BioPhorum

AR-VR

Risk considerations for the implementation of extended reality solutions within a GxP environment in the biopharma industry

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About BioPhorum

BioPhorum's mission is to create environments where the global biopharmaceutical and device industry can collaborate and accelerate its rate of progress, for the benefit of all.

Since its inception in 2004, BioPhorum has become the open and trusted environment where senior leaders of the biopharmaceutical industry come together to openly share and discuss the emerging trends and challenges facing their industry.

Growing from an end-user group in 2008, BioPhorum's membership now comprises top leaders and subject matter experts from global biopharmaceutical manufacturers and suppliers, working in both long-established and new Phorums. They articulate the industry's technology roadmap, define the supply partner practices of the future, and develop and adopt best practices in drug substance, fill finish, process development and manufacturing IT.

In each of these Phorums, BioPhorum facilitators bring leaders together to create future visions, mobilize teams of experts on the opportunities, create partnerships that enable change and provide the quickest route to implementation, so that the industry shares, learns and builds the best solutions together.

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1.0

Introduction

Extended reality (XR) is a term used to encompass different types of immersive technologies that integrate both digital and physical environments. It includes augmented reality (AR), virtual reality (VR) and mixed reality (MR).

AR solutions add new digital elements to the user's vision, letting them see the 'real' world in front of them but with additions to the line of sight. AR devices range from smartphones and tablets to specialized glasses and headsets.

VR solutions, on the other hand, are a fully immersive experience, completely taking over the user's vision to give them the impression of being somewhere else. Users wear a VR headset that displays a 3D computer-generated environment, providing audio, visual and sometimes haptic feedback.

MR blends digital and real-world elements so they appear as if in the same space. MR devices are typically transparent, usually appearing as see-through glasses.

The use of XR solutions is often linked to home entertainment and the gaming industry, however, XR solutions are becoming more common in the workplace in a range of industries including healthcare and biopharma.

This paper will focus on the AR and VR technologies, and their implementation for use within GxP environments.

When implementing this technology for use in GxP environments, careful consideration needs to be given to the risks associated with deployment. This paper gives risk considerations in different categories based on the appetite of the organization for risk, local country laws, company policies and IT hardware/software standards. This paper includes risk/impact statements to provide context for the risks being considered. The risk considerations are not intended to replace traditional risk assessment but rather to support that process.

While AR/VR implementations are often seen as IT projects, business and technology risks are also considered here because collaboration with the business teams that the processes will impact is essential.

With regard to data storage in an AR/VR application, in many cases data will be stored outside of the device being used. However, there may be occasions when data are temporarily stored on the device until they can be moved, or it may be a configuration choice to store data on the device itself. In either scenario, data management should be aligned with company policy and identical to any regulatory-compliant system.

The purpose of this paper is to aid deployment of AR/VR technology in the biopharma environment. It gives areas of risk for IT professionals and users of these technologies at biopharma organizations to consider when developing the technology internally or implementing an off-the-shelf product.

"AR/VR technologies can have an evolutionary impact on both time and cost of training, manufacturing, quality, engineers, and sales and marketing in biopharmaceuticals. To capture the value of these recent technologies, the industry needs to understand them and their associated risks. This paper brings together the pioneering AR/VR experiences of leading biotech companies and will help guide further investment decisions for AR/VR in our regulated industry."
Jonathan MacDonnell,
Director Digital Transformation – Group Operations, Lonza

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Risk considerations

2.1 Regulatory risk

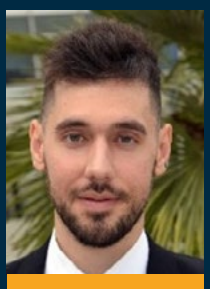
Risk/Impact statement

IF data can be accessed, changed or stored in a non-compliant manner, THEN data will not be compliant with 21 CFR Part 11 in respect of audit trails.

IF data can be accessed, changed or stored in a non-compliant manner, THEN data will not be attributable, legible, contemporaneous, original and accurate.

