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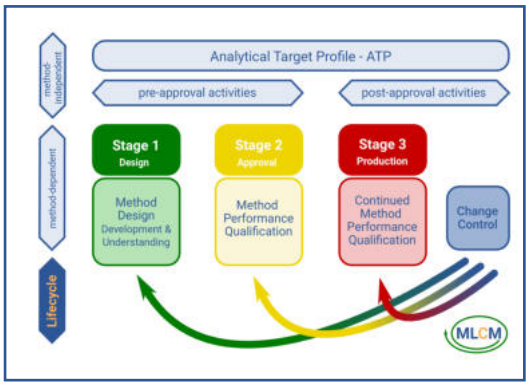
USP Chapter <1221> – Ongoing Procedure Performance Verification (OPPV)

Dear customers and friends of Chromicent,

Chromicent is your partner for the development of chromatographic methods.
Our method development (Stage 1) is consistently based on the principles of **Quality by Design (QbD)** and considers the **entire life cycle of analytical procedures (LCM)** in accordance with **ICH Q14** and **ICH Q2(R2)**.



We are please that our expertise in Stage 1 is internationally recognised. However, we would like to emphasise at this point that **Chromicent supports you throughout the entire method life cycle – especially in Stage 3.**

We are taking the upcoming publication of **USP Chapter <1221> – Ongoing Procedure Performance Verification (OPPV)** as an opportunity to take a closer look at this topic. Chapter <1221> finally provides the long-awaited guidance on how analytical methods can be **efficiently monitored and further developed after validation**.

In contrast to traditional routine checks, OPPV focuses on:

- **proactive monitoring**
- **trend analyses** including risk assessment
- and timely **corrective measures**

Analytical methods are thereby transformed from rigid, reactive tools into **flexible, robust and continuously optimised processes.**

Monitoring can be performed using a defined **Analytical Target Profile (ATP)** – or **verification criteria can be derived from existing knowledge.**
This opens up **new options** and combines **proven concepts with forward-looking principles.**

The purpose of OPPV is to systematically analyse data in order to **identify performance declines at an early stage** and **take targeted countermeasures**. In addition, OPPV also considers **technological, scientific and strategic developments**, thereby opening up genuine potential for improvement.

Product safety and process efficiency go hand in hand at OPPV. And that's exactly what makes Chromicent the ideal partner for you.

Our expertise in **life cycle management**, **quality by design** and the **practical implementation of USP <1220>, ICH Q2(R2) and ICH Q14** is unique both nationally and internationally.

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Game changer stability testing – The new ICH Q1 guideline (2025)

Published in June, the draft **ICH Q1** guideline is intended to replace the previous guidelines **Q1A–Q1F** and **Q5C**, which address stability testing for active ingredients and finished medicinal products. The objective of the new guideline is to:

- close existing gaps
- integrate current scientific insights
- and to emphasise **risk- and science-based principles**

Chromicent offers you not only comprehensive stability testing (including the necessary climate chambers for different climate zones and photo exposure systems), but has always relied on **LCM-supported stability strategies**.

The principles of **QbD (in accordance with ICH Q8–Q11 and Q14)** and the **future USP Chapter <1221>** are consistently applied to the development and evaluation of stability protocols – even today!

Our stability testing guarantees:

- the highest quality
- regulatory certainty
- and flexibility in the face of **post-approval changes**

We consider not only the effects of temperature, light or humidity on a product, but also its **entire life cycle**, including:

- intermediate product stability
- short-term and in-use stability
- new excipients and dosage forms

From **established products to new drugs in the approval process, we are at your side**.

Nitrosamine analysis as part of modern stability concepts

A highly relevant application area for **Stage 3 – Ongoing Procedure Performance Verification (OPPV)** and the new **ICH Q1 Guideline** is **nitrosamine analysis.**
Nitrosamines can form **in situ** over time when active ingredients react with **traces of nitrite** from excipients – a risk which should not be underestimated, especially in the context of **stability checks**.

Chromicent offers you **state-of-the-art analytical solutions** for this purpose:

Using the **Waters Xevo™ TQD Absolute**, a highly sensitive tandem mass spectrometer, we identify and quantify nitrosamines reliably down to trace levels – **reliably, quickly and in compliance with regulations.**

The new ICH Q1 guideline redefines stability –
and Chromicent is ready.

Contact us – we look forward to supporting you.