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ALTERNATIVE AND RAPID MICRO METHODS

From process monitoring to real-time release: OWBA implementation in pharma

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1.0

Introduction

Online water bioburden analyzers (OWBAs) are emerging as a transformative technology in pharmaceutical water system monitoring. Designed to provide near-real-time detection and quantification of microbial bioburden, OWBAs utilize advanced techniques such as laser-induced autofluorescence, flow cytometry, impedance, enzyme activity and adenosine ariphosphate (ATP) bioluminescence. These technologies offer enhanced sensitivity and faster response times compared to traditional culture-based methods, which typically require several days to yield results.

OWBAs are particularly relevant for monitoring purified water (PW) and water for injection (WFI) systems, where microbial control is critical. However, implementing OWBA for release testing presents several challenges. OWBA systems operate on fundamentally different detection principles compared to traditional methods. Consequently, direct comparisons with colony-forming unit (CFU) counts are not feasible. This lack of equivalence contributes to a broader industry challenge in interpreting and applying OWBA data effectively.

Pharmacopeial standards are currently based on CFU-based limits. According to Annex 1[1], introducing alternative microbiological methods requires rigorous validation to demonstrate equivalency of the alternative method. The documentation burden and cost of qualification for good manufacturing practice (GMP) use are substantial, making it difficult to justify business cases for OWBA implementation. Despite efforts by industry groups to promote OWBA as a real-time release testing (RTRT) tool, regulatory endorsement for release strategies based on OWBA data has yet to be achieved.

However, by enabling continuous monitoring, OWBAs support proactive contamination control, improved process understanding and opportunities for operational optimization. This aligns with the industry shift toward faster, more sustainable, cost-effective and risk-based approaches to pharmaceutical manufacturing.

This paper presents a structured, experience-based 10-step roadmap for the implementation of OWBAs as process monitoring tools. It is intended to provide practical guidance, highlight key considerations and share insights from early adopters to support informed decision-making.

Disclaimers:

The application of any implementation strategy must be tailored to the specific context and infrastructure of each manufacturing site. The roadmap provided in this document should be assessed for suitability considering the end-user's own operational and quality requirements.

This roadmap reflects current understanding and technologies at the time of writing. As scientific knowledge, industry practices and regulatory expectations continue to evolve, it is the responsibility of the end-user to remain informed of new developments and to adapt their implementation strategies accordingly.

2.0

Benefits of implementing OWBAs for process monitoring

The pharmaceutical industry is undergoing a paradigm shift in how water systems are monitored, driven by the need for faster, more efficient and sustainable practices.

With the traditional offline culture-based methods, measurements are reported with a lag time due to processing, transportation and analysis of samples, which contributes to a delayed response regarding the status of the system.

OWBAs offer a compelling alternative to these traditional methods, enabling near-real-time microbial detection. This capability supports a proactive, data-driven approach to contamination control. Implementing OWBA for process monitoring allows manufacturers to monitor water systems continuously, respond swiftly to deviations, de-risking water release and optimizing operations without waiting for retrospective lab results (Figure 1).

2.1 Immediate detection and proactive response

OWBAs provide continuous, near-real-time monitoring of water systems, allowing for:

- **Rapid detection of contamination**, enabling immediate action before issues escalate
- **Proactive management**, where operators can respond to trends and anomalies as they arise, rather than waiting for delayed culture-based results
- **Flexibility in action limits**, tailored to the specific OWBA technology implemented, supporting more nuanced control strategies.

This capability significantly reduces the risk of contamination spreading and supports a more agile operational environment.

2.2 Enhanced process control and risk-based decision-making

OWBAs contribute to deeper process understanding by:

- Collecting additional **data** on water systems, offering a better understanding of water system performance
- Enabling **data-driven decision-making**, which improves reliability and robustness of water system operations
- Supporting **risk-based approaches** to maintenance and control, aligning with modern contamination control strategies (CCSs).

This shift from reactive to predictive control enhances overall process control.

