

TRAINING COURSE

What's New in ICH Drafts for Q2(R2) and Q14?

[Total Learning time = 3.5 hours]

On this course you will learn about the proposed changes to the ICH guidance, Q2(R2), 'Validation of Analytical Procedures', and the new guidance Q14, 'Analytical Procedure Development', both currently available as draft documents.

Learning Objectives:

1. Understand the proposed changes to ICH Q2 and their significance.
2. Be aware of the key features of ICH Q14.
3. Be able to implement the new requirements as appropriate.

Delivery options for this course:

This half day course is available as an in-house option where the course is run for employees in a specific company. The course may be delivered either in a 'virtual' live online format or in a classroom based format at your site.

This course is suitable for:

Anyone with a good understanding of the current ICH Q2(R1) guidance who wants to learn about the proposed changes in the draft of ICH Q2(R2) and also would like to know how the guidance works in combination with the new proposed guidance on analytical procedure development, Q14.

Ideally this course is a follow-up for those who have attended our training course, 'Validation, Verification & Transfer of Methods for Pharmaceutical/Biopharmaceutical Analysis'

Included in the course fees:

- Comprehensive course hand-outs - The training book is provided as an electronic copy (pdf)
- Certificate of Attendance
- Access to training materials via e-MTS
- Post training support – Attendees can contact the trainer with questions that may occur when they apply their learning to real life situations

Course Agenda & Outline

Typical timings

(approximate) Content

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0900 to 1030	Overview of draft ICH Q14 and proposed changes to ICH Q2. How they combine to provide guidance on analytical procedure lifecycle management. Introduction to main features of Q14.
1030 to 1045	<i>Refreshment break</i>
1045 to 1245	Changes to the assessment of analytical performance characteristics in Q2(R2): <ul style="list-style-type: none">• Robustness• Working range• Accuracy and precision• Specificity/selectivity New information in Q2(R2) Gap analysis of validation of analytical procedures performed as per Q2(R1) against Q2(R2).