



## Medical Document Terminology Glossary

### Key Terms for Translation Service Buyers in the Life Sciences Sector

This glossary provides clear definitions of the core document types and acronyms encountered in pharmaceutical, biotechnology, and medical device industries. Understanding these terms is essential for buyers of language and translation services when scoping projects, briefing vendors, and ensuring regulatory compliance.

#### **IFU** — Instructions for Use

---

*Category: Regulatory / Product Documentation*

A document provided with a medical device or medicinal product that gives end users ( patients, caregivers, or healthcare professionals) clear guidance on how to safely and correctly use the product. IFUs are a regulatory requirement in most markets and must comply with regional standards such as EU MDR/IVDR, FDA 21 CFR, and ISO 15223.

#### **Translation and Language Service Considerations:**

- Legally required in virtually every regulated market worldwide
- Must be translated into all official languages of target markets (e.g., all 24 EU official languages)
- Requires medical/technical translators with device-specific expertise
- Subject to strict terminology consistency and regulatory review
- Often includes pictograms, warnings, contraindications, and dosage information

#### **SmPC** — Summary of Product Characteristics

---

*Category: Regulatory / Pharmaceutical Documentation*

An official document that forms part of a marketing authorisation for a medicinal product in the European Union. It provides comprehensive scientific information about the medicine, including indications, contraindications, dosage, pharmacology, and safety data. The SmPC is intended for healthcare professionals and is reviewed and approved by regulatory authorities such as the EMA.

#### **Translation and Language Service Considerations:**

- Mandatory translation into all relevant EU member state languages
- Highly technical and scientific language requiring specialist pharmaceutical translators
- Must align precisely with approved regulatory text — no paraphrasing permitted
- Translations are submitted as part of the marketing authorisation dossier
- Closely linked to the PIL (see below) — both must be consistent

## **PIL** — Patient Information Leaflet

---

### *Category: Regulatory / Patient-Facing Documentation*

A document included inside medicinal product packaging that provides patient-friendly information about the medicine. Unlike the SmPC (which targets healthcare professionals), the PIL is written for patients and must be clear, readable, and accurate. In the EU, PILs must pass user-testing to confirm patients can understand and act on the information provided.

#### **Translation and Language Service Considerations:**

- Required in all languages of the countries where the product is marketed
- Plain language requirements demand expertise in both medical translation and health literacy
- Must reflect and remain consistent with the approved SmPC
- User-testing of translated PILs may be required by regulators
- High volume documents updated with every label change or safety update

## **eCTD** — Electronic Common Technical Document

---

### *Category: Regulatory Submission Documentation*

The standardised format for submitting pharmaceutical product dossiers to regulatory authorities worldwide, including the EMA, FDA, Health Canada, and others. An eCTD contains all information required for a marketing authorisation application (MAA) or new drug application (NDA), organised into five modules covering administrative data, clinical, non-clinical, and quality information.

#### **Translation and Language Service Considerations:**

- eCTD dossiers can contain thousands of pages across multiple modules
- Translation scope varies by region, some authorities require full translation, others accept English
- Requires translators with deep regulatory, clinical, and pharmaceutical expertise
- File format, metadata, and structure must comply with ICH M4 guidelines
- Language service providers must understand version control and submission timelines

## **PSUR** — Periodic Safety Update Report

---

### *Category: Pharmacovigilance Documentation*

A pharmacovigilance document submitted by marketing authorisation holders to regulatory authorities at defined intervals. The PSUR evaluates the benefit-risk profile of a medicinal product using accumulated safety data from clinical trials, post-marketing surveillance, and spontaneous adverse event reports. It is a key tool in ongoing product safety monitoring.

#### **Translation and Language Service Considerations:**

- Complex scientific and medical content requiring specialist pharmacovigilance translators
- Strict submission deadlines, delays can result in regulatory non-compliance
- May reference international data sources and clinical terminology
- Terminology must align with MedDRA coding conventions and regulatory standards
- Increasingly submitted as a PBRER (Periodic Benefit-Risk Evaluation Report) under ICH E2C(R2)

## **ICF** — Informed Consent Form

---

### *Category: Clinical Trial Documentation*

A document used in clinical research that provides potential study participants with all the information they need to make a voluntary and informed decision about participating in a trial. ICFs must explain the purpose,

risks, benefits, procedures, and rights of participants in plain, accessible language. They are governed by ethical guidelines including the Declaration of Helsinki and ICH GCP E6.

