

18th EBF Open Symposium

**Tune in to Tomorrow
Science in High Definition**

Implementation of Cloud-Based Applications in Regulated Bioanalysis Labs – EBF recommendations

Cecilia Arfvidsson, on behalf of the EBF

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The cloud definition

- “The Cloud” - a **digital infrastructure** in which computing resources and analytics, are **delivered over the internet** rather than being hosted on local devices or on-premises data centers.
- Instead of managing and maintaining physical hardware, **organizations use shared, remote resources** provided by third-party cloud service providers.



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Cloud implementation - Identified need

- **Increased dialogue** within the regulated bioanalysis community on the implementation of cloud-based applications
- **Provide further confidence** in the use of cloud-based applications in a regulated bioanalysis environment

MEETING REPORT Check for updates

Moving Into the cloud: a summary from a European Bioanalysis forum workshop on introducing cloud applications in bioanalytical laboratories

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ABSTRACT
In this manuscript, we summarize the discussions and key messages from developed in the e-environment team of the European Bioanalysis forum, which were the basis of a subsequent workshop on cloud applications in a regulated bioanalysis lab environment, hosted by the European Bioanalysis Forum e-environment team at their 16th Open Symposium in Barcelona, Spain in November 2023. The purpose of our discussions is to provide further insight and understanding on the status of having cloud applications implemented in a regulated bioanalysis laboratory and the challenges experienced. The discussions highlight the importance of cross functional collaboration during the entire process of cloud implementation and some of the uncertainties in the different functions roles and responsibilities.

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1. Introduction

The use of third-party cloud services has become widespread for a variety of functions in the last few years [1]. Despite a more universal use of cloud services the implementation of an end-to-end cloud service solution in regulated bioanalysis laboratories on the implementation of cloud-based applications in regulated bioanalytical laboratories. The workshop also aimed to provide further confidence in the use of cloud-based applications by increasing the insights and understanding within the community on where cloud-based applications may already be applied. In preparation for the workshop, a survey was sent out to all EBF members to

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EBF e-environment team 2024/2025



- **Cross-functional team** (BioA, IT & QA) - an **effective 'forum'** for sharing of learnings and experiences as the regulatory bioanalysis labs continue their move into the cloud.
- **Build confidence** in the transition into the cloud and **reduce uncertainties** as precedence in cloud implementation is being established.
- **Recommendation paper** – summarising our key discussion points and learnings **from a BioA perspective**
- Sharing our joint best practices and experiences to **avoid setting the bar too high**

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Key Barriers to Cloud Implementation

➤ **Regulatory Complexity**

- Strict GxP regulations create hesitation due to unclear cloud compliance requirements.

➤ **Data Integrity Concerns**

- Strict oversight is needed, but cloud environments raise risks of unauthorized access and data control issues.

➤ **Vendor Qualification Challenges**

- Cloud providers often lack bioanalysis compliance, complicating audits and evidence collection.

➤ **Resistance to Change**

- Legacy mindsets hinder cloud adoption due to comfort with direct system control.

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OECD Advisory Document on GLP & Cloud Computing

*“[...] the potential impact on GLP compliance should be considered when using cloud solutions. **GLP test facilities have the ultimate responsibility for GLP compliance to assess risks to data integrity, data quality, data availability, data retention and data archiving.**”*

*“When conducting an inspection with cloud-based services involved in the test facility processes, **GLP inspectors expect TFM to be able to demonstrate that GLP compliance is still ensured with the implemented cloud service and that TFM has adequate means to control it.**”*

*“GLP systems should be validated and operated in a way which ensures the outcome and integrity of GLP data **regardless of whether they are installed locally or provided as a cloud service.**”*



Organisation for Economic Co-operation and Development

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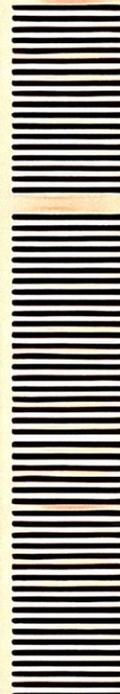
29 June 2023

ENVIRONMENT DIRECTORATE
CHEMICALS AND BIOTECHNOLOGY COMMITTEE

OECD SERIES ON PRINCIPLES OF GOOD LABORATORY PRACTICE AND COMPLIANCE
MONITORING

Advisory Document on GLP & Cloud Computing
Supplement 1 to Document Number 17 on Application of GLP Principles to Computerised
Systems

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The EBF recommendation paper



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What service model is needed?

- Depends on the functions and support that are required
- The company's IT infrastructure and resources, data security requirements, and budget.



IaaS – Infrastructure as a service



PaaS – Platform as a service



SaaS – Software as a service



Shared Responsibility Model

- Test Facility Management's overall responsibility for the data is multi-layered
 - TFM do not need to know and execute everything related to cloud-based services.

