Certification of suitability at a glance

Certificates of suitability (CEPs) delivered by the European Directorate for the Quality of Medicines & HealthCare (EDQM) are a tool to facilitate the management of marketing authorisation applications (MAAs) for medicinal products. They are recognised by the signatory parties of the Convention on the Elaboration of a European Pharmacopoeia, but also by an increasing number of licensing authorities worldwide, which accept CEPs to support (fully or partially) the data related to the quality of substances covered by a monograph of the European Pharmacopoeia used in medicinal products.

Certification of suitability

The Certification of suitability to the monographs of the European Pharmacopoeia procedure is a key element of the systems ensuring the quality of pharmaceutical substances marketed in Europe and beyond.

Purpose

Using CEPs, manufacturers can demonstrate that the quality of a pharmaceutical substance is suitably controlled by the respective monograph of the European Pharmacopoeia and complies with current regulatory requirements. This procedure benefits from a centralised assessment and contributes to keeping the monographs of the European Pharmacopoeia up to date.

Procedure

To obtain a CEP for a pharmaceutical substance, a manufacturer submits an application to the EDQM, describing the manufacturing process for the substance in question and the control strategy applied, namely for the determination of impurities. A network of experienced quality assessors nominated by national competent authorities and the EDQM then assess the data provided, determining whether a CEP can be granted for that specific substance.

Inspection programme

The EDQM inspection programme is an integral part of this procedure. Inspections verify that GMP (Good Manufacturing Practice) is applied at the manufacturing site(s) and that the information in CEP applications is accurate. Manufacturing sites are selected for inspection based on a risk assessment.

Use

A valid CEP may be introduced in an MAA for a medicinal product in which the substance from this specific source is included. Regulatory authorities reviewing the MAA rely on the CEP and the work performed by the EDQM.

Advantages

The CEP procedure centralises the evaluation of the quality of pharmaceutical substances for the benefit of regulatory authorities and industry alike, saving time and resources and ensuring harmonisation in the assessment of data. This is a widely accepted tool which contributes to simplifying access to markets in Europe and beyond.

FIND OUT MORE

go.edqm.eu/CEP

CEP general information

go.edqm.eu/CEPinfo

CEP infographic

go.edqm.eu/CEPinspect

CEP inspection programme

go.edqm.eu/CEPgl

Policy documents & guidelines

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How to **improve the quality** of your **Chemical CEP dossier**

Use the EDQM Certification policy document "Content of the dossier for chemical purity and microbiological quality of substances for pharmaceutical use" which describes the information to be included in the three modules of a CEP application.

go.edqm.eu/CEPchemicalpurity

Chemical purity & microbiological quality

This guideline and other key documents (QOS, Top ten deficiencies), as well as the use of EMA SPOR/OMS ORG_ID and LOC_ID, are essential to avoid a CEP dossier being blocked at receipt or receiving requests for additional information.

In **Module 1**, particular attention should be paid to use the appropriate EMA SPOR/OMS ORG_ID and LOC_ID for the CEP holder and manufacturing sites, and to duly fill in the declarations in annex of the application form. Consult the communication on the use of SPOR ID data for more details.

go.edqm.eu/CEPsporID

Use of SPOR ID data

Module 2 is the Quality Overall Summary (QOS) updated template. It is a mandatory component of the CEP application and serves as a concise overview of Module 3, highlighting the control strategy applied and how regulatory requirements are met to ensure the quality of the substance. It provides assessors with a clear understanding of the substance's specification and manufacturing process.

Be aware that an inadequate or incomplete QOS can hinder the assessment process and lead to delays, potentially jeopardising the overall timelines for obtaining a CEP.

go.edqm.eu/CEPqos

Quality Overall Summary template

Module 3 includes detailed expectations for sections related to the manufacturing process, starting materials and intermediates, facilitating the understanding of the control strategy proposed. This includes the need to build a comprehensive risk assessment based on ICH M7 and also taking into account the potential risk of nitrosamine formation and carry-over. The new requirements for CEP 2.0, an encouragement to apply for a re-test period with the possibility of referring to all ICH climatic zones and the Post-Approval Change Management Protocol(s) have been introduced in the recent revision of the EDQM guideline. A document intended to applicants summarises the top ten deficiencies after the initial evaluation of new CEP applications.

go.edqm.eu/CEPdeficiencies

Top 10 deficiencies

CEP 2.0 – A redesigned CEP

go.edqm.eu/CEP20

The CEP 2.0 was implemented in 2023 to better meet the current needs of stakeholders.

What's the CEP 2.0 ?

go.edqm.eu/CEPfaqs