

# RACI 2025

**3 A 5 DE OUTUBRO**

Blue & Green Tróia Design Hotel

The future-proof Industrial Pharmacist:  
Thinking ahead & ready to act

## **RACI 2025**

Conselho do Colégio de Especialidade  
de Indústria Farmacêutica da Ordem  
dos Farmacêuticos

**3 a 5 de outubro 2025**

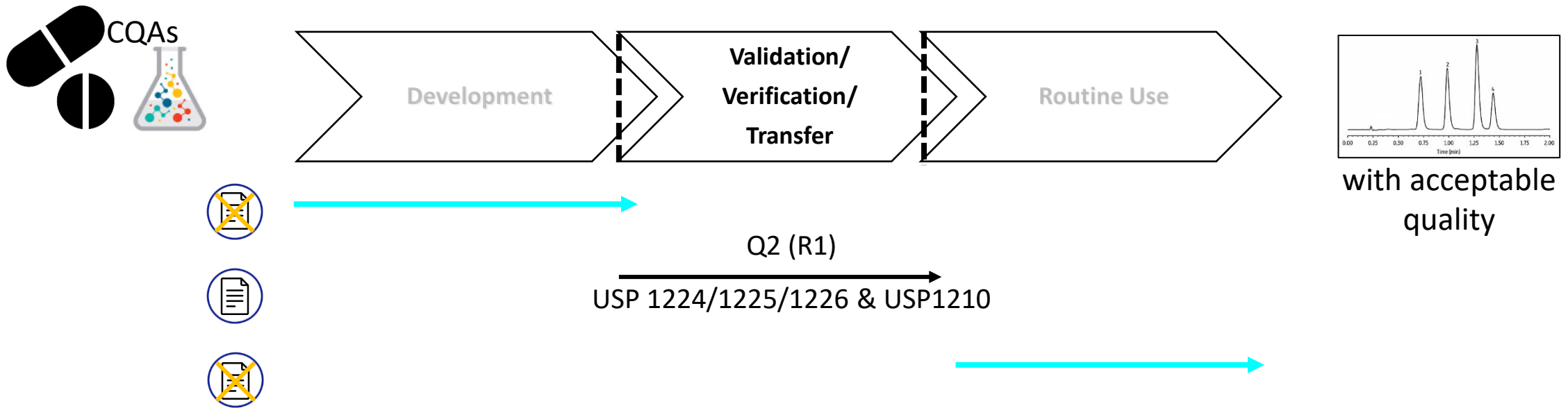
*Ordem dos Farmacêuticos, Lisboa*



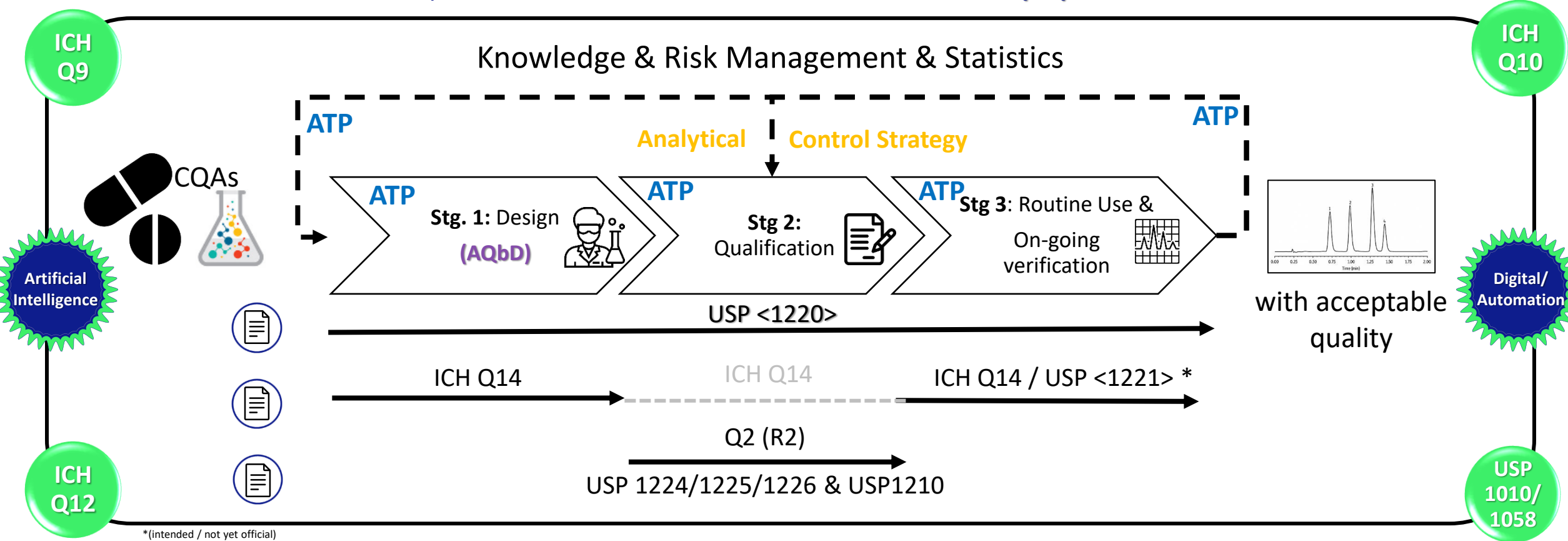
# *What's New, What's Next:* **ICH Q14 and Analytical Transformation**

