# Kantisto’s expertise in (Bio)pharmaceutical analysis and Analytical Quality by Design (AQbD)

Cari Sänger – van de Griend, PhD
Ewoud van Tricht, PhD

Kantisto
INNOVATING PHARMACEUTICAL ANALYSIS

# Kantisto innovates and supports (bio)pharmaceutical analysis

## How could we support you?

Expert advice, consultancy, training, and coaching for analytical development and (bio)pharmaceutical analysis


## Our specialties:

- (Bio)pharmaceutical Analysis
- Method Development and Validation
- Quality Control
- Analytical Procedure Control Strategy
- Analytical Quality by Design (AQbD)
- ICH Q14 and ICH Q2(R2)
- Capillary Electrophoresis (CE)
- Troubleshooting

# Who are we?

## Prof. Dr. Cari E. Sänger – van de Griend

Cari is an expert in (bio)pharmaceutical analytical chemistry with 30+ years of industrial and academic experience in method development and control strategies, including Analytical Quality by Design (AQbD). She is focused on best practices and knowledge sharing. Cari has previously worked with Astra Pain Control, AstraZeneca, Solvay Pharmaceuticals, and Abbott Healthcare Products, focusing on small molecules, therapeutic proteins, vaccines, and nucleotides. She is Associate Professor at Uppsala Universitet.

## Dr. Ewoud van Tricht

Ewoud has over 18 years of experience in the (bio)pharmaceutical industry. He has worked on small molecules, antibodies, proteins, viruses, and cell therapies at companies such as Abbott Healthcare Products, Janssen Vaccines, and Sanofi Cell Therapy. Alongside his full-time career, he completed a Bachelor's, Master's, and PhD in Analytical Chemistry. Ewoud specialises in Analytical Quality by Design (AQbD), having developed and implemented strategies to enhance pharmaceutical methods.

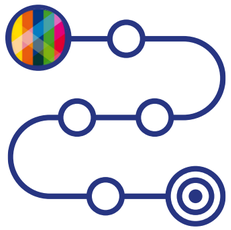
# How we could train and support you?

## CLASSROOM TRAINING

## EXPERT ADVICE

## CONSULTING

## IMPLEMENTATION SUPPORT



## ON-SITE SUPPORT


## WEBINARS

# Our expertise and training in (bio)pharmaceutical analysis

## Method Development, Transfer & Validation

- Method Development
- Method Qualification & Validation
- Method Transfer
- Method Implementation
- Implementation of New Technologies
- Troubeshooting
- Good Practices for Method Development
- Trending and Monitoring
- Method bridging

## Analytical Quality by Design (AQbD)

- Analytical Target Profile (ATP)
- Critical Method Parameters
- Technology Selection
- Risk Assessment
- Design of Experiments
- Life-Cycle Management

## Statistics

- Design of Experiments
- Trending and Monitoring
- Error Propagation
  Calcultate the error you make during your lab work
- Method validation
  Precision, accuracy, linearity etc.

## Compliance & Guidelines

- ICH Q2(R2) - Method Validation
- ICH Q14 and USP <1220> Method Development
- Dossier Writing
- Analytical Control Strategy

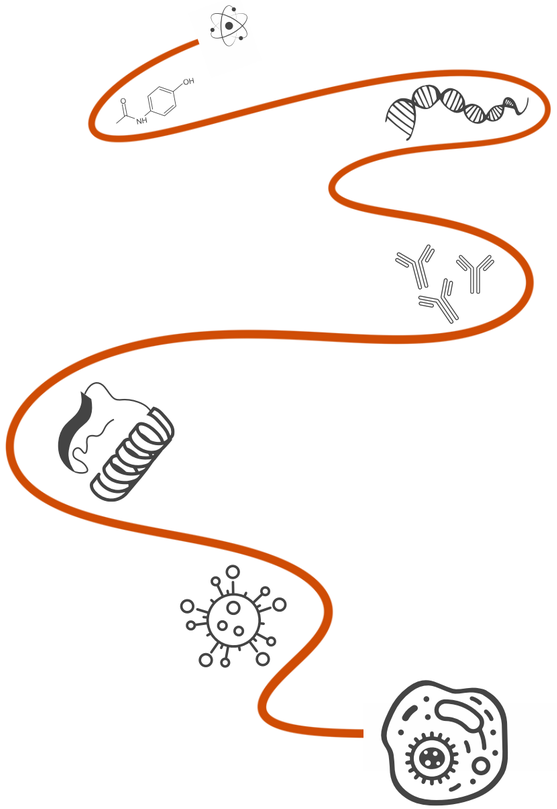
These topics reflect our core expertise and are also available as practical training modules, tailored to your organisation’s needs.

