

Report on EUROLAB WGD

AI in QMS

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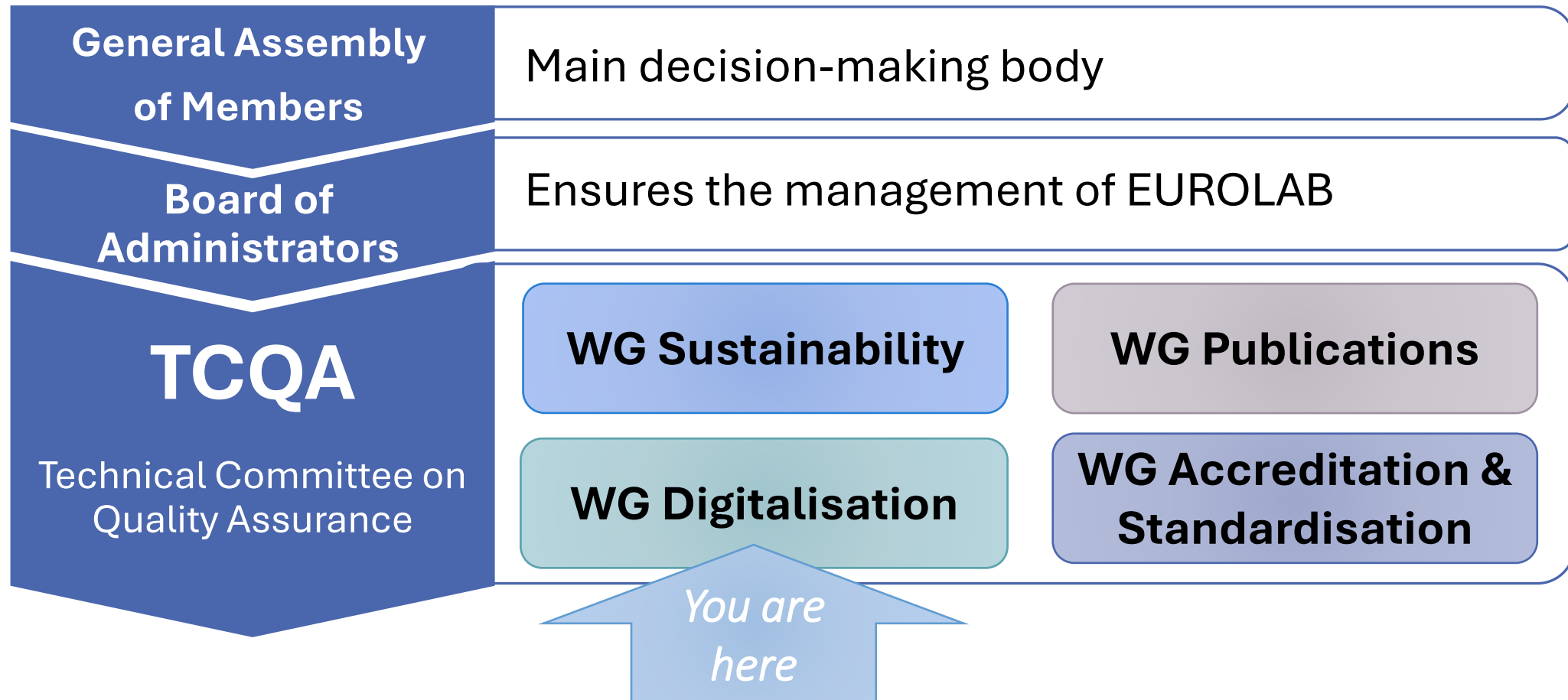
BELAB GENERAL ASSEMBLY– 2025-05-21

Gembloux agro-bio tech, university of liège, Belgium
BELAB



Report on EUROLAB WGD

EUROLAB structure



EUROLAB WGD

MISSION

- Support laboratories in their **digital transformation**

HOW ?

- ✓ Cookbooks, reports and guidelines
 - ✓ Webinars
 - ✓ Projects with other stakeholders
- } **Online training platform**
–
Mutualise efforts

Technical topics

- ⚙ Cloud computing
- ⚙ Laboratory Information Management Systems (LIMS)
- ⚙ Internet of Things (IoT)
- ⚙ Interoperability of data and systems
- ⚙ Robotics
- ⚙ Blockchain
- ⚙ Digital calibration/testing certificates (DCC/DTC)
- ⚙ Artificial Intelligence



Data integrity
Cybersecurity
Compliance

Regulatory context

- **GDPR (2018)**
([Regulation \(EU\) 2016/679](#))
- **NIS 2 on cybersecurity** (entry into force: 2024)
([Directive \(EU\) 2022/2555](#))
- **AI Act on AI development and deployment**
([Regulation \(EU\) 2024/1689](#))
- ...





