Inside Pharma: Understanding Translation and Documentation Needs for a Growing Industry

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Translation, my passion

- Bachelor's Degree in Modern Languages and Translation (University of Alcalá de Henares, Spain)
- Master's Degree in Professional Translation (University of Granada, Spain)
- Master's Degree in Medical and Healthcare Translation (Jaume I University, Spain)

- In-house translator
- Freelance medical translator
- In-house position as translation supervisor of NORMON (Spain)

- Teaching staff: "Translation in the pharmaceutical field" (AulaSIC)
- Board of Directors Asetrad
- Member of Tremédica

EMWA EUROPEAN MEDICAL WRITERS ASSOCIATION

Session Overview

1. Translation and linguistic needs
2. Type of documents and workflow
3. Translation department within a pharmaceutical company

Translation and linguistic needs of pharmaceutical companies

Pharma: A Growing Industry

- Develop and distribute medicines worldwide.
- Remarkable growth:
  - Increasing prevalence of chronic diseases
  - Advancements in personalised medicine
  - Biotechnology innovations
  - Global demand for new treatments

Translation and linguistic needs

- **Translation** plays an **essential role**.
- **Challenging** specialisation:
  - **Multidisciplinary** industry: medicine, pharmacology, chemistry, microbiology, engineering, marketing, clinical research…
  - **Highly specialised** field

MISTRANSLATION → SERIOUS ERRORS 

Translation and linguistic needs

- In-depth knowledge
  - High **proficiency** in the working languages
  - Deep **subject matter** expertise
  - Attention to detail

Direct translation
and
Inverse translation
(into one's B language)

Translation and linguistic needs

EUROPEAN PHARMACOPOEIA

ICH
harmonisation for better health

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ICH Guidelines

The ICH topics are divided into the four categories below and ICH topic codes are assigned according to these categories.

COUNCIL OF EUROPE 75 1949 - 2024 CONSEIL DE L'EUROPE

STANDARD TERMS

EDQM 60 1964 - 2024

LOG IN

21 August 2017: Major update of Standard Terms database

An updated version of the Standard Terms database was released on 21 August 2017. A new tagging feature has been added, which will allow the introduction of 'non-

usp®

- Technical genres
- Structured and formal language
- Technical terminology internationally standardised

Translation and linguistic needs

- More language combinations: German, French, Greek, Arabic

  → Outsource
  Approved translation company

- Other linguistic needs and services: sworn translations, linguistic quality assurance (LQA), proofreading of artwork mock-ups, interpretation (*in situ*, offline, online)

Type of documents and workflow

Documentation

Regulatory submissions

Registration dossier

Documentation

Registration dossier (M1, M2, M3, M4 and M5)

- Technical data (quality, safety, and efficacy of the drug)
- Administrative documents
  - Application forms
  - Marketing authorisation application
  - Certificates of compliance
  - Declarations

MINISTERIO DE SANIDAD, POLÍTICA SOCIAL E IGUALDAD

agencia española de medicamentos y productos sanitarios

Certificado Nº / *Certificate No*: XX/000/XX

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Parte 1 / *Part 1*

Emitido en virtud de una inspección según artículo 111(5) de la Directiva 2001/83/CE, artículo 15 de la Directiva 2001/20/CE.
Issued following an inspection in accordance with article 111(5) of Directive 2001/83/EC, article 15 of Directive 2001/20/EC.

La autoridad competente de España certifica lo siguiente:

The competent authority of Spain confirms the following:

Documentation

Registration dossier

- Manufacturing information
- Safety and quality reports
  - Control of excipients
  - Control of the drug product and drug substance (API)
  - Certificates of analysis
  - Specifications
  - Analytical methods
  - Stability studies

