

## Glossary of Terms\*

### **IMPT Webinar “MPT Regulatory Pathways”: Suggested Reading Material**

**February 2022**

1. **Apostille:** An apostille certifies a document by affixing a seal to the document itself or to a separate sheet and attaches that to the document. When both the origin and destination countries are members of the 1961 Hague Convention,<sup>[1]</sup> the country where the document originates can approve and certify it as an authentic copy of the original. In this case, apostille is the only certification needed. To apostille a document in the U.S., you send it to the U.S. State Department. The process for apostille outside of the U.S. varies by country, but typically it is conducted by a government agency or office.
2. **Authentication:** The process by which the authenticity of a document is confirmed, either via a Notary Public, apostille, or legalization.
3. **Active Pharmaceutical Ingredient (API):** Any substance or combination of substances used in a finished pharmaceutical product (FPP), intended to furnish pharmacological activity or to otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have direct effect in restoring, correcting or modifying physiological functions in human beings.<sup>[2]</sup>
4. **Adverse Event:** Medical occurrence temporally associated with the use of a medicinal product, but not necessarily casually related.<sup>[3]</sup>
5. **Adverse Reaction:** A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function.<sup>[4]</sup>
6. **Bioavailability/Bioequivalence (BA/BE):** BA means the rate and extent to which the active ingredient or active moiety is absorbed from a drug product and becomes available at the site of action. BA data provide an estimate of the fraction of the drug absorbed, as well as provide information related to the pharmacokinetics of the drug. BE means the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives become available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study. Studies to establish BE between two products are important for certain formulation or manufacturing changes occurring during the drug development and post-approval stages. In

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BE studies, the exposure profile of a test drug product is compared to that of a reference drug product.<sup>[5]</sup>

7. **Common Technical Document (CTD):** An agreement to assemble all the Quality, Safety and Efficacy information in a common format organized into five modules. Module 1 (Administrative Information) is region specific and Modules 2 (Common Technical Document Summaries), 3 (Quality), 4 (Nonclinical Study Reports) and 5 (Clinical Study Reports) are intended to be common for all regions. This method was developed under the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).
8. **Certificate of Pharmaceutical Product (CPP):** A document issued by the National Medicines Regulatory Authority (NMRA) from the exporting country that conforms to the format established by the World Health Organization (WHO).<sup>[6]</sup> It establishes the details of the applicant as well as the status of the pharmaceutical product status in the exporting country.
9. **Certificate of Analysis (CoA):** The list of test procedures applied to a particular sample with the results obtained and the acceptance criteria applied. The CoA indicates whether or not the sample complies with the specification.<sup>[7]</sup>
10. **Combination product:** A product comprised of two or more regulated components (i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic) that are physically, chemically, or otherwise combined or mixed and produced as a single entity.<sup>[8]</sup>
11. **DMF:** A document issued by a manufacturer to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs.
12. **Dossier:** A collection of documents that contain all technical data (administrative, quality, nonclinical, and clinical) of a pharmaceutical product according to the local NMRA's formatting requirements. The dossier is submitted to an NRA for evaluation and approval.
13. **eCTD:** The electronic Common Technical Document (eCTD) allows for the electronic submission of the Common Technical Document (CTD) from applicant to regulator.
14. **Excipient:** According to the European Pharmacopoeia (Ph. Eur), an excipient is any component, other than the active substance(s), present in a medicinal product or used in the manufacture of the product.
15. **Finished Pharmaceutical Product (FPP):** A finished dosage form of a pharmaceutical product that has undergone all stages of manufacture, including packaging in its final container and labelling.<sup>[9]</sup>