Questions to consider:

- What is and what is not considered GxP data in the system?
- What is the system used for?
- Is supporting data to be used alongside other systems or is the system the only source of data?
- How will data integrity be maintained for GxP records?
- With reference to the Attributable, Legible, Contemporaneous, Original and Accurate (ALCOA+) principles, how do you define data integrity elements in a 'virtual world', e.g. capturing an image as an audit trail and a record of a completed task in a process?
- What is your approach to the General Data Protection Regulation (GDPR) when using biometrics, e.g. retinal scans to identify device users?
- Where is the data being stored?
- Is the data on or off-site?
- If required, how will you blur images in the area the device is being used? Consider protecting any aspects that could impact privacy, e.g. workers' faces, product-related information. Will this protection take place in real time or post processing?
- If the solution is cloud-based, is the geographical location known?
- Who has control and access to this information?
- What are the encryption and security arrangements for business data?
- What are the arrangements for critical and sensitive information, and patient and personal information flow, e.g. duration and purpose, impact of data breach?
- What is required for the user access management process?
- How will the AR/VR devices be managed to ensure data security and integrity?
- Is an internal review required before the distribution of any captured media?



"Augmented reality has the potential to transform the pharma industry and add tremendous value to the shop floor, but we need to make sure we are set up for success by taking into consideration all the risks that come with emerging technologies."
Georgios Chantziaras,
Senior Associate Smart Factory Technology – Pfizer

2.2 Business risk

Risk/Impact statement

IF the vendor maturity and capability to implement GxP-compliant solutions is untested, THEN the processes are at risk of non-compliance.

Questions to consider:

- What is the financial stability of the vendor?
- Is the vendor's product roadmap aligned to biopharma objectives?
- Is there a business risk in rapidly evolving AR/VR solutions?
- How many deployments are currently in operation in a biopharma environment?
- What is the impact on the business process if the solution is not available?
- Is there a business continuity plan in place?
- Can the vendor provide a robust support service covering relevant geographies in case of failure meeting the expected service level agreements?
- What arrangements are in place to protect biopharma company Intellectual Property (IP), e.g. a video of the shop floor showing information about a company IP process?
- What consideration has been given to data ownership if the solution is provided by a third party?
- Does the solution carry 'early adopter' or 'sole supplier' risk in biopharmaceuticals? If so, how is that being mitigated?
- Does the vendor distribute hardware to all countries?
- What is the warranty and availability of support?
- What would happen if the hardware were discontinued or if the vendor moves away from the domain in general?
- Does the vendor distribute directly or via a distributor channel (or both)?
- Are the right business subject matter experts (SMEs) in place and available for rollout and implementation planning?
- What is the lifecycle status of the current hardware? If close to end of life, consider the expense of new hardware.

"Organizations commonly want to incorporate AR/VR into every aspect of their operations from the start, which presents issues for change management. Start with a specific use case, learn from it and make any necessary adjustments, then scale it up."
Adam Cormack,
Director of Product Management – Apprentice IO

2.3 Technology risk

Risk/Impact statement

IF the technology solution does not work reliably and in a timely manner THEN it cannot replace existing manual processes.

- How will you ensure that the technology solution performs consistently? (Consider where devices will be positioned and on what surface, e.g. the shine impact of stainless steel)
- Does the lifetime of the device battery cover a whole shift and if not are replacements readily available and easy to swap out?
- How important is real-time reliability of the device? This will depend on the use case and may be more important in AR than VR devices.
- Can the solution work offline, and re-sync information back to the online system when a connection is restored?
- Does the solution integrate into other applications (e.g. a learning management system), ideally using an open standard?
- Can the release/configuration lifecycle management processes be validated?
- If a vendor is providing software as a service, can updates be reviewed and tested before release?
- What demands is the AR/VR solution placing on the local infrastructure?
- Can the demands for central processing unit (CPU)/ bandwidth be reduced?
- What kind of internal support (local, central) is needed? Will there be internal SMEs available to troubleshoot issues or is there reliance on the vendor?
- Is there sufficient network coverage in the area in which the technology is going to be used?
- Has the solution been evaluated by internal security?
- Are any firewall and security changes required?
- Has security certificate deployment been considered?
- If using a wireless network, has this been assessed, e.g. a manufacturing/laboratory network may have more restrictions than a guest network?
- Is the provided hardware locked to the vendor software?
- Can the hardware be used for multiple solutions?