- Identify who is responsible for specific tasks, internally (BioA, IT, QM) as well as externally
- Document these responsibilities clearly

	On-prem	IaaS	PaaS	SaaS			
Content							
Access policies						Customer	
Usage							
Deployment						Could Provider	
Web App security							
Access and authentication							
Operations							
Network Security							
Guest OS, data and content							
Audit logging							
Network							
Storage and encryption							
Hardened Kernel and IPC							
Boot							
Hardware							
Physical security							



Vendor selection and Third-Party Risk Management

- TFM must know and ensure that **all parties involved are fulfilling their responsibilities** and that the data management processes are functioning seamlessly
 - **ISO/IEC 27002:2022, Control 5.23** ("Information Security for Use of Cloud Services") directs organizations to ensure that information security risks associated with cloud services are identified, assessed, and appropriately managed.
 - The **organizational obligations** outlined in control 5.23 highlight the importance of a **cross functional collaboration**

EBF recommendation paper provides a recommendation for the internal roles and responsibilities



Cloud Service Agreement

- Sets out **how the service will be managed** throughout its **lifecycle**, from initiation through updates, incidents, audits and exit
- Typically owned by IT (with Procurement & Legal) but its effectiveness depends on a cross-functional effort that brings together:
 - technical expertise (architecture, security, integrations)
 - operational insight (lab workflows)
 - regulatory knowledge (GLP/Annex 11/Part 11)
 - legal skills (data ownership, liability, risk allocation)
 - data security capability (e.g., GDPR and breach controls).

EBF recommendation paper advises on early BioA involvement and TFM consultation on all GxP-relevant content to ensure fitness for regulated bioanalysis.



Data Lifecycle and Cross-Functional Roles

➤ Comprehensive Data Lifecycle

- Data lifecycle includes creation, use, sharing, storage, and archiving in both cloud and on-premises systems.

➤ Accountability vs Responsibility

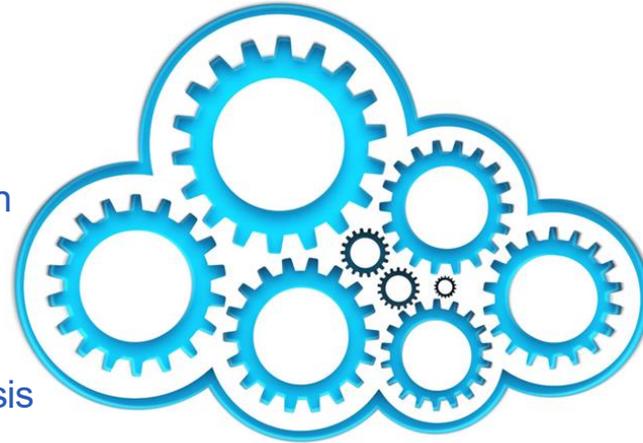
- Bioanalytical labs are accountable for data integrity while IT and QA handle implementation responsibilities.

➤ Regulatory and Standards Guidance

- OECD GLP advisory and ISO/IEC 27002:2022 provide regulatory principles for cloud bioanalysis environments.

➤ Cross-Functional Collaboration

- Clear documentation and collaboration of roles ensure compliance and effective data management processes.



The Bioanalytical Scientists role

- Subject matter experts (SMEs) such as **bioanalytical scientists** are crucial throughout the stages of **evaluating and implementing a cloud-based application**
 - **Facilitate the adoption** of cloud services in a regulated bioanalysis lab
 - Ensure the solution fits **scientific workflows, regulatory needs, data integrity standards, and organizational objectives**
 - Remove anxiety and concerns



The Bioanalytical Scientists role

Requirements definition – provide critical input on the application's functional and data requirements. The bioanalytical scientists' feedback ensures scientific accuracy and relevance.

Data Integrity & Compliance – help define and validate data integrity and security requirements, ensuring application workflows support regulatory compliance (GxP, FDA, EMA, etc.), accurate audit trails, and appropriate data validation rules.

Evaluation of cloud solutions – assess potential cloud solutions for technical suitability and functionality and guide the selection toward a solution with tools that genuinely enhance productivity without forcing awkward workarounds.

Implementation and Workflow Design - map laboratory workflows into the cloud application, test scientific features, validate integration and confirm the application's accuracy in processing, analyzing, and reporting bioanalytical data.

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The Bioanalytical Scientists role

User Acceptance Testing – participate in pilot testing, method validation, and cross-checking results to confirm scientific data quality, usability, and robustness. Feedback is vital for identifying gaps, errors, or usability issues before full rollout.

Continuous Improvement and Post-Deployment Support - ensures that feedback from daily cloud application use is collected, that future updates enhance scientific functionality, and that issues are addressed as the application scales or evolves.

Training and Change Management – involved in developing training materials, delivering education to peers, and acting as champions for adoption - aids user engagement and reduces resistance to change.

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Enabling successful cloud implementation through collaboration

➤ **Cross-functional Collaborative Roles**

- Bioanalytical scientists to collaborate throughout the process with IT and QA to ensure data integrity, compliance and usability

➤ **Regulatory Compliance**

- Clear roles with relevant GxP knowledge to support regulatory standards and maintain data quality in cloud adoption.

➤ **Innovation and Confidence**

- Cloud systems enhance data quality, support innovation and productivity, and build confidence in bioanalysis.

➤ **Structured Framework for Bioanalysis**

- EBF recommendation paper provides guidance for the bioanalytical community on smooth transition into the cloud without raising the bar.

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- EBF core community
- EBF e-environment team





More information on the EBF: www.e-b-f.eu

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