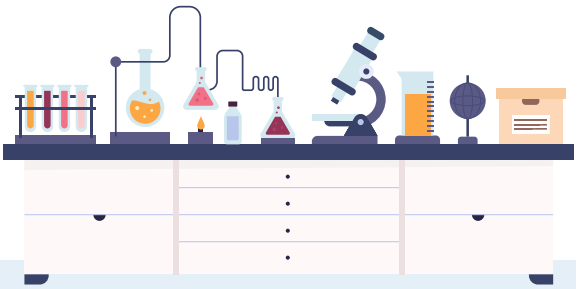
NAVIGATING DIFFERENT REQUIREMENTS FOR

CERTIFICATE OF PHARMACEUTICAL PRODUCT (CPP)



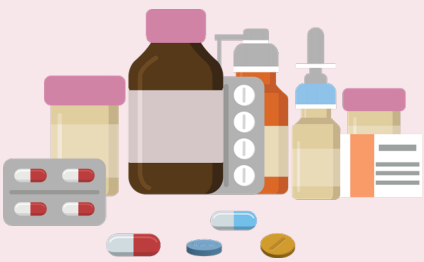
WHAT IS A CPP?

The Certificate of Pharmaceutical Product (CPP) is an official document issued by certifying regulatory authorities upon the request of national regulatory authorities (NRAs) for the assessment of dossiers for marketing authorization, renewals, and variations. The certificate establishes the status of the pharmaceutical product and is developed following the format recommended by the World Health Organization (WHO).

WHAT IS THE WHO CPP SCHEME?

The WHO CPP Scheme supports the regulatory review in countries without sufficient capability to conduct a full Quality, Safety, and Efficacy (QSE) dossier review themselves for a product. It is an international voluntary agreement to provide assurance to countries participating in the Scheme about the quality of pharmaceutical products moving in international commerce. The primary document of the scheme is the Certificate of the Pharmaceutical Product (CPP). Since 1969, the Scheme facilitates reliance among the participating authorities and its use enables a timely access to medicinal products.

However, despite the original intent to provide a standard process and avoid duplication of work, the regulatory procedures among countries have varied significantly and different approaches and interpretations of the WHO CPP Scheme have applied from one country to another. This can lead to confusion between regulatory authorities, but also to substantial delay in registration and patient access to medicines.



ABOUT THE TRAINING TOOLKIT

IFPMA has developed a training toolkit to provide a greater understanding of the current process as well as, highlighting the challenges and opportunities needed to improve and modernize the regulatory procedures that will ultimately accelerate patient access to medicines. The IFPMA CPP Toolkit should be used in conjunction with the current WHO guidelines and relevant local legislative requirements.

The toolkit empowers companies to navigate different CPP requirements and scenarios.

The IFPMA CPP Toolkit outlines examples and improvements on 4 scenarios: **1)** CPP Harmonization; **2)** Authentication of CPP; **3)** CPP only reflects the registered information of the certifying NRA; **4)** CPP requested even when a full dossier QSE review occurs.

The toolkit supports the conversation with NRAs to modernize the CPP.

The IFPMA CPP Toolkit highlights the lack of harmonization and improvement suggestions. It provides guidance on the evolution and modernization of the CPP (i.e., electronic CPP).

IFPMA

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Access Additional Information on CPP

Access the Training Toolkit