Survey on « Daily Pains »

1 Complex Data Handling Requirements

2 Lack of Change Management Strategy

3 Lack of Technology Expertise

4 Interoperability Issues

5 Regulatory Compliance & Privacy

6 Information Security Threats

7 Financial Constraints

8 Cultural Resistance to Change

9 Ressource Management

10 Continuous Evolution of Customer Need

The logo for eurolab, with 'eurolab' in a bold, blue, sans-serif font. The 'e' and 'l' are lowercase, while 'uro' and 'ab' are uppercase.

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**GUIDELINES FOR
THE MANAGEMENT OF
DIGITALISED SYSTEMS
IN LABORATORIES
ACCREDITED TO
ISO/IEC 17025**

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-

Cookbooks update

- *Use and handling of spreadsheets*
- *Classification and Handling of Information in a Laboratory*
- *GDPR – General Data Protection Regulation*
- *Position Paper on Artificial Intelligence in Conformity Assessment*

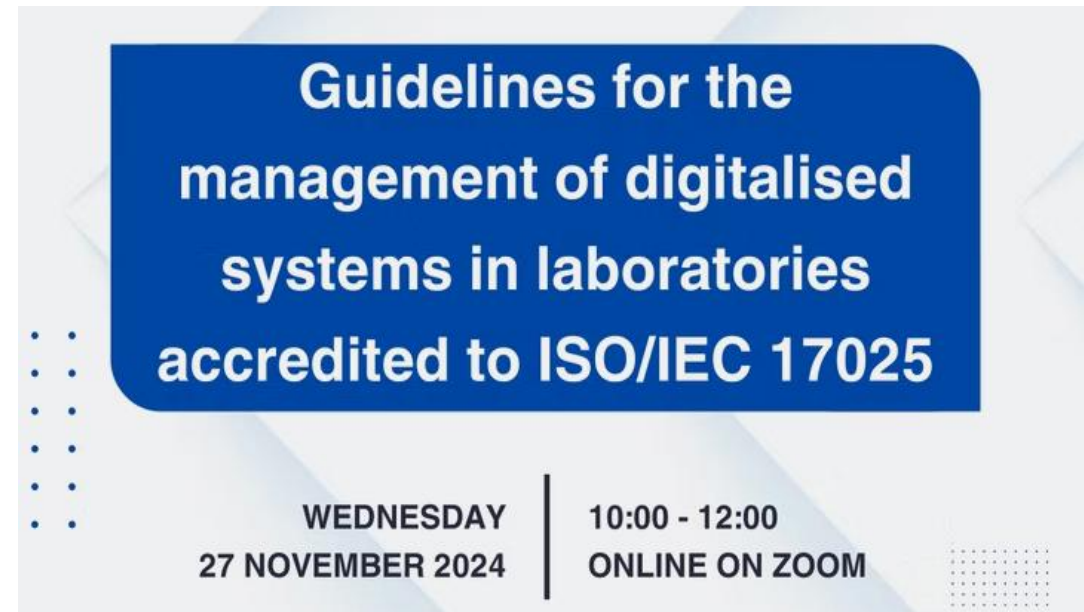
Webinars



**LAB
OF THE
FUTURE**

Sharing best practices and expertise for
implementing innovation in your
laboratory

28 MAY 2024
10:00 - 13:30 CEST



**Guidelines for the
management of digitalised
systems in laboratories
accredited to ISO/IEC 17025**

• •
• •
• •
• •
• •
• •

WEDNESDAY | **10:00 - 12:00**
27 NOVEMBER 2024 | **ONLINE ON ZOOM**

Collaboration with other stakeholders

❖ European Quality Infrastructure Network

❖ AIQI



❖ QI-Digital Forum



❖ EURACHEM



❖ CECIP



❖ PTB



❖ ...



Artificial Intelligence in Quality Management Systems

NEXT REVOLUTION OR EMPTY PROMISES ?

