peter Newmark (1988:40) has shown the above three functions of language, text-categories and text-types in terms of a table which look as follows:

Chart 4 Text Analysis

Function	Expressive	Informative	Vocative
Core	Writer	Truth	Readership
Author's status	Scared	'Anonymous'	Anonymous
Text Type	Serious Imaginative Literature, Authoritative Statements,	Topic Scientific, Technological Commercial	Notices, Propaganda, Instruction, Publicity,

	Autobiography Personal Correspondence	Industrial, Economic; Other areas of knowledge or events Formal Text-Book, Report, Paper, Memorandum, Minutes	Popular fiction

(Own source)

Therefore, before carrying out the translation of drug product dossiers the text analysis was developed as shown in the following example:

Chart 5 Translation Example

Source Text	Target Text
5.1.1.2 Test solution Dissolve 0.95 g of substance (equivalent to 0.5 g of Na_2HPO_4) in 40 ml water for injection and, if necessary, neutralize the solution with nitric acid to litmus. Add 1 ml nitric acid and 1 ml of silver nitrate TS and sufficient water for injection to make 50 ml. Mix, allow to stand for 5 minutes protected from direct sunlight and compare the turbidity, if any, with test solution. **5.1.2 Interpretation** The turbidity produced by test solution should not be more intense than that of standard solution.	**5.1.1.2 Solución de prueba** Disolver 0.95 g de la sustancia (equivalente a 0.5 g de Na_2HPO_4) en 40 ml de agua para inyectable y, si fuera necesario, neutralizar la solución con ácido nítrico empleando papel de tornasol. Agregar 1 ml de ácido nítrico, 1 ml de nitrato de plata (SR) y cantidad suficiente de agua para inyectable hasta obtener 50 ml. Mezclar, dejar en reposo durante 5 minutos protegido de la luz solar directa y comparar la turbidez, si la hubiera, con la solución de prueba. **5.1.2 Interpretación** La turbidez producida por la solución de prueba no debe ser más intensa que la de la solución estándar.

Intention of the text :	Informative: a procedure or a series of steps for preparing the test solution (pharmacological field).
Style:	It is a descriptive text. As shown in the example, verbs and adjectives are used to describe the way to carry out an experiment.
Tone:	It is neutral. The author states a fact but doesn´t give opinions or try to persuade reader to believe his/her point of view.
Intention of the translator:	Being a technical-scientific text, whose intention is to make other scientist can repeat the procedure or steps to carry out the task, the translator intention is identical to the author.
Readership:	The readers of the drug product dossiers are doctors and biochemists.
Setting:	The present translation is presented to the specialized personnel at FARMEDICAL SRL and to the Ministry of Health.
Register:	It is technical. The vocabulary in the text belongs to the pharmacological field; the specialized concepts are relayed by means of technical language.
Language function:	It is informative. The idea of the text is to provide/communicate true information in order to be understood by any person who belongs to the pharmacological field.

(Own source)

Based on the previous concepts, we can infer that before choosing an appropriate method and procedure to carry out the translation it is important to determine the text type of the dossier. The type of text concerning this work is the scientific technical translation.

2.1.4 SCIENTIFIC TECHNICAL TRANSLATION

According to Peter Newmark Technical translation is primarily distinguished from other forms of translation by terminology, although terminology usually makes up about

5-10% of a text. It is non-cultural, and therefore universal: the advantages of technology are not restricted to one speech community. The technical style usually lacks the emotional component, connotations, metaphors, if the text is well written. However, the central difficulty of technical translation is usually in the new terms.

a) Technical style

Based on medical vocabulary Newmark proposes:

- **Academic** Transferred Greco-Roman words associated with academic articles.
- **Professional** Formal terms used by experts.
- **Popular** Layman vocabulary, which may include familiar alternative terms.

However, these are general categories to which it is often arbitrary to assign one or another term.

Example: During the translation of the drug products dossier we found the following terms which were used to explain some concepts that belongs to a clinical study; they are not necessarily common nor frequently encountered in informal conversation.

Chart 6 Technical Terms

ACADEMIC	
Source text	**Target text**
Strong solution	Solución concentrada
Randomized essay	Ensayo aleatorizado
BMI	(IMB) Indice de masa corporal
Screening	De selección, de cribado o detección
Head to head studies	Estudios directos
Dose finding	Determinación de la dosis
PROFESSIONAL	
Source text	**Target text**
Upper respiratory infection	Infección de las vías respiratorias altas
Thoracic dumbbell type	Tipo de ensanchamiento torácico

Increased binding bilirubin	Aumento de la unión de la bilirrubina
PPI	(IBP) Inhibidor de la bomba de protones
PAI-1	Inhibidor del activador del plasminógeno 1
Effect-site concentration	Concentración en el sitio donde el fármaco ejerce su efecto
POPULAR	
Source text	**Target text**
Allergic reaction	Reacción alérgica
Chronic	Crónico
Cutaneous	Cutánea
Combination therapy	Terapia de combinación
Immunological	Inmunológico
Site injection	Lugar de la inyección

(Own Source)

b) Technical and descriptive terms

The SL writer may use a descriptive term for a technical object for three reasons:

- The object is new, and has not yet got a name;
- The descriptive term is being used as a familiar alternative, to avoid repetition;
- The descriptive term is being used to make a contrast with another one.

A technical term (standardized language) is always more precise (narrower in semantic range) than a descriptive term (non-standardized language), where an SL technical term has no known TL equivalent, a descriptive term should be used.

The following example is a term which does not have an equivalence in Spanish yet, so a description was necessary at the time of the translation.

Chart 7 Word without meaning on the TL

Source text	Target text	Description	Image
Pass box	Pass box	Es uno de los sistemas de sala limpia, que se utiliza para transferir materiales de un lado a otro a través de un ambiente controlado para evitar la contaminación cruzada en el aire.)	

(Own Source)

c) Going through the text

It is important to read the article through and underline all words and structures that appear to contain problems. Translator can then translate sentence by sentence, making grammatical shifts to form natural language. The main thrust is always on loosening up the syntax in a natural way; on bringing in the English gerund that all foreign languages lack; on finding a more natural word order.

In a technical translation we can be as bold and free in recasting grammar (cutting up sentences, transposing clauses, converting verbs to nouns, etc.) as in any other type of informative or vocative text, provided the original is defective, as a technical translator you vary your format in relation to your customer. If he wants a "cover-TO-cover" translation, you normally keep the house-style of the original.

Example: In the next example, all words and structures that appear to contain problems are underlined.

To calculate the absorbance at 280 nm (± 2nm) due to light scattering, record the O. D of the test solution at wavelengths of 320 nm, 325nm 330 nm, 335 nm, 340nm, 345 nm and 350nm. Plot the logarithm of the observed absorbance against the logarithm of the

wavelength and determine the standard curve best fitting the plotted points by linear regression. Extrapolate the curve to determine the logarithm of the absorbance at 280 nm (± 2nm). The antilogarithm of this value is the absorbance attributed to light scattering. Correct the observed value by subtracting the absorbance attributed to light scattering from the total absorbance at 280 nm (± 2nm) to obtain the absorbance value of the protein in solution.

2.1.5 DIFFERENCE BETWEEN TRANSLATION PROCEDURE, METHOD AND STRATEGY

Translation procedures, as its name indicated, are strategies that help us to solve problems presented at the moment of transferring the meaning from a written text in a language A into a written text in a language B.

> (…) A translation strategy is a potentially and consciously procedure used to solve a problem that occurs in the translation of a text or segment thereof. It can be divided into local strategies (for the treatment of segments of the text) and global (for the treatment of complete texts) (Baker and Malmkjær, 1998: 188).

When we talk about *problems at the local level*, we refer to those that occur in segments or parts of the source text, it would be a word, a phrase or sentence, an idiomatic expression, a neologism or foreignness, or a metaphor. When talking about *problems that affect the entire text*, we refer above all to problems related to the theme or global sense of the text, which may present a problem of understanding for the reader of the target text. During the translation process, it is possible to find texts that are so attached to the source culture, or texts in which the central theme is so specific, that may present a great difficulty for the translator as an intercultural mediator.

Many authors use the terms translation methods and procedures interchangeably, however, when we refer to Peter Newmark (1995), a clarification is necessary. The author makes a distinction and uses the expression **translation methods** to refer to the techniques

used to solve problems related to the text as a whole, such as the preservation of the message and global structure, type and textual class, among others. When he talks about **procedures**, he specifically refers to the strategies used to solve problems at the local level, it means, problems related to sentences or lower language units.

Author	**Translation Method** (Techniques)	**Procedures** (Strategies)
Peter Newmark	-Word-for-word translation -Literal translation -Faithful translation -Semantic translation -Semantic translation -Free translation -Idiomatic translation -Communicative translation	- Transference - Naturalization - Cultural Equivalent -Functional Equivalent - descriptive Equivalent -Synonymy - Direct translation - Transposition - Modulation - Recognized Translation - Compensation - Paraphrase - Couples - Notes

While Vinay and Darbelnet proposed seven **procedures** or strategies: borrowing, calque, literal, transposition, modulation, equivalence, adaptation. As **method** of translation, they proposed the direct and oblique translation; their view was that if direct translation were impossible, then the translator would have to resort to what they termed oblique translation. Oblique translation is another term for free translation where the translator exercises his/her freedom to attain equivalence.

Author	**Translation Method**	**Strategies/Procedures**
	Direct Translation	- Borrowing

Vinay y Darbelnet (1958)		- Calque - Literal Translation
	Oblique Translation	-Transposition, - Modulation, - Equivalence - Adaptation.

The present supervised work translation methods selected belongs to Vinay and Darbelnet dichotomy (Direct Translation and Oblique Translation). For them, one of the most common problem for translators is to select the appropriate process for translation, because there is not a single translation for a given passage. In addition, Vinay and Darbelnet believe that each translator through personal experiences, and reflection would select automatically a mechanism for translation.

Direct Translation

A direct translation, which generally resembles word by word quotation of the original message in the target language, includes borrowing, calque and literal translation.

- **Borrowing.** A word taken directly from another language, e.g., the Greek word *oncogenesis (tumor)* and *genesis (origen)* have been incorporated directly into every day English or Spanish speakers to refer to formation or production of tumor.
- **Calque.** A foreign word or phrase translated or incorporated into another language, e.g., the Latin phrase: *Chloramphenicol succinate sodium salt* to *sal de Succinato Sódico de Cloranfenicol.*
- **Literal translation.** Word for word translation, e.g., *white powder to Polvo blanco.*

Oblique translation

In which the translator interprets, e.g. elaborates or summarizes, the explicit contents of the original, embraces transposition, modulation, equivalence, and adaptation translation procedures.

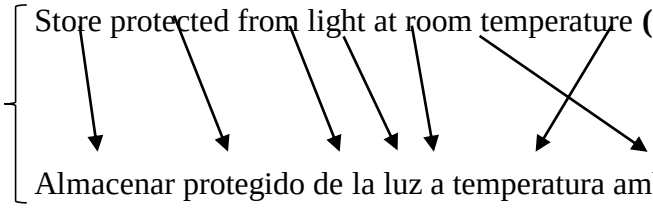
- **Transposition.** A shift of word class, i.e., verb for noun, noun for preposition e.g. *After cooling* to *despues de enfriar* in this case it is necessary to change the grammatical category "Cooling" Adjective to Spanish verb "enfriar".

- **Modulation**. A shift in point of view. Whereas transposition is a shift between grammatical categories, modulation is a shift in cognitive categories. Vinay and Darbelnet postulate eleven types of modulation: abstract for concrete, cause for effect, means for result, a part for the whole, geographical change, etc., *Pass/fail* to *Cumple/no cumple*

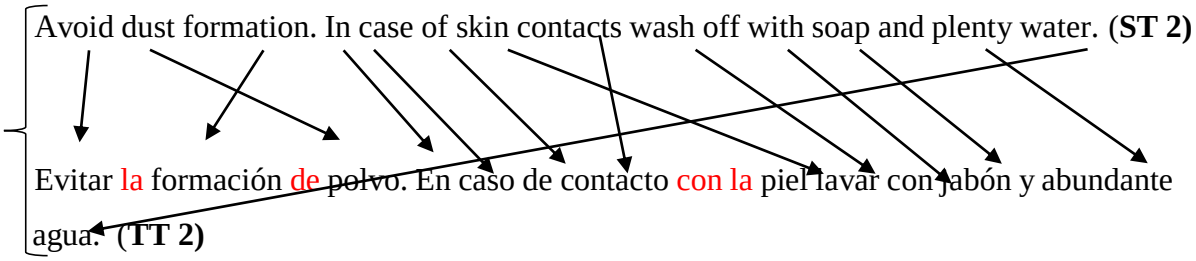
- **Equivalence.** This accounts for the same situation using a completely different phrase, e.g., the translation of proverbs or idiomatic expressions like. E.g *Hand to hand variation* to *Variación entre analistas/ Variación de analista a analista*

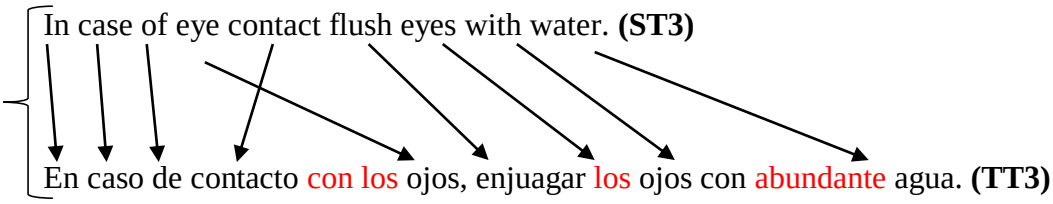
- **Adaptation**. A shift in cultural environment, i.e., to express the message using a different situation E.g. *water bath to baño Maria*

Examples

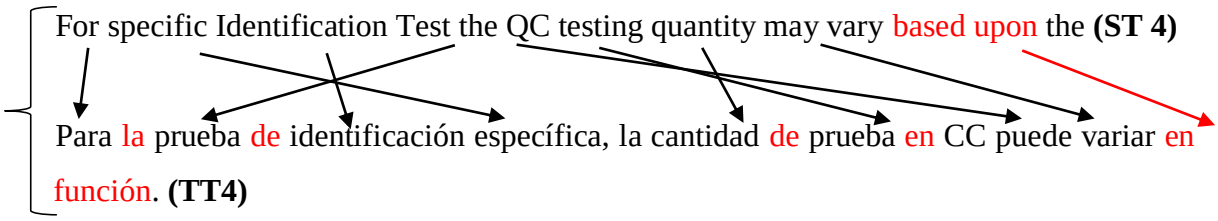


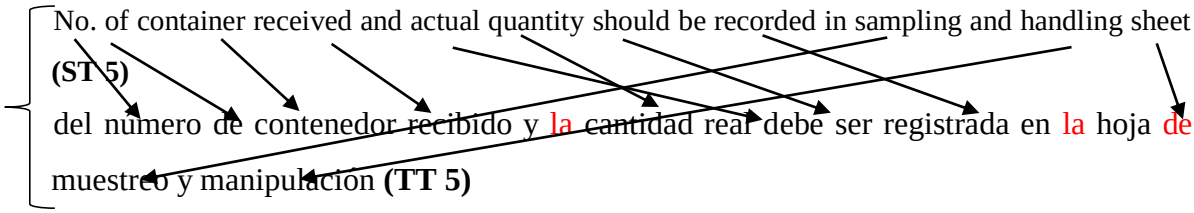
- Exact correspondence in the syntax, grammar, and semantics.





- In this case it was necessary to modify the TL by using articles "la", preposition "de, con la", or the adjective "abundante" in order to give emphasis because its grammar asks to do that, but it is still considered a literal translation.





- The modification on the structure of the last sentence from the ST (Based upon) into the TT (función) was evident and necessary, but that does not change the method (Literal translation).

2.2 JUSTIFICATION

In Bolivia, some years ago the Medicines act was not rigorously controlled by the Ministry of Health staff. However, a new regulation establishes that all the procedures that involve documentation need to be submitted into the official language of the Plurinational State of Bolivia. Due to the fact that pharmaceutical industry is responsible for the continuous generation of health sector innovations, it generates translation needs related to the development and marketing of drug products, and the research of new applications or enhancing existing ones. In addition, necessary documents to conduct clinical trials

often require translation in order for local clinicians and patients, and regulatory representatives to be able to read them. These needs let us apply all the translation knowledge acquired along the years of study in the Linguistics and Languages Department.

The following reasons express and justify the importance of the present investigation

2.2.1 Innovation

The present project is considered innovator because it faces new challenges in the pharmaceutical and scientific field, and technical translation. It is worth to mention that documentation and terminology require translators to be able to search for and to discriminate the information. As a result, a glossary will be attached as a part of the contribution to the Linguistics and Languages Department.

2.2.2 Originality

This supervised work differs from previous projects conducted in the translation field because the scope of this supervised work not only helps to obtain the license for preparing, distributing, importing, and marketing drug products to the company but also it facilitates the access to information to Farmedical's staff.

2.2.3 Social Relevance

Companies such as FARMEDICAL SRL have the responsibility to provide health to the general public through the marketing of pharmaceutical products with high standards of quality, safety and accessibility in terms of cost-treatment. Then the commitment to accomplish with all the requirements established, by the institution in charge of the revision and reception of all the documents, is a duty. For that reason we as translators have the task of translating the documentation in order to help FARMEDICAL SRL meet the requirements to obtain the license for preparing, distributing, importing, and marketing drug products.

