



# European Directorate for the Quality of Medicines & HealthCare

## Council of Europe

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Using the CEP Procedure to elevate quality and drive trust

**23-24 September 2025 | Budapest, Hungary**

# Exploring the use of AI at EDQM

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# Agenda

- ★ Why AI at EDQM?
- ★ Our AI Journey Timeline
- ★ Current Initiatives & Use Cases
- ★ Challenges encountered and expected
- ★ Recommendations
- ★ The Road Ahead





# Why AI at EDQM?

- ★ AI is transforming pharmaceutical regulation globally
- ★ Need to maintain our leadership in the area of quality of medicines and healthcare
- ★ Opportunity to enhance efficiency and decision-making
- ★ Essential to prepare our workforce for the future



# Our AI Journey Timeline

- ★ **2019** First reflections on AI use to explore scientific information
  - ★ *Too early - technology not ready*
- ★ **2024** Structured approach begins
  - ★ Interviews with heads of entities
- ★ **2024-2025** Multiple initiatives underway
  - ★ Building foundation for AI integration

# Current Initiatives-Governance & Strategy

## ★ Internal Coordination and Collaboration

- ★ EDQM AI working group with representation from each entity
- ★ Participating in Council of Europe AI working group

## ★ Strategic Planning

- ★ EDQM roadmap development

## ★ Enterprise Architecture

- ★ Building an AI catalogue



# Current Initiatives-Infrastructure & Training

## ★ Deployment of "secure" AI solution for non-confidential documents

★ *Main aim: Reduce shadow AI and familiarise staff with AI*

★ Current solution in place, but future solution to be decided (**Challenge:** Elaboration of evaluation criteria for universal AI tools)

## ★ AI Literacy Program development in strong collaboration with HR

★ **Fundamentals:** All staff

★ **Advanced:** ~10% of staff

★ **Business-specific:** as needed





# Current Initiatives-Practical Applications

## ★ Support Services

- ★ AI Chatbot (for non-scientific topics)
- ★ Internal AI assistance for non-scientific helpdesk questions

## ★ Document Management

- ★ AI assistance in contract drafting/reviewing

## ★ Content Creation

- ★ Training/communication video generation
- ★ Translation assistance
  - ★ Mixed results on controlled translations