2.3 Cost and resource efficiency

OWBA implementation can lead to substantial operational savings through:

- **Optimized sanitization cycles**, facilitating flexibility for systems to be sanitized based on actual microbial activity rather than fixed schedules that are not data driven (refer to Section 7 for a real-world example of how OWBA data can inform sanitization schedules)
- **Reduced sampling frequency**, particularly in low-risk ports/areas, which eventually decreases labor and material costs associated with sampling
- **Streamlined documentation and monitoring**, reducing the burden on quality teams.

These efficiencies contribute to leaner operations without compromising compliance or safety.

2.4 Sustainability and environmental impact

OWBAs support corporate sustainability goals by:

- **Reducing energy consumption** through targeted sanitization
- **Minimizing water waste**, thanks to improved monitoring and optimized sanitization cycles
- **Lowering the carbon footprint** of water system operations, aligning with environmental regulations.

This makes OWBAs not only a technical upgrade but also a strategic investment in sustainable manufacturing.

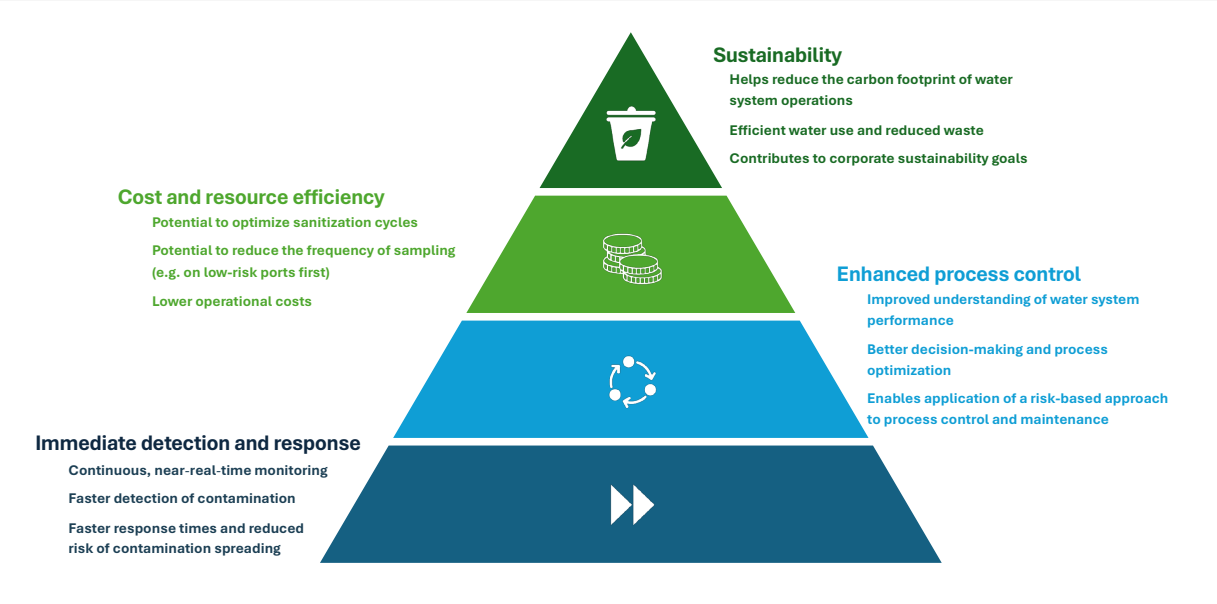
2.5 Regulatory alignment and strategic implementation

While full GMP validation of OWBAs remains a challenge, their use for **process monitoring** offers a practical entry point:

- OWBAs can be deployed as an **early warning system**, complementing traditional methods
- **Parallel use** with pharmacopeial sampling ensures compliance while building confidence in the new technology.

This strategy allows organizations to benefit from OWBAs today while preparing for broader regulatory acceptance tomorrow.