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Analytical Method must be shown to be **fit for its intended purpose** before use

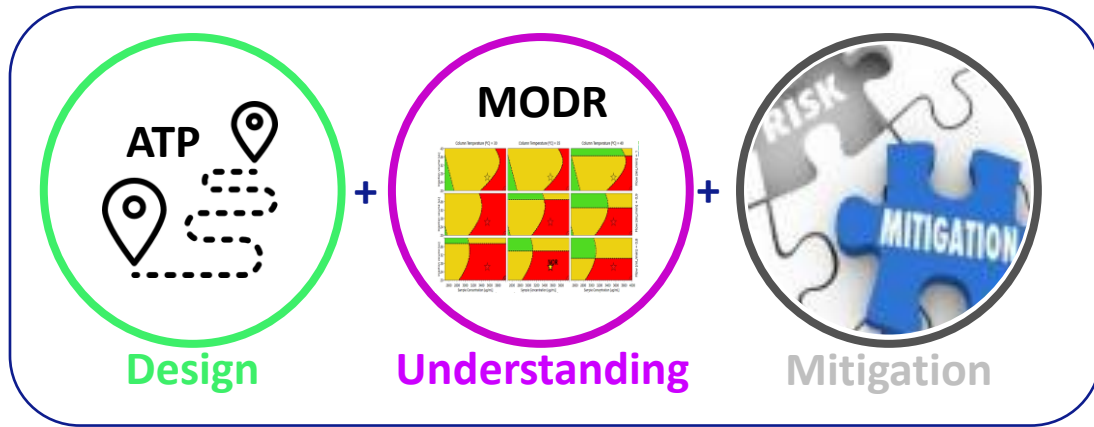


Analytical Method must be shown to be **fit** for **its intended purpose** before use



\*(intended / not yet official)

**Objective:** Set analytical method conditions



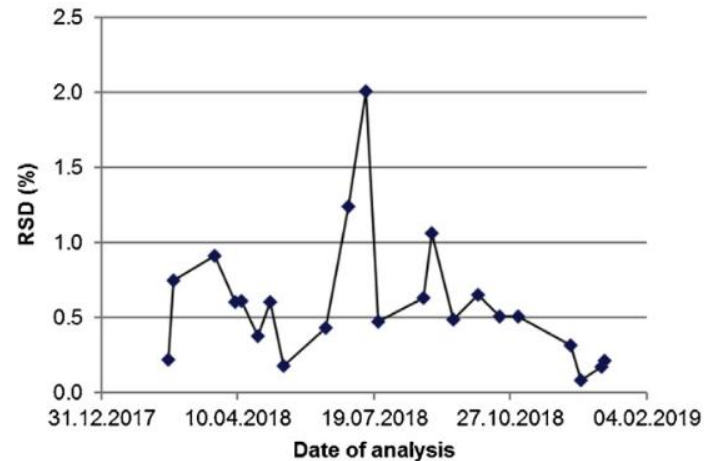
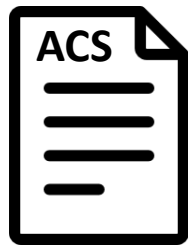
**Analytical Quality by Design (AQbD)**

- ✓ Define the **end in mind (ATP)**
- ✓ Increase **method understanding** > prior knowledge & statistical tools (e.g., DoE)
- ✓ Identify & understand **sources of variability (MODR)**
- ✓ Optimize and select **robust** conditions
- ✓ Establish **Analytical Control Strategy (ACS)**
- ✓ Apply **knowledge & risk** management throughout
- ✓ Ensure method **consistently** meets **ATP**

Automation, Digital & AI: enhance development activities & turn time into knowledge

**Objective:** Ensures that the analytical procedure remains in control during routine use and thus continues to meet the ATP criteria<sup>1</sup> (meeting the acceptance criteria defined in the ACS, for SST).