Machinery-related terminology

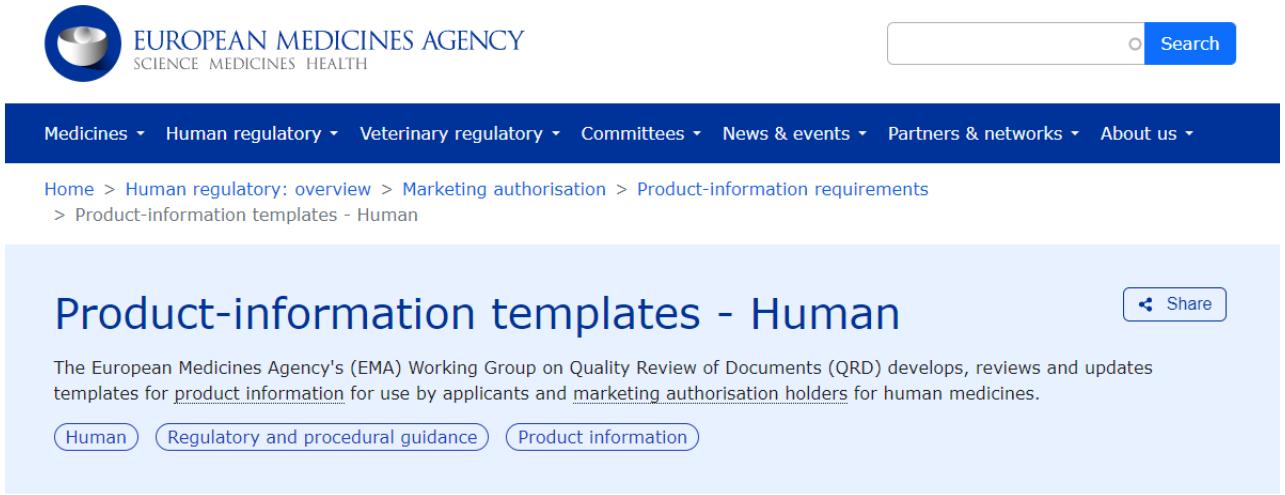
blister packing machine/blisterer, cartoning machine/cartoner, lyophiliser/freeze-dryer, capsule filling and closing machines, etc.

Documentation

Registration dossier

- **Non-clinical** (*in vivo* and *in vitro* studies) and **clinical** (clinical trials with volunteers and patients) information

- **Product information**
  - Summary of Product Characteristics
  - Labelling
  - Package Leaflet



Documentation

Submission → Clarifications

Clarifications ↓

More documentation ↓

More translation

Documentation

Other documents:

- IFUs (medical devices)
- OTC products (labelling and leaflets)
  - Food supplements

Melatonin	Melatonin contributes to the reduction of time taken to fall asleep	The claim may be used only for food which contains 1 mg of melatonin per quantified portion. In order to bear the claim, information shall be given to the consumer that the beneficial effect is obtained by consuming 1 mg of melatonin close to bedtime.

