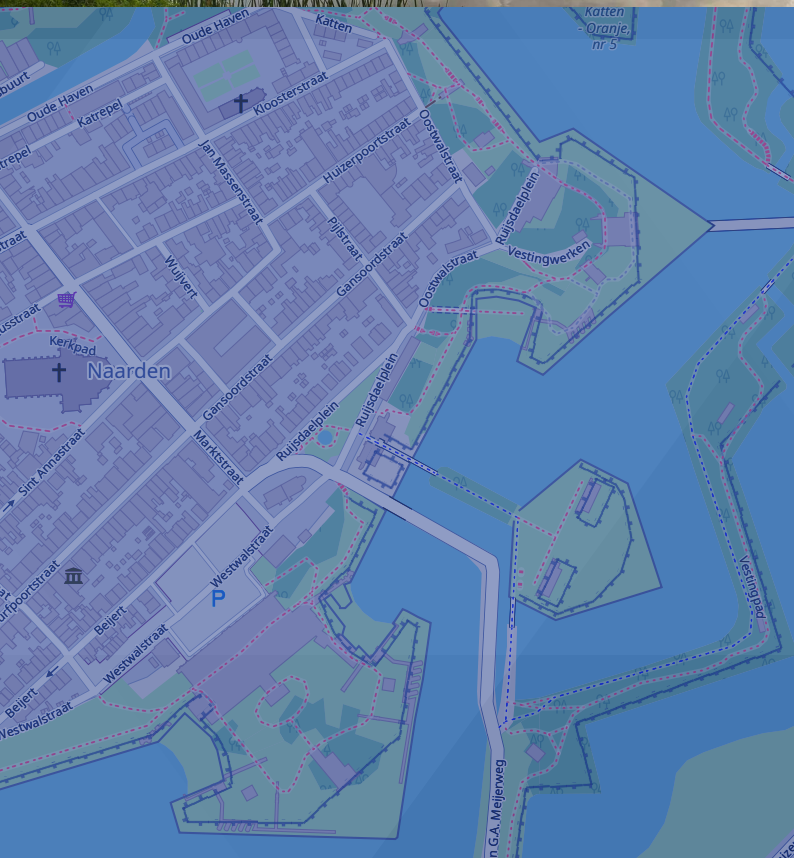
3-Days training course

Analytical Quality by Design (AQbD) and Analytical Procedure Life Cycle Management

12 – 14 December 2022, the Netherlands

→ *Early bird reduced fees until 31 August 2022*
→ *Deadline for registration 1 October 2022*
→ *Register at info@kantisto.nl*

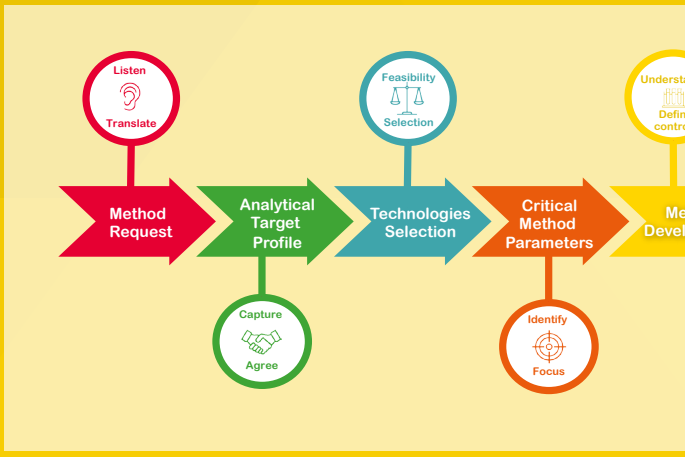
Fortification of Naarden



Analytical procedures fit for decision making

Are you ready for the new and upcoming ICH Q14 and USP <1220> guidelines and the complementary 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 present the scientific framework build during development in the validation reporting of the analytical methods. By following these guidelines and implementing the appropriate tools, the focus of analytical method developers will change back to scientifically sound method development of state-of-the-art techniques while expanding their knowledge and reducing time spend on outdated methods, (re)validations and paperwork. Authorities will facilitate efficient and risk-based approval of analytical methods with flexibility for post-approval changes, keeping product and process control strategies fit-for-purpose. The guidelines are almost ready, and this promising and desired tool? Analytical Quality by Design (AQbD)!