2.2.4 Scope

In order to help FARMEDICAL SRL to meet the requirements for the license and marketing of the drug products. Six dossiers about drug products are translated from English into Spanish. Dossiers comprises literature and labelling associated with medical devices and pharmaceuticals, so the type of texts translated included are;

- Certificate of Analysis (COA)[2]
- Analytical Procedures[3]
- Excipients[4]
- Monograph[5]
- Galenic Development [6]

This supervised work focuses on technical translation, therefore it requires precision, accuracy and an appropriate use of specialized terminology during the translation process. The content of the Dossiers involves technical information of pharmaceutical products to be approved, registered and marketed. Data providing that the drug has quality, efficacy and safety properties suitable for the intended use, samples of finished products or related substances and reagents necessary to perform analyses of finished products.

[2] COA's are defined as "documents issued by Quality Assurance that confirms a regulated product meets its product specification. They commonly contain the actual results obtained from testing performed as part of quality control of an individual batch of a product

[3] Analytical Procedures and Methods Validation provides recommendations on how the applicant, can submit analytical procedures and methods validation data to support the documentation of the identity, strength, quality, purity, and potency of drug substances and drug products

[4] Excipients are: "any component, other than the active substance(s), present in a medicinal product or used in the manufacture of the product.

[5] Drug monographs are a kind of "recipe book" covering acceptable ingredients, doses, formulations, and labeling.

[6] Galenic is the process that turns an active ingredient into a ready-to-use medicine that can be dosed as required. Galenic formulation deals with the principles of preparing and compounding medicines in order to optimize their absorption and forms part of pharmaceutics, the discipline (or science) of dosage form design.

2.2.5 Material, Technical and Economic Resources, and Schedule

As before mentioned this project takes place at Farmedical's premises; the material (PDF format), instruments (a laptop per translator), economical resources and internet connection are provided by the institution.

The source texts are in PDF format, the original format of pages must be kept. The translation will be checked by Farmedical's staff, mainly by the personnel in charge of the translation field, doctors and pharmacologist.

According to the schedule, an approximate of 36 pages are translated per day from English into Spanish. It means that each translator translates approximately about 10 to 12 pages depending on the content. The number of pages varies taking into account parameters such as the format of the documents, number of words, graphics, tables, and lists per page. The project is performed from Monday to Friday, 8 hours a day (from 08:00 am to 16:30 pm), and half hour for lunch.

2.3 OBJECTIVES

2.3.1 General Objective

- To translate dossiers of drug products to obtain the license for preparing, distributing, importing, and marketing drug products from English into Spanish at FARMEDICAL SRL.

2.3.2 Specific Objectives

- To choose the suitable method along the translation process of Drug Products dossiers.
- To identify technical and ambiguous terms and analyze them to find out the accurate equivalent according to the context.

- To create a bilingual glossary that works as reference for doctors, health personnel, patients, legal representatives and others.

2.4 FULFILLMENT INDICATORS

According to Tintaya (2008, 398), indicators mean reference or aspects for verifying whether the objectives have been reached through considering results.

Chart 8 Indicators

OBJECTIVE	INDICATORS
General objective: To translate dossiers of drug products to obtain the license for preparing, distributing, importing, and marketing drug products from English into Spanish at FARMEDICAL SRL.	Six translated dossiers presented to the Ministry of Health.
Specific objective: To choose the suitable method along the translation process of Drug Products dossiers.	Samples of the method and procedures used in the translation process
Specific objective: To identify technical and ambiguous terms and analyze them to find out the accurate equivalent according to the context.	Elaboration of two charts where technical and ambiguous terms are explained.
Specific objective: To create a bilingual glossary that works as reference for doctors, health personnel, patients, legal representatives and others.	A bilingual glossary of pharmacological terms presented as a lexicographical work compiled from the translation of drug products dossiers.

2.5 ACTION STRATEGY

According to Tintaya (2005) the action strategies are the stages or steps, activities, procedures, techniques and tool to develop the supervised work. The translation process was divided into the following six stages:

- 1st stage: Reading and analysis of the information (the first reading was for deep understandings of key ideas).
- 2nd stage: Analysis of the technical terms (to carry out any research required to translate technical terms).
- 3th stage: First-draft translation (translation of the first draft using different translation methods: literal, transposition, modulation, omission, amplification, compensation, redaction)
- 4th stage: Revision and correction of the first draft (to verify that the translation keeps the meaning of the source text).
- 5th stage: Proofreading (to check that the translation was written appropriately without errors of cohesion and coherence, spelling and punctuation).

RESOURCES

Now of developing the translation, the following resources were used:

a) Written Resources

- Pharmacopeia Argentina and EE. UU
- Diccionario Stedman's de Ciencias Médicas Inglés-Español
- American Medical Manual of Style

b) Online Resources

- www.acronymfinder.com to look for English acronyms divided in technology, medicine, society, etc.
- The RAE dictionary online https://dle.rae.es/?id=DgIqVCc
- The Oxford dictionary https://en.oxforddictionaries.com/
- http://www.onlineconversion.com/ this web page helps to convert different measurement units (Metric System to English Unit System or vice versa)
- http://europa.eu.int/eurodicautom/Controller an online dictionary from European Commission of Translation
- http://vademecum.medicom.es the Medicom official web page
- www.portalfarma.com the Organization of Pharmacy College from Spain web page.
- http://www.sedom.es/diccionario a Medical Abbreviations and Pharmaceutical Abbreviations Dictionary.
- https://www.fda.gov Food And Drug Administration web page

2.6 ACTION PLAN

Chart 9 Action Plan

STAGES	OBJECTIVES	ACTIVITIES	METHOD	MOMENT	RESOURCES	RESPONSIBLE
1st Stage	Recognition of the source text	To read and analyze the information of the dossiers (function, style, register and tone)	Data research reading text analysis	From Dec 5th, 2018 to June 5st, 2019	Technical dictionaries, internet, literature related to the area, support from doctors, biochemists and the institutional tutor	Translator
2nd Stage	Recognition of technical terminology	To identify and select technical terms	Data collection			
3th stage	Translation of the first draft	To translate the dossier	Direct translation			
4th stage	Review and correction of the first draft	To perform a correct and accurate review by comparing the translated text with the source text	Analysis and review of the whole translation		Academic advice from the tutor	Institutional tutor Academic tutor
5th stage	Proof reading	To read the final version	Editing and Proof Reading		Academic advice from the tutor	Doctors, biochemists

CHAPTER III

DEVELOPMENT OF THE PROPOSAL

3.1 WORK SCHEDULE

This supervised work lasted six months working at FARMEDICAL SRL from December 2018 to May 2019. At the end, a written report was elaborated. Below you can see a chart of the schedule of the supervised work which explains in detail the number of hours worked in relation to the number of days and months.

Chart 10 Work Schedule

TERM	MONTHS	No DAYS	WORKED HOURS
SWOT ANALYSIS	September to October	20	160
TRANSLATION TIME	December	18	144
	January	21	168
	February	20	160
	March	19	152
	April	20	160
	May	21	168
PREPARATION OF WRITTEN REPORT	June to July	35	280
TOTAL	**11**	**174**	**1392**

The following charts show chronologically by months and weeks the process of tasks performed during the complete supervised work development:

Chart 11 Preliminary stage

During this stage first, the data was collected in order to identify the company's needs; second, we elaborated the profile of the supervised work; and finally we obtained the approval of the profile. Below you can see the dates in which each stage was performed.

TASK	MONTHS (2018)							
	September				October			
WEEKS	1	2	3	4	1	2	3	4
Process of agreement of supervised work at FARMEDICAL SRL								
Diagnosis of needs								
Elaboration of the Profile								
Approval of the supervised work profile								

Chart 12 Intervention stage

In this stage we translated the dossier from English into Spanish, six dossiers were translated, one monthly. Each dossier contains 5 chapters: Certificate of Analysis (COA), Analytical procedure, Excipients, Monograph and Galenic Development. The translation of each chapter lasted from 1-2 weeks.

TASK		MONTHS (2018 - 2019)							
		December				January			
PRODUCT	WEEKS	1	2	3	4	1	2	3	4
Product 1	Certificate of Analysis (COA)								
	Analytical Procedure								
	Excipients								

	Monograph								
	Galenic Development								
Product 2	**Certificate of Analysis (COA)**								
	Analytical Procedure								
	Excipients								
	Monograph								
	Galenic Development								
TASK		**MONTHS (2019)**							
		February				**March**			
PRODUCT	**WEEKS**	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**
Product 3	**Certificate of Analysis (COA)**								
	Analytical Procedure								
	Excipients								
	Monograph								
	Galenic Development								
Product 4	**Certificate of Analysis (COA)**								
	Analytical Procedure								
	Excipients								
	Monograph								
	Galenic development								
TASK		**MONTHS (2019)**							
		April				**May**			
PRODUCT	**WEEKS**	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**
Product 5	**Certificate of Analysis (COA)**								

	Analytical Procedure								
	Excipients								
	Monograph								
	Galenic Development								
Product 6	**Certificate of Analysis (COA)**								
	Analytical Procedure								
	Excipients								
	Monograph								
	Galenic development								

Chart 13 Work Schedule

Once translations were concluded we elaborated the written report as a final stage, then we handed in it to the academic tutor for its appropriate revision.

TASK	**MONTHS (2018)**							
	June				**July**			
WEEKS	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**
Elaboration of the Written Report								
Checking of the Written Report by the Academic Tutor								

Chart 14 Translation schedule

A total of 3.867 pages were translated in the six months, the number of pages translated per day were about 36 pages, i.e. that each student translated from 10 to 12 pages per day. The days worked per month were about 20 days, 8 hours a day.

Product	Parts	Translated by	Started on	Finished on
Product 1 (590 pages)				
Certificate of Analysis (COA)	(5 pages)	Ines Arana	Dec 05th, 2018	Dec 05th, 2018
Analytical Procedure (135 pages)	Part 1 (48 pages) Part 2 (47 pages) Part 3 (40 pages)	Alejandra Copa Fernando Flores Ines Arana	Dec 05th, 2018 Dec 05th, 2018 Dec 05th, 2018	Dec 11th, 2018 Dec 11th, 2018 Dec 10th, 2018
5 Excipients (307 pages)	Excipient 1 (70 pages) Excipient 2 (57 pages) Excipient 3 (60 pages) Excipient 4 (65 pages) Excipient 5 (55 pages)	Alejandra Copa Fernando Flores Ines Arana Alejandra Copa Fernando Flores	Dec 12th, 2018 Dec 12th, 2018 Dec 11th, 2018 Dec 20th, 2018 Dec 19th, 2018	Dec 19th, 2018 Dec 18th, 2018 Dec 18th, 2018 Dec 28th, 2018 Dec 26th, 2018
Monograph (113 pages)	Part 1 (48 pages) Part 2 (30 pages) Part 3 (35 pages)	Ines Arana Alejandra Copa Fernando Flores	Dec 19th, 2018 Dec 31st, 2018 Dec 27th, 2018	Dec 26th, 2018 Jan 03th, 2018 Dec 31st, 2018
Galenic development	(30 pages)	Ines Arana	Dec 27th, 2018	Dec 31st, 2018
Product 2 (645 pages)				
Certificate of Analysis (COA)	(7 pages)	Alejandra Copa	Jan 04th, 2019	Jan 04th, 2019
Analytical Procedure (143 pages)	Part 1 (53 pages) Part 2 (48 pages) Part 3 (42 pages)	Fernando Flores Ines Arana Alejandra Copa	Jan 02nd , 2019 Jan 02nd, 2019 Jan 04th, 2019	Jan 08th, 2019 Jan 08th, 2019 Jan 10th, 2019
5 Excipients	Excipient 1 (52 pages)	Fernando Flores	Jan 09th, 2019	Jan 15th, 2019

(373 pages)	Excipient 2 (55 pages)	Ines Arana	Jan 09th, 2019	Jan 15th, 2019
	Excipient 3 (50 pages)	Alejandra Copa	Jan 11th, 2019	Jan 17th, 2019
	Excipient 4 (54 pages)	Fernando Flores	Jan 16th, 2019	Jan 23th, 2019
	Excipient 5 (52 pages)	Ines Arana	Jan 16th, 2019	Jan 23th, 2019
	Excipient 6 (58 pages)	Alejandra Copa	Jan 18th, 2019	Jan 25th, 2019
	Excipient 7 (52 pages)	Fernando Flores	Jan 24th, 2019	Jan 30th, 2019
Monograph (70 pages)	Part 1 (25 pages)	Ines Arana	Jan 24th, 2019	Jan 25th, 2019
	Part 2 (20 pages)	Alejandra Copa	Jan 28th, 2019	Jan 29th, 2019
	Part 3 (25 pages)	Fernando Flores	Jan 31th, 2019	Feb 01st, 2019
Galenic development	(52 pages)	Ines Arana	Jan 28th, 2019	Feb 01st, 2019
Product 3 (595 pages)				
Certificate of Analysis (COA)	(4 pages)	Alejandra Copa	Jan 30th, 2019	Jan 30th, 2019
Analytical Procedure (178 pages)	Part 1 (65 pages)	Fernando Flores	Feb 04th, 2019	Feb 11th, 2019
	Part 2 (58 pages)	Ines Arana	Feb 04st, 2019	Feb 08th, 2019
	Part 3 (55 pages)	Alejandra Copa	Jan 30th , 2019	Feb 06th, 2019
5 Excipients (241 pages)	Excipient 1 (79 pages)	Fernando Flores	Feb 12th, 2019	Feb 20th, 2019
	Excipient 2 (77 pages)	Ines Arana	Feb 11th, 2019	Feb 19th, 2019
	Excipient 3 (85 pages)	Alejandra Copa	Feb 07th, 2019	Feb 18th, 2019
Monograph (137 pages)	Part 1 (32 pages)	Fernando Flores	Feb 21th, 2019	Feb 25th, 2019
	Part 2 (52 pages)	Ines Arana	Feb 20th, 2019	Feb 26th, 2019
	Part 3 (53 pages)	Alejandra Copa	Feb 19th, 2019	Feb 25th, 2019
Galenic development	(35 pages)	Fernando Flores	Feb 26th, 2019	Feb 28th, 2019

Product 4 (670 pages)				
Certificate of Analysis (COA)	(8 pages)	Ines Arana	Feb 27th, 2019	Feb 27th, 2019
Analytical Procedure (86 pages)	Part 1 (31 pages) Part 2 (30 pages) Part 3 (25 pages)	Alejandra Copa Fernando Flores Ines Arana	Feb 26th, 2019 Jan 01st, 2019 Feb 28th, 2019	Feb 28th, 2019 Mar 07th, 2019 Mar 01st, 2019
5 Excipients (384 pages)	Excipient 1 (57 pages) Excipient 2 (47 pages) Excipient 3 (45 pages) Excipient 4 (41 pages) Excipient 5 (45 pages) Excipient 6 (42 pages) Excipient 7 (54 pages) Excipient 8 (53 pages)	Alejandra Copa Fernando Flores Ines Arana Alejandra Copa Fernando Flores Ines Arana Alejandra Copa Fernando Flores	Mar 01st, 2019 Mar 08th, 2019 Mar 06th, 2019 Mar 12th, 2019 Mar 14th, 2019 Mar 12th, 2019 Mar 18th, 2019 Mar 20th, 2019	Mar 11th, 2019 Mar 13th, 2019 Mar 11th, 2019 Mar 15th, 2019 Mar 19th, 2019 Mar 15th, 2019 Mar 22th, 2019 Mar 26th, 2019
Monograph (128 pages)	Part 1 (58 pages) Part 2 (32 pages) Part 3 (38 pages)	Ines Arana Alejandra Copa Fernando Flores	Mar 18th, 2019 Mar 25th, 2019 Mar 27th, 2019	Mar 25th, 2019 Mar 27th, 2019 Apr 01st, 2019
Galenic development	(64 pages)	Ines Arana	Mar 26th, 2019	Apr 02nd, 2019
Product 5 (682 pages)				
Certificate of Analysis (COA)	(7 pages)	Alejandra Copa	Mar 28th, 2019	Mar 28th, 2019
Analytical Procedure (128 pages)	Part 1 (48 pages) Part 2 (50 pages)	Fernando Flores Ines Arana	Apr 02nd, 2019 Apr 03th, 2019	Apr 05th, 2019 Apr 09th, 2019

	Part 3 (30 pages)	Alejandra Copa	Mar 28th, 2019	Apr 01st, 2019
5 Excipients (355 pages)	Excipient 1(53 pages)	Fernando Flores	Apr 08th, 2019	Apr 12th, 2019
	Excipient 2 (67 pages)	Ines Arana	Apr 10th, 2019	Apr 18th, 2019
	Excipient 3 (49 pages)	Alejandra Copa	Apr 02th, 2019	Apr 08th, 2019
	Excipient 4 (58 pages)	Fernando Flores	Apr 15th, 2019	Apr 23th, 2019
	Excipient 5 (73 pages)	Ines Arana	Apr22nd, 2019	Apr 30th, 2019
	Excipient 6 (55 pages)	Alejandra Copa	Apr 09th, 2019	Apr 15th, 2019
Monograph (135 pages)	Part 1 (33 pages)	Fernando Flores	Apr 24th, 2019	Apr 26th, 2019
	Part 2 (50 pages)	Ines Arana	May 02th, 2019	May 08th, 2019
	Part 3 (52 pages)	Alejandra Copa	Apr 16th, 2019	Apr 24th, 2019
Galenic development	(57 pages)	Fernando Flores	Apr 29th, 2019	May 06th, 2019
Product 6 (685 pages)				
Certificate of Analysis (COA)	(5 pages)	Ines Arana	May 09th, 2019	May 09th, 2019
Analytical Procedure (151 pages)	Part 1 (51 pages)	Alejandra Copa	Apr 25th, 2019	May 02th, 2019
	Part 2 (55 pages)	Fernando Flores	May 07th, 2019	May 13th, 2019
	Part 3 (45 pages)	Ines Arana	May 09th, 2019	May 15th, 2019
5 Excipients (339 pages)	Excipient 1 (84 pages)	Alejandra Copa	May 03th, 2019	May 14th, 2019
	Excipient 2 (79 pages)	Fernando Flores	May 14th, 2019	May 23th, 2019
	Excipient 3 (87 pages)	Ines Arana	May 16th, 2019	May 28th, 2019
	Excipient 4 (89 pages)	Alejandra Copa	May 15th, 2019	May 27th, 2019
Monograph (126 pages)	Part 1 (26 pages)	Fernando Flores	May 24th, 2019	May 27th, 2019
	Part 2 (56 pages)	Ines Arana	May 29th, 2019	Jun 04th, 2019
	Part 3 (44 pages)	Alejandra Copa	May 28th, 2019	Jun 03rd, 2019

Galenic development	(64 pages)	Fernando Flores	May 28th, 2019	Jun 04th, 2019

3.2 SEQUENCE OF ACTIVITIES

The activities at FARMEDICAL SRL consisted of the following phases: reception of dossiers (PDF); the process of translation; revision by the institutional tutor; and final submission. This supervised work focused on the translation process in order to achieve the objectives, we followed 5 stages:

- 1st stage: Reading and analysis of the information (the first reading was for deep understandings of key ideas).
- 2nd stage: Analysis of the technical terms (to carry out any research required to translate technical terms).
- 3rd stage: First-draft translation (translation of the first draft using the direct and oblique translation).
- 4th stage: Revision and correction of the first draft (to verify that the translation keeps the meaning of the source text).
- 5th stage: Proofreading (To check that the translation was developed appropriately without errors of cohesion and coherence, spelling and punctuation).

