

Course

Analytical Quality by Design (AQbD)

Analytical Procedure Development & Life Cycle Management

8 – 10 April 2024, the Netherlands

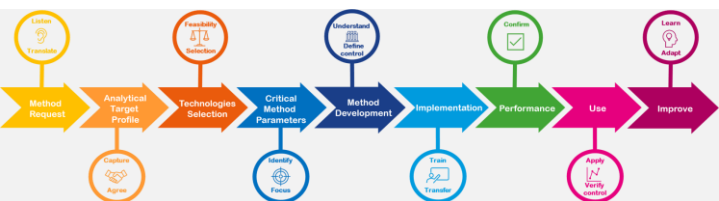
Analytical procedures fit for decision making

Are you ready for the new ICH Q14 and USP <1220> guidelines and the revision (R2) of ICH Q2? These forthcoming guidelines are designed to fill a void in the toolbox of analytical method development. They provide the opportunity to capture the scientific knowledge built during analytical method development and better share this knowledge internally or with the regulatory bodies. This will facilitate efficient and risk-based approval of analytical methods and create flexibility for post-approval changes and for keeping product and process control strategies scientifically sound and fit-for-purpose. The guidelines are almost ready, and this promising and desired tool? Analytical Quality by Design.

Analytical methods are employed throughout pharmaceutical development and manufacturing. Analytical results provide data, translated into information, to make decisions on the safety, efficacy, and quality of medicines. This decision-making process should be science-centred to acknowledge the uncertainty of a measurement and to reduce the risk of making the wrong decision. Analytical Quality by Design (AQbD) is a structured, risk-based approach that supports the process of effectively designing analytical procedures that focus on the intended purpose and that fulfil the anticipated requirements.

The process starts with defining objectives and a handshake between project and the analytical department. 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.

- Early Bird reduced fees until 1 Feb 2024
- Deadline for registration 1 March 2024
- Register at info@kantisto.nl



For whom

This course aims at managers and scientists who want to apply a scientific AQbD approach 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 out come

This 3-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 Cari Sanger-van de Griend (Kantisto) and Ewoud van Tricht (Sanofi). We share years of experience applying and implementing the principles of AQbD within our companies. By doing so, we improved the interconnection 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. Reduced course fee of € 2295 + VAT when registering before 1 February 2024. Location: Bussum, the Netherlands. Register by sending an email to info@kantisto.nl. There is a maximum of 20 attendees, make sure you register in time!

Refund policy: written cancellation before 1 March 2024 will result in a full refund minus a 20 % processing fee.

Cancellation made after 1 March 2024 will not be refunded, but registration can be transferred to another person. Deadline for registration: 1 March 2024, after this date, only upon availability.

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



Kantisto
SEPARATION SCIENCES

Callenburglaan 22
3742 MV Baarn
The Netherlands

info@kantisto.nl
www.kantisto.nl