Course

Analytical Quality by Design (AQbD)
Analytical Procedure Development & Life Cycle Management

March, June and September 2025

Enhancing Analytical Method Development and Knowledge Sharing
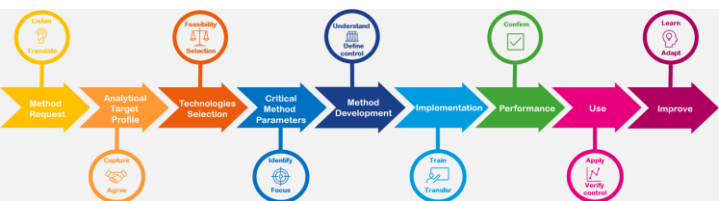
Do you want to break down the guidelines (ICHQ14, ICHQ2(R2), and USP <1220>) into a practical AQbD workflow with tools? Do you want to take the opportunity to capture the scientific knowledge built during analytical method development and better share this knowledge internally or with the regulatory bodies? The AQbD tools will facilitate efficient and risk-based development and validation of analytical methods and for keeping product and process control strategies scientifically sound and fit-for-purpose. This course demystifies and presents AQbD in a digestible way.

The AQbD process starts with defining objectives and a handshake between project and analytical development. It includes identifying critical method parameters, risk-based decision making, and continuously following and improving the procedure. The resulting method is better understood, more robust, and in control, thus reducing the need for troubleshooting and costly reanalysis. The knowledge and decisions made during development are captured, shareable, and reusable throughout the whole pharmaceutical life cycle.

Feedback from previous courses
- This course is an excellent way to learn the AQbD concepts.
- The rhythm of the training was perfect! Well fragmented, good timings, exercises at the right time.
- It is very inspiring to see the course leaders talk so enthusiastically about their field.
- The exercises in this course took me over the fear of starting to use AQbD myself.
- I liked the exercises and the playfulness of them and the teachers.
- I'm so exited to go back to the lab to develop a new method with all I learned!
- AQbD demystified and presented in a digestible way!

→ *Contact us for a Early Bird reduced fee*
→ *Register at info@kantisto.nl*

For whom

This course aims at managers and scientists who want to use a practical and scientific AQbD workflow in their daily work or gain knowledge on how to implement AQbD within their organization.

Training course content

• Background of Analytical Quality by Design
• Analytical request & Analytical Target Profile
• Technologies selection
• Critical Method Parameters
• Method Development, including Design of Experiments
• Method implementation
• Method verification
• Procedure life cycle management
• How to implement AQbD within your organization
• Exercises for each module
• Discussions in an open and positive environment
• Sharing examples and experiences from industry
• Templates you can adapt for your own organization

Learning outcome

This 2-days course will provide time to network and discuss with fellow scientists. After this course you have learned how to apply AQbD in your daily work and are motivated to (further) implement this approach within your organization. A training certificate, practical templates and hand-outs will be provided.

Who are we?

The training will be provided by Prof. Dr. Cari Sänger - van de Griend and Dr. Ewoud van Tricht. We share years of experience applying and implementing the principles of AQbD within (bio)pharmaceutical companies. By doing so, we improved the coherence between analytical methods and the process and quality profile of the product, strengthening the concept of "right analytics at the right time". AQbD increased our level of control and understanding of the analytics as well as reduced our development costs and time.

Registration

Course fee: €2495 + VAT. Early bird registration offers a reduced fee of €2295 + VAT. Location: easily accessible in the Netherlands. Register by sending an email to info@kantisto.nl. There is a maximum of 20 attendees, make sure you register in time!

Kantisto also offers on-site in-company courses and support with content tailored to you needs.

Kantisto
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