Analytical methods are employed throughout pharmaceutical development and manufacturing to generate analytical results fit to make decisions. This decision-making process should be science-centered to acknowledge the uncertainty of a measurement and the risk of making a wrong decision. AQbD is a structured, risk-based approach that supports the design of analytical procedures that focus on the intended purpose and that fulfil the anticipated requirements. This approach extends beyond the application of design of experiments, or even the method on its own.



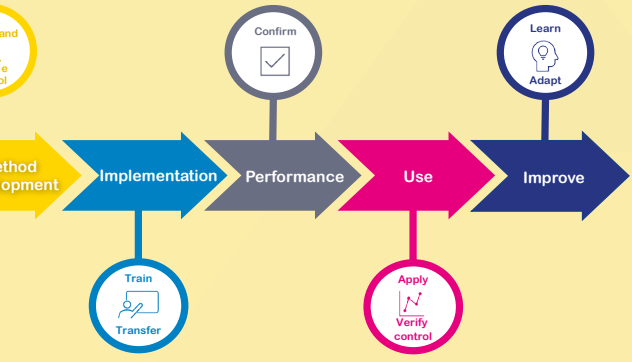
The process comprehends predefined objectives and a handshake between project and the analytical department, identifies critical method parameters, supports risk-based decision making, and continuously following and improving your procedure. The resulting method is better understood, more robust, and in control. This reduces 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.

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 start implementing AQbD within their organization.

Course content

- Theory on Analytical Quality by Design
- Detailed training on the AQbD flow and the specific modules:
  - Method requests and Analytical Target Profile (ATP)
  - Technologies selection
  - Critical Method Parameters
  - Method Development (including Design of experiments)
  - Method implementation and training
  - Method performance
  - Method use and procedure life cycle management
- How to implement AQbD within your organization
- Hands-on practice for each module
- Rapid learning cycles by combining theory and exercises
- Discussions in an open and positive environment
- Real examples and experiences from industry
- Templates you can adapt for your own organization



Learning outcome

This 3-day 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 start implementing 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 Sänger-van de Griend (Kantisto), Eline van den Berg (Byondis), Lars Geurink (Janssen) and Ewoud van Tricht (Janssen). We share years of experience applying and implementing the principle of AQbD within companies. By incorporating AQbD in our method development process, we improved the interconnection between analytical methods and the process and quality profile of our product, strengthening the concept of "right analytics at the right time". AQbD increased our level of understanding and control of the analytics as well as reduced our development costs and time.

Registration

Course fee: € 2395 + VAT. Reduced course fee of € 2195 + VAT when registering before 31 Aug 2022. Detailed conditions on www.kantisto.nl.
Location: Naarden-Bussum (25 km from Amsterdam).
Register by sending an e-mail to info@kantisto.nl. There is a maximum of 20 attendees, make sure you register in time! Refund policy: Written cancellation before 1 Oct 2022 will result in a full refund minus a 20 % processing fee. Cancellation made after 1 Oct 2022 will not be refunded, but registration can be transferred to another person.

Kantisto also offers on-site in-company courses and support with content tailored to you needs.
For more information check www.kantisto.nl or contact us via info@kantisto.nl

Feedback from previous courses

- *Everyone in our organization should do this course. Many applicable solutions were discussed in a comprehensible way that we can apply immediately.*
- *The course covers the fundamentals of the AQbD and it gives the courage to try it for yourself.*
- *My basic knowledge about AQbD was mostly on DoE robustness. I now feel secure that the course helps me to support my group in every AQbD subject.*
- *The course made me better understand the whole workflow and the relationship between all different steps.*
- *Many practical examples that give grip on the topic. The exercises clearly demonstrated and underlined the need for an AQbD mind set.*
- *The teachers had a good balance, they have lots of experience and complement each other.*
- *There was plenty of opportunity to ask questions and the speed of the training was flexible and adapted to our uptake.*
- *I have really enjoyed this course and look forward to use all that I've learned to my method development at work. Thank you very much!*

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