

Community of Practice

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- Welcome & Objective
- What is a Community of Practice (CoP)
- Showcase from COAST: Pharma / ICH Q14
- Other Examples
- Interactive: what are the drivers of success?
- Wrap-up & Invite for a Cop of Coffee

THE COAST COMMUNITY

↳ Comprehensive Analytical
Science and Technology

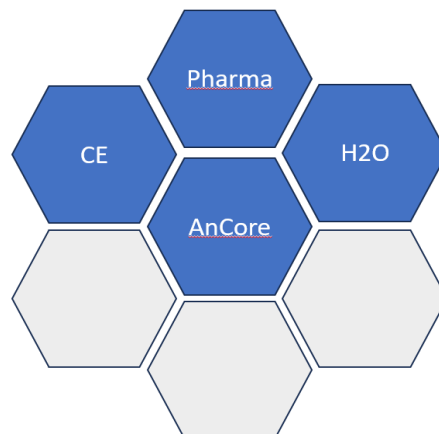
 **R&D**
Advancing R&D and innovation
in analytical technologies


Uniting and connecting
analytical professionals


formulate and tackle
analytical challenges


joint research programs

Our mission:
"To advance analytical science
in the Netherlands by strengthening
R&D, human capital and analytical community"



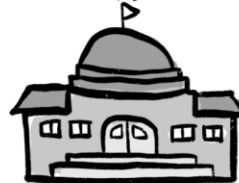
- * thematically
- * expertise
- * strategic

connecting

education



(semi-)government



companies



Sharing knowledge
via joint programs
and learning community



Improving education
in analytical science



increase the number
of graduates



Providing access to top students
and an active international
world-class network

Objective of today?

- Create awareness and insights of a Community of Practice (CoP)
- Showcase how a community of practice can function and how you might benefit from it
- Capture the key drivers for success (together) & the benefits of a CoP
- Learn from your experiences and perspectives

Gauge the room:

- Who are you?
- What's your affiliation?
- Why are you here?

Question(s):

- a) What does a Community of Practice mean to you?
- b) Do you have examples of successful collaboration?
- c) Where is learning or innovation currently blocked in your environment?

What is a Community of Practice? (our interpretation)

- People with shared challenges in a professional working environment
- Active learning, iterations and sharing knowledge & experiences
- Community driven: the members define the agenda
- Strong focus on leaning and sharing solutions

Why does it work?


- Let explore why this works in practice.

Community of Practice Pharma: ICH Q14 working group

ThermoFisher
SCIENTIFIC

ARDENA

 **aspen**

 **Pharming**[®]

 **ABBOTT**

 **eurofins**

 **TIO
FARMA**

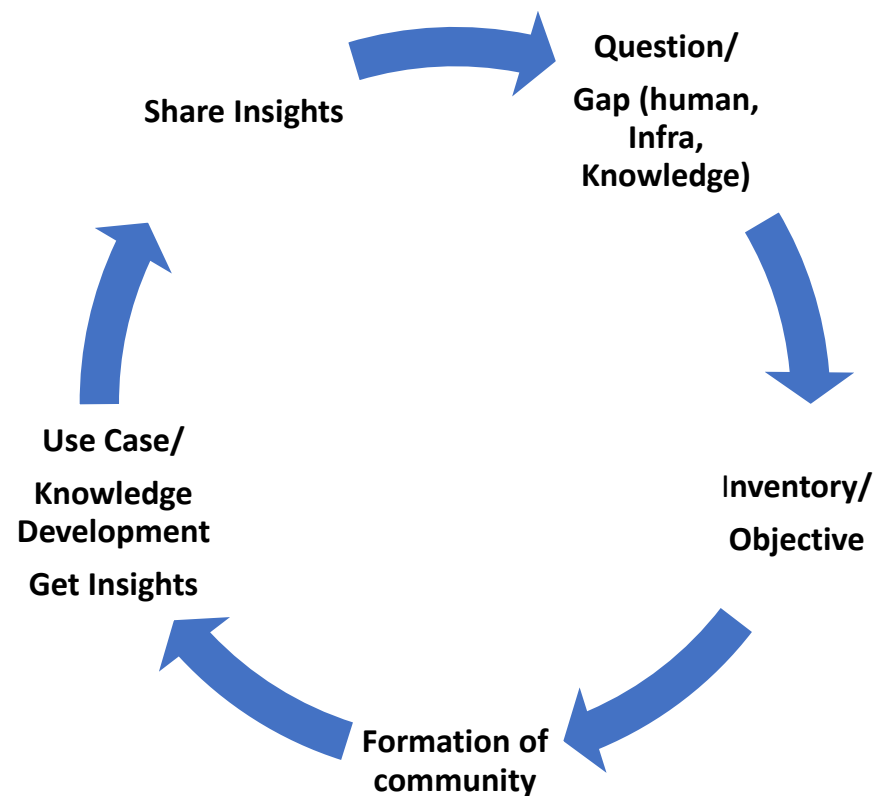
 **Santen**

 **BRIGHTLABS**
BE RIGHT!

 **Maastricht University**

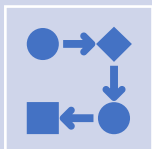
Radboud Universiteit







Understanding the impact of
the new guideline



From guideline → practice
through a step-by-step
approach



Participants worked on their
own use cases
Gaps → training, workshops,
student projects



INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL
REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE

ICH HARMONISED GUIDELINE

ANALYTICAL PROCEDURE DEVELOPMENT
Q14

Draft version

Endorsed on 24 March 2022

Currently under public consultation

Scouting session Kick-off

Identify **shared challenges** and **relevance**
(Impact)

Demand/Challenge(s):

- What is the impact of the ICH Q14 guideline on my organization?
- What does it mean?
- Where do I start?
- How do I implement such a guideline?
- How do I communicate with the regulatory bodies?
- Who can help me?
-

Session I:

From Guideline to Practice

- Breakdown of the guideline (steps)
- Assess the impact of each step within your organization (Technical, Management)
- Apply each step on own use case
- Share experiences & Collect insights
- Define next steps

Session II:

From Gaps to Learning Actions

- New insights reveal knowledge gaps and missing capabilities
- Input to define concrete internships and student assignments
- Feed back into talent programmes and professional development
- Identify training needs and missing competences
- Organize targeted workshops or courses

Circular Economy (CE) – Demand/Needs

- Insight into circular material streams and analytical issues
- Tools for sorting, quality assessment, and recycling
- Value-chain collaboration on shared challenges
- Support to initiate and structure circular R&D projects

Analytical Core – Demand/Needs

- AI/ML for analytical data interpretation and method development
- Lab automation and digitalized, high-throughput workflows
- PAT technologies and new measurement principles
- Industry 4.0/5.0 applications (soft sensors, predictive maintenance, digital twins)
- Enhanced real-time monitoring and process control

H2O Demand/Needs

- Stronger links between labs, research groups, and education
- Development of shared R&D lines in wastewater topics
- Joint identification of industrial water challenges

Pharma Demand/Needs

- Clear implementation approach for ICH Q14
- Harmonized analytical method development practices
- Exchange of challenges across companies and suppliers
- Strengthened human capital and analytical infrastructure

What is a CoP for us?

- A strategic, structured active-learning group
- Community-driven: defined by members and their shared challenge
- Connecting education, research and business practice
- Developing expertise faster, sharing it wider, securing it better
- Applying knowledge with impact to current and future challenges

Could your organization benefit from a Community of Practice?

Let's explore together what a CoP could look like for your context

You are always welcome for a 'CoP Coffee'

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EXAMPLE

<https://biotech.com/2024/06/26/ich-q14-analytical-procedure-development/>