Figure 1: Benefits of using OWBAs for process monitoring

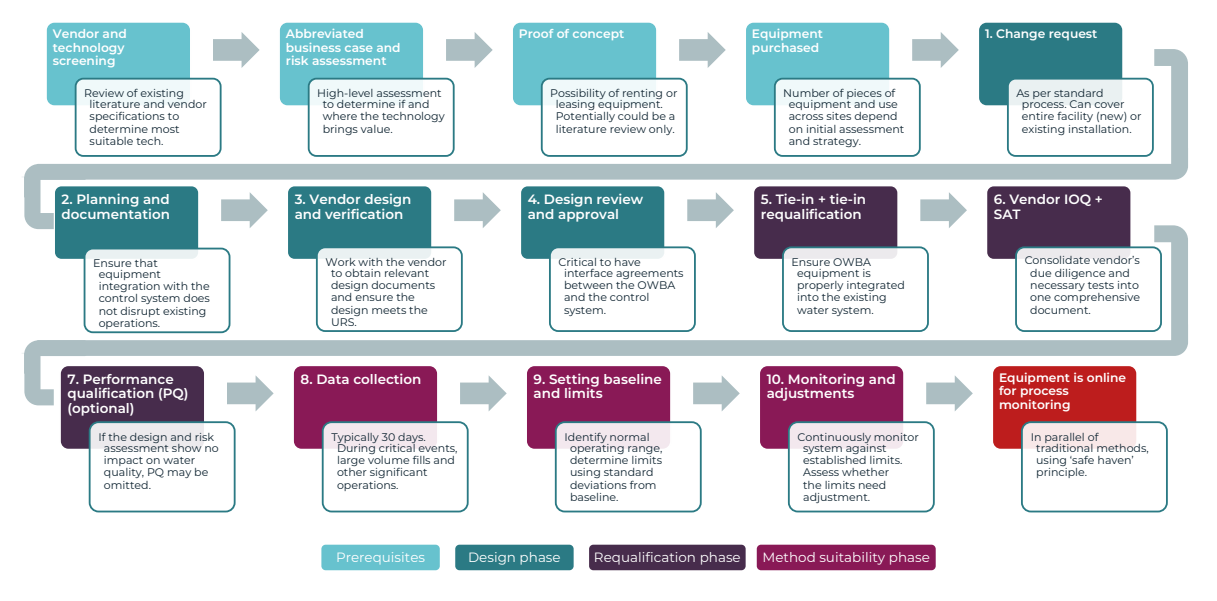


3.0

10-step phased implementation roadmap

The following 10-step roadmap outlines the key phases of implementation of OWBAs for process monitoring, from initial planning to operational monitoring. It supports a phased approach, reducing the immediate burden of validation and minimizing disruption to existing systems, while enabling smoother transitions to future GMP applications.

Figure 2: 10-step phased roadmap of OWBA implementation for process monitoring



3.1 Prerequisites

Vendor and technology screening

- Evaluating different vendors and technologies to determine which are most suitable for the project. It involves reviewing existing literature, vendor specifications and possibly conducting a literature assessment to narrow down options.

Abbreviated business case and risk assessment

- High-level assessment to determine whether the technology brings value and how it addresses specific process needs and user requirements in the business.

Proof of concept (POC)

- The POC should be developed in conjunction with local subject matter experts to ensure the experimental design is appropriate for the specific OWBA technology being tested. The scientific relevance and limitations of the testing method should be considered. For example, conducting a POC in a static water tank to test an enzymatic activity-based technology may not be successful due to bacteria becoming dormant.
- Possibility of renting or leasing equipment for POC, which can simplify the process and reduce upfront costs
- An assessment based on existing literature and vendor claims could be used to determine the most suitable technology, potentially eliminating the need for a full POC. This depends on the specific needs, time pressures and risk tolerance of the organization.

Typically at this stage, moving forward with purchasing the equipment would be considered.

3.2 Design phase

1. Change request

- The approach to the change request will differ based on whether the implementation is part of a new project (new line) or a change to an existing production site. For new facilities, the change request will cover the entire factory or system, while for existing sites, it would be specific to the change to existing equipment installation.

2. Planning and documentation

- Determine the exact location for the OWBA installation within the existing water system
- Identify necessary modifications to the system to accommodate the new equipment
- Ensure that integrating the equipment with the control system does not disrupt existing operations. This includes verifying that any automated valves or control mechanisms associated with the installation of the system are properly qualified and do not interfere with the water system's performance.
- Consider preference for a slipstream installation, where the equipment is installed in a way that diverts a portion of the water flow without affecting the main loop.

