TRAINING COURSE

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

[Total Learning time = 3.5 hours]

Draft versions of the revision of ICH Q2, *Validation of Analytical Procedures*, and also the new guideline Q14, *Analytical Procedure Development*, were published on the 24th March 2022. The aim of these updated and new guidelines is to provide a harmonised and scientific approach to method development and to update the guidance on method validation to be more applicable for the techniques commonly used in a pharmaceutical and biopharmaceutical setting.

On this half day course you will learn about the proposed changes to the ICH guidance. The aim is to fully explore the updates to Q2 in terms of potential additional validation requirements and associated gap assessment when compared to current requirements, and also to provide an overview of the contents of Q14.

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 course is available either as an open enrolment option, where anyone can book onto the course, or as an in-house option where the course is run for employees in a specific company.

The open enrolment option is delivered as a half day 'virtual' live online training event which is delivered over a 3 hours and 45 minutes period, from 12pm to

3:45pm, including a short break. The time zone is typically based on GMT (UTC) from November to March, and BST (UTC+1) from April to October.

The agenda is provided on page 3 and the full schedule of dates is available on the MTS website, click here.

The in-house option may be delivered either in the live online format or in a classroom based format at your site. It is typically delivered from 9am to 12:45pm but the timings are based on customer preference.

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.

This course is an ideal follow-up for those who have attended either of our validation training courses: 'Validation, Verification & Transfer of Methods for Pharmaceutical Analysis'; or 'Validation, Verification & Transfer of Methods for 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
1200 to 1330	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.
1330 to 1345	*Refreshment break*
1345 to 1545	Changes to the assessment of analytical performance characteristics in Q2(R2): • 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).