"As part of a complex and highly regulated industry, the biopharmaceutical process development and manufacturing require adaptative capabilities to accelerate the delivery of life-changing therapeutics. Customers are looking for flexible solutions helping them to continuously develop people skills, reduce errors, accelerate time-to-market, and enhance both data monitoring and real-time global collaboration. As the industry evolves toward more intensified and integrated processes, AR and VR technologies are expected to play an ever-increasing role in boosting efficiency and maintaining a high quality in production processes."
René Reinbigler,
Head of Digital Innovation – Merck

2.4 Safety, health and environment risks

Risk/Impact statement

IF the device is not comfortable to wear and fails to meet minimum safety, health and environment standards, THEN there are risks of personal injury and discomfort for operators and task completion is much less efficient.

Questions to consider:

- What ergonomic risks need to be assessed and mitigated? (e.g. user comfort when wearing a device for extended periods, repeated use of device controls by hand, wearing additional PPE, consideration for users that may already wear glasses—either prescription or safety glasses)
- What medical/health risks need to be assessed and mitigated? (e.g. headaches, motion sickness, eye strain, cleanliness if same device worn by many operators)
- Is the solution safe to wear in a complex environment?
- What additional measures are needed to keep operators safe? (e.g. trainers present, control operators in an enclosed space, geolocators)
- What is the protocol for sterilizing the hardware before and after usage?
- What cleaning solutions are acceptable for use on devices, e.g. isopropanol alcohol (IPA) sprays and wipes/sporicidal agents, etc.
- Are devices being shared?
- What is the level of noise pollution in the operation area? Will audio be picked up clearly? Consider the capability of the software and whether any accessories, e.g. headphones, are needed.
- Does the hardware specification align to that required in the biopharma use environment, e.g. ingress protection ratings?
- What contamination risks need to be addressed?

"AR/XR solutions in manufacturing, labs or maintenance will be an integral part of the digitalization journey of many, if not all, companies in the near future. We are pleased to contribute to this paper by shedding light on the opportunities, as well as the challenges some of our clients face in terms of managing change throughout the digital transformation journey in a GxP setting."
Robert Hoffmeister,
Chief Technology Officer – Goodly Innovations

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Conclusion

This paper has provided, for the relevant risk categories, useful questions to ask when implementing AR/VR solutions in a GxP environment. This list does not cover every risk in each scenario but helps define the types of risk that need to be considered.

The risk/impact statements have been offered to highlight the consequences if risks are ignored and not mitigated.

This paper is designed to help avoid pitfalls and set up for success in AR/VR deployments in the biopharma industry.

If you have any real-life experiences to share please feel free to reach out to Steve.Zartarian@biophorum.com

"We are confident that augmented reality, combined with our vision of connected worker, will become a game changer for our manufacturing colleagues, enabling them to be more focused on task execution via one streamlined view, but careful consideration needs to be given to introducing this technology into a highly regulated environment. We hope this paper helps you navigate these hurdles."
Ronan Kelly, Global Director, Smart Factory Technology – Pfizer

Acronyms

Term	Definition
ALCOA+	A set of principles (Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, Available) ensuring data integrity in the life sciences sector
AR	Augmented reality
GDPR	General Data Protection Regulation
GxP	'Good practice' guidelines and regulations that cover a range of disciplines including Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP) and so on
IPA	Isopropyl alcohol disinfectant
MR	Mixed reality
SME	Subject matter expert
VR	Virtual reality
XR	Extended reality

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