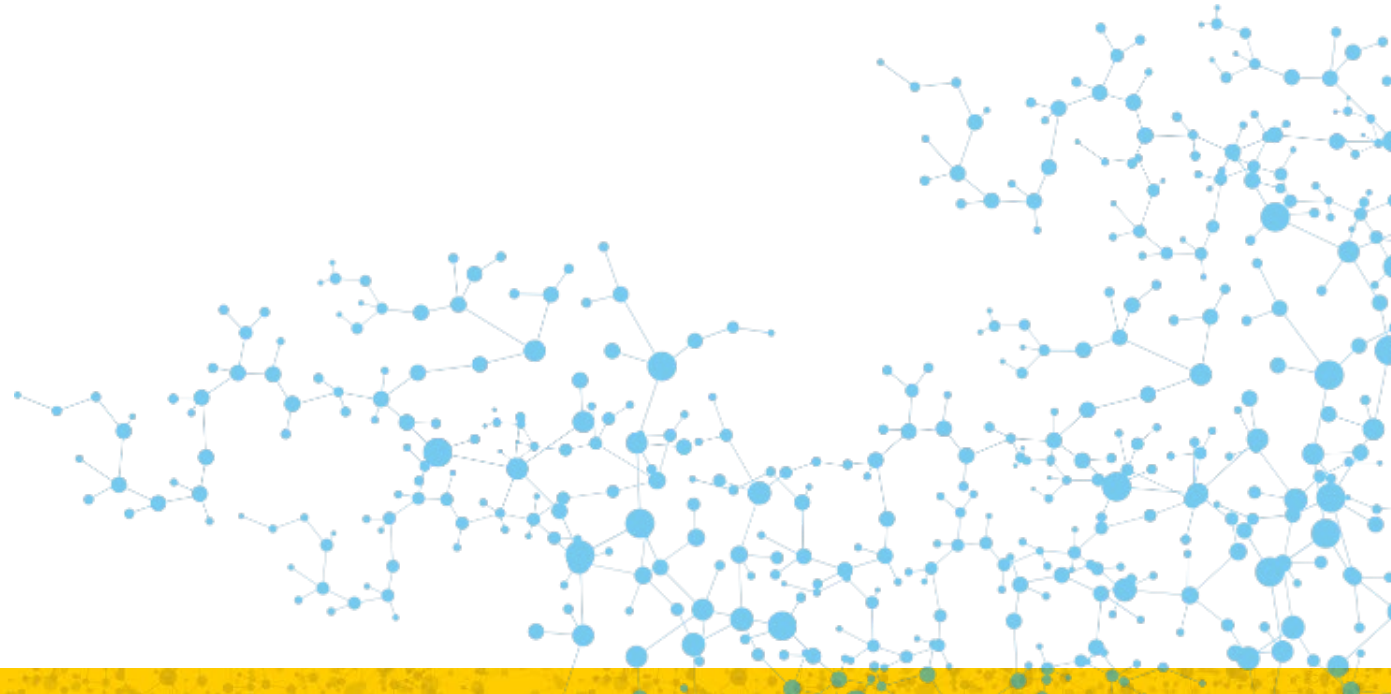
# External Collaboration

## ★ **Regulatory Authorities**

- ★ Working with regulatory authorities to share knowledge and best practices

## ★ **Knowledge Sharing**

- ★ Collaboration with external stakeholders across the pharmaceutical ecosystem



# Challenges encountered (and expected)

- ★ Lack or difficult to prove business value
- ★ Increasing TCO (Total Cost of Ownership)
- ★ GenAI alone isn't sufficient
- ★ Responsible AI must be built-in from beginning
- ★ AI and data literacy gaps
- ★ Lack of AI-specific roles
- ★ Data readiness issues
- ★ GenAI platform robustness
- ★ Poor change management

# Recommendations (for us).....



## ★ Business Value

### ★ Prioritise Strategically

- ★ Focus on (Gen)AI use cases with high business value and technical feasibility

### ★ Measure & Communicate

- ★ Establish clear metrics and communicate value to stakeholders

### ★ Cost Optimisation

- ★ Optimise costs from day one - don't wait until the end of the implementation

## ★ Technology

### ★ Future-Proof Architecture

- ★ Build composable platform architecture to avoid technology obsolescence

### ★ Right Tools for the Job

- ★ Use appropriate AI techniques rather than jumping on latest trends

### ★ Data Foundation

- ★ Emphasize AI-ready data - quality and accessibility are crucial

# ....Recommendations (for us)

## ★ Governance

### ★ Responsible AI First

- ★ Put responsible AI at the heart of all generative efforts
- ★ *"Ethics and responsibility cannot be an afterthought"*

### ★ Change Management

- ★ Include good change management practices from the very beginning

## ★ People

### ★ Invest in Skills

- ★ Data and AI literacy with adapted training programs

### ★ Knowledge & Execution

- ★ Focus both on theoretical knowledge and practical execution

### ★ New Roles

- ★ Create AI-specific roles to operationalise AI and drive continuous value



# The Road Ahead

## ★ Continued Learning

- ★ Iterative approach with continuous improvement

## ★ Enhanced Collaboration

- ★ Deeper partnerships with regulatory bodies and stakeholders

## ★ Scaling Success

- ★ Expand proven use cases across the organisation

## ★ Innovation Leadership

- ★ Maintain EDQM's position at the forefront of the quality of medicines and healthcare

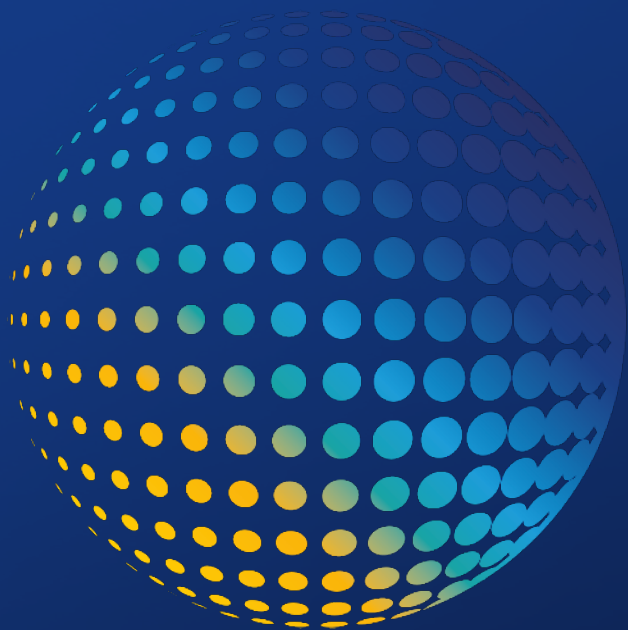
AI implementation is

Not



Is rather





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