ICH Q14

Analytical development of procedures for active pharmaceutical ingredients and medicinal products

Background

The final version of ICH Q14 "Guideline on analytical procedure development" was published at the end of December 2023. It describes science and risk-based approaches for the development and life-cycle management of analytical procedures, which offer a suitable means of evaluating the quality of active pharmaceutical ingredients (APIs) and drug products.

Strategic evaluation

The guideline applies to analytical procedures used for release and stability testing of commercial drug substances and medicinal products. However, it can also be applied to other analytical procedures used as part of the control strategy following a risk-based approach (e.g. in-process controls).

A new aspect is the distinction between a minimal (also known as traditional) approach and an enhanced approach. The enhanced approach incorporates additional findings from the analytical development of parameters, which can influence the performance of the process, and is intended as a means of adding greater flexibility to the life-cycle management of these procedures.

Applicants can also submit additional development data and findings which may facilitate communication with the authorities regarding post-approval change management. Furthermore, the guideline contains information concerning the development of multivariate analytical procedures and real-time release testing. It also describes the way in which the information obtained within the framework of the analytical development process should be presented in the marketing authorisation dossier, thus establishing a link to scientific guideline ICH M4Q.

Analytical procedure development at PhytoLab

"Fit for the intended purpose" is the key phrase that sums up the performance criteria for analytical procedures in this guideline. Every analytical procedure is developed with the aim of ensuring that robust and reliable application is assured during routine use throughout the longest possible period of the product life cycle. However, GMP considerations require that the analytical procedure is monitored continuously in order to achieve a continuous improvement. From the industry's point of view, there are economic interests, which exert an influence on the selection of equipment, reagents, reference standards and analysis times, that must be taken into account in this respect.

We work in close cooperation with our clients to find optimum solutions. We would be happy to advise you on the advantages and disadvantages of the minimal (traditional) and enhanced approaches to analytical method development in the context of your specific requirements.

The combination of analytical experience and regulatory expertise that PhytoLab brings into projects ensures that customised analytical methods are developed which unite all of these aspects in the best possible way. From development and validation of analytical procedures in accordance with ICH Q2 (R2) – with Revision 2 also published at the end of 2023 – to the documentation of results ready for approval, we work in accordance with the applicable guidelines in a GMP-regulated environment.

Any questions? Your contacts at PhytoLab

Analysis:
DR. KLAUS REIF
Phone +49 9163 88-337
klaus.reif@phytolab.de

Regulatory Affairs:
ANKE STEUBER
Phone +49 9163 88-446
anke.steuber@phytolab.de

PhytoLab GmbH & Co. KG / Dutendorfer Str. 5–7 / 91487 Vestenbergsgreuth / GERMANY / Tel.: +49 9163 88-330
Sitz / Registered seat: Vestenbergsgreuth / Amtsgericht / Register court: Fürth HRA 6362
Persönlich haftende Gesellschafterin / General Partner: Phytolab Verwaltungs GmbH / Amtsgericht / Register court: Fürth HRB 5151
Geschäftsführer / Managing Director: Reyk Radojewski, Anne Wedel-Klein