REGULATIONS

COMMISSION REGULATION (EU) No 432/2012

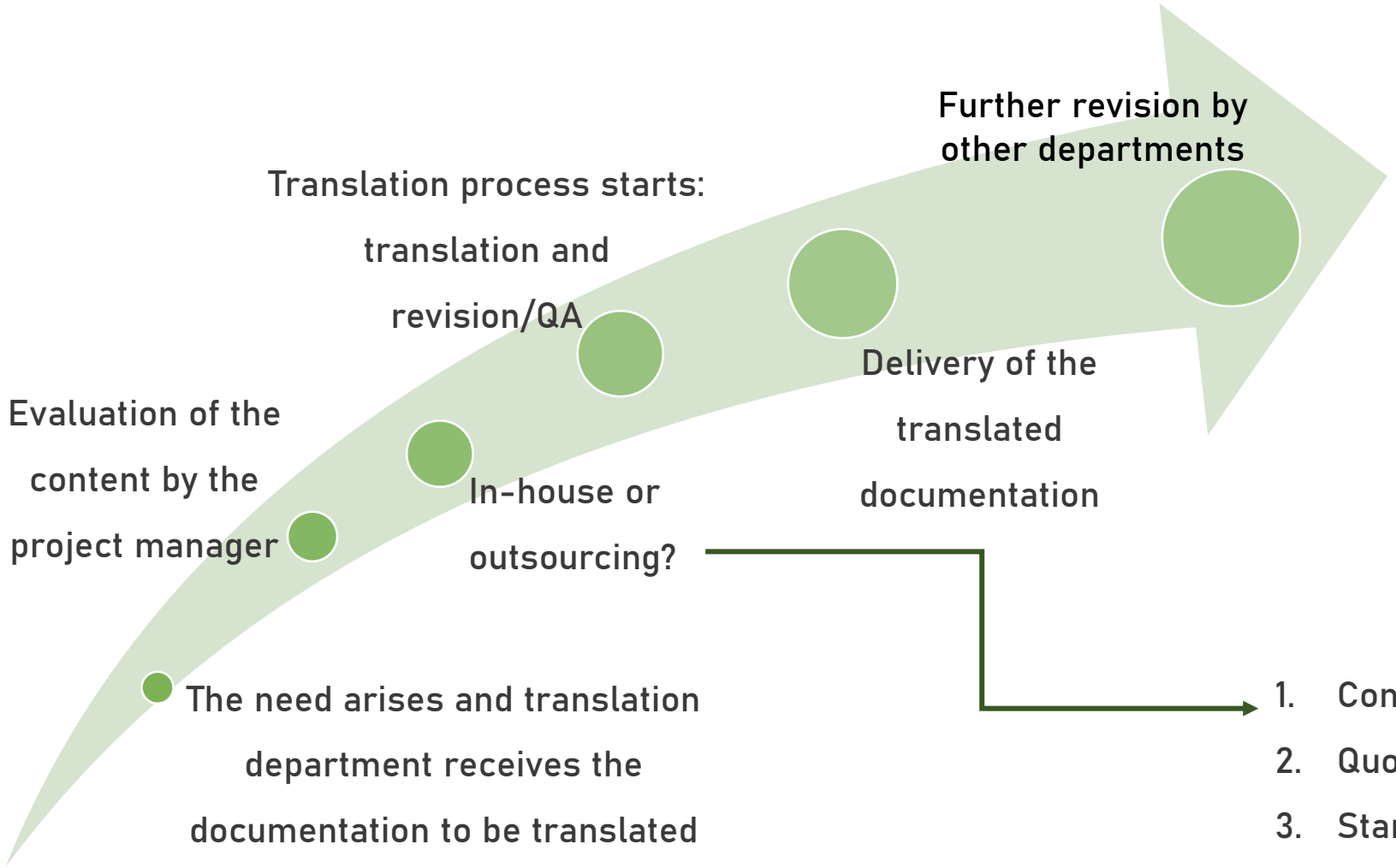
of 16 May 2012

establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health

(Text with EEA relevance)

- Marketing materials (for healthcare professionals and patients)
- Documents from departments such as Pharmacovigilance, Legal, R&D, Quality Control, Quality Assurance (e.g., Standard Operating Procedures, process validation reports, inspection reports, raw material control procedures, batch records, change control documents…)

Workflow



Accurate and on time

Outsourcing

1. Contact with translation company
2. Quote receipt/approval
3. Start of the translation process
4. Translation receipt

Translation department: Why?

Importance of the translation department

- Operating similarly to a translation agency.
- Dealing with tight deadlines.
- Terminology **quality and consistency** using internal translation memory systems and termbases.
- Interdepartmental interaction. **Queries addressed on the spot**.
- Translation and linguistic demands through the same **channel**.
- Problem (and urgencies) **solvers**.

Importance of the translation department

- The translation team:
  - acts as language **consultants**.
  - is composed of linguists, language experts of the company.
  - represents and defends the translation sector.
  - is a key factor in business strategy.
  - has the knowledge to provide advice on the correct practices regarding the AI.

9 September 2024
EMA/CHMP/CVMP/83833/2023
Committee for Medicinal Products for Human Use (CHMP)
Committee for Medicinal Products for Veterinary Use (CVMP)

Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle

2.3.5. Product information

AI/ML applications used for drafting, compiling, editing, translating, tailoring, or reviewing medicinal product information documents should be used under close human supervision. Given that generative language models are prone to include plausible but erroneous or incomplete output, quality review mechanisms need to be in place to ensure that all model-generated text is both factually and syntactically correct before submission for regulatory review.

Importance of the translation department

A laboratory with a dedicated translation department or division is a company that shows true commitment to the quality of its products and the safety and health of patients worldwide.

Thanks to translation departments, our profession is recognised as a crucial link in the chain of medicines commercialisation and in the internationalisation of pharmaceutical companies.

Without translation, we
would be living in provinces bordering on silence.

- George Steiner

Thus…

Translators in the pharmaceutical industry are a bridge connecting patients, healthcare providers, and pharmaceutical companies across borders.

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