**Translation and Language Service Considerations:**

- Must be translated into the native language of every trial participant
- Plain language requirements to ensure participant comprehension regardless of health literacy
- Regulatory and ethics committee approval required for each translated version
- Sensitivity required, content involves patient rights, risks, and medical procedures
- Often accompanied by assent forms for minors or legally authorised representatives

**CSR — Clinical Study Report**

*Category: Clinical Trial Documentation*

A comprehensive scientific document that presents the full methodology and results of a clinical trial. CSRs are submitted to regulatory authorities as part of marketing authorisation applications and must follow the ICH E3 guideline. They include statistical analyses, adverse event data, protocol details, and conclusions on efficacy and safety, and can run to hundreds or thousands of pages.

**Translation and Language Service Considerations:**

- One of the most complex and lengthy document types in the life sciences industry
- Requires translators with clinical research, biostatistics, and regulatory expertise
- Precise translation of statistical terminology, table headers, and footnotes is critical
- Delays in CSR translation can directly impact regulatory submission timelines
- Often accompanied by supporting appendices including case report forms and data listings

**ADDITIONAL REGULATORY AND CLINICAL ACRONYMS**

*The following terms appear frequently in regulatory affairs, clinical development, and quality management contexts. Translation service buyers may encounter these in project briefs and RFPs.*

Acronym	Full Term	Definition
<b>MAA</b>	Marketing Authorisation Application	The formal application submitted to a regulatory authority to obtain approval to market a medicinal product.
<b>NDA</b>	New Drug Application	The US FDA equivalent of an MAA, submitted to seek approval to market a new pharmaceutical product in the United States.
<b>IND</b>	Investigational New Drug Application	Filed with the FDA before clinical trials begin, allowing an unapproved drug to be shipped across state lines for investigational use.
<b>GCP</b>	Good Clinical Practice	An international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve human subjects.
<b>GMP</b>	Good Manufacturing Practice	Regulations ensuring products are consistently produced and controlled according to quality

Acronym	Full Term	Definition
		standards, minimising risks involved in pharmaceutical production.
<b>SOP</b>	Standard Operating Procedure	Step-by-step instructions to achieve efficiency and quality output in pharmaceutical or clinical settings. Frequently requires multilingual translation for global teams.
<b>CRF / eCRF</b>	Case Report Form / Electronic Case Report Form	Data collection tools used in clinical trials to record information about each participant per protocol. Requires translation for international studies.
<b>DSMB</b>	Data Safety Monitoring Board	An independent committee that monitors clinical trial safety data and advises the sponsor on continuation, modification, or termination of a trial.
<b>MedDRA</b>	Medical Dictionary for Regulatory Activities	The international medical terminology dictionary used in regulatory submissions, pharmacovigilance, and clinical research for coding adverse events and medical history.
<b>EMA</b>	European Medicines Agency	The EU regulatory body responsible for evaluating and supervising medicinal products across European member states.
<b>FDA</b>	Food and Drug Administration	The US federal agency responsible for protecting public health by regulating food, drugs, medical devices, and biologics.
<b>ICH</b>	International Council for Harmonisation	Brings together regulatory authorities and pharmaceutical industry bodies to develop internationally harmonised guidelines for medicinal product registration.
<b>CAPA</b>	Corrective and Preventive Action	A process improvement framework used in pharmaceutical quality systems to investigate deviations, identify root causes, and prevent recurrence.
<b>IVRS / IWRS</b>	Interactive Voice/Web Response System	Technology platforms used in clinical trials to manage randomisation, drug supply, and patient allocation. Scripts and user guides require translation for global trials.

*Note: Regulatory requirements and document formats vary by jurisdiction. Always consult current guidance from the relevant regulatory authority (EMA, FDA, PMDA, etc.) and verify translation requirements with your language service provider.*