1st Stage: Reading and analysis of the information

The objective of the analysis of the text is to understand and get to know about the nature of the text being translated before choosing a translation method for a text. Thus, text analysis implies to know about the function, the style, the register and tone of the dossiers.

Type of documents	Function	Style	Register	Tone
Certificate of Analysis (COA)	Informative	Descriptive	Technical	Neutral
Analytical Procedure	Informative	Descriptive	Technical	Neutral
Excipients	Informative	Descriptive	Technical	Neutral
Monograph	Informative	Descriptive	Technical	Neutral
Galenic Development	Informative	Descriptive	Technical	Neutral

2nd Stage: Analysis of the technical terms

The first reading was for deep understandings of key ideas. Then, the second reading was to analyze the technical terms of the dossiers.

- **Reading and identification of the technical terms**

Example:

The total duration of subject participation was approximately three weeks, including a two-day **screening period,** a five-day treatment period and a 14-day **follow-up period**. The primary **end-point** of the study was to determine whether serum concentrations were inferior not to the therapeutic threshold of 10.0 mg/l.

- **Analysis of the technical terms:**

Item No.	Technical term	Equivalence	Equivalence used for the context	Justification
1	Screening period	Proceso de selección	Periodo de selección/detección	In clinical research the verb "to screen" refer

		Período sin tratamiento Período de reposo farmacológico// Período de lavado.		to the procedure of verifying (to check) that a person fulfills the criteria for inclusion in the study
2	Follow-up period	Periodo de revisión// Periodo de seguimiento// Periodo de consulta	Periodo de seguimiento	In this context "Follow-up" refers to "maintaining contact (with the pacients of the study) by, telephone calls, words or other means to observe the effects, to modify the course of the treatment, etc.
3.	End point	Punto final, Valor final, Conclusión [de un estudio clínico, de un período de observación, de un proceso] // interrupción anticipada [de un estudio clínico]	Criterio de valoración	In clinical research, it is often used with the equivalence of "criterio de valoración", normally of effectiveness or as a synonym for result variable:

Technical and descriptive terms:

Example:

S.T. **Pass Boxes** are used for the transfer of materials in controlled contamination environments.

T.T. Las **Pass Boxes** se utilizan para la transferencia de materiales en entornos de contaminación controlada.

Source text	Target text	Description	Image
Pass box	Pass box	Es uno de los sistemas de sala limpia, que se utiliza para transferir materiales de un lado a otro a través de un ambiente controlado para evitar la contaminación cruzada en el aire.)	

3rd Stage First draft translation

For this stage, we developed the translation using the appropriate methods and procedures for the technical-scientific translation. The translation procedures applied were based on the approach of Vinay and Darbelnet (direct and oblique translation). We translated sentence by sentence to keep the intention of the source text as follows:

Method: Direct translation

Procedures: literal translation, calque, borrowing

- **Literal translation:**

S.T. Virus clearance by nano-filtration was performed following the manufacturer's instructions.

T.T. La eliminación del virus por nanofiltración se realizó siguiendo las instrucciones del fabricante.

S.T. Reported malformations include congenital heart disease, such as tetralogy of Fallot, atrial and ventricular septal defects, and renal and musculoskeletal abnormalities.

T.T. Las malformaciones reportadas incluyen enfermedades cardíacas congénitas, como la tetralogía de Fallot, defectos septales atriales y ventriculares, y anormalidades renales y musculoesqueléticas.

S.T. The drug substance is analysed as per In-House Specifications.

T.T. La sustancia de la droga se analiza según las especificaciones internas.

- **Calque**:

S.T. Tell your doctor about all the prescription and over-the-counter medications you use

T.T. Informar a su médico sobre todos los medicamentos de venta con o sin receta que utilice

Other examples of calque:

S.T.	**S.T**	**Calque**
chlorine	cloro	clorina
flow rate	caudal	Tasa de flujo, velocidad de flujo
volumetric flask	Matraz aforado	Matraz volumétrico

- **Borrowing:**

S.T. The in vitro bioactivity assay was performed for XXX.

T.T. El ensayo de bioactividad in vitro se llevó a cabo para XXX.

Other examples of borrowing:

S.T	**T.T.**
Buffer	Buffer
Kit	Kit
Scanner	Scanner
Shock	Shock

Method: Oblique translation

Procedures: Transposition, Modulation, equivalence, adaptation

Transposition:

S.T. Side effects may develop after two weeks. (v)

T.T. El desarrollo de los efectos secundarios puede ocurrir después de dos semanas. (n)

Modulation:

S.T. because both pooled human plasma and bovine products are used to obtain some of its components

T.T. porque se usan tanto mezclas de plasma humano como productos bovinos para obtener algunos de los componentes

Equivalence:

S.T. Hand to hand variation

T.T. Variación entre analistas/ analista a analista

Adaptation:

S.T. Water bath

T.T. Baño Maria

Example 1:

- **Reading and identification of the technical terms**

S.T.: A total of 37 patients from four hospitals and intensive care units in the Gauteng province of South Africa with severe gram-positive infection, who required glycopeptide antibiotic treatment, were enrolled in this study. A dose schedule consisting of multiple doses was used to reduce the time until steady-state concentration was achieved. In brief, patients received an initial dose of 800 mg of the drug product, either intravenously or intramuscularly, followed by three further doses of 400 mg, administered every 12 hours.

Translation

T.T. Un total de 37 pacientes de cuatro hospitales y unidades de cuidados intensivos en la provincia de Gauteng de Sudáfrica con infección grampositiva severa, que requirieron tratamiento con antibióticos glucopéptidos se inscribieron en este estudio. Se usó un régimen de dosificación que consistía en dosis múltiples para reducir el tiempo hasta alcanzar la concentración en estado de equilibrio. En resumen, los pacientes recibieron una dosis inicial de 800 mg del medicamento, ya sea por vía intravenosa o intramuscular, seguida de tres dosis adicionales de 400 mg, administradas cada 12 horas.

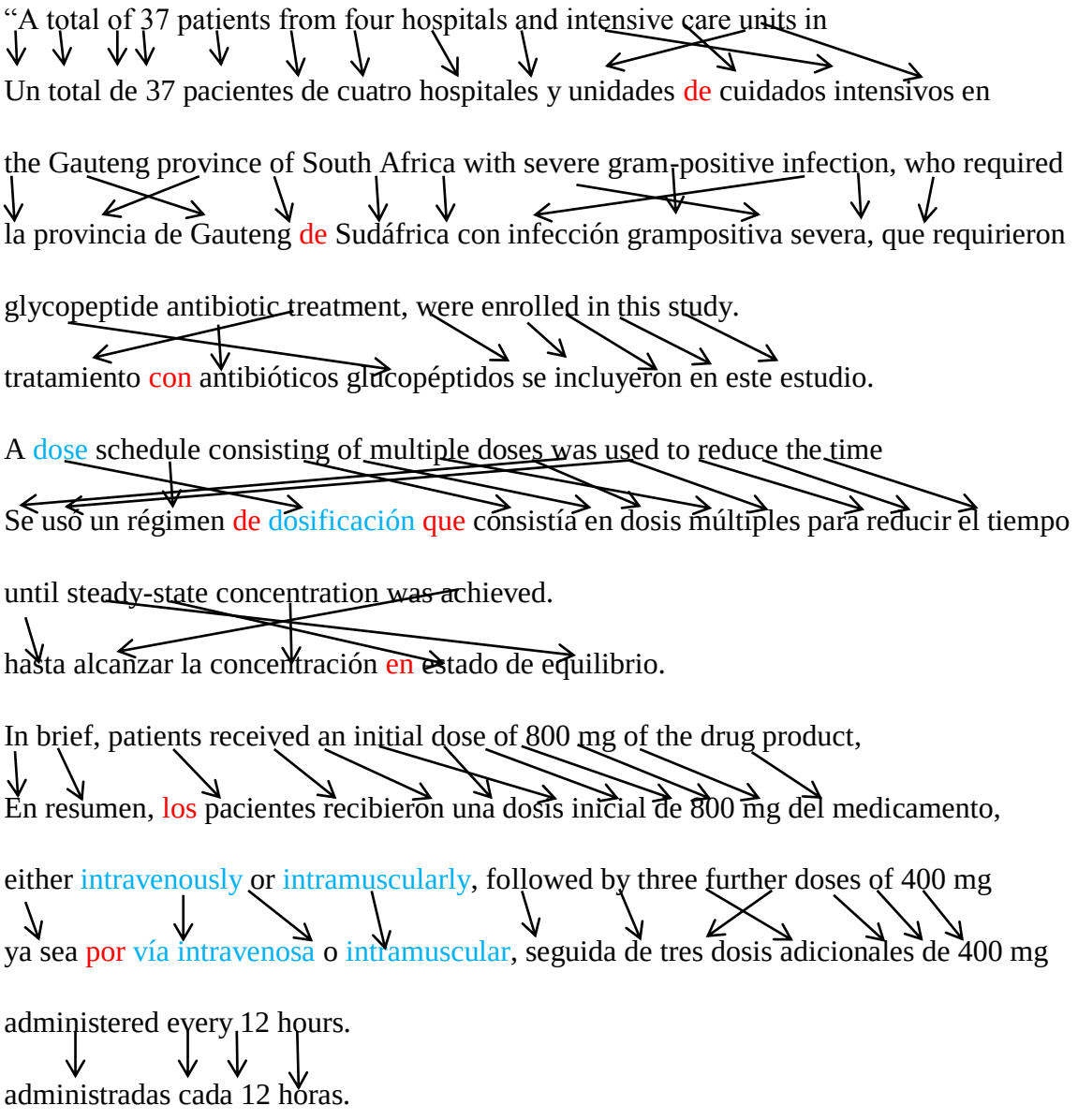
- **Text Analysis**

Document	Function	Style	Register	Tone
Monograph	Informative	Descriptive	Technical	Neutral

- **Analysis of the technical terms:**

Item No.	Technical term	Equivalence	Equivalence used for the context	Comment
1.	Multiple dose	Multiples dosis// dosis multiples	Con dosis múltiples/ múltiples administraciones	It is not appropriate to speak of "multidosis", in this context dose acts with another of its meanings, which is "administración".
2	Steady –state concentration	Estado equilibrio//estado estacionario	Concentración en estado de equilibrio	For this context it refers to a state in which the concentration of a substance is maintained within relatively constant values. By virtue of the balance established between the formation and contribution of the substance, its distribution and its elimination from the organism.

- **Analysis of translation**



Comment: The translation of this paragraph has the following characteristics:

- There is a kind of parallelism between the ST and TT, it means, sentences have almost identical structures in both languages.
- As we can see most of the translation procedure used was the literal translation, keeping the main meaning of the paragraph and the grammatical rules (**black words/direct translation**).
- The use of definite articles (la, los) and prepositions (de, con, por) were completely necessary at the TT (**red words).**
- The words "intravenously or intramuscularly" which were working as adverb in the ST, were changed to adjectives at the TT (**sky blue words / transposition**).

Example 2:

- **Reading and identification of the technical terms**

ST: The primary end-point at 90 days was increased in the facilitated group (19% vs 13%, p = 0.0045), along with the stroke rate (1.8% vs 0%, p < 0.0001). These disappointing results have been attributed, in retrospect, to an alleged pro-thrombotic effect of TBL and, more convincingly, to the risk of creating an intra-plaque hemorrhage by inflating the balloon in the first 2 hours after TBL (ie, in a lytic state). In retrospect, the risk of death at 90 days was reduced by XXXase facilitation when patients were randomized in ambulance (relative risk 0.74, 95% CI 0.24–2.30) and mostly increased when patients were recruited in P-PCI capable hospitals (relative risk 1.62, 95% CI 0.94–2.81).

- **Translation**

TT: El criterio de valoración primario a los 90 días se incrementó en el grupo proporcionado (19% vs 13%, p = 0.0045), junto con la tasa de accidente cerebro vascular (1.8% vs 0%, p < 0.0001). Estos resultados desalentadores se han atribuido, en retrospectiva, a un supuesto efecto pro-trombótico de TBL y, de manera más convincente,

al riesgo de crear una hemorragia intraplaca mediante la inflación de balón en las primeras 2 horas después de TBL (es decir, en un estado lítico). En retrospectiva, el riesgo de muerte a los 90 días se redujo por la facilitación de XXXasa cuando los pacientes fueron asignados al azar en ambulancia (riesgo relativo 0,74; IC del 95%: 0,24 a 2,30) y aumentó principalmente cuando los pacientes fueron reclutados en hospitales con capacidad P-PCI (riesgo relativo 1.62, IC del 95%: 0.94 a 2.81).

- **Text Analysis**

Document	Function	Style	Register	Tone
Excipients	Informative	Descriptive	Technical	Neutral

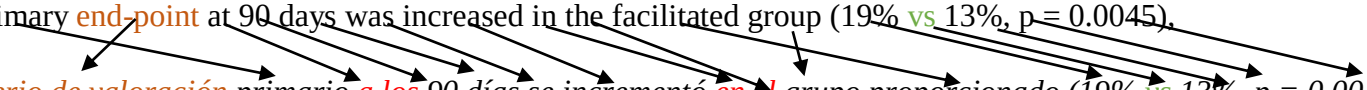
- **Analysis of the technical terms:**

Item No.	Technical term	Equivalence	Equivalence use for the context	Observation
1	End-point	Punto final Punto extremo Criterio de valoración Objetivo clínico Variable principal	Criterio de valoración	According to the context the Word end point is used frequently to evaluate the efficacy and safety of the drug.
2	Balloon	Globo Balón	Balón	In this case it refers to the angioplasty process where a catheter with a balloon at one end is

				used to open and block blood vessels and improve blood flow
3	Facilitation (s)	Facilitación (s) Asistencia (s)	Facilitación (s)	It should be noted that the connotation of this word refers to a process by which a reflection is established more easily the more frequently the excitations caused by this reflection are repeated.
4	Randomized	Aleatorizados Asignados al azar Distribuir al zar	Asignados al azar	According to the context the word acquire this meaning because it speaks of patients.

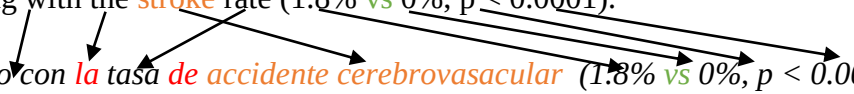
- **Analysis of translation**

The primary end-point at 90 days was increased in the facilitated group (19% vs 13%, p = 0.0045),



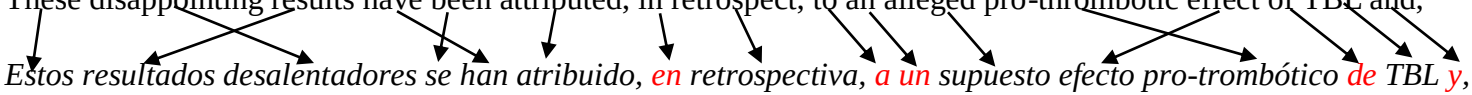
El criterio de valoración primario a los 90 días se incrementó en el grupo proporcionado (19% vs 13%, p = 0.0045),

along with the stroke rate (1.8% vs 0%, p < 0.0001).



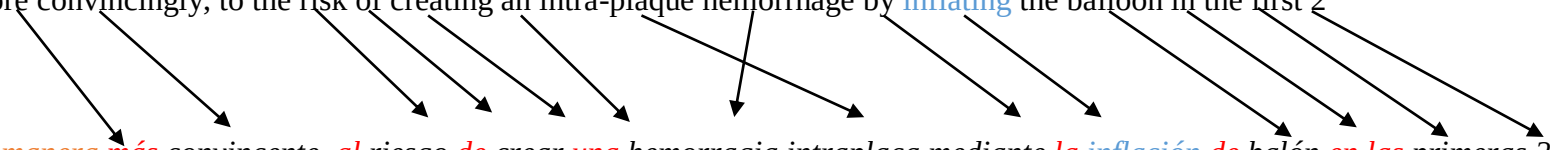
junto con la tasa de accidente cerebrovasacular (1.8% vs 0%, p < 0.0001).

These disappointing results have been attributed, in retrospect, to an alleged pro-thrombotic effect of TBL and,



Estos resultados desalentadores se han atribuido, en retrospectiva, a un supuesto efecto pro-trombótico de TBL y,

more convincingly, to the risk of creating an intra-plaque hemorrhage by inflating the balloon in the first 2

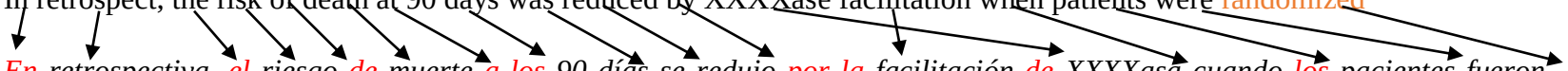


de manera más convincente, al riesgo de crear una hemorragia intraplaca mediante la inflación de balón en las primeras 2

hours after TBL (ie, in a lytic state).

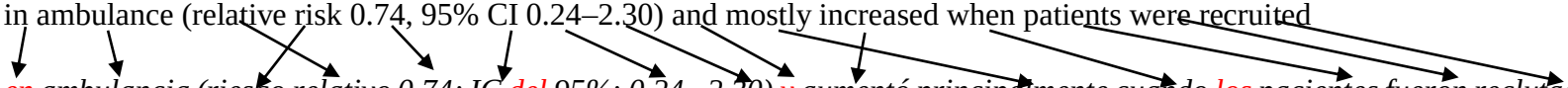
Horas después de TBL (es decir, en un estado lítico).

In retrospect, the risk of death at 90 days was reduced by XXXXase facilitation when patients were randomized



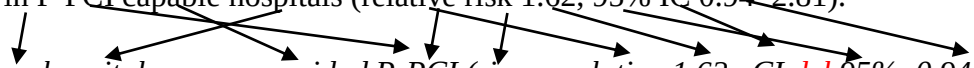
En retrospectiva, el riesgo de muerte a los 90 días se redujo por la facilitación de XXXXasa cuando los pacientes fueron asignados al azar

in ambulance (relative risk 0.74, 95% CI 0.24–2.30) and mostly increased when patients were recruited



en ambulancia (riesgo relativo 0,74; IC del 95%: 0,24 - 2,30) y aumentó principalmente cuando los pacientes fueron reclutados

in P-PCI capable hospitals (relative risk 1.62, 95% IC 0.94–2.81).



en hospitales con capacidad P-PCI (riesgo relativo 1,62 , CI del 95%: 0,94 - 2,81).

Comment:

Here the literal translation was applied. It was not necessary to apply other procedure, because as it can be observed the precision of this type of text focuses more on the precision of the terms where we had to look for information in the specific field per se. In addition, it was required to add some articles and prepositions (red words) to give sense to the text. In order to keep the sense of the text it was required to look for additional information to understand the text completely (orange words). For instance: it was found the expression "i.e", which is the abbreviation of the Latin expression "Id est" which can be translated as "es decir". Then, we had to look for the meaning of the abbreviation "*IC"* (which we discovered that comes from the phrase "interval confidence") into "*CI"* which describes the variability between obtained measure in a study and the real measure of the population (real value). The acronyms TBL makes reference to the word trombolisis. "P-PCI capable hospitals" refer to hospitals with capacity to realize a primary coronary angioplasty and P-PCI (referring hospitals) have defined protocols, with transfer criteria and agreements established with a trained hospital (receiving hospital). If we do not go beyond to understand the maybe the text can miss of sense.

4th stage: Revision and correction of the first draft (to verify that the translation keeps the meaning of the source text)

The institutional tutor was in charge of the revision of dossiers, not only the content of the T. T. must be well translated; but also we had to keep the format of the S. T. elaborating the images, flow charts, and chromatograms. The institutional tutor corrected each translation per week; the correction of the written text was at the sentence level: the correct use of verbs, prepositions, connectors, spelling, grammar, syntax, punctuation, precision in word choice.

5th stage: Proofreading (To check that the translation was developed appropriately without errors of cohesion and coherence, spelling and punctuation).

The doctors in charge of the dossiers at FARMEDICAL SRL did the proofreading of the translation. They also verified that the technical terms were the correct ones in order to keep the meaning and the format of the source text by comparing the two texts. It is important to mention that they were in charge of the final draft as well.

3.3 INITIAL ACHIEVEMENT

The translation of the six dossiers (PDF) from English into Spanish at FARMEDICAL SRL was the main achievement of this supervised work. Each dossier varies from 590 to 685 pages. At the end, we translated 3.867 pages on six months, and as a result, FARMEDICAL SRL presented on time the dossiers to the Minister of Health and fulfilled the sanitary register to obtain the license for preparing, distributing, importing, and marketing of drug products. In this sense, we satisfied the needs of the institution related to the translation field.

The dossiers include investigations based on pharmacological procedures, all this written documentation had to be translated from English into Spanish. The present list of technical terms is intended to be a practical guide for translators who faces problems with the translation of unfamiliar, confusing or unclear terms related to the pharmacological field. About 100 technical and ambiguous terms have been selected and organized with the purpose of achieving an optimal equivalence.

By developing the translation of a technical and scientific text (dossiers), some technical terms were gathered with the aim to elaborate a glossary related to the pharmacological field. To develop this glossary we worked in the following stages:

a) Identification of the technical and key terms during the translation of the first draft. During this stage any terms that seemed unfamiliar, confusing or unclear were underlined.

b) Searching of all the possible equivalences of the terms according to the context.

c) Selection of the equivalence according to the criteria of the doctor at FARMEDICAL SRL

3.4 EXPERIENCES

Working on the translation of dossiers from English into Spanish AT FARMEDICAL SRL was a fascinating experience, but also it was difficult. Even, if we can highlight the knowledge and experience gained during the process of scientific technical translation and at the same time we were able to put into practice all our translation competence (punctuation, spelling, procedures of translation, grammar and terminology adequacy), we cannot minimize the fact that translating the dossiers represented a great challenge.

Why was the translation of the dossier a challenge?

Let us answer this question by clarifying what kind of information a dossier contains. Well, a dossier is a very voluminous file that provides all the chemical, pharmaceutical, biological and clinical data of the medicine, therefore, according to Navarro this type of documents must be translated by a) a graduated in medicine, b) graduated in translation (specialized in medical and scientific translation). At the beginning, we commit very serious mistakes in the translation of the dossiers (since we are not specialized translators in the medical field), that is why it was essential to perform such translation with the tutelage of doctors or pharmacologists to ensure the correct translation of the medical part of the dossiers.

Hence, the purpose of the following information is that our readers know specifically what kind of difficulties represented a challenge for us when translating the dossiers.

1. Lack of knowledge about the terminology related to the area

Since we did the corresponding text analysis, we realized that there were quite a few terms completely new to us. We know that it is normal that a scientific text frequently has technical terms, but the problem was that as we already mentioned previously, none of us is a translator specialized in medicine or pharmacological field. It was then that online glossaries and dictionaries became our "friends", but being honest, it did not always solve our difficulties, although these tools allowed us to obtain a variety of equivalences of the terms and even their definitions, having no technical knowledge of which equivalence to use in the specific context made us to make several mistakes. Let us look at some examples:

Technical term	**Equivalence**	**Equivalence used for our context**
Screening (s)	Prueba, examen, diagnóstico, investigación, selección, análisis, cribado	Selección

This term is commonly found in flow charts (in which it is mentioned how many patients participated in the test in order to perform the inclusion or exclusion process). Now, if we pay attention to the Spanish translations of the term “Screening” to us any of them fit into the context (or at least we believed that during our first weeks as translators). However, how to know which translation corresponded to our context? For this, we began a small stage of research, that is to say, we looked the word “screening” in scientific articles or monographs in English, once reading all the information we could understand by “screening the process of selecting the possible candidates for inclusion in study". In

addition, to be completely sure that this translation was correct for our context, we consulted one of the doctors of the company who confirmed if the translation was adequate. We follow this procedure with all the technical terms to ensure that our translation was correct.

2. Adjective order

Anyone who has studied English knows that the name goes after the adjective, for us the "assumption" that it is translated from right to left made us believe that there was no difficulty with the order of the adjectives, but well, when translating the dossiers we found cases in which we had difficulties with the order of adjectives. If we pay attention to the following examples, we noticed that they do not follow the traditional translation scheme that goes from right to left, since when translating them from left to right the idea would be misunderstood. For instance:

- **Plasma concentration time profile (ST)**
  - *El perfil de tiempo de la concentración plasmática (wrong)*
  - *El perfil de concentración plasmática en función del tiempo. (Right)*
- **Sterile edge hydrophobic membranes (ST)**
  - *Membranas hidrofóbicas de borde estéril. (wrong)*
  - *Membranas estériles con borde hidrofóbico (right)*

3. The compound words

For us, one of the most confusing task was to determine the most suitable translation of compound words, that can represented a recurrent difficulty when translating this technical texts. In the dossiers, we found words that we classified into:

- Closed form like baseline.
- Hyphenated like head-to-head
- Open form like extended release.

In such cases, it can get very tricky for us to make de following differences:

- High dosage chemotherapy quimioterapia a alta dosis
- High-dose chemotherapy quimioterapia a altas dosis
- High dose chemotherapy quimioterapia a dosis alta

In order to solve this doubts we needed to work hand to hand with doctors who are familiar with these technical texts.

4. Polysemy

Since each of us translate in a different way, we differ greatly in the results obtained. The complexity of the current medical language is the source of many other serious difficulties, such as synonymy or polysemy. In technical translation must find the precise term in order not to change the meaning. For instance,

We found the term "*baseline*" that can have many equivalences in Spanish, and almost all deem that it is "the information found at the beginning of a study or other initial known value which is used for comparison with later data". Of course, we select the meaning according to the context. We found the word ***Baseline*** in the following context:

"Global subjective facial expression rate will be summarized at each visit. Change from ***baseline*** to each visit in Period I and Period II will also be presented."

As it can be observed in the sentence the word *baseline* functions as a noun, therefore we tried to select the appropriate equivalence that fits in the context and the correct equivalence for this sentence was "es un valor conocido o inicial a partir del cual pueden compararse valores posteriores de lo que se está midiendo"

Along the translation, we noted that the word *Baseline* mostly works as an adjective such is the case of the next phrase:

"Baseline temperature or blood pressure"

That can be understood as: temperatura/presión arterial al inicio/al principio

Or

- "Baseline results": resultados iniciales.
- *Baseline level*: nivel inicial/de partida.

In addition, it can also mean fundamental. For instances:

- *Baseline data:* datos fundamentales/ originales.
- *Baseline disease*: enfermedad de base.

We needed to be very cautious when we dealt with this term because of the precision we must have to make the text understandable.

5. False cognates

In the process of translation, one of the recurrent identified problem were the words that in different languages were written in the same way, or in a similar way, but actually, they have completely different meanings. The fearsome "*false friends*". Sometimes at the time of translating the exact word into Spanish, we try to guess with the one that sounds more similar to us in English. This can work some times, but not always. For example: when we dealt with the Word constipated, we were almost sure that it was referring to a person who has difficulty passing a bowel movement "estreñido", however, we did not imagine that, it was making reference to a person with respiratory disease. As can be observed in the above example, this type of words can alter the version translated. In addition, when we performed the translation we had to be careful with the unknown technical words and to put special attention to the context in which the word was found. Other examples found were the following words:

- Sane: cuerdo, sensato (does not refer to a person who is healthy or in good health).
- To assist: ayudar, prestar asistencia, auxiliar, prestar ayuda (and not 'asistir' in the sense of to attend);
- Gripe: cólico o retortijón (and not 'gripe', which is flu o influenza).

These are just some examples we found along the translation.

6. Use of abbreviations, acronyms, units of measurement and chemical symbols

The next experience gained, at the time we were working at FARMEDICAL SRL, was the importance of distinguish the use of abbreviations, acronyms, units of measurement and chemical symbols found on the dossiers.

As an anecdote, at the beginning of the translation process our translation was observed because we did not know how to translate the abbreviations, acronyms, units of measurement and chemical symbols found on the ST. For that reason, we consider important to highlight the differences among them, because, the abbreviations and acronyms could be or not translated. Example: English acronyms "WHO" is translated to "OMS" in Spanish, but the abbreviation Rt (retention time) does not have Spanish equivalence. Meanwhile, the units of measurement and chemical elements are universal, they do not change, example: Na (sodium), or g (gram).

Example: for us the most relevant examples are the next:

Quantities: taking from the ST: *"Batch Size: 10.0 kgs.", "pH (50mg/ml) Dissolve in 50 mL" or "dissolve 45.42gm."* However, according what the International System (IS) of measurement it has its own rules to write symbols, and according the rules the correct translations are:

Source Text	Target Text	IS
Batch Size: 10.0 kgs.	**Tamaño del Lote:** 10.0 kg	Never use period after the symbol nor plural because they are not abbreviations.
pH (50mg/ml) Dissolve in 500 mL	pH (50mg/ml) o pH (50mg/mL) Disolver en 500 mL o Disolver en 500 ml	Liter accept two symbols "L" or "l" to not confuse the number "1" with the lower case "l".
Dissolve 45.42 gm	Dissolver 45.42 g	According with IS the symbol for gram is "g".

The next example is related with the periodic table: The periodic table of elements shows the elements and their symbols, which are usually the first letter or first two words of the element's name. A few elements, however, have been known that their symbols derive from their Latin or Greek names. For example, the symbol for *lead (Pb)* comes from the Latin word "plumbum". Chemical symbols with two words always have the first letter capitalized and the second letter written in lower case. This standard format prevents confusion. For example, the symbol Bi represents bismuth, element 83. If you see BI, that represents a compound made of boron (B, element 5) and iodine (I, element 53).

When the doctor in charge found these errors on the TT, she came to our office and explained what is the IS, the chemical nomenclature that they use, and for acronyms she suggested us some web pages in order to get more information to correct these translation problems.

7. Format of the ST

The last experience gained, that we considered important to indicate, was the importance of the ST format because we need to replicate the exactly format on the TT. To mention some examples: The ST has a specific number of pages (page 2 of 39) and the TT must have the same number of pages. Another characteristic that we need to meet is the page header and page footer, because in these parts are the mane of the product, the part, number of page, dates, and the responsible. Other important aspect to take care are drawings, charts, graphic, tabulation etc.

Example: the next two examples shows the format of the page header and page footer on the ST.

QUALITY CONTROL DEPARTMENT

STANDARD TESTING PROCEDURE (In Process)		**STP No. : TP-10-028**
Title: [illegible]		**Revision No : 04**
Department Quality Control	**Location** [illegible]	**Effective Date : 24/07/17**
		Page No. : Page 2 of 39

(Page header)

	Prepared By	Checked By	Approved By
Name			
Signature			
Date			

(Page footer)

The next example shows the page format of the ST

5	Water - R	Wash 3 times with WFI and incubate on shaker	3 x 5 mins.
6	Solution D (Developing Solution)	Developing (Maintain dark During this operation and develop the gel manually)	Till band appears with the Reference Solution
7	Solution E (Stop Solution)	Stopping: Soak the gel in stop solution and incubate on shaker.	5 - 10 Min
8	Water - R	Wash with Water – R and preserve the gel in Water – R till the gel is dried.	

8.2.7.5 Drying of gel

Dry the gel as per procedure given in SOP for Gel-dryer (SOP No.: QC/H036 [Operation of Gel drying system])

It looks irrelevant or meaningless for translation process, or for recommending to future translators to be careful with that. However, we saved time only when we improved our office program *Word* skills because in 39 pages maybe it could affect less than one hour in the whole translation process, but imagine how it affects in six hundred or more pages, and as it was mention on the objectives, the translation should have presented on time .

CHAPTER IV

RESULTS

Through this supervised work, we responded to Farmedical's need, which states that "for preparing, manufacturing, distributing, importing, and marketing of drug products dossiers should be presented in Spanish to the Ministry of Health."

Due to the six dossiers were translated from English into Spanish, FARMEDICAL SRL presented the dossiers to the Minister of Health on time. As a result, FARMEDICAL SRL fulfilled the sanitary register and obtained the license for preparing, distributing, importing, and marketing drug products.

Therefore, the final product presented to FARMEDICAL SRL was the translation of six Dossiers, for translating the dossiers was necessary to use appropriate methods and techniques, and to elaborate a glossary. Each dossier was divided in 5 parts: COA (certificate of analysis), analytical procedure, excipients, monograph and galenic development; the number of pages from each dossier varies from 590 to 685 pages, 3.867 pages were translated on the six months.

The translation method used along the supervised work were the Direct Translation, and in some parts it was necessary to use the Oblique Translation. The most common translation procedure used in this supervised work was "Literal Translation".

The technical glossary presented to the institution contains 171 technical terms related to medicine and pharmacological field. The glossary is divided in two parts: Acronyms (71) and technical terms (100). They are presented in alphabetical order. The meaning of the words are presented in Spanish because not all doctors or pharmacologists speak English, most of them have an intermediate or basic level, but only few of them have an advance level of English. As an additional contribution to FARMEDICAL SRL we elaborated a list of acronyms used on the ST.

CHAPTER V

CONCLUSIONS AND RECOMMENDATIONS

5.1 CONCLUSIONS

The central problem of this supervised work was to find out how to translate pharmaceutical dossiers in the most communicative and reader-friendly manner for experts, semi-experts and nonprofessionals respectively.

As medical language is a sub-category to scientific language. It is important to know that the purpose and style of scientific and technical translation is different. Based on the analyses, there are some recommendations that are important for a translator to consider when translating into Spanish.

Six pharmacological texts were translated due to regulatory requirements concerning new medical products and medical devices or new applications of pharmacological products. What also generates the demand for the translation of medical texts is the need to conform to the formal requirements applicable to clinical trial registration and conduct or marketing new drugs, which involves translating the registration documents and other necessary materials to the local language. The translators of pharmacological dossiers face a number of challenges, some of which are the subject of supervised work.

- To choose the suitable method along the translation process of Drug Products dossiers

In order to fulfill this purpose and to present it as a translation, we preserved the semantic and structural similarity of the target text.

Direct Translation was mostly used along the translation of dossiers; however, some parts needed to use Oblique Translation. Considering the type of translation, we applied different techniques, but the most common technique used was “Literal Translation.” This technique allowed us to focus predominantly on adhering to the

linguistic rules of the target language and concentrate on the precision of technical terminology.

The whole translation process involved *Reading and Analysis of the information*, identification of the technical terms through data collection, analysis of the technical terms, first-draft translation, revision and correction of the first draft, and the proof reading.

- To identify technical and ambiguous terms and analyze them to find out the accurate equivalent according to the context.

The medical translator deals with what is called medical language, which differs from everyday language in the specificity of its terminology. This proposal has been concerned with identifying the problem of terminological inconsistency in medical translation from English into Spanish. It has attempted to discover the most successful type of equivalence in specialized and non-specialized contexts of medical books and drug products insert (DPI) based on criteria of usability and circulation of the equivalence in relation to the context of use and the type of the target audience.

- To create a bilingual glossary that works as reference for doctors, health personnel, patients, legal representatives and others.

This English-Spanish Glossary of Health Related Terms was developed as an instrument for health care personnel and other professionals working. The main purpose of the glossary is to facilitates doctors, health personnel, patients, legal representatives and others the understanding of the information, and facilitate dialogue by reducing the linguistic barriers.

In our mission to close the language gap, we created our glossary as an integral mechanism for ensuring and controlling the quality of our translation. This also implicates that we monitored and controlled the quality of terminology. To do that; first, we identified the terms in our main text that need to go into the glossary. Then, we created definitions

for these terms and make sure the formatting of the glossary is correct so it is polished and easy to read.

5.2 RECOMMENDATIONS

Based on experiences fulfilled along the supervised work performed on translation of dossiers from English into Spanish is relevant to make some recommendation and suggestions about the STT to the novice translators:

One of the challenges in technical translation is the appropriate translation of the technical terms. In this case the use of a dictionary is not enough, the consultation of specific material in the area should be used, and perhaps support from people who use this terminology in the language to which they want to translate in order to create a glossary of key terms that can help improve the quality and consistency of the translation.

Any translator must submit his/her work to supervision of personnel who is able to perform the role of reviewer. It is advisable that a general reviewer should take care of the revision of most of the translation, and another doctor or one with a degree in health sciences is responsible for reviewing the scientific part.

In order to ensure terminology consistency, save time, increase their productivity and improve the general quality of their translations, translators must use some informatics applications useful for the translation. In the Internet, it is not enough to have much specialized encyclopedias, dictionaries or glossaries as "specialized professionals", but to know how to use the sources of documentation and use memories of translations will be very helpful. It is advisable to take additional courses of translation tools. With regard to informatics, one must keep in mind that the work performed should maintain the style of the source text

Before making any modification to the text, it is important to peruse and to understand completely the text. It is crucial to understand the essence of the text in order to produce a faithful rendering of the target text it means that it is preferable not translating word by word.

Within the technical translation, a translator must be very careful with the false cognates because this can significantly alter or change the meaning of the text. Another aspect to be taken into account is the syntactic ambiguity along the translation one must be enough clear when translating this type of text.

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ANNEXES

I) THE INSTITUTIONAL AGREEMENT OF COLLABORATION

a) Institutional Agreement

CONVENIO INTERINSTITUCIONAL DE COOPERACIÓN ACADÉMICA ENTRE LA CARRERA DE LINGÜÍSTICA E IDIOMAS DE LA UNIVERSIDAD MAYOR DE SAN ANDRÉS Y FARMEDICAL SRL

Conste por el presente Convenio Interinstitucional de Cooperación Académica, cuyo contenido y alcance están enmarcados en el ordenamiento jurídico vigente, así como las competencias y atribuciones de las entidades mencionadas, bajo término y condiciones descritas en las siguientes cláusulas.

PRIMERA.- (DE LAS PARTES INTERVINIENTES)

Concurren a la firma y suscripción del presente Convenio Interinstitucional de Cooperación Académica:

1. La **FACULTAD DE HUMANIDADES Y CIENCIAS DE LA EDUCACIÓN - CARRERA DE LINGÜÍSTICA E IDIOMAS DE LA UNIVERSIDAD MAYOR DE SAN ANDRÉS,** representado legalmente por el Lic. Orlando Montaño Molina Director de la Carrera de Lingüística e Idiomas, que en adelante y para fines del presente convenio se denominará **LA CARRERA.**

2. **FARMEDICAL SRL** representado legalmente por el Señor Carlos Fernández, quién para fines del presente Convenio se denominará **FARMEDICAL.**

A efectos del presente documento, las personas jurídicas identificadas en los numerales anteriores, serán denominadas en su conjunto como **PARTES** e individualmente como **PARTE.**

SEGUNDA.- (DE LOS ANTECEDENTES)

Las PARTES, han resuelto aunar esfuerzos para cooperarse mutuamente a fin de lograr un mejor desarrollo académico.

FARMEDICAL tiene como misión y visión:

a. Proveer salud a la población en general, a través de la comercialización de productos farmacéuticos con altos estándares de calidad, seguridad y accesibilidad de costo tratamiento.
b. Constituirnos en una empresa del rubro farmacéutico líder a nivel internacional, con participación en toda la cadena productiva, desde la investigación y desarrollo hasta el consumidor final; generando imagen y desarrollo de la industria farmacéutica con proyección y liderazgo mundial.

Por su parte la Carrera de Lingüística e Idiomas, en el marco de sus fines y principios orientados a formar profesionales comprometidos con la problemática social y que afecta a la población y a la práctica comunitaria, tiene previsto en su plan curricular la realización de prácticas pre profesionales de Trabajo Dirigido como modalidad de graduación.

TERCERA.- (DEL OBJETO)

El presente convenio interinstitucional, tiene por objeto la traducción de Dossiers Farmacéuticos del inglés al castellano utilizando los métodos apropiados para garantizar una traducción apropiada.

Para el efecto, **FARMEDICAL** dará lugar a la realización de Trabajos Dirigidos a egresados de la CARRERA DE LINGÜÍSTICA E IDIOMAS.

CUARTA.- (DEL ALCANCE)

El presente convenio interinstitucional, pretende coadyuvar al desarrollo de los programas y proyectos en dependencias de **FARMEDICAL**. Por parte de los estudiantes egresados que obtienen su licenciatura en la modalidad de Trabajo Dirigido, con el seguimiento de docentes tutores de la Carrera de Lingüística e Idiomas.

QUINTA.- (DE LAS RESPONSABILIDADES Y COMPROMISOS)

Las partes se responsabilizan y se someten al cumplimiento de las siguientes obligaciones:

5.1 FARMEDICAL se compromete a:

a) Facilitar las prácticas de los pres profesionales de la Carrera de Lingüística e Idiomas otorgando información necesaria de las actividades y proyectos.
b) Otorgar a los facilitadores, los espacios físicos y el material logístico necesarios para la realización de la práctica en el marco de los requisitos exigidos para ambas instituciones.
c) Presentar informes bimestrales y en el informe final las respectivas calificaciones otorgadas a los traductores.

5.1 La **CARRERA DE LINGÜÍSTICA E IDIOMAS** se compromete a:

a) Definir las áreas de aplicación en coordinación con el tutor asignado.
b) Asegurar, la continuidad de las prácticas de los pres profesionales mientras dure el presente convenio.
c) Asignar y apoyar con el número suficiente de estudiantes de la Carrera de Lingüística e Idiomas, para la enseñanza de idiomas.
d) Brindar, asesoramiento teórico, metodológico, técnico de los profesionales para este efecto, los requerimientos académicos con las políticas institucionales y las demandas de población.
e) Los aplicantes pondrán en práctica su conocimiento, competencias y estrategias en traducción de textos escritos del idioma inglés al castellano.

f) Garantizar que los practicantes cumplan un mínimo de 1000 horas de trabajo que serán desarrolladas dentro de la Institución.

SÉXTA.- (CONFIDENCIALIDAD)

Por la naturaleza de las atribuciones y competencias de **FARMEDICAL** el contenido de documentos es de carácter CONFIDENCIAL lo que es de conocimiento de los pasantes y no podrá ser divulgado ni revelado.

SÉPTIMA.- (MODALIDAD DE EJECUCIÓN)

Para efectivizar el presente convenio de la Carrera de Lingüística e Idiomas, realizará la evaluación de los estudiantes que estén en condiciones de realizar sus prácticas pre-profesionales.

Posteriormente se procederá a la suscripción del "Documento de Compromiso Individual", con cada pasante, donde se establecerán las condiciones, tiempo de duración y horarios. Finalmente los egresados que se encuentren realizando pasantías serán sometidos a las evaluaciones de rendimiento que **FARMEDICAL** estime necesarias.

OCTAVA.- (DURACIÓN Y VIGENCIA DEL CONVENIO)

El presente Convenio tendrá como plazo de vigencia de un (1) año computable a partir de la fecha de su suscripción, pudiendo renovarse mediante un documento similar, de acuerdo con la conveniencia y previa evaluación de las Partes.

NOVENA.- (NOTIFICACIONES)

Cualquier aviso o notificación que deba efectuarse entre las partes, en el marco del presente Convenio, será remitido a:

- **La CARRERA:** Av. 6 de Agosto N° 2080-Casa Montes.
  - La Paz - Bolivia
  - **Teléfono:** 2444165
  - **Email:** linguistica_2010@hotmail.com
- **FARMEDICAL SRL:**
  - **Oficina Central:** Av. Hernando Siles N° 6007 esq. Calle 14 de Obrajes
  - **Teléfono:** 2788494
  - **Teléfono/fax:** 2782349
  - **Email:** traduccion@farmedicalcorp.net

Avenida 6 de Agosto N° 2080 • Telf./Fax: (591-2) 2444165 Telf. IP. 2612509
Sitio Web: www.linguistica_umsa.edu.bo • E-mail: informes@linguistica_umsa.edu.bo • La Paz - Bolivia

DÉCIMA. - (MODIFICACIONES)

El presente Convenio podrá ser complementado o modificado en cualquier momento durante su vigencia por mutuo acuerdo de las PARTES, mediante la suscripción de una Adenda, previa evaluación técnico legal.

DÉCIMA PRIMERA.- (SOLUCIÓN DE CONTROVERSIAS)

El presente Convenio se suscribe amparado en el principio de Buena Fe, por tanto las partes establecen que en caso de producirse alguna controversia en relación a su ejecución, la misma será resuelta por medio de la negociación directa.

DÉCIMA SEGUNDA.- (CAUSALES Y PROCEDIMIENTO DE CONCLUSIÓN DEL CONVENIO).-

El presente Convenio podrá ser disuelto en caso de verificarse cualquiera de las siguientes situaciones:

a) Por mutuo acuerdo de partes.
b) Por cumplimiento del plazo establecido, si no mediara la renovación del Convenio.
c) Unilateralmente, ante el incumplimiento de cualquiera de las cláusulas de este Convenio, por una de las partes.

Previamente a la resolución del Convenio en forma unilateral por cualquiera de las partes suscribientes, se deberá notificar por escrito a la otra con treinta (30) días de anticipación.

En caso de resolverse, las actividades iniciadas y en curso de ejecución deben culminarse.

DÉCIMA TERCERA.- (CONFORMIDAD)

Las partes manifiestan su plena conformidad con todas y cada una de las cláusulas que preceden, obligándose a su fiel y estricto cumplimiento, en fe de lo cual suscriben al pie del presente documento, en dos ejemplares; es dado en la ciudad de La Paz, a los doce días del mes de noviembre del año 2018.

Sr. Carlos Fernández Aguilar
GERENTE GENERAL
FARMEDICAL SRL

Lic. Orlando Montaño Molina
DIRECTOR
CARRERA LINGÜÍSTICA E IDIOMAS

b) Confidentiality Agreement

FARMEDICAL
Corporación Internacional

La Paz, 26 de Noviembre de 2019

Señores
Alejandra Copa Criales
Ines Noemí Arana Alcazar
Larry Fernando Flores Miranda
Presente

REF: RESPUESTA A SOLICITUD DE INFORMACION DE DOSSIERS

Estimados estudiantes,
En respuesta a su solicitud y de acuerdo con el contrato de confidencialidad firmado por sus personas con la empresa, y de acuerdo con el " **CONVENIO INTERINSTITUCIONAL DE COOPERACIÓN ACADÉMICA ENTRE LA CARRERA DE LINGÜÍSTICA E IDIOMAS DE LA UNIVERSIDAD MAYOR DE SAN ANDRÉS Y FARMEDICAL SRL** " (punto sexto de Confidencialidad) firmado por el Lic. Orlando Montaño Molina en fecha: 12 de noviembre de 2018, reiteramos que la información de los Dossiers es de carácter estrictamente confidencial, por lo tanto dicha información no puede ser entregada a terceros.

La empresa FARMEDICAL S.R.L. mantiene acuerdos internacionales de comercialización en los cuales se señalan puntos de confidencialidad con los proveedores del exterior respecto a toda la información de sus productos:

*"**d. INFORMACIÓN CONFIDENCIAL**: Se refiere a cualquier información y datos recibidos del PROVEEDOR en conformidad con este Acuerdo, dichos datos e información no deben ser conocidos por terceros y no son de dominio público (incluidos, entre otros, información de los Dossiers farmacéuticos, el plazo de registro y la comercialización del Producto en el Territorio, planes de comercialización, datos sobre know-how, marcas registradas, procesos tecnológicos, etc.)."*

"FARMEDICAL acepta mantener en secreto toda la información obtenida del PROVEEDOR y hacer todo lo que FARMEDICAL pueda hacer para evitar que dicha información se divulgue a terceros. FARMEDICAL acuerda revelar solo a cierto personal y autoridades de FARMEDICAL, pero solo sobre la base de "need to know" con el fin de obtener las Autorizaciones de Comercialización de los Productos en el Territorio durante la vigencia de este Acuerdo, y por un periodo de diez (10) años después de la expiración del mismo, cualquier información confidencial además de este Acuerdo no se utilizarán, excepto para los fines indicados en el punto 2.1 de este Acuerdo."

Por lo expuesto anteriormente, reiteramos que la empresa no puede autorizarles la divulgación de la información solicitada,

Atentamente,

Carlos Alberto Fernandez S.
REPRESENTANTE LEGAL
FARMEDICAL S.R.L.

Carlos A. Fernandez Salguedo
GERENTE DE PLANIFICACION
FARMEDICAL S.R.L.

FARMEDICAL S.R.L. La Paz - Bolivia

www.farmedicalcorp.net

La Paz - Oficina Central
Av. Hernando Siles Nº 5007
esq. Calle 14 de Obrajes
Telf.: 2788494 Telf/Fax: 2782348
info@farmedicalcorp.net

Regional La Paz
Av. Hernando Siles Nº 5007
esq. Calle 14 de Obrajes
Cel.: 69795114 Telf.: 2788484
Telf/Fax: 2782348
regionallp@farmedicalcorp.net

Regional Santa Cruz
Calle Guillermo Burton Nº 100
esq. Calle Calle Salinas
(Condo. del Col. La Salle)
Telf: 3443380 - Cel: 69795142
regionalscz@farmedicalcorp.net

Regional El Alto
Av. Lecuna esq. Av. Rabiñe
Nº 1314 Piso 3
Cel.: 69795122
regionalea@farmedicalcorp.net

Regional Cochabamba
Av. Heroinas Nº 177,
Edif. Santiago Ter Piso
Telf/Fax: 4581190 Cel: 69795131
regionalcbba@farmedicalcorp.net

Regional Sucre
Calle Tarapacá Nº 189
(Entre C/ Florelo y Av. Hernando Siles)
Telf/Fax: 6466870 - Cel: 69795215
regionalsucre@farmedicalcorp.net

Regional Beni - Pando
Calle Pedro Vaca "El Palmar Nº 28"
Telf/Fax.: 4629810 - Cel: 69795197
regionalbeni@farmedicalcorp.net

Potosí
Cel: 69795740 - 69721160

Oruro
Cel: 69795730 - 78903453 - 69800047

Regional Tarija
Av. Pedro Nº 540 entre c/Santa Cruz y Junin
Telf/Fax 6672024 - Cel: 69723737

ITEM	REQUISITOS	1ra. PARTE	2da. PARTE
2.1	FORMULARIO		
	Formulario de Solicitud para Registro y Control de Calidad de Medicamentos (DINAMED Form. 005)	X	X
2.2.	DOCUMENTACIÓN LEGAL – ADMINISTRATIVA DE LAS EMPRESAS	1ra. PARTE	2da. PARTE
2.2.1.	Fotocopia de Resolución Ministerial o Secretarial	X	
2.2.2.	Fotocopia de Certificado de Empresa Vigente	X	
2.2.3.	Información General de Licencia y Fabricantes	X	
2.2.4.	Formato para Aclaración de Particularidades	X	
2.3.	DOCUMENTACIÓN GENERAL DEL PRODUCTO	1ra. PARTE	2da. PARTE
2.3.1.	Certificación del Director Técnico-Regente Farmacéutico	X	
2.3.2.	Certificado de Buenas Prácticas de Manufactura (BPM)	X	
2.3.3.	Contrato de Fabricación o Control de Calidad por Terceros	X	
2.3.4.	Certificado de Producto Farmacéutico Sujeto a Comercio Internacional Consularizado	X	
2.3.5.	Fotocopia de Registro Sanitario Anterior	X	
2.3.6.	Representación Legal	X	
2.3.7.	Fotocopia de Certificado de Despacho Aduanero, solo para los casos de (psicotrópicos o estupefacientes)	X	
2.4.	INFORMACIÓN TÉCNICA DEL PRINCIPIO ACTIVO	1ra. PARTE	2da. PARTE
2.4.1.	Fotocopia de Certificado de Análisis de la Materia Prima	X	X
2.4.2.	Nombre Genérico (D.C.I.) y Clasificación Anátomo Terapéutica (A.T.Q.)	X	X
2.4.3.	Nombre Químico, Formula Estructural, Formula Molecular y Peso Molecular		X
2.4.4.	Características Físicas y Químicas del Principio Activo		X
2.4.5.	Características Organolépticas		X
2.4.6.	Vías de Síntesis o de Obtención de Productos Biológicos		X
2.4.7.	Impurezas y Productos de Degradación		X
2.4.8.	Estabilidad de Principios Activos	X	X
2.4.9.	Metodología Analítica		X
2.4.10.	Validación del Método Analítico		X
2.5.	INFORMACIÓN TÉCNICA DEL PRODUCTO TERMINADO	1ra. PARTE	2da. PARTE
2.5.1.	Desarrollo Galénico del Producto	X	X
2.5.2.	Fórmula Cuali-Cuantitativa	X	X
2.5.3.	Fotocopia del Certificado de Análisis del Producto Terminado	X	X
2.5.4.	Fotocopia del Certificado de Control de Calidad Emitido por el Laboratorio de Control de Calidad de Medicamentos y Toxicología (CONCAMYT)	X	
2.5.5.	Características Fisicoquímicas de los Excipientes	X	X
2.5.6.	Métodos de Manufactura (un resumen o flujograma)	X	X
2.5.7.	Metodología Analítica	X	X
2.5.8.	Validación del Método Analítico		X
2.5.9.	Patrón(es) de Referencia Primarios o Secundarios		X
2.5.10.	Liberación del Producto Terminado	X	X
2.5.11.	Estudios de Estabilidad	X	X
2.5.12.	Condiciones de Almacenamiento	X	X
2.5.13.	Características del Material de Envase	X	X
2.5.14.	Codificación del Lote	X	X
2.6.	DOCUMENTACIÓN TÉCNICA BIOFARMACÉUTICA		
2.6.1.	Estudios de Biodisponobilidad *		
2.6.2.	Estudios de Bioequivalencia *		
2.7.	ETIQUETAS Y RÓTULOS, INSERTOS O PROSPECTOS		
2.7.1.	Etiquetas, Rótulos y Estuches	X	X
2.7.2.	Insertos o Prospectos	X	X
2.8.	EVALUACION FARMACOLOGICA		
2.8.1.	Formulario de Solicitud Calificación DINAMED form. 007	X	
2.8.2.	Formulario de Calificación de Eficacia y Seguridad DINAMED form. 019	X	
2.8.3.	Resumen de Monografía Farmacológica	X	
2.9.	MUESTRA	X	
2.10.	PAGO POR CONCEPTO DE SERVICIO	X	

II) SWOT QUESTIONNAIRE

ENCUESTA DIAGNOSTICO FODA Fecha: _____

Este cuestionario tiene como objeto recolectar opiniones del personal a cargo acerca de las FORTALEZAS, OPORTUNIDADES, DEBILIDADES y AMENAAS en la incorporación del área de traducción en FAARMEDICAL S.R.L.

Por cada una de las declaraciones, marque la opción de acuerdo a la siguiente clasificación.

1. En total desacuerdo
2. En desacuerdo
3. Ni de acuerdo, ni desacuerdo
4. De acuerdo
5. Muy de acuerdo

1. El cumplimiento de las leyes para el registro de los medicamentos de lugar a la necesidad de contratar el servicio de traductores para conseguir el registro de los mismos.

   1 2 3 4 5

2. El área de traducción de FARMEDICAL cuenta con el apoyo de profesionales en el área de farmacología con dominio del idioma inglés, los cuales están dispuestos a ayudar en la clasificación de términos técnicos ambiguos.

   1 2 3 4 5

3. La traducción de dossiers ayudará con el cumplimiento de la Misión de la empresa y es parte de la Visión general de la empresa.

   1 2 3 4 5

4. Se tiene claridad con respecto de hacia dónde va la empresa y cómo la traducción va a ayudar a cumplir los objetivos de la misma

   1 2 3 4 5

5. La documentación traducida beneficiará a la presentación de publicidad, insertos u otra información solicitada por el Ministerio de salud.

   1 2 3 4 5

6. El líder o facilitador designado para el área de traducción tiene buenas habilidades para escuchar, y puede mantener el proceso del grupo en movimiento y orden.

   1 2 3 4 5

7. El responsable del área de traducción se preocupa de evaluar continuamente el desempeño del personal de traducción.

   1 2 3 4 5

Fecha: _____

8. La falta del dominio de la lengua inglesa por parte de las diferentes áreas de la empresa limita el acceso a información de los dossiers.

   1 2 3 4 5

9. Las traducciones pueden afectar negativamente al rendimiento de la empresa.

   1 2 3 4 5

10. El ministerio de salud establece una fecha determinada para la presentación de documentación de registro sanitario, por lo cual la traducción de dossiers tienen una fecha límite.

    - ❑ Si
    - ❑ No

11. Cuál es el plazo de entrega para cada dossier traducido:

    - ❑ Días
    - ❑ Semanas
    - ❑ Meses

12. Dispone FARMEDICAL de estas tecnologías para poder realizar la traducción: (marque las casillas afirmativas)

    - ❑ Computadoras portátiles
    - ❑ Acceso a internet
    - ❑ Correo electrónico
    - ❑ Página web

13. Se realiza cursos de capacitación de terminología técnica al personal de traducción

    - ❑ Si
    - ❑ No

Fecha: 25/09/2018

ENCUESTA-DIAGNÓSTICO FODA

Este cuestionario tiene como objeto recolectar opiniones del personal a cargo acerca de las FORTALEZAS, OPORTUNIDADES, DEBILIDADES y AMENAZAS en la incorporación del área de traducción en FARMEDICAL S.R.L.

Por cada una de las declaraciones, marque la opción de acuerdo a la siguiente clasificación.

1. En total desacuerdo
2. En desacuerdo
3. Ni de acuerdo ni en desacuerdo
4. De acuerdo
5. Muy de acuerdo

1. El cumplimiento de las leyes para el registro de los medicamentos da lugar a la necesidad de contratar el servicio de traductores para conseguir el registro de los mismos.

   1 2 3 4 (5)

2. El área de traducción de FARMEDICAL cuenta con el apoyo de profesionales en el área de farmacología con dominio del idioma inglés, los cuales están dispuesto a ayudar en la clarificación de términos técnicos ambiguos.

   1 2 3 (4) 5

3. La traducción de dossiers ayudará con el cumplimiento de la Misión de la empresa y es parte de la Visión general de la empresa.

   1 2 3 (4) 5

4. Se tiene claridad con respecto de hacia dónde va la empresa y como la traducción va a ayudar a cumplir los objetivos de misma.

   1 2 3 4 (5)

5. La documentación traducida beneficiará en la presentación de publicidad, insertos u otra información solicitada por el Ministerio de Salud.

   1 2 3 (4) 5

6. El líder o facilitador designado para el área de traducción tiene buenas habilidades para escuchar, y puede mantener el proceso del grupo en movimiento y orden.

   1 2 3 (4) 5

X

Fecha:_____

7. El responsable del área de traducción se preocupa de evaluar continuamente el desempeño del personal de traducción.

1 2 3 4 5

8. La falta del dominio de la lengua Inglesa por parte del personal de las diferentes áreas de la empresa limita el acceso a información de los dossiers.

1 2 3 4 5

9. Las traducciones pueden afectar negativamente al rendimiento de la empresa

1 2 3 4 5

10. El ministerio de salud establece una fecha determinada para la presentación de documentos de registro sanitario, por lo cual la traducción de dossiers tiene una fecha límite.

- ❑ Si
- ❑ No

11. Cuál es el plazo de entrega para cada dossier traducido:

- ❑ Días
- ❑ Semanas
- ❑ Meses

12. Dispone FARMEDICAL de estas tecnologías para poder realizar la traducción: (marque las casillas afirmativas)

- ☑ Computadoras portátiles
- ☑ Acceso a Internet
- ☑ Correo electrónico
- ❑ Página web

13. Se realizan cursos de capacitación de terminología técnica al personal de traducción

- ❑ Si
- ❑ No

III) TECHNICAL TERMS

TECHNICAL TERMS		
Item	**Source Text**	**Target Text**
1.	Adult Respiratory Distress Syndrome (ARDS)	Sindrome de dificultad respiratoria del adulto (SDRA)
2.	Active ingredient	Principio activo
3.	Afterloading	Carga diferida o poscarga
4.	Agent	Representante, individuo, agente
5.	Aluminium cap	Cápsula metálica
6.	Apoptosis	Apoptosis.
7.	Aspergillus brasiliensis	Aspergillus brasiliensis
8.	Autoclave	Enterilizar en autoclave
9.	Bacillus subtilis	Bacillus subtilis
10.	Bacterial Endotoxin Test	Ensayo de Endotoxinas Bacterianas
11.	Baseline value	Valor de partida, inicial o basal
12.	Bias search	Sesgo de búsqueda
13.	Bioassay	Ensayos Biológicos (bioensayos)
14.	Blind	Desconocer
15.	Blind study	Ensayo a ciegas
16.	Blood pressure	Presión arterial.

17.	Candida albicans	Candida albicans
18.	Case-Control Study	Estudio de Casos y Controles
19.	Chloramphenicol Sodium Succinate	Succinato Sódico de Cloranfenicol
20.	Cohort	Cohorte, grupo
21.	Collar	Banda de precinto
22.	Culture	Cultivo
23.	Defervesced	Defervescencia
24.	DNA library	Genoteca
25.	Dosage	Posología.
26.	Dosing schedule	Regimen de dosificación
27.	Double-Dummy	Doble simulación
28.	Double-stranded	Bicatenario
29.	Down-titration:	Ajuste descendente de la dosis
30.	Drug	Droga, Fármaco o principio activo
31.	Dyspnea	Dispnea
32.	Effect size	Magnitud del efecto
33.	Enzymatic digest of soya bean	digerido enzimático de caseína de soja
34.	Escherichia coli	E. coli
35.	Excipients	Excipientes
36.	Full analysis set	Grupo completo de análisis

37.	Funnel plots	Gráficos en embudo
38.	Gaskets	Junta mecánica
39.	Gel Clot Method	Método Gel Clot
40.	Gram Positive Bacteria	Bacteria Gram Positiva
41.	Gram-Negative Bacteria	Bacteria Gram negativa
42.	Grown stock culture	Cultivo de crecimiento
43.	Hazard ratio	Cociente (o razón) de riesgos instantáneos
44.	Head-to-head	Ensayo comparativo directo
45.	ICH HARMONIZED GUIDELINE	GUÍA TRIPARTITA ARMONIZADA DE LA ICH
46.	Infrared absorption spectrophotometry	Espectrofotometría de absorción infrarroja
47.	Infusion (noun)	Infusión
48.	Infusion (verb)	Inyectar
49.	Inmune	Inmune
50.	Inmunity	Inmunidad
51.	Inmunology	Inmunología
52.	Intention-to-treat population	Población de análisis por intención de tratar
53.	Ionic strength	Fuerza iónica
54.	Light scattering	Dispersión de Luz
55.	Loss on drying	Perdida por secado

56.	Magnetic Stirring	Agitador magnético
57.	Motor system	Sistema nervioso motor
58.	Naïve	Personas sin tratamiento previo
59.	Neutropenia	Netrocitopenia
60.	Neutrophilis	Neutrófilis
61.	Odds ratio	Razón de posibilidades
62.	Off-white	Blanquecino o blancuzco
63.	Onset	Inicio
64.	Open trial	Ensayo abierto
65.	Pancreatic digest of casein	Digerido pancreático de caseína
66.	Perfusion	Perfusión
67.	Pharmaceutical Cytotoxicity Testing	Prueba de citotoxicidad farmacéutica
68.	Predictive	Valor predictivo
69.	Pseudomonas aeruginosa	Pseudomonas aeruginosa
70.	Pulse rate	Frecuencia de pulso
71.	Recall:	Capacidad de retención y recuerdo.
72.	Receiver	Administrador, receptor
73.	Receptor agonist:	Agonista del receptor
74.	Receptor antagonist:	Antagonista del receptor
75.	Relative potency	Potencia declarada

76.	residual Host Cell DNA Contamination	Contaminación residual de célula huésped
77.	Risk factor	Factor de riesgo
78.	Run-in period	Periodo de prueba
79.	Sabouraud Dextrose Agar	Agar Sabouraud-Dextrosa
80.	Saline infusion	Infusión salina
81.	Sandwich	Sandwich
82.	Soyabean Casein Digest Medium	Caldo Digerido de Caseína Soja
83.	Spike sample	Muestra enriquecida
84.	Standard potency	Potencia Asignada
85.	Staphylococcus aureus	Estafilococos aureus
86.	Strain	Cepa
87.	Strength	Concentración
88.	Streptococcus pneumoniae	Streptococcus pneumoniae
89.	Strong solution	Solución concentrada
90.	Supernatant	Sobrenadante
91.	Tablets	Comprimidos
92.	Target	Objetivo, diana
93.	Template	Patrón, plantilla , modelo, matriz, molde

94.	The transfer of analytical procedures (TAP)	Transferencia de los métodos analíticos (TAP)
95.	Thin-layer chromatography (TLC)	Cromatografía de capa delgada (TLC)
96.	Tumor necrosis factor alpha (TNF-α)	Factor de necrosis tumoral alfa (TNF-α)
97.	Vacuum cleaner	Aspirador
98.	Washout period	Período sin tratamiento, período de reposo, farmacológico, período de lavado.
99.	Wedge filter	Cuña
100.	Window period	Periodo ventana

III) ANALYSIS OF TECHNICAL AND AMBIGUOUS TERMS

A bilingual list of technical ambiguous terms is presented. These are difficult words with misleading translation. The terms belong to the field of clinical research, pharmacological research and "evidence-based medicine found at the dossiers. The reasoned proposals for translation offered are in each case accompanied by critical comments about the usual use among doctors, the basic spelling rules in Spanish, the official recommendations of the standard nomenclatures and the main international organizations.

Item No.	Technical Term	Translation equivalence	Translation used for the context of the dossiers	Comments/ Observations
1.	Arm	Brazo Rama Grupo	Grupo	Recomendamos evitar en español el uso metafórico de "brazo" para referirse a los distintos grupos de un estudio clínico.
2.	Bias	Predisposición Sesgo Parcialidad Tendencia Inclinación	Sesgo	En bioestadística, llamamos sesgo al error sistemático por defectos de muestreo o de medición, que introduce una distorsión estadística sistemática (y, a diferencia de lo que

				sucede con el error estadístico, no disminuye al aumentar el tamaño de la muestra). Ejs.: allocation bias (sesgo de asignación), gender bias (sesgo de sexo).
3.	Blind	Anonimato Ocultación Encubrimiento Ciego Enmascarada Cegado A ciegas	Ciego	Este término hace referencia a «desconocer (el paciente, el investigador u otra persona) la naturaleza del tratamiento asignado»
4.	Bolus	Bolo Bolus	Bolo	En el lenguaje médico, el término bolo tiene dos acepciones clásicas: píldora de gran tamaño y masa de alimento. No se recomienda su utilización para

				designar una dosis intravenosa en embolada.
5.	Buffer	Tampón Búfer Amortiguador Barrera Buffer Solución tampón	Buffer	El término buffer forma parte del lenguaje habitual de diversas disciplinas, como la química, la bioquímica, la biología, la fisiología, la medicina, la odontología y la agricultura. Varios diccionarios especializados de lengua inglesa, como el Dorland y el Stedman, recogen la acepción de buffer en la esfera química.
6.	Cost-effectiveness	Costo-eficacia Relación costo-eficacia Rentabilidad	Rentabilidad	Cuando la relación entre el costo y la eficacia de un procedimiento terapéutico es favorable, decimos

		Eficacia en función del costo		de él que es rentable (*cost-effective*).
7.	Disclaimer	Aviso legal Nota aclaratorio Declaración Descargo de responsabilidad legal	Nota aclaratoria	
8.	Dose escalating	Con escala de dosis Con aumento de la dosis	Con aumento de dosis	Se prefiere evitar la traducción de escala.
9.	End-point	Punto final Punto extremo Punto de finalización Criterio de valoración Nodo final	Criterio de valoración	Se recomienda evitar los anglicismos “end-point” o “punto final” para designar en los estudios clínicos, la variable predefinida que permite cuantificar el efecto de una intervención

10.	Forest plot	Parcela forestal Diagrama de bosque Diagrama de efectos	Diagrama de bosque	Este nombre se ha dado en inglés a los gráficos sinópticos utilizados en los metanálisis para visualizar de forma conjunta los resultados individuales de los distintos estudios analizados y la estimación del resultado global, mediante un auténtico bosque de líneas horizontales.
11.	Gen cassette	Contenedor Casete Cápsula Gen Cassette	Gen cassette	En este caso se mantiene la palabra cassette que actúa como préstamo del inglés.
12.	Half-life	Semivida Semidesintegración Vida media	Semivida	En farmacología es recomendado usar el término semivida, puesto que este representa el promedio de vida de

				un núcleo del fármaco.
13.	Head to head comparison	Comparación cara a cara Con tratamiento activo	Con tratamiento activo	Se trata de una comparación directa entre dos o más fármacos
14.	Infusion	Infusión Perfusión Inyección	Infusión	La infusión es aplicada por goteo y depende de la gravedad por goteo.
15.	In-house	Interno Propio Residente De fabricación propia	Interno	Estudio o análisis de diferentes factores o elementos realizados internamente por un laboratorio.
16.	Landmark study	Estudio sin precedente Estudio determinante Estudio de referencia	Estudio de referencia	Este nombre dan en inglés al estudio clínico de gran tamaño que busca zanjar definitivamente una cuestión diagnóstica o terapéutica en medicina.