3. Vendor design and verification

- Work with the vendor to obtain relevant design documents and ensure that the equipment design meets required specifications
- Ensure that the design includes IT and programmable logic controller (PLC) solutions that meet required specifications and link to the existing user requirements. This is standard practice for all computerized equipment purchases.
- Define with the vendor the process for exporting and managing the data. It is essential to integrate OWBA data into existing automation systems rather than relying on local storage to ensure data accessibility for analysis and response. This aspect may be handled by the automation or IT team. Failure to do so can result in data being inaccessible or underutilized, ultimately limiting the effectiveness of the monitoring system.

4. Design review and approval

- Review and sign off the design documents to confirm that all aspects are agreed and understood by both the vendor and the implementing team
- Note the importance of having interface agreements between the OWBA and the control system. This ensures that equipment integrates seamlessly with the existing control system and meets all required specifications.
- Based on the experience of the authors of this paper, not focusing on the POC and interface agreements could slow down the project by as much as a year. This highlights the importance of addressing these aspects early in the process.

3.3 Requalification phase

5. Tie-in and tie-in qualification

- Adapt the water system to include the OWBA, typically involving the installation of a valve
- Qualify the tie-in, ensuring that the valve and any new piping or tubing meet the necessary standards
- These steps are necessary to ensure that the OWBA equipment is properly integrated into the existing water system. This includes verifying that the tie-in does not impact the quality of the water system.
- For new facilities, qualify the loop as per standard process
- For existing facilities, after tie-in qualification, instead of requalifying the entire loop, requalifying only the effected section of the loop may be considered based on risk assessment. This would involve ensuring that the section operates as it did before the modifications.
- If the tie-in involves a valve controlled by the control system, the control system must also be requalified to ensure proper integration and operation
- The requalification process should adhere to local restart qualification procedures.

6. Vendor installation and operational qualification (IOQ) + site acceptance test (SAT)

- **Qualification plan:** Develop a comprehensive qualification plan that includes installation qualification (IQ), operational qualification (OQ) and computer system validation (CSV). This plan is prepared before executing the qualification. It must be detailed and cover all aspects of the equipment's integration into the water system.
- **Vendor IOQ:** The vendor follows a standard protocol to perform the initial IQ and OQ after the equipment is installed. This involves the vendor performing their due diligence and providing the necessary documentation and test results. Collaboration with the vendor is essential to ensure all necessary documentation and testing are complete.
- **Maintenance and calibration strategy:** A maintenance and calibration strategy should be established. This strategy must be defined during or immediately after the IQ/OQ phase, ensuring the equipment is fully calibrated and maintained according to the manufacturer's guidelines. The plan should address routine service intervals, calibration schedules and contingency actions in case of equipment failure (e.g. reverting to manual testing or having pre-qualified spare devices available). Early planning of maintenance and calibration ensures reliable data generation, minimizes downtime and supports ongoing compliance throughout the system lifecycle. This could be either handled internally or documented in a service level agreement (SLA) with the vendor.
- **Site acceptance test (SAT):** Conduct a site acceptance test to verify the equipment's performance at the installation site
- **Documentation:** Consolidate the vendor's due diligence and the SAT results into one comprehensive document. Suggestion to incorporate the specific internal requirements into the vendor's documentation.

7. Performance qualification (PQ) (optional)

- This step involves testing the equipment in combination with the water system to ensure it operates correctly under real conditions
- For simple systems like OWBAs, PQ might not always be necessary. The rationale is that the OWBA system is not directly tied to the performance of the water production or distribution system.
- If the design and risk assessment show no impact on water quality, PQ may be omitted. This decision is company-dependent and should be based on a risk assessment and design evaluation.
- Eventually, if the OWBA is included in the CCS and decisions that impact water quality are made based on the OWBA data (e.g. a change in sanitization frequency), then a PQ should be considered.