16. **Generic Medicines:** Generic medicines work in the same way and provide the same clinical benefit and risks as their brand-name counterparts. A generic medicine is required to be the same as a brand-name medicine in dosage, safety, effectiveness, strength, stability, and quality, as well as in the way it is taken. Generic medicines also have the same risks and benefits as their brand-name counterparts.[\[10\]](#)
17. **Guidance:** Guidance documents are documents prepared for the National Regulatory Agency staff, applicants/sponsors, and the public that describe the agency's interpretation of or policy on a regulatory issue. Guidance documents include, but are not limited to, documents that relate to: The design, production, labeling, promotion, manufacturing, and testing of regulated products; the processing, content, and evaluation or approval of submissions; and inspection and enforcement policies.[\[11\]](#)
18. **Certificate of Free Sale (CFS):** Document that certifies a product can be exported from the country of origin. You may also hear it referred to as a "Certificate for Export" or a "Certificate to Foreign Governments."
19. **Good Clinical Practice (GCP):** This is a process that incorporates established ethical and scientific quality standards for the design, conduct, recording and reporting of clinical research involving the participation of human subjects. Compliance with GCP provides public assurance that the rights, safety, and well-being of research subjects are protected and respected, consistent with the principles enunciated in the Declaration of Helsinki and other internationally recognized ethical guidelines and ensures the integrity of clinical research data.[\[12\]](#)
20. **Good Manufacturing Practice (GMP):** A system of controls to ensure that medicinal products are consistently manufactured according to quality standards established by the National Regulatory Agency.
21. **Innovator/Originator Pharmaceutical Product:** Generally, the product that was first authorized worldwide for marketing (normally as a patented product) on the basis of the documentation of its efficacy, safety and quality, according to requirements at the time of authorization. The originator product always has a brand name; this name may, however, vary between countries.[\[13\]](#)
22. **Intended use:** Intended use is the objective intent of the persons legally responsible for the labeling of drugs. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article.[\[14\]](#)
23. **Indication:** The disease or condition, or manifestation or symptoms thereof, for which the drug is approved, as well as whether the drug is indicated for the treatment, prevention, mitigation, cure, or diagnosis of that disease or condition, including relief of symptoms.[\[15\]](#)

24. **International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH):** comprised of members from regulatory authorities and the pharmaceutical industry to provide harmonized guidance on the scientific and technical aspects of product registration. ICH currently maintains the CTD guidelines.
25. **International Organization for Standardization (ISO):** An independent, non-governmental international organization that comprises standards bodies from more than 160 countries, with one standards body representing each member country. ISO members are national standards organizations that collaborate in the development and promotion of international standards for technology, scientific testing processes, working conditions, societal issues and more.
26. **Labeling:** Product labeling, or artwork, refers to all layers of product packaging. Maintaining updated product labeling is a critical part of regulatory lifecycle management. The components of product labeling include:
- a. Primary packaging: the sachet, blister pack, container, etc. that the product directly touches
  - b. Patient Information Leaflet (PIL): contains instructions, dosage, and safety information for the patient
  - c. Summary of Product Characteristics (SmPC): describes the approved uses of the medicine and is used by healthcare providers
  - d. Secondary packaging: the outer carton or container that is visible to the eye without opening the product
27. **Legalization:** International documents that have originated in one country but are intended for use in another country require embassy legalization to be recognized by the legal system of the foreign country. Embassy legalization is the alternative method for authenticating a document that is utilized for countries that are Non-Hague Convention countries. These countries do not recognize the Apostille as a means to authenticating documents per the 1961 Hague Convention.
28. **Letter of Authorization (LoA) / Power of Attorney (PoA):** A legal document typically issued by the product licensor or licensee to a distributor, LTR, MAH, etc. to establish the relationship between them.
29. **Local Technical Representative (LTR):** If the applicant for product registration is not based in the country of registration, the regulatory authority may require that a local representative be appointed. If applicable, this requirement will be included in the country-specific registration guidelines.
30. **Marketing Authorization Holder (MAH):** a company, firm, legal person, or non-profit organization that has the right to market a specific product in a given country. The MAH is often selected by the product manufacturer and listed on the product registration application. The national regulatory authority grants Marketing Authorization Approval (MAA) to the MAH. Typically, marketing authorization must be renewed every few years, though this varies by country.