Definition of « Artificial Intelligence »

*Capability of a functional unit to perform functions that are generally **associated with human intelligence such as reasoning and learning.***

ISO/IEC 2382:2015

*Capability of an engineered system to **acquire, process and apply knowledge and skills.***

ISO/IEC 2382:2015

Regulatory context

Definition of « Artificial Intelligence »

AI Act definition of "Artificial intelligence" :

- Machine-based
- Designed to operate with **varying levels of autonomy**
- May exhibit **adaptiveness** after deployment
- Have explicit or implicit objectives
- **Infers**, from the input it receives, how to generate outputs
- Outputs can influence physical or virtual environments;

Definition of « Artificial Intelligence »

ANNEX

to the

Communication to the Commission

**Approval of the content of the draft Communication from the Commission -
Commission Guidelines on the definition of an artificial intelligence system
established by Regulation (EU) 2024/1689 (AI Act)**

- 13 pages discussing the definition of AI in the AI act
- **Yet, unambiguous identification of AI as such is still not so easy**

Regulatory context

AI Act (Regulation (EU) 2024/1689)

- Unacceptable risk (prohibited)
- High risk
- General purpose
- Limited risk
- Minimal risk (Research)

AI Act

High risk – Examples

- Medical diagnostics or decision support (Art. 6, Annex II)
- QC in pharmaceutical sector

AI Act

High risk – Derogations

- *"the AI system is intended to perform a **narrow procedural task**;"*
- *"the AI system is intended to **improve the result of a previously completed human activity**;"*
- *"the AI system is intended to detect decision-making patterns or deviations from prior decision-making patterns and is **not meant to replace or influence the previously completed human assessment, without proper human review**; or"*
- *"the AI system is intended to perform a **preparatory task** to an assessment relevant for the purposes of the use cases listed in Annex III."*

AI Act

High risk – Requirements

- ✓ Risk management system should manage AI-related risk
- ✓ High-quality training/validation datasets
- ✓ Technical documentation
- ✓ Automatic recording of events (logs)
- ✓ Instructions for use
- ✓ Transparency
- ✓ Available human oversight
- ✓ Accuracy, robustness and cybersecurity through whole lifecycle
- ✓ Conformity assessment and CE marking
- ✓ Registration in EU database

AI Act

High risk – Responsibility of deployers

- ✓ Ensure instructions of use are followed
- ✓ Assign competent and capable human oversight
- ✓ Representative data
- ✓ Suspend use and notify provider and authority in case of risk or incident
- ✓ Keep logs
- ✓ Inform involved personnel
- ✓ Data protection impact assessment
- ✓ Inform the patients
- ✓ Cooperate with competent authorities

General purpose AI

*AI model that is capable of performing a wide range of **distinct tasks**, irrespective of the way the model is placed on the market or put into service."*



Standards

ISO/IEC Standards

- ❖ ISO/IEC 22989:2022
- ❖ ISO/IEC 42001:2023
- ❖ ISO/IEC 23894:2023

ISO/IEC 22989:2022

- Concepts and terminology related to AI
- Available free of charge

ISO/IEC 42001:2023

- « *Artificial Intelligence Management System* »
- Governance, management, and continuous improvement for the **development and use** of AI systems.
- Analog to ISO/IEC 9001, ISO /IEC 17025...