3.4 Method suitability phase

8. Data collection

- After the IOQ is completed and the system is verified to be working correctly, data collection should begin immediately. This data collection is crucial for setting a new baseline for the system.
- The proposed duration for collecting baseline data is 30 days. This period is considered sufficient to capture the necessary data points and understand the water system's performance. The rationale is that if a water system can be qualified in 30 days, based on general industry experience, the same should apply to the OWBA system to obtain a robust dataset.
- The focus should be on collecting data during critical events and uses of the water system. This includes capturing data during large volume fills and other significant operations to ensure a comprehensive understanding of the system's performance.
- Consider collaborating with the vendor to ensure data collected is within their parameters and expectations.

9. Setting baseline and limits

- Once the baseline data is collected, it is essential to set criteria for when to react to deviations from the baseline. This involves determining the acceptable limits and standard deviations from the baseline to monitor and manage the system effectively.
- Analyze the collected data to identify the normal operating range and any patterns or trends. This analysis helps in understanding the typical behavior of the system and establishing a baseline.
- Determine acceptable limits based on the baseline data. This involves setting thresholds for when to react to deviations. Common approaches include using standard deviations from the baseline to define these limits. For example, the thresholds may be based on two, three and five standard deviations from the average of the baseline, for alert, action and rejection limits respectively.
- Prepare a report to document the findings from the data collection phase. This report includes the new baseline established for the OWBA system, any observed trends and recommendations for operations to use the new baseline.
- When monitoring data exceeds established limits, to define what constitutes a true deviation, it may be helpful to consider factors such as the duration and frequency of elevated readings, rather than reacting to a single transient data point (isolated spikes). Evaluating trends over a relevant time period, such as the circulation cycle of the water loop, and assessing whether multiple peaks or sustained elevations occur, can support informed decisions about when a response may be appropriate. For example: three peaks within a 20-minute period or sustained data above the limit.

10. Monitoring and adjustments

- Continuously monitor the system against the established baseline and limits. If deviations occur, assess whether the limits need adjustment based on new data or changes in the system's performance. This ongoing monitoring ensures that the system remains within acceptable parameters and helps in managing contamination risks effectively.
- The piping or tubing between the OWBA and the water system should allow for adequate flow and be capable of being sanitized along with the water system. This ensures that the analyzer itself does not become a source of contamination and that the measurements taken are accurate.
- Conduct proper maintenance per the SLA with the vendor as defined earlier
- Describing the approach in detail and communicating it effectively to regulatory authorities is essential. This includes explaining that the OWBA system is not used to make any GMP decisions until it is fully validated and released.

3.5 Equipment online for process monitoring

At this point, the OWBA equipment is online and can be used for process monitoring.

After several months of operating OWBA in parallel with traditional methods under the safe harbor principle, organizations can begin to explore operational optimizations based on the insights gained. Although the system is not GMP-validated, its data can be used to inform decisions without directly impacting product release.

For example, teams can revisit their sanitization strategy. By re-performing the risk assessment and incorporating OWBA data into the scoring, it becomes possible to justify reducing the frequency of sanitization, while remaining within regulatory boundaries. This demonstrates to the business that OWBAs contribute to lowering contamination risk and supports a more dynamic, data-driven approach to water system management.

If elevated bioburden levels are detected, immediate sanitization can be triggered to prevent escalation. Over time, this capability supports broader changes, such as:

- Adjusting sampling frequency based on risk profiles
- Modifying process parameters to optimize system performance
- Enhancing responsiveness to contamination events.

This approach mirrors other unvalidated parameters (e.g. loop pressure) that are monitored but not validated as a GMP-critical parameter. It is used to support operational decisions (e.g. troubleshooting flow issues or pump performance), but not for product release or compliance documentation.

During this phase, data is valuable for understanding and improving system performance but not used for regulatory decisions. The OWBA system is not validated and not used for release decisions. However, its data can be used for validation purposes (see Section 6). The goal is also to build a robust dataset that supports future validation and integration into the control strategy.

4.0

Next steps toward GMP applications

For some organizations, continued use of OWBA in parallel with traditional methods may represent a viable stopping point, particularly if the benefits in operational efficiency, contamination control and sustainability are well established and documented. However, for those aiming to transition toward GMP applications, this journey involves a series of technical, regulatory and organizational steps designed to ensure compliance, reliability and user confidence.