31. **Marketing Authorization (MA):** Also referred to as product license or registration certificate. A legal document issued by the competent medicines regulatory authority that authorizes the marketing or free distribution of a medical product in the respective country after evaluation of safety, efficacy and quality. In terms of quality, it establishes, among other things, the detailed composition and formulation of the medical product as well as the quality requirements for the product and its ingredients. It also includes details of the packaging, labelling, storage conditions, shelf life and approved conditions of use. May also be referred to as “product license” or “license” in this and other documents.[\[16\]](#)
32. **National Medicines Regulatory Agency / National Medicines Regulatory Authority (NMRA):** Local governmental agency responsible for ensuring that products released for public distribution (normally pharmaceuticals and biological products, such as vaccines and medical devices including test kits) are evaluated properly and meet international standards of quality and safety and efficacy.[\[17\]](#)
33. **Pharmacodynamics (PD):** The study of the relationship between drug level and drug effect. It involves the study of the response of the target tissues in the body to a given concentration of drug.[\[18\]](#)
34. **Pharmacokinetics (PK):** The study of the relationship between the dose of drug administered and the serum or blood level achieved. It deals with drug absorption, distribution, metabolism and excretion.[\[19\]](#)
35. **Pharmacovigilance (PV):** The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problem.[\[20\]](#)
36. **Regional harmonization initiatives:** A process where regulatory authorities align technical requirements for the development and marketing of pharmaceutical products among multiple countries in a region.[\[21\]](#)
37. **Quality Information Summary (QIS):** Typically required in registrations in low- and middle-income countries, the QIS is a condensed version of the QOS with key quality information of the product.
38. **Quality Overall Summary (QOS):** A summary of all quality-related information provided in the product dossier. This summary usually follows the CTD dossier Module 3 Body of Data.
39. **Serious Adverse Event or Reaction:** Any untoward medical occurrence that at any dose; results in death, life threatening, requires inpatient hospitalization or prolongation of existing hospitalization, or results in persistent of significant disability or incapacity.[\[22\]](#)
40. **Site Master File:** A document prepared by the manufacturer containing information with respect to the production and/or control of pharmaceutical

manufacturing operations carried out at a named site, and to any closely integrated operations at adjacent and/or nearby buildings, if only part of a pharmaceutical operation is carried out.<sup>[23]</sup>

41. **Stringent Regulatory Authority (SRA):** Defined by their status as a member or observer of the ICH. SRAs are recognized for having the highest standards for quality, safety, and efficacy of pharmaceutical products. As such, national regulatory authorities and the WHO take the approval of a product by an SRA into consideration during their review processes. Refer to WHO for a comprehensive list of SRAs.<sup>[24]</sup>
42. **Technical File:** The collection of all technical documents that a medical device manufacturer must submit for product registration. This is the medical device equivalent of the dossier for pharmaceutical products.
43. **Unexpected Adverse Reaction:** Not consistent with applicable product information or characteristics of a drug.<sup>[25]</sup>
44. **Variation:** A change to the terms of a marketing authorization.
45. **Warning Letter:** When NRA finds that a manufacturer has significantly violated NRA regulations, the NRA notifies the manufacturer. This notification is often in the form of a Warning Letter. The Warning Letter identifies the violation, such as poor manufacturing practices, problems with claims for what a product can do, or incorrect directions for use. The letter also makes clear that the company must correct the problem and provides directions and a timeframe for the company to inform NRA of its plans for correction.<sup>[26]</sup>
46. **WHO Prequalification (WHO PQ):** a process established by the WHO to facilitate access to medicines that meet unified standards of quality, safety and efficacy. If a product secures WHO PQ, it may be eligible for accelerated registration processes at the country level.

## References:

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- <sup>[5]</sup> <https://www.fda.gov/files/drugs/published/Bioavailability-and-Bioequivalence-Studies-Submitted-in-NDAs-or-INDs-%E2%80%94-94-General-Considerations.pdf>
- <sup>[6]</sup> <https://www.who.int/teams/regulation-prequalification/regulation-and-safety/rss/certification-scheme/model-certificate-of-a-pharmaceutical-product>
- <sup>[7]</sup> <https://extranet.who.int/pqweb/content/glossary>
- <sup>[8]</sup> <https://www.fda.gov/combination-products/about-combination-products/frequently-asked-questions-about-combination-products#CP>
- <sup>[9]</sup> <https://extranet.who.int/pqweb/content/glossary>
- <sup>[10]</sup> <https://www.fda.gov/drugs/generic-drugs/generic-drug-facts>
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- <sup>[18]</sup> [https://www.who.int/medicines/areas/quality\\_safety/safety\\_efficacy/Annex1GlossaryofTerms.pdf](https://www.who.int/medicines/areas/quality_safety/safety_efficacy/Annex1GlossaryofTerms.pdf)
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