ISO/IEC 42001:2023

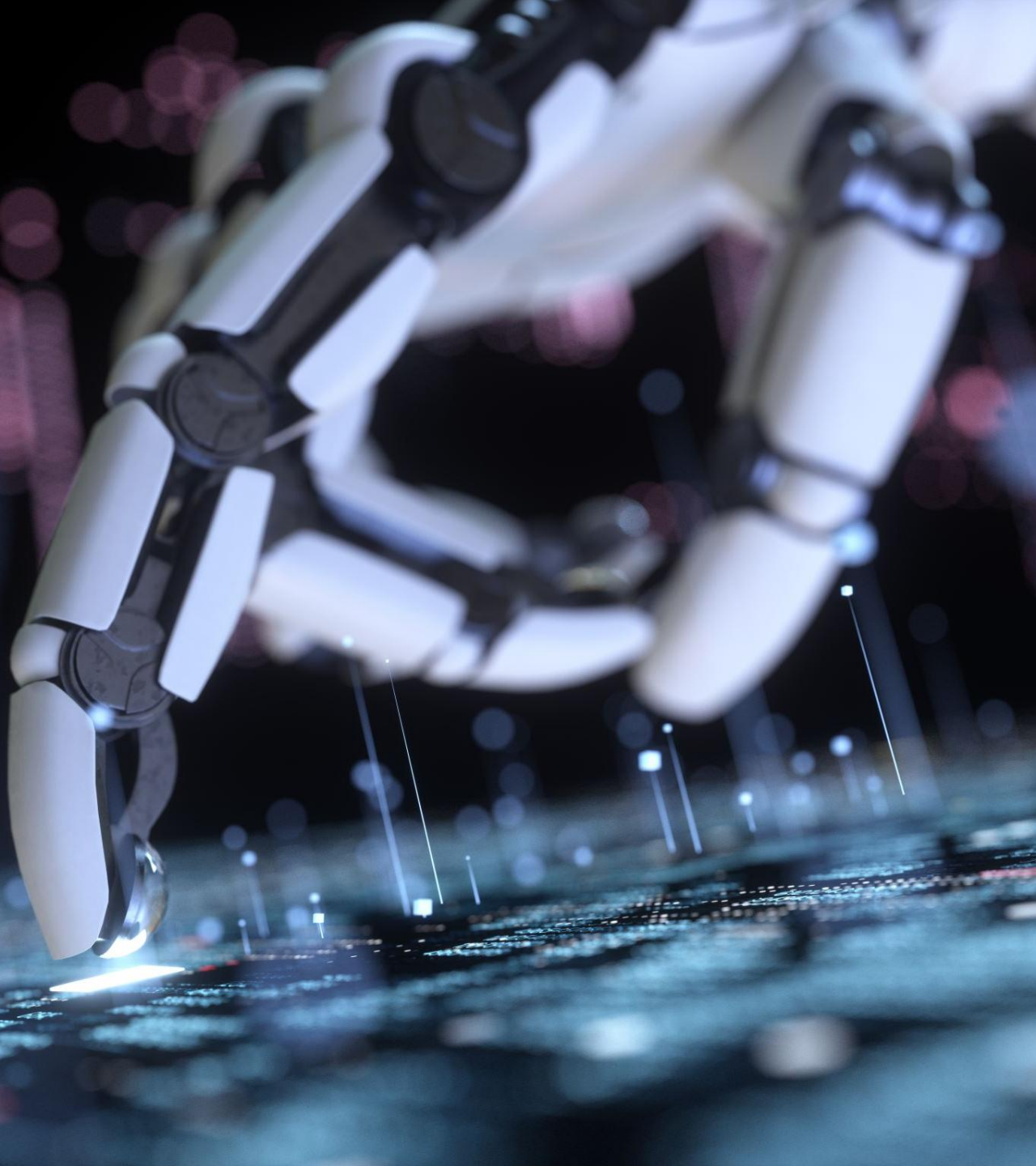
- Certifiable
- Free course on ISO/IEC 42001



<https://www.aiqi.org/42001-course>

ISO/IEC 23894:2023

- Guidelines for risk management related to AI
- Analog to ISO/IEC 31000
- Non-certifiable



AI to support QMS

A QUICK TOUR

Risk management

Large language models (LLM) can :

- ✓ Assist risk assessment by
 - Suggesting risks to consider
 - Evaluate risk (likelihood x criticality)
- ✓ Suggest preventive & corrective actions

Client service

Large language models (LLM) can :

- ✓ Answer questions from clients

Document management

Large language models (LLM) can :

- ✓ Summarise documents (regulation...)
- ✓ Translate documents
- ✓ Classify documents automatically
- ✓ Answer specific questions related to SOPs
- ✓ Find documents based on a description

Document management


Optical character recognition (OCR) can :

- ✓ Make digitized documents “searchable”
- ✓ Make digitized documents available for NLP

Cybersecurity

- ✓ Spam/phishing emails detection
- ✓ Intrusion Detection System (IDS)
- ✓ Malware detection
- ✓ User and Entity Behavior Analytics

Other QMS activities

- Inventory management
- Personnel management  **High risk**
- Quality control / Defect prevention

Unclear methods

Not AI (in the sense of the AI Act)

- Automatisation (automatic backups...)
- Rule-based systems

Manufacturer often do not disclose sufficient information to be able to distinguish "real" AI and "abusive marketing"



AI management

AI-related risks

- **Mismatch** between **training** and **real** data
- **Cyberattacks** (see NIST AI 100-2e2023)
 - **Poisoning** (training with wrong data)
 - **Injection attacks** (passing unauthorised instructions to AI)
 - **Model inversion** (access to training data)
 - ...
- **Service discontinuation**
- **ISO/IEC 23894:2023**

Management of AI-related risks

- AI Act
- ISO/IEC 42001:2023
- EUROLAB Cookbook (to be reviewed)

Still too early for laboratories...



THANK YOU!