4.1 Early considerations

The following steps may be considered in the previous roadmap and may occur earlier depending on internal company processes and regional regulatory requirements:

- **Notification to authorities:** In certain regions, regulatory bodies must be notified before implementing new technologies. While this is often best done after data collection to demonstrate system performance, or after qualification/validation, some markets may require earlier notification. This should be assessed on a case-by-case basis.
- **Factory acceptance test (FAT):** Might not be necessary for commercial off-the-shelf (COTS) systems. Since these systems are not specifically designed for a particular user, the FAT step can be skipped. A FAT is not typically performed for quality control (QC) equipment. A FAT should only be considered if the system is specifically designed and developed for the user. Considerations if conducting a FAT:
  - Conduct a FAT at the vendor's site to verify that the equipment meets the agreed specifications
  - Address any issues identified during the FAT before moving on to the next phase.

4.2 Full GMP validation

The goal is to gradually introduce OWBAs in selected GMP applications through completing comprehensive validation to obtain regulatory approval.

- **Parallel data collection:** After a year of using the OWBA alongside the traditional method, a robust dataset is established. This includes seasonal variations, sanitization effects and mechanical influences (e.g. pump vibrations).
- **Phased replacement:** With sufficient data and confidence, traditional methods can begin to be replaced in a phased manner
- **Validation data:** The data collected over time during use for process monitoring serves as parallel validation data. It will be analyzed to assess the OWBA system's performance against traditional methods. This involves identifying any discrepancies, trends or patterns that may impact the OWBA system's reliability.

4.3 Business continuity plan

Ensuring operational resilience and user adoption is critical:

User onboarding

- Present the method suitability validation data to the user group, showing the collected data and the scientific background to demonstrate the system's reliability
- Onboard users after presenting the method suitability data. This involves ensuring that users understand and trust the new system, which is crucial for successful implementation.

Business continuity plan

- Develop a business continuity plan. The plan should define scenarios for when the OWBA system is not working, including fallback options such as reverting to traditional methods.
- Develop the business continuity plan in collaboration with the user group.

Reconciliation

- Reconciliation should involve ensuring that any data discrepancies are addressed and that the system's performance is monitored continuously.

4.4 Contamination control strategy

- Update the CCS document to include the new OWBA technology. This document describes how the water system is controlled and monitored.
- Build the control strategy into the distributed control system (DCS) or other systems used to record the water system's performance and control measures
- An update of the CCS is essential in order to document to regulatory authorities how the water system is controlled and monitored with the new technology.

4.5 Training

Training strategy

- Develop a training strategy for engineering, maintenance and different teams to ensure they understand how to operate the new OWBA system and interpret the data it generates.

Training delivery

- Ensure that operators and users are well-trained to interpret the new data trends.

Support

- It may be helpful to have a hyper care team or champion team in place to support the transition to the new OWBA system. This team would consist of individuals who are knowledgeable about the system and can provide ongoing support and training.
- The hyper care team would help with troubleshooting during the initial implementation phase. They would ensure that operators and other personnel are comfortable with the new system and can use it effectively.

4.6 Performance verification

- The entire water system needs to undergo performance verification with the OWBA equipment integrated.

4.7 System acceptance and release

- The report from the performance verification serves as the system acceptance and release document, indicating that the water system with the OWBA technology is ready for use.

4.8 System monitoring

Periodic system review

- Conduct a periodic system review of data to ensure ongoing performance and compliance. Initially, this review can be conducted conservatively, such as every six months, to monitor the system's performance closely.
- Conduct periodic system review to assess the stability and accuracy of the established baseline and associated limits for the OWBA system. This review may involve comparing current data trends to historical baselines at defined intervals, identifying any drift or significant changes that may impact alert or action thresholds.
- If baseline drift is detected, criteria should be in place to determine when limits require adjustment or further investigation
- Regular evaluation ensures that monitoring remains effective and that the system continues to provide reliable, actionable information for water quality management.

Lifecycle management

- The periodic system review is part of the lifecycