# The bureaucratic, regulatory and legal adventures of a non-legal Spanish-to-English medical translator: challenges and resources

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For the primarily medical translator, with little or no legal training in any language, dealing with the legalistic aspects of medically- and pharmaceutically-related texts is an adventure in on-the-job training. Almost inevitably one encounters legislative, bureaucratic, regulatory, and legal elements when translating many other-than-purely-clinical texts. For example, informed consents always contain sections on confidentiality, compensation for injury, patients' rights, etc. Clinical trial approvals regularly run the gauntlet of ethics committee procedures and their minutiae, sometimes including the legislative background, the formalities of minutes of meetings, and the attendant boilerplate language. Materials dealing with marketing authorizations and pharmacovigilance typically involve the specific language of regulations. All of these come somewhat as shock to the neophyte in these areas, and represent a range of challenges. However, there are many resources that make such work possible in many instances.

## 1. Laws and regulations

In the multinational Spanish-speaking world, each country has its own laws, regulations, oversight agencies, legalisms. The legal and regulatory bodies of each country typically have their own web sites, e.g.: COFEPRIS (Mexico), INVIMA (Colombia), and these not infrequently have an English link (e.g., <http://web.invima.gov.co/portal/faces/index.jsp?id=3225>, which itself has a glossary of terms, etc.).

Many documents (e.g., ethics committee rulings for clinical trials) dealing with regulatory matters make reference to relevant laws, decrees, etc., of the various legal systems. These documents utilize their own systems of nomenclature for their constituent parts, formal language, etc. Very often these laws, etc., or parts of them, can be found on the Internet by utilizing their numbers and dates in Spanish and English. For example, *Real Decreto 414/1996, de 1 de marzo, por el que se regula los productos sanitarios* (Royal Decree No. 414/96, of 1 March 1996, concerning medical devices).

Sometimes *large chunks* of standard referencing of laws, decrees, etc, can be found by searching for distinctive fragments of the Spanish text (e.g., looking for "con fundamento en los artículos 4° párrafo tercero" finds <http://www.neurometrix.com/Collateral/Documents/English-US/Mexican%20Registration%20Resgistro%20Advance%20Neurometrix.pdf>) which contains the entire 22-line block of citations). *More or less* standard translations of this type of material can then be found by searching for reasonably presumed translations of distinctive fragments: e.g., "articles 4 third paragraph" finds the following large chunk: "pursuant to Articles 4, third paragraph, 73, paragraph XVI, bases 1 to 4 of the Constitution itself; Articles 3, …, paragraphs V, VII bis, IX and X, 15, 33, …, paragraph II, 135, 139…,181 to 184, 402 and 404 of the General Health Law; Article 41, paragraphs II and V of the Law on Public Sector Acquisitions, Leases and Services, and Article 39 of the Organic Law of the Federal Public Administration". While this procedure doesn't necessarily give whole parallel texts, it can help to build the translation of such material by giving samples of phrasing and specific technical legislative terms such as "article", "bis," etc.

## 2. Governmental and regulatory structures, pharmacovigilance, marketing authorizations

As an example, bodies such as the COFEPRIS of Mexico are charged with such activities as the following: Sanitary regulation and promotion of the production, commercialization, import, export, publicity of, or involuntary exposure to health-related drugs and technologies, products and services, toxic or dangerous substances, etc. Its mission, objectives, organizational structure, and administrative units are available in English at <http://www.cofepris.gob.mx/Paginas/Idiomas/Ingles.aspx>. Sites of this type can provide portals for further searching for standard documents, templates, rulings, etc.

Other kinds of material can also be found. For example, from <www.farmaindustria.es> in Spain, *Disposiciones sobre farmacovigilancia en España* (Rules governing pharmacovigilance in Spain) provides 64 pages of bilingual parallel texts of ROYAL DECREE 711/2002, of 19 July 2002, regulating pharmacovigilance of medicinal products for human use, Circular No. 15/2002 of the Spanish Medicine Agency on Pharmacovigilance, and ROYAL DECREE 520/1999 of 26 March 1999 approving the Charter of the Spanish Medicine Agency. (The <www.farmaindustria.es> site is a portal to a variety of other information in Spanish and English.)

In addition, ANMAT (National Administration of Drugs, Food, and Medical Technology of Argentina) is another potential resource: <http://www.anmat.gov.ar/principal.asp>. It has a home page with an English-language parallel. Not all items on any of these sites are completely bilingual, but some diligent, targeted searching may help you find useful parallels with a fairly high degree of authoritative officialese. For example, the Institutional Information link leads to an Agreements link; the Electronic Management System link leads to Sistema de Gestión Electrónica, but it has an English

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version (a green-highlighted button in the upper left) with details of the system paralleling the Spanish text.

### 3. Ethics and institutional review boards, committees, trial protocols, and procedures

The mixed clinical and legalistic/regulatory vocabulary dealing with this frequently encountered subject matter is dealt with extensively (with many Spanish-English equivalents) in the *Glosario de Medicamentos: Desarrollo, Evaluación y Uso* at:<http://www.cofepris.gob.mx/Documents/Bibliografias/Medicamentos/Glosario.PDF>.

Such boards and committees review and monitor trial protocols and implementation, and documents commonly refer to their findings (approvals of protocols, review of deviations, etc.). The language of such documents typically contain some formal boiler-plate.

EudraLex, Volume 10 Clinical trials guidelines(<http://ec.europa.eu/health/documents/eudralex/index_en.htm>) *The rules governing medicinal products in the European Union* contains guidance documents applying to clinical trials. E.g., the following are available in multiple languages:

1) Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use;

2) Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products; and - Ethical considerations for clinical trials on medicinal products conducted with the paediatric population.

### 4. Phraseology and formulae

On the one hand, the formulaic phraseology in which many documents of a legalistic character are couched is highly idiomatic. Therefore, for the translator whose familiarity with legal texts in the target language is very limited, they are far more resistant to straightforward translation than the rest of even the most convoluted sentences of legalistic document: they can be a true monkey wrench thrown into the gears of an otherwise smoothly running translation. For example (of varying degrees of resistance to strop straightforward translation):

1) declara "LA INSTITUCIÓN", por conducto de su representante, lo siguiente;
2) en lo sucesivo denominado como;
3) que tiene personalidad jurídica y patrimonio propios;
4) expuesto lo anterior, las partes celebran el presente Convenio;
5) que consta de fojas útiles y enteradas las partes del valor y alcance legal de cada una de las cláusulas que los conforman, al margen y al calce para constancia en tres tantos;
6) sin perjuicio de lo dispuesto en la Sección 1.1.

On the other hand, the fact that every legal system utilizes standard, boiler-plate phraseology frequently makes it possible to locate type, template, or model Spanish documents that are close to the document you are working on as a stepping stone to finding comparable, previously translated documents in English (with a caution not to assume that any block of boiler-plate is identical to the document you are working on — each document must be meticulously translated directly from the original). The existence and availability of boiler-plate may save time otherwise spent in re-inventing the wheel, having to look up individual words, perhaps translating well-established phraseology clumsily.

Examples of such finds (containing the "enteradas las partes" mentioned above):

From: <http://www.ljh.com.mx/pdf/sample_contract_financiated.pdf> and <http://www.sec.gov/Archives/edgar/data/1201935/000101915511000024/mineracpojoin.htm> (which provides the whole Spanish text and an "English language translation for convenience purposes only").

Other formulations that may aid searching for parallel texts are:

1) Translation for informational purposes only;
2) English version.

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|---|---|
| **ENTERADAS LAS PARTES** del alcance y consecuencias legales del presente contrato, lo firman de conformidad | **IN WITNESS HEREOF**, having acknowledged the legal scope and consequences of this agreement, the parties hereby sign it in consent. |
| Enteradas las partes del contenido y alcances del presente convenio, lo firman de conformidad en la Ciudad de México, Distrito Federal, a los 5 días del mes de enero de 2011 | Knowledgeable of the contents and scope of this agreement, the Parties hereby execute it in acceptance in Mexico City, Federal District, on January 5, 2011. |

### 5. Forms and regulatory documents

Standard forms can be a real headache, from the point of view both of the terminology and the layout. A time- and headache-sparing approach that often works is locating the actual or similar forms on-line, either separately or though the agency that generates them. They typically have assigned code numbers: e.g.: F13-PM05-ECT (the Spanish format can be found as a .doc at <www.invima.gov.co>).

**A)** Reference materials, templates, prior translations of similar materials, etc., *supplied by the translation agency*. I make it a practice to ask for these if available.

**B)** Similar documents *on the Internet*. Google search strategies include the obvious use of the titles, numbers, dates, etc. of the Spanish documents, the use of distinctive fragments from such documents to

locate similar or same texts. The *Normas de Buena Práctica Clínica* (CPMP/ICH/135/95) (<http://www.aemps.gob.es/industria/inspeccionBPC/docs/guia-BPC_octubre-2008.pdf>) have their English counterpart at <http://ec.europa.eu/health/files/eudralex/vol-10/3cc1aen_en.pdf>.

**C)** Forms supplied by regulatory agencies on their Web sites that can be used to minimize formatting, often offering clear texts that improve on poorly transmitted documents. An example from Buenos Aires: <www.cba.gov.ar/imagenes/fotos/sal_serfis_invn-opat.doc> (the home page has an English link); forms are available at the present time at: <http://www.cba.gov.ar/canal.jsp?idCanal=33>, by clicking on the flashing blue-green SERFIS/CoEIS/RePIS button.

**D)** Glossaries, legal, but also business, administrative, for example, KudoZ glossaries (<http://www.proz.com/glossary-translations/>); the *Glosario de Negocios Castellano-Inglés* by A.D. Miles (<http://www.ctv.es/USERS/amiles/glossarysa.htm>); the multi-glossary site: *glosarios-juridicos-bilingües - recursos-español-inglés* (<http://glosarios-juridicos-bilingues.wikispaces.com/recursos-español-inglés>); *Glosario de términos jurídicos* (<http://www.susana-translations.de/legal.htm>), etc. (at <http://www.nova-transnet.com/zonanova/downloads/documentos/Glosario%20de%20investigaci%C3%B3n%20cl%C3%ADnica%20y%20epidemiol%C3%B3gica.pdf>); the *Manual de traducción inglés-español de protocolos de ensayos clínicos*, from <http://www.esteve.org>.

**E)** Eur-Lex bilingual: This can be extremely useful for legalese and bureaucratese, as well as more generally. The main portal is: <http://eur-lex.europa.eu/en/index.htm>. Once there, click on "Simple Search"; next, click on "Search Terms"; next, input word or phrase (e.g., Administración Pública), select Title and text, and choose Spanish in the drop-down menu. Click SEARCH. Then click the Bibliographic notice + Text (bilingual display) link. At the top of the page click ES for Spanish, then search for the term *administración pública* in the bilingual display ("por ejemplo en gestión y *administración pública*, y el mayor reparto geográfico posible dentro de la Unión" = "for instance in management and in *public administration*, and the broadest possible geographic distribution within the Union".)

**F)** Linguee: Can be very useful for contextualized examples of a term or phrase. E.G.: <http://www.linguee.es/search?tool=opensearch&query=Procedimientos+Administrativosmay> yield typical examples, such as: "El motivo del cambio era simplificar los procedimientos administrativos" = "The reason for the change was to simplify administrative procedures". Of course, all such resources must be used judiciously, with caution.

**G)** TERMIUM: The Canadian government's trilingual site (now includes Spanish and some Portuguese): <http://www.termiumplus.gc.ca/tpv2alpha/alpha-eng.html?lang=eng&i=1&index=est&__index=est&srchtxt=COMUNICACI%D3N+&comencsrch.x=9&comencsrch.y=12>.

**H)** OFFICIAL NAMES OF GOVERNMENTAL AND REGULATORY STRUCTURES: These and their equivalents in English can often be found on official Web sites. For example: "Comisión de Evidencia y Manejo de Riesgos" can be found on: <http://www.cofepris.gob.mx/cofepris/Paginas/Directorio.aspx> and the equivalent "Evidence and Risk Management Commission" can be found, by clicking on its ENGLISH link, at: <http://www.cofepris.gob.mx/Paginas/Idiomas/Ingles.aspx>.

**Limitations**

When using any of the approaches and resources cited above, regular checking of one's provisional solutions to unfamiliar terms and phrases individually against reliable texts found on the Internet is essential. While the many resources make it possible to develop working knowledge and experience in these areas, one must always be aware of one's limitations, where the requirements of a particular job demand a more advanced level than one has accumulated at a given time (for example, where a document is to be presented in court, or where the details of contractual language exceed one's "pay grade"). In such circumstances prudence and professional integrity call upon the translator to decline such an assignment.