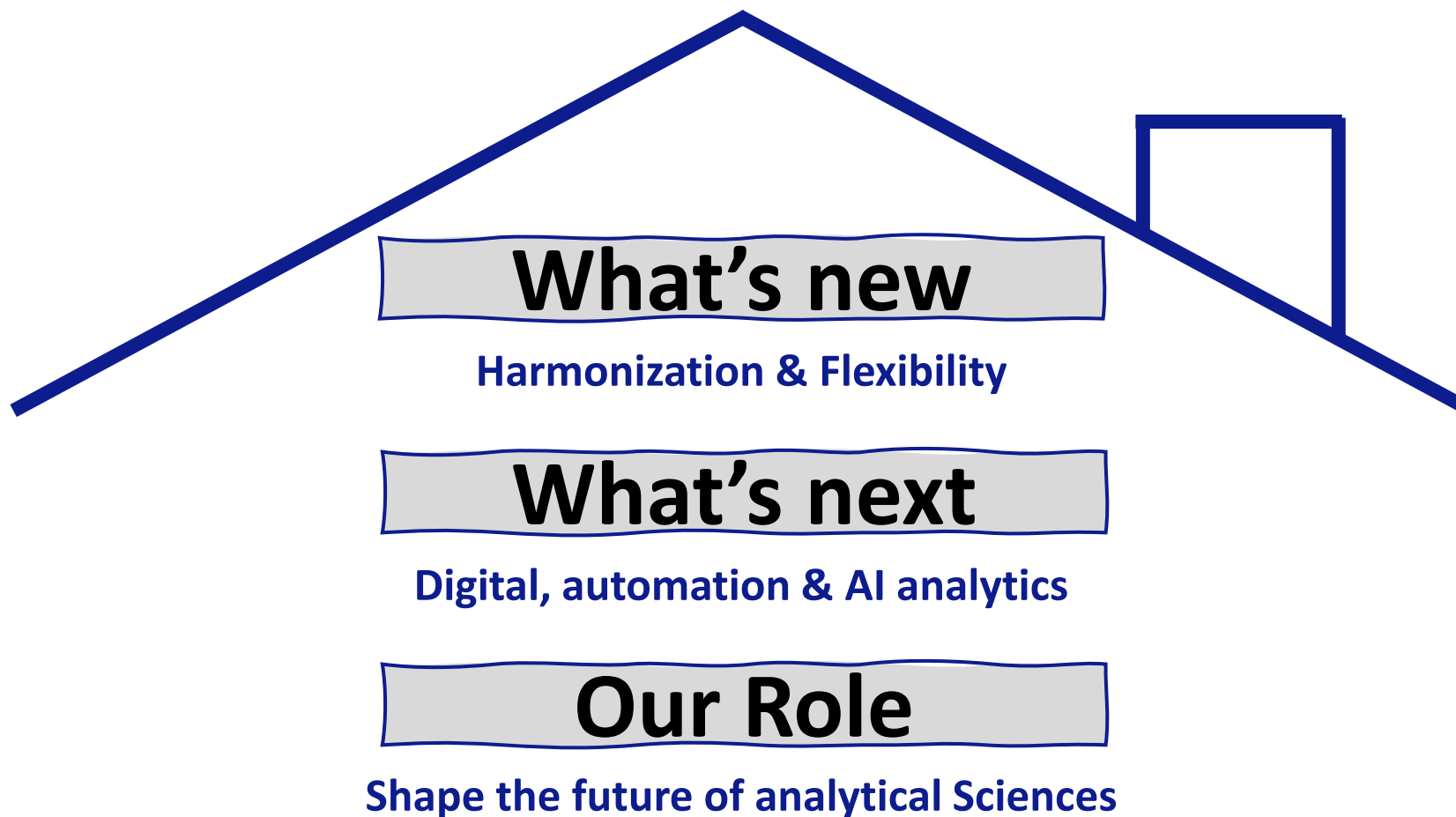
<sup>1</sup>USP <1220> Analytical procedure Life Cycle. USPNF 2022 issue 1



Source: Ermer, J.; Aguiar, D.; Boden, A.; Ding, B.; Obeng, D.; Rose, M.; Vokrot, J. Lifecycle Management in Pharmaceutical Analysis: How to Establish an Efficient and Relevant Continued Performance Monitoring Program. J. Pharm. Biomed. Anal. 2020, 181, 113051. <https://doi.org/10.1016/j.jpba.2019.113051>.

Risk-based program to collect, analyse and evaluate reliable performance data

- ✓ Performance monitoring system
- ✓ CAPA System
- ✓ Change Management System
- ✓ Management review



***THANK YOU***  
***Happy to take questions!***

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