17.	Matched	Emparejado Pareado	Emparejado	Puede significar "equivalente" (con un sentido de "compatible")
18.	Meta-analysis	Metanálisis Meta-análisis Metaanálisis	Metanálisis	Según la nueva Ortografía (2010) de la RAE, la forma correcta en español no debe ser "meta-análisis" ni "metaanálisis", sino metanálisis.
19.	Missing data	Datos perdidos Datos ausentes Datos faltantes	Datos ausentes	Término estadístico para referirse a los datos experimentales o de investigación clínica que deberían haberse registrado, pero que, por el motivo que fuere, no se registraron o se registraron únicamente de forma incompleta o deficiente, por lo que no resultan válidos ni aprovechables.

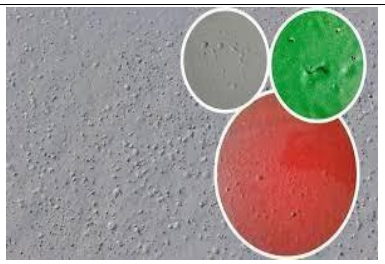
20.	Odds ratio	Razón de momios Cociente de probabilidades Cociente de posibilidades Razón de oportunidad Oportunidad relativa	Odds ratio Razón (o cociente) de posibilidades y razón de momios	Ante tal proliferación de sinónimos, y para evitar confusiones terminológicas, se ha planteado incluso con frecuencia la conveniencia de no traducir esta expresión y aceptar directamente los anglicismos "odds ratio" o "razón de odds". De todas las traducciones propuestas, las de más aceptación han sido razón (o cociente) de posibilidades y razón de momios.
21.	Open-label study	De etiqueta abierta Sin ocultación	Sin ocultación	Es un tipo de ensayo clínico en el cual no se oculta la información a los participantes.

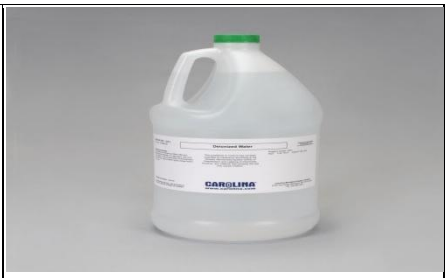
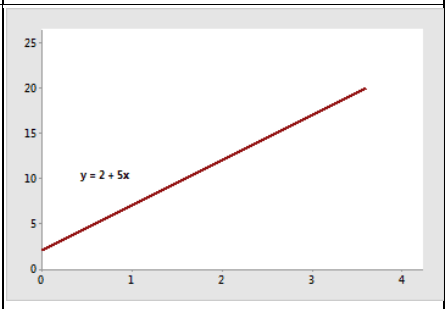
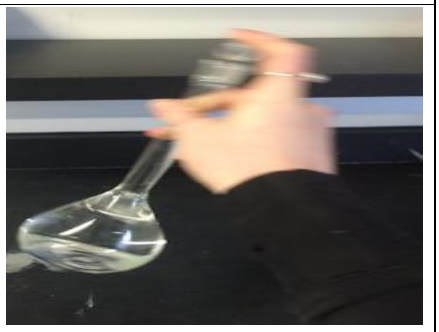
22.	Pie chart	Gráfico circular Gráfico sectorial Diagrama circular	Diagrama de sectores	No es una “carta de pie” ni nada por el estilo, sino el gráfico que nosotros llamamos diagrama (o gráfico) de sectores
23.	Placebo group	Grupo placebo Grupo de placebo Grupo tratado con placebo	Grupo tratado con placebo	La traducción correcta no es, pues, “grupo placebo”, sino grupo (tratado) con placebo o, con frecuencia, aun cuando en sentido estricto no sean términos sinónimos, ‘grupo de referencia’.
24.	Randomization	Aleatorización Aleatoriedad Asignación al azar Asignación aleatoria Randomización	Asignación al azar	En estudios clínicos se debe evitar el uso del anglisismo randomización que puede traducirse por asignación al azar o aleatorización.

25.	Run-in period	Periodo de pre-inclusión Periodo de prueba	Período de preinclusión	Recomendamos evitar los anglicismos “periodo run-in” y “periodo lead-in”, que pueden traducirse al español como período de preinclusión o período de rodaje.
26.	Soft data	Información secundaria Datos blandos Datos flexivos Datos subjetivos	Datos cualitativos	Desaconsejamos en español el calco “datos blandos” en el sentido (por oposición a los llamados en inglés *Æ* HARD DATA, que son los datos cuantitativos u objetivos).
27.	Triage	De triage Clasificación Selección cribado	Clasificación de triage	Es un término francés que se emplea en el ámbito de la medicina para clasificar a los pacientes de acuerdo

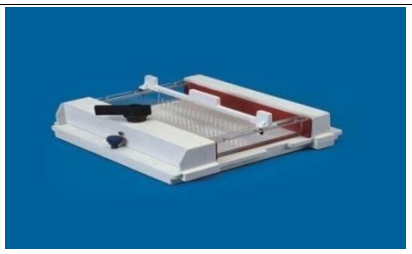
				a la urgencia de la atención
28.	Two-tailed test	Test de dos vías Prueba de dos colas Prueba bilateral	Prueba bilateral	Se recomienda evitar el calco “test de dos colas”

Item No.	Technical term	Translation equivalence	Translation used for the context of the dossiers	Graphic description
29.	Aluminium cap	Tapa de aluminio	Cápsula metálica	
30.	Amber plastic pet bottle	Botella de plástico ámbar	Botella de plástico color ámbar	
31.	Ashing	Reducción a cenizas	Incineración	
32.	Chic Salt	Sal chic Sal de moda	Sal refinada	
33.	Glidant	Glidante Deslizante	Deslizante	

34.	Micro spray pump	Micro bomba de spray Micro bomba rociadora Micro bomba de pulverización	Micro bomba de pulverización	
35.	Pin holes	Agujeros de alfiler	Agujeros de alveolos	
36.	Label claim	Reclamo de la etiqueta	Información declarada en la etiqueta	
37.	Lake sunset yellow	Lago atardecer amarillo	Laqueado de amarillo ocaso	
38.	Loop injector	Inyector de bucle Inyector de lazo	Inyector de lazo	

39.	Reagent water	Agua reactiva	Agua de reactivo	
40.	Screw cap bottle	Botella con tapón de rosca	Botella tapa rosca esterilizada	
41.	Slop of regression	Pendiente de regresión	Inclinación de la línea de regresión	
42.	Vortex	Vortex Vortice Torbellino	Agitar	

43.	Wash buffer	Tampón de lavado	Buffer de lavado	
44.	Power pack	Fuente de alimentación Fuente de energía Unidad de energía	Adaptador	
45.	Canister holder	Porta recipientes Porta bidones	Soporte de recipiente	
46.	Seed	Semilla Grano Pepita	Muestra	

47.	Gas carrier	Portador de gas	Gas carrier	
48.	Crush	Aplastar Triturar Moler Machacar	Pulverizar	
49.	Gel caster	Gel de moldeo	Molde para el gel	
50.	Heat sanitization	Desinfección de calor	Desinfección mediante calor	

IV) ACRONYMS

AAALAC: Asociación para la Evaluación y Acreditación de Laboratorio de Cuidado Animal

ADVP: Adicción a drogas por vía parenteral

B. wt: Peso Corporal

BGN: Bacilo gramnegativo

BLEE: Betalactamasas de espectro extendido

BQ: Bronquiectasias

CDC: The centers of Disease Control and Prevention

CHO: Ovario de Hámster Chino

CMI: Concentración inhibitoria mínima

CMS: Colistimetato sódico

CORPA: Pseudomonas aeruginosa resistente a la colistina

CPCSEA: Comité para el Control y la Supervisión de Experimentos en Animales

CPMP: Comité de especialidades farmacéuticas

DBT Departamento de Biotecnología

DCGI Control General de Fármacos de la India

DDD: Dosis Diaria Definida

EARS-NET: The European antimicrobial resistance surveillance network

EMA: Agencia de Europea de Medicamentos

EPOC: Enfermedad pulmonar obstructiva crónica

ERV: Enterococcus resistente a la vancomicina

EV: Endovenosa

FDA: Administración de Farmacos y Alimentos

FG: Filtrado glomerular

FQ: Fibrosis quística

FR: Factor de riesgo

GLP: Buenas Prácticas de Laboratorio

HPLC: Cromatografía líquida de alta resolución

IAEC: Comité de Ética Animal Institucional

IBSC Comité Institucional de Bioseguridad

IC 95%: Intervalo de confianza del 95%

ICAAC: Conferencia Intercientífica Sobre Agentes Antimicrobianos y Quimioterapia

ICH: Conferencia Internacional de Armonización

IDSA: Infectious Diseases Society of America

IDSA: Sociedad de Enfermedades Infecciosas de América

IECAS: Inhibidores de la enzima de conversión de la angiotensina

IRC: Insuficiencia renal Crónica

Kg: Kilogramo

MBL: Métalo-beta-lactamasas

mg: Miligramo

mL: Milímetro

MU: Millones de unidades

N.H. Autopista Nacional

NAVM: Neumonía asociada a la ventilación mecánica

No.: Número

ºC: Grados Celsius

OECD: Organización para la Cooperación y Desarrollo Económico

OMP: Proteínas de membrana externa

OMS: Organización mundial de la salud

ORL: Otorrinolaringología

PA: Pseudomonas aeruginosa

PAB: Bacteriemia por Pseudomonas aeruginosa

PAMR: Pseudomonas aeruginosa multiresistente

PAN: No aislamiento de Pseudomonas aeruginosa

PAS: Pseudomonas aeruginosa sensible

PD: Farmacodinamia

PK: Farmacocinética

QAU & RA: Unidad de Garantía de Calidad y Asuntos Regulatorios

RCGM: Comité de Revisión de Manipulación Genética

RDIVRB: Estudio Intravenosa de la Dosis Repetida en Conejos

REIPI: Red Española de Investigación de Patología Infecciosa

SARM: Staphylococcus aureus resistente a la meticilina

SIDA: Síndrome de inmunodeficiencia adquirida

SNC: Sistema nervioso central

SNP: Sistema nervioso periférico

SOP: Procedimiento Operativo Estándar

SPSS: Stadistical Package for Social Sciences

SPSS: Statistical Package for the Social Sciences

TNF: Factor de Necrosis Tumoral

UCI: Unidad de cuidados Intensivos

ZRC: Centro de Investigación Zydus

ZYT: Centro de Investigación Zydus – Código del Estudio de Toxicidad.

V) GLOSSARY

1 Adult respiratory distress syndrome (ARDS) s/m. Insuficiencia respiratoria (pulmonar) causada por diversos trastornos que provocan la acumulación de líquido en los pulmones y concentraciones de oxígeno sanguíneo demasiado bajas.

2 Active ingredient s/m. El término principio activo se usa generalmente para referirse a la sustancia capaz de producir cambios en los procesos fisiológicos o bioquímicos de los seres vivos, que por lo general redundan en el mejoramiento de la salud de éstos. Se trata, por lo tanto, de sustancias químicas o biológicas con características apropiadas para constituir un medicamento.

3 Afterloading s/m. Procedimiento en el que se coloca primero en la zona que se desea tratar unos tubos o agujas, o cualquier otro material adecuado, y sólo después se sitúan en su interior las fuentes radiactivas, con lo cual disminuye la exposición del personal a la radiación.

4 Agent s/m. Representante, individuo "generalmente un familiar o amigo de confianza" autorizado por un poder notarial para tomar decisiones legales en nombre de otro individuo.

5 Aluminium cap s/m. Se usa ampliamente en el embalaje de los productos, porque el aluminio tiene una buena resistencia a la oxidación, formando una película de óxido densa en la superficie del aluminio, que protege las propiedades físicas del producto, el sellado es bueno, para garantizar que el producto no entre en contacto con el mundo exterior.

6 Apoptosis s/f. Forma de muerte celular programada, caracterizada por la digestión de DNA endonucleasa, degeneración nuclear y condensación seguido de la fagocitosis de los residuos celulares.

7 Aspergillus brasiliensis s/m. Hongo mitospórico cuyas formas perfectas se incluyen dentro de la familia Tríchocomaceae, del orden de los

Eurotiales, perteneciente al phylum Ascomycota.

8 Autoclave s/m. Máquina que utiliza la combinación de alta presión y vapor con el fin de transferir el calor a los artículos colocados dentro de él. En la actualidad, los hospitales, laboratorios y consultorios médicos utilizan autoclaves para esterilizar equipos sólidos y huecos, suministros, líquidos y desechos. Y en las industrias químicas, las autoclaves vulcanizan el caucho, curan revestimientos y sintetizan cristales – como por ejemplo en las crecientes industrias del cuarzo y las gemas sintéticas.

9 Bacillus subtilis s/m. Bacteria Gram positiva que produce una gran cantidad de lipopeptidos, metabolitos primarios o secundarios, con amplio espectro antibiótico. Dichos metabolitos son supresores efectivos de algunos patógenos de plantas incluyendo; especies de Fusarium, Pythium, Phytophthora, Rhizoctonia, Sclerotinia, Septoria, y Verticillium.

10 Bacterial Endotoxin Test s/f. Determinación o cuantificación de endotoxinas provenientes de las bacterias Gram negativas, empleando como reactivo, lisados de amibocitos circulantes del cangrejo herradura de Limulus polyphemus (ensayo LAL), de Tachypleus tridentatus, etc.

11 Baseline value s/m. Suele referirse a la primera consulta de todas las del estudio.

12 Bias search s/m. Error sistemático introducido cuando la búsqueda se centra en una sola base de datos.

13 Bioassay s/m. Uso de un organismo "vivo" como agente de prueba para detectar la presencia o la concentración de un compuesto químico.

14 Blind v/m. Ocultar a los pacientes el fármaco que reciben en un determinado tratamiento.

15 Blind study Adj/m. Experimento a ciegas donde los individuos no saben si pertenecen al grupo experimental o si son parte del grupo de control del experimento.

16 Blood pressure s/f. Presión de la sangre en el sistema circulatorio, a

menudo medida para el diagnóstico, ya que está estrechamente relacionada con la fuerza y la frecuencia del latido cardíaco y el diámetro y la elasticidad de las paredes arteriales.

17 Case-Control Study s/m. Es un estudio epidemiológico, observacional, analítico, en el cual los sujetos se seleccionan en función de que tengan o no una determinada enfermedad.

18 Candida albicans s/f. Hongo patógeno oportunista en mamíferos, entre ellos el hombre, que puede causar varias formas de candidiasis, desde infecciones superficiales en mucosas hasta enfermedades sistémicas que comprometen la vida, predominantemente, en individuos con el sistema inmune debilitado. C. albicans al igual que otros patógenos tiene la capacidad de adherirse y formar biopelículas en aparatos implantados, especialmente catéteres intravasculares lo que les confiere mayor resistencia a antifúngicos.

19 Chloramphenicol Sodium Succinate s/m. Antibiótico de amplio espectro potente.

20 Cohort s/f. Se refiere a un grupo de sujetos de un estudio que comparten una característica común.

21 Collar s/f. Banda o anillo (anilla) que sirve de precinto para comprobar si se ha abierto un envase.

22 Culture s/m. Crecimiento microbiano en un medio nutritivo sólido o líquido; el aumento del número de microorganismos facilita su identificación.

23 Defervesced Adj/m. Disminución o desaparición completa de la fiebre.

24 DNA library s/m. Colección de clones cada uno de los cuales contiene un vector al que se le ha insertado un fragmento de ADN derivado del ADN o el ARN totales de la célula o tejido.

25 Dosage s/m. Determinación de las dosis en que deben administrarse los medicamentos.// 2 Dosificación. Graduar o determinar las dosis de un medicamento.// 3 Dosis. Una cantidad de un medicamento o droga que se toma o se recomienda tomar en un momento determinado.// 4 Administración.

Administrar una dosis a (una persona o animal).

26 Dosing Schedule s/m. Se refiere a la cantidad indicada para la administración de un medicamento, los intervalos entre las administraciones y la duración del tratamiento.

27 Double-dummy s/m. Comparación de dos fármacos cuyas formas galénicas no son idénticas en cuanto a sus propiedades físicas u organolépticas (forma, color, tamaño, sabor, olor, etc.). En este caso deben producirse placebos idénticos a cada forma galénica (comprimido, cápsula, parche transdérmico, etc.) que contiene el fármaco.

28 Double-stranded s/Adj. Adjetivo que califica a un ácido nucleico formado por dos cadenas de nucleótidos.

29 Down-titration s/m. Ajuste de las dosis en caso de que esta hay sido aumentada.

30 Drug s/m. Denominada droga, fármaco o principio activo a toda sustancia que pueda utilizarse para la curación, el tratamiento o la prevención de enfermedades. Sin embargo, estos términos tienen connotaciones distintas: una droga puede modificar las funciones orgánicas y crear dependencia o tolerancia, por lo cual se la asocia en general con un daño al organismo, mientras que un fármaco se administra con fines terapéuticos y sólo en beneficio del individuo.

31 Dyspnea s/f. Sensación subjetiva de dificultad en la respiración, que engloba sensaciones cualitativamente diferentes y de intensidad variable. Su origen es multifactorial, pudiendo intervenir factores fisiológicos, psíquicos, sociales y medioambientales del sujeto. La disnea aguda se define como inicio de los síntomas en horas a días y la disnea crónica se presenta con síntomas de más de 3 semanas de evolución. En la parte clínica, es importante diferenciar en primer lugar si la disnea es de origen respiratorio o cardiaco. Los síntomas y signos acompañantes ya sean de origen cardiaco o respiratorio nos ayudan a tal diferenciación.

32 Effect size s/m. Término aplicado a cualquier medida de la diferencia en el resultado entre los grupos de estudio; de tal manera que el riesgo relativo, la razón de posibilidades y la diferencia de riesgos son "magnitudes de efecto".

33 Enzymatic digest of soya vean s/m. Digerido usado en la preparación de medios de cultivo microbiológicos en un entorno de laboratorio. El digerido de peptona de caseína no está destinado a ser utilizado en el diagnóstico de enfermedades u otras condiciones en humanos.

34 Escherichia coli s/f. Bacteria presente frecuentemente en el intestino distal de los organismos de sangre caliente. La mayoría de las cepas de E. coli son inocuas, pero algunas pueden causar graves intoxicaciones alimentarias.

35 Excipients s/m. Componente que se agrega intencionalmente a la formulación de una forma farmacéutica, que es diferente del principio activo.

36 Full analysis set s/m. Se trata de que este grupo sea lo más completo y cercano posible al de sujetos inicialmente aleatorizados es decir, a la «población de análisis por intención de tratar.

37 Funnel plots s/m. Conjunto de métodos gráficos para representar la existencia de un posible sesgo de publicación. Muestra la relación entre la magnitud del efecto (eje de ordenadas) y el tamaño del estudio (eje de abscisas), que se puede medir de distintas maneras (error estándar de la magnitud del efecto, su inverso, el tamaño de la muestra o el número de efectos observados). Se dibuja una línea horizontal que pasa por el valor ponderado global. Si no hay sesgo de publicación aparece la forma de un embudo típico (simetría con relación a la línea dibujada).

38 Gaskets s/m. Pieza formada por materiales relativamente blandos, que se coloca entre otras dos piezas, cuya superficie de unión reproduce. Con ello se logra un buen ajuste entre ambas, evitando pérdidas o entradas de fluidos no deseadas.

39 Gel Clot Method s/m. Método usado para determinar si aparece un gel, la gelificación ocurre al coagularse las

proteínas por la presencia de endotoxinas.

40 Gram Positive Bacteria s/f. Bacterias que responden al pigmento y aparecerán al microscopio en color azul o violeta. Las bacterias las grampositivas poseen una capa gruesa de peptidoglicano (mureína), lo cual les confiere gran resistencia pero las hace retener mucho mejor el tinte.

41 Gram-Negative Bacteria s/f. Bacterias que tienen una reacción con la tinción Gram en su pared celular diferente a las Gram positivas, pues no se tiñen de color azul oscuro o violeta, sino de color rosa. Las bacterias Gram negativas no retienen el colorante de cristal violeta durante el proceso de coloración porque presentan una capa muy delgada de peptidoglucano en su pared celular y su capa más externa está cubierta por una membrana de lipoproteínas.

42 Grown stock culture s/m. Proceso de propagar los microorganismos, proporcionándoles las condiciones ambientales adecuadas. Los microorganismos en fase de crecimiento realizan réplicas de sí mismos y requieren de los elementos que se encuentran en su composición química. Se le deben brindar los elementos nutritivos en una forma accesible desde el punto de vista metabólico. Además, los microorganismos requieren energía metabólica con el objetivo de sintetizar macromoléculas y conservar los gradientes químicos esenciales a través de sus membranas. Durante el crecimiento se deben regular los factores nutricionales (carbono, nitrógeno, azufre y fósforo, elementos trazas y vitaminas) y los factores físicos (pH, temperatura, oxígeno, humedad, presión hidrostática, presión osmótica y radiación).

43 Hazard ratio s/m. Cociente de dos tasas de riesgo instantáneo o de dos funciones de riesgo instantáneo, ya sean puntuales (correspondiente a un determinado momento) o promediadas a lo largo de un período extenso.

44 Head-to-head s/m. Ensayo comparativo directo. Se trata simplemente de una “comparación directa entre dos o más fármacos”.

45 ICH HARMONIZED GUIDELINE s/f. Consejo internacional que regula los requisitos técnicos de productos farmacéuticos de uso humano (ICH).

46 Infrared absorption spectrophotometry s/f. Tipo de espectrometría de absorción que utiliza la región infrarroja del espectro electromagnético. Como las demás técnicas espectroscópicas, puede ser utilizada para identificar un compuesto o investigar la composición de la muestra. La espectrometría infrarroja se basa en el hecho de que los enlaces químicos de las sustancias tienen frecuencias de vibración específicas, que corresponden a los niveles de energía de la molécula. Estas frecuencias dependen de la forma de la superficie de energía potencial de la molécula, la geometría molecular, las masas atómicas y, posiblemente, el acoplamiento vibracional.

47 Infusion[1] s/f. Producto de esta operación; infuso. Introducción terapéutica de un líquido, especialmente de una disolución salina en una vena.

48 Infusion[2] v/f. Operación farmacéutica de verter agua hirviente sobre drogas vegetales para obtener sus principios medicamentosos, o de echar la droga en un vaso de agua hirviente.

49 Inmune Adj/f. Que presenta inmunidad.

50 Inmunity s/f. Cualidad de inmune. //2. Estado de resistencia, natural o adquirida, que poseen ciertos individuos o especies frente a determinadas acciones patógenas de microorganismos o sustancias extrañas. //3. Respuesta específica de un organismo a la acción de los antígenos.

51 Inmunology s/f. Estudio de la inmunidad biológica y de sus aplicaciones.

52 Intention-to-treat population s/f. Todos los sujetos asignados de forma aleatoria a cada grupo de tratamiento (es decir, a todos los sujetos inicialmente aleatorizados para recibir un tratamiento específico), con independencia de que finalmente hayan recibido el tratamiento en cuestión de forma íntegra o parcial, de que no lo hayan recibido en absoluto por el motivo que fuere o de que hayan

cambiado de tratamiento sobre la marcha.

53 Ionic strength s/m. Propiedad de una solución que depende de la concentración total de iones en la solución, así como de la carga de dichos iones.

54 Light scattering s/m. Fenómeno mediante el cual la radiación electromagnética, al chocar con pequeñas partículas de tipo coloidal o incluso molecular, es desviada en su dirección de propagación, de forma aparentemente caótica, en cada uno de los núcleos de dispersión, por tener un índice de refracción diferente al del medio. La medida de la luz dispersada (o difusa) da lugar a técnicas muy útiles en la determinación de la concentración de sustancias en suspensión, así como en la caracterización de la forma y del tamaño de las partículas coloidales y macromoleculares.

55 Loss on drying s/m. Procedimiento que se usa para determinar en una muestra, la cantidad de materia volátil de cualquier naturaleza que se elimina bajo condiciones especificadas.

56 Magnetic Stirring s/m. Dispositivo electrónico que utiliza un campo magnético para mezclar de manera automatizada un solvente y uno o más solutos.

57 Motor system s/m. Parte del sistema nervioso central que se encarga del movimiento.

58 Naïve s/f. Personas no tratadas con anterioridad o, más estrictamente, a aquellas que no se han visto expuestas a una intervención determinada (médica, quirúrgica o del tipo que sea).

59 Neutropenia s/f. Reducción del recuento de neutrófilos sanguíneos. Si es severa, aumentan el riesgo y la gravedad de las infecciones bacterianas y micóticas. Pueden pasar inadvertidos los síntomas focales de infección, pero hay fiebre durante la mayoría de las infecciones graves. El diagnóstico se realiza por recuento de leucocitos con fórmula diferencial, pero la evaluación exige identificar la causa. Si hay fiebre, se presume una infección, y se requiere tratamiento empírico inmediato con

antibióticos de amplio espectro, especialmente cuando la neutropenia es grave. En ocasiones, es útil el tratamiento con factor estimulante de la colonia de granulocitos-macrófagos o con factor estimulante de la colonia de granulocitos.

60 Neutrophilis s/m. Leucocitos polimorfonucleares (PMN), componentes esenciales del Sistema Inmune Natural. Son las principales células fagocíticas encontradas en sangre periférica; correspondiéndose con un 50-70% del total de células de la serie blanca. Se les considera la primera línea de defensa contra infecciones bacterianas y fúngicas (además de las barreras naturales anteriormente citadas).

61 Odds ratio s/m. Herramienta estadística/epidemiológica que puede utilizarse para mostrar asociaciones entre dos variables binarias. El cálculo de OR requiere la disposición de los datos en una tabla 2x2, por lo que tienen que estar formateados en forma categórica (por ejemplo, sí y no para dos variables independientes).

62 Off-white Adj/m. Color que en puede oscilar entre el blanco grisáceo y el blanco amarillento que habitualmente llamamos 'color hueso'.

63 Onset s/m. Momento de la vida en el que se manifiesta una enfermedad.

64 Open trial s/m. Ensayo clínico en el que tanto los investigadores y los participantes conocen el tratamiento que se está administrando. El ensayo abierto contrasta con los ensayos ciegos, en los que los participantes no conocen qué tratamiento están recibiendo, si el de control o el experimental.

65 Pancreatic digest of casein s/m. Hidrolizado de proteína "GE" adecuado para el cultivo de diferentes grupos de bacterias.

66 Perfusion s/f. Circulación artificial en un órgano de un líquido de composición apropiada para mantener las funciones de aquél en la experimentación fisiológica.

67 Pharmaceutical Cytotoxicity Testing s/f. 1. Herramienta de cribado farmacéutico. 2. Prueba usada en control de calidad para la liberación de materia prima o de producto terminado.

68 Predictive m/adj. Valor que tiene un dato para predecir si una persona tiene o no una enfermedad. Por ejemplo, el valor que tiene un hematocrito bajo para predecir que el paciente correspondiente tiene una hemorragia interna es bajo si se trata de un paciente sano que consulta por dolores de cabeza y bastante mayor si es una paciente que acude a urgencias y explica que tuvo un aborto hace un par de días.

69 Pseudomonas Aeruginosa s/f. Patógeno de la familia Pseudomonadaceae y se identifica por ser un bacilo gramnegativo ligeramente curvado que crece mejor en aerobiosis, es muy versátil nutritivamente y no fermenta hidratos de carbono pero produce ácido a partir de azúcares como la glucosa, fructosa y lactosa o sacarosa.

70 Pulse rate s/f. Frecuencia de pulso. Es la cantidad de latidos por minuto.

71 Recall s/f. Capacidad de retención y recuerdo. Capacidad para repetir una lista de palabras unos minutos después de haberlas oído. Se mide en el Examen breve del estado mental.

72 Receiver s/m. Persona designada para responsabilizarse de gestionar los asuntos económicos de una persona que sufre demencia, cuando ésta ya no es capaz de hacerlo por sí misma. Puede ser un pariente cercano, un amigo, la autoridad local o un abogado.

73 Receptor agonist s/m. Sustancia con capacidad para modificar la molécula receptora en la forma necesaria para desencadenar un efecto. Algunas sustancias imitan a un neurotransmisor específico y son capaces de acoplarse al receptor de este neurotransmisor y producir, por tanto, la misma acción que generalmente produce dicho neurotransmisor. Los fármacos agonistas se utilizan para tratar diversas enfermedades y trastornos en los que la sustancia química original está ausente o en concentración reducida.

74 Receptor antagonist s/m. Sustancia que tiende a anular la acción de otra, como los fármacos que se unen a receptores celulares sin provocar una respuesta biológica e impiden que se unan a ellos otras sustancias que sí la provocarían.

75 Relative potency s/f. Valor nominal asignado a partir del conocimiento de la potencia de la materia prima; en el caso de la materia prima es la potencia estimada por el fabricante.

76 Residual Host Cell DNA Contamination s/m. Contaminación producida en el proceso de manufactura de medicamentos bioterapeúticos.

77 Risk factor s/m. Factores que aumentan las probabilidades de que un individuo sufra una determinada enfermedad. En el caso del Alzheimer, los únicos factores de riesgo demostrados hasta el momento son la edad, los antecedentes familiares y la genética.

78 Run-in period s/m. Tiempo transcurrido antes de que comience un ensayo cuando no se administra ningún tratamiento a los participantes en el estudio.

79 Sabouraud Dextrose Agar s/f. Medio desarrollado para el cultivo de dermatofitos. Hoy en día se utiliza para el aislamiento y cultivo de todo tipo de hongos.

80 Saline infusion s/f. Inyección hipodérmica o intravenosa de disolución salina.

81 Sandwich Adj/m. Metodo de identificación de anticuerpos o células de síntesis de anticuerpos en una preparación de tejido. Se aplica a la preparación una solución que contiene un antígeno específico. Si se encuentran presentes antígenos en el tejido. Los anticuerpos deben estar unidos a estos.

82 Soyabean Casein Digest Medium s/m. Medio líquido, para enriquecimiento de uso general, utilizado en procedimientos cualitativos para la prueba de esterilidad y para el enriquecimiento y cultivo de microorganismos aerobios no exigentes en exceso. En la microbiología clínica, puede utilizarse para la suspensión, el enriquecimiento y el cultivo de cepas aisladas en otros medios.

83 Spike sample s/m. Muestra preparada agregando una cantidad conocida de analito a una matriz que es cercana o idéntica a la de la muestra de interés.

84 Standard potency s/f. Potencia de una preparación estándar.

85 Staphylococcus aureus s/m. Bacteria gram-positiva, catalasa-positiva dispuestas en racimos, de manera general, los componentes de la bacteria son peptidoglicanos y ácidos teicoicos, además de la proteína A. Es una de las principales bacterias implicadas en enfermedades transmitidas por alimentos (ETA).

86 Strain s/f. Conjunto de animales (particularmente ratones y ratas) en el que cada animal es criado para ser genéticamente idéntico.

87 Strength s/m. Proporción o relación que hay entre la cantidad de soluto y la cantidad de disolución o, a veces, de disolvente, donde el soluto es la sustancia que se disuelve, el solvente es la sustancia que disuelve al soluto, y la disolución es el resultado de la mezcla homogénea de las dos anteriores.

88 Streptococcus pneumoniae s/m. Bacteria común de las enfermedades respiratorias bajas y altas, tales como neumonía y otitis media aguda (infecciones del oído medio), y de meningitis, que afectan a los niños y los adultos en todo el mundo.

89 Strong solution s/m. Solución que contiene una gran cantidad de soluto en relación con la cantidad que podría disolver.

90 Supernatant s/m. La parte superior clara de cualquier mezcla después de ser centrifugada.

91 Tablets s/m. Formas farmacéuticas sólidas de dosificación unitaria, obtenidas por compresión mecánica de granulados o de mezclas pulverulentas de uno o varios principios activos, con la adición, en la mayoría de los casos, de diversos excipientes

92 Target s/m. Un objeto o área hacia el cual algo se dirige.// 2 El área del ánodo del tubo de rayos X donde el destello del haz del electrones colisionan, ocasionando la emisión de los rayos X. // Una célula u órgano que es afectado por agente particular como ser una hormona o un fármaco.

93 Template s/m. Secuencia de ácidos nucleicos que sirve para la síntesis de cadenas complementarias de ADN.

94 The transfer of analytical procedures (TAP) s/f. Requisitos técnicos para demostrar que el producto transferido cumple con sus especificaciones de registro.

95 Thin-layer chromatography (TLC) s/f. Técnica analítica rápida y sencilla, muy utilizada en un laboratorio de Química Orgánica. Entre otras cosas permite: - Determinar el grado de pureza de un compuesto. - Comparar muestras. Si dos muestras corren igual en placa podrían ser idénticas. Si, por el contrario, corren distinto entonces no son la misma sustancia. - Comparar muestras. Si dos muestras corren igual en placa podrían ser idénticas. Si, por el contrario, corren distinto entonces no es la misma sustancia.- Realizar el seguimiento de una reacción. Es posible estudiar cómo desaparecen los reactivos y cómo aparecen los productos finales o, lo que es lo mismo, saber cuándo la reacción ha terminado.

96 Tumor Necrosis Factor Alpha (TNFα) s/m. Citoquina pro-inflamatoria y de defensa del huésped, cuya producción exagerada lleva a enfermedades inflamatorias crónicas.

97 Vacuum cleaner s/m. Dispositivo que utiliza una bomba de aire para aspirar el polvo y otras partículas pequeñas de suciedad.

98 Washout period s/m. Período sin tratamiento, período de reposo, farmacológico, período de lavado. Se define como el tiempo entre períodos de tratamiento. En lugar de interrumpir inmediatamente y luego comenzar el nuevo tratamiento, habrá un período de tiempo en el que el tratamiento del primer período en el que el medicamento se elimina del sistema del paciente.

99 Wedge filter s/m. Dispositivo en forma de cuña que se sitúa en el recorrido de un haz de irradiación para disminuir la intensidad de una región del haz.

100 Window period s/m. Es el tiempo entre la primera infección y el momento en el que la prueba ya puede detectar de manera segura la infección.