

#### **Steps to Master**

### **Analytical Quality by Design (AQbD)**



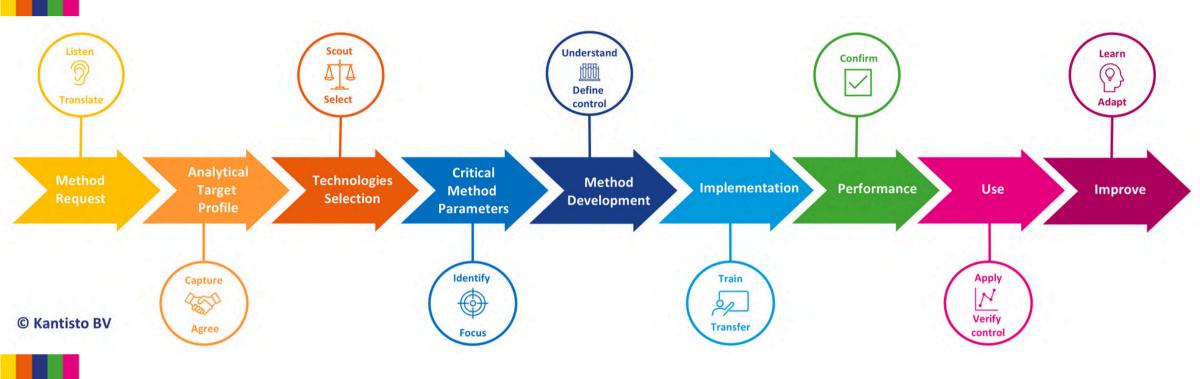


### Do you also get **overwhelmed** when you read ICH Q14?



Unsure where to begin?

# We successfully taught this simplified approach to **over 150** technicians, scientists, and managers:





Want to see how this simplified approach works?

Let's dive into the details!

### **Method Request**

Listen to understand the customer's needs

Translate these needs into a clear request



# Analytical Target Profile (ATP)



Capture all (technical and business) requirements

Agree on the targets that ensure method success



#### Technologies selection



**Scout** for all suitable technologies **Select** the ones that best align with the analytical target profile (ATP)

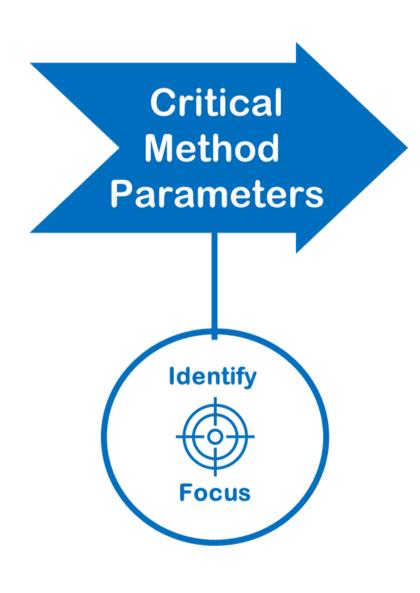




## Critical method parameters (CMPs)



**Identify** the most critical parameters **Focus** on those that directly impact performance





#### Method development



**Understand** your method parameters **Define** the control strategy to ensure robustness and consistency



#### Implementation



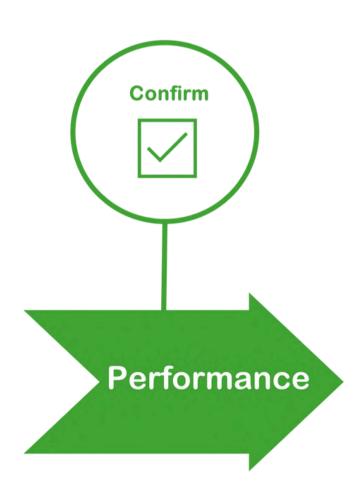
**Train** the teams on the analytical procedure **Transfer** the developed procedure into practice for execution



#### Performance

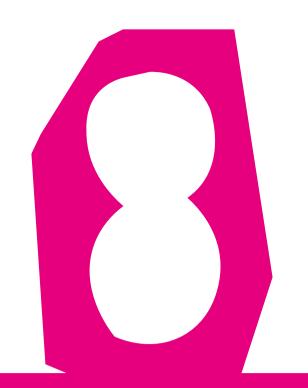


**Confirm** method performance by testing against the agreed targets and benchmarks using ICH Q2(R2)

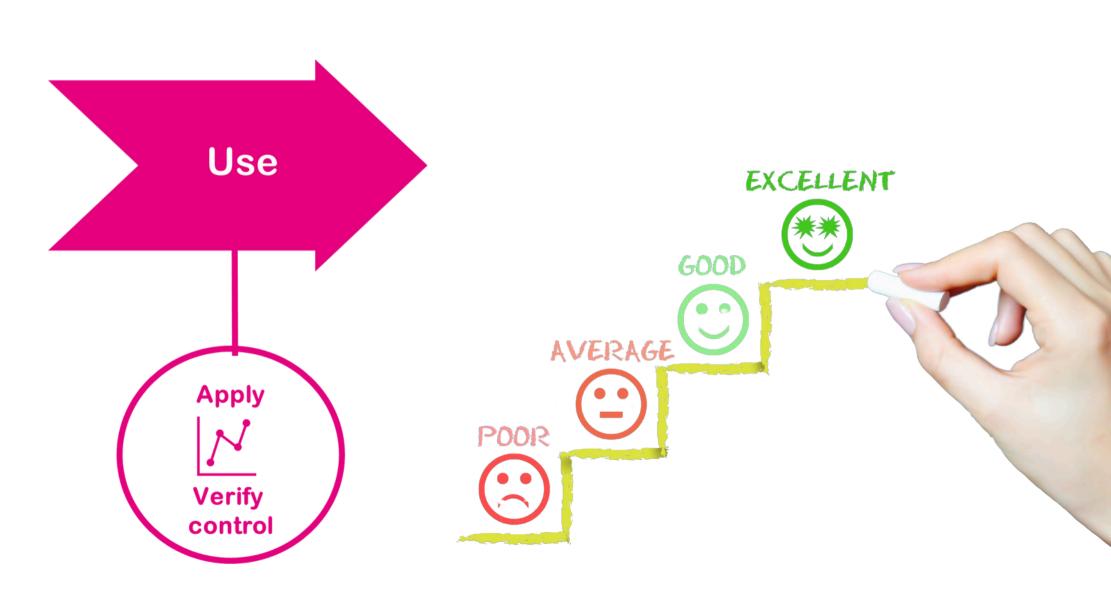




#### Use



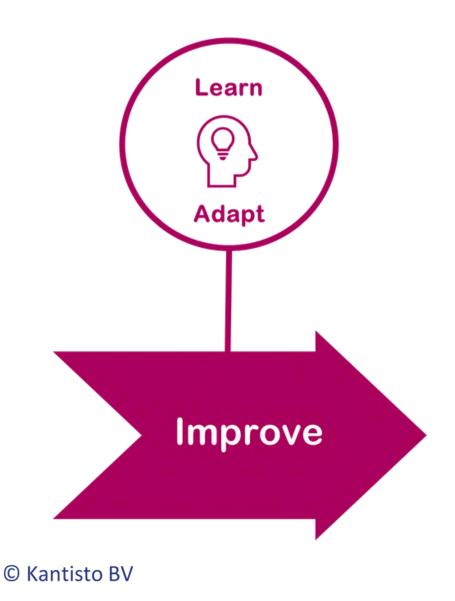
**Apply** the method in real scenarios **Verify** that the control strategy continues to perform as expected



#### **Improve**



**Learn** from the users and from performance data **Adapt** and improve the method for continuous optimization





### Learn more and download the PDF at Kantisto.nl/AQbD



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Have suggestions for future posts?

Let us know in the comments!

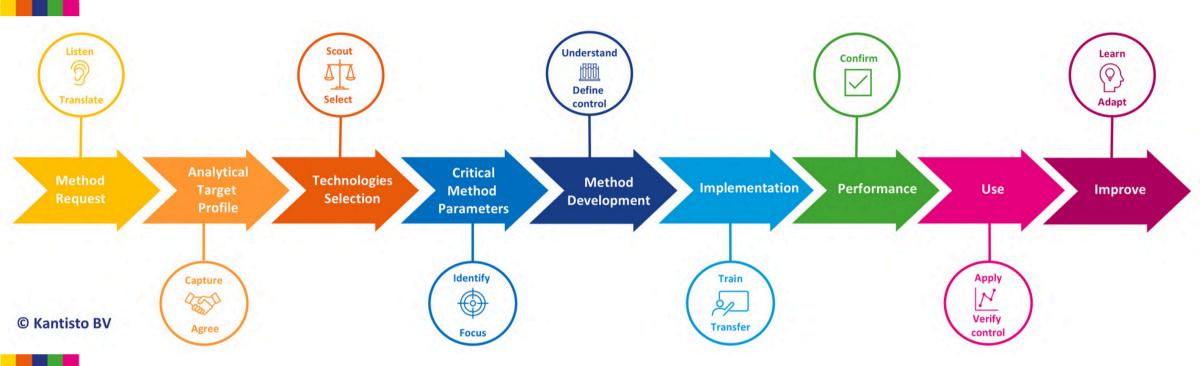


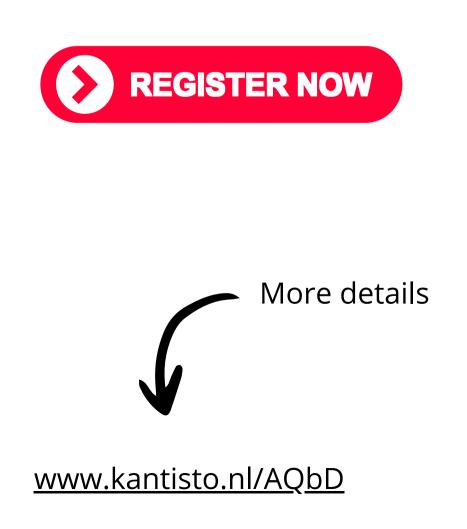


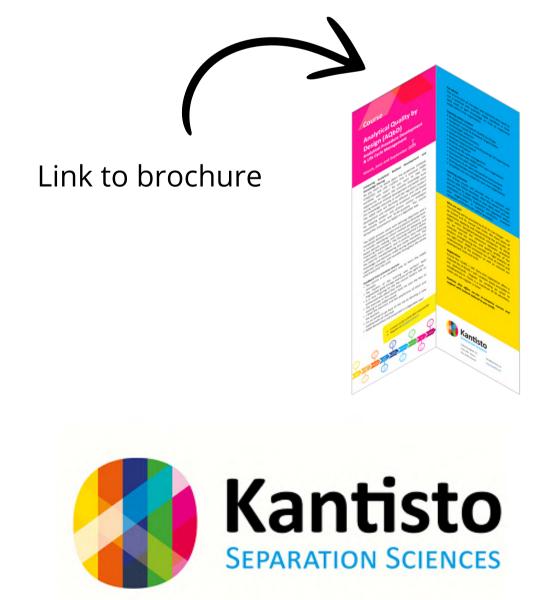
#### 2-day AQbD course

- March, June, and September 2025
- The Netherlands

Course participant feedback: "AQbD demystified and presented in a digestible way!"







**Kantisto BV** is an independent chemical and pharmaceutical analysis consultancy. Kantisto offers support in practical and strategic issues through long or short-term assignments. Kantisto also provides in-company training and courses. Based in the Netherlands, Kantisto delivers its services in Europe and throughout the world. A focus on knowledge transfer and implementation means that Kantisto prefers to work not just for you, but with you on-site, in close cooperation and collaboration, with a pragmatic scientific and personal approach.

#### What we offer:

At Kantisto, we provide expert services to support (bio)pharmaceutical analytical development and quality control. Our offerings include:

- Training & Courses:
  - Delivered on-site or through open-registration/classroom formats.
- Scientific Support & Coaching:
   Personalized guidance for analytical challenges.
- Interim Management:
  Temporary leadership and expertise to support your projects.
- Lecturing & Supervision:
   Teaching, PhD supervision, and fostering knowledge-sharing.

#### We specialize in:

- Method development, validation, and transfer
- Design of Experiments (DOE)
- Troubleshooting and risk assessment
- Analytical Quality by Design (AQbD)
- Liquid Chromatography and Capillary Electrophoresis
- Process optimization using Lean or Agile principles