# Our Expertise in Analysing a Wide Range of Products

Covering all phases from pre-clinical to commercial

## Analytes

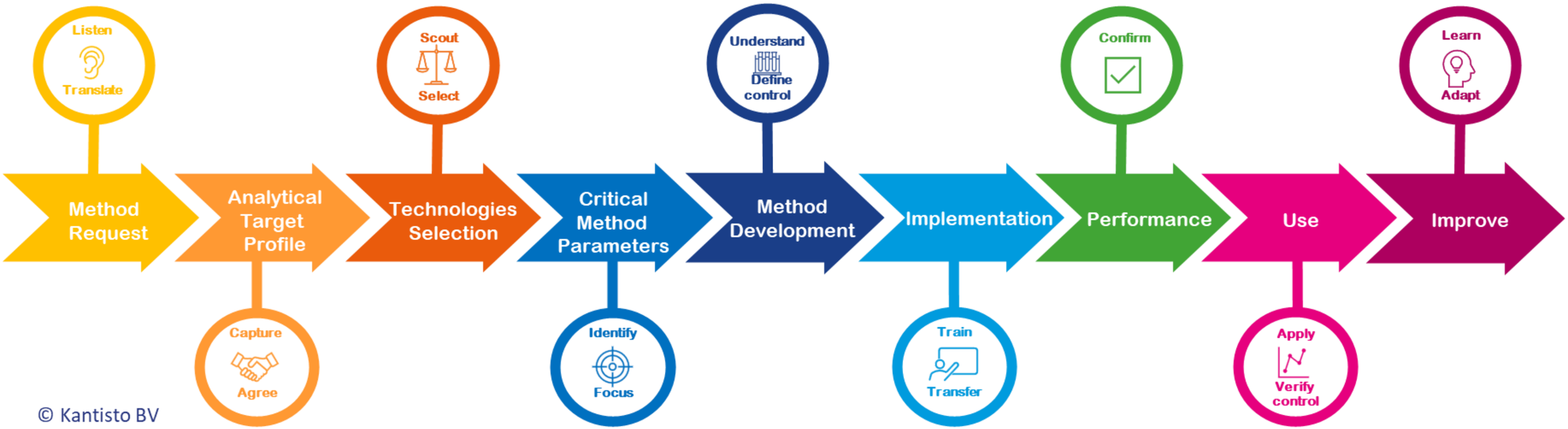
- Ions
- Small molecules
- Oligonucleotides
- RNA
- DNA
- Antibodies
- Proteins
- Virus-like particles
- Viruses
- Cells



## Therapeutic areas

- Neurological disorders
- Infectious diseases
- Oncology
- Local Anaesthetics
- Nervous System Diseases
- Cardiometabolic
- Neuroscience
- Women’s and men’s health
- Vaccines
- Cell and Gene Therapy
- Toxins, chemical warfare agents

# Our AQbD flow



# Our AQbD training setup


Our practical AQbD workflow for method development and validation

Aligned with ICH Q14, ICH Q2 and USP <1220>

Practical exercises covering all AQbD steps

Download the brochure


Course handouts containing all slides and exercises

Free Excel AQbD template containing all tools


Real-world case studies

# Why attending our AQbD course?


## Hands-on learning

Practice every step of our AQbD process

## Simplified workflow & smart tools

No theory overload, just applicable insights

## Clear and accessible guidance

We translate ICH Q14 into practical strategies

## Immediate impact

Apply what you learn directly to your method development work

## Be compliant with new guideline ICH Q14


ICH harmonisation for better health

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 December 2023
EMA/CHMP/ICH/195040/2022
Committee for Medicinal Products for Human Use

ICH Q14 Guideline on analytical procedure development
Step 5

**With a structured approach, smart tools, and hands-on practice, you can start right away.**

# Benefits of using ICH Q14 and implementing AQbD

## Achievements observed in other Companies:

- Reduced assay implementation timeline
- Reduced hands-on time
- Fewer invalid tests
- Less troubleshooting
- All assays fitness-for-purpose
- Fewer method re-developments

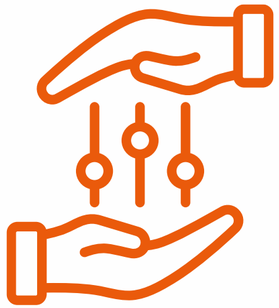
# Why choose for Kantisto?

## Experience

We bring over 50 years of experience from both academia and industry, allowing us to provide practical, pragmatic, and effective advice.

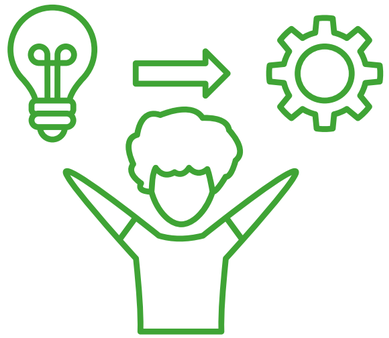
## Perzonalized expertise

As a two-person team, you'll always have direct contact with the specialists, ensuring a personal and hands-on approach.



## Pragmatic support

We translate theory into practice, ensuring that the solutions we provide are directly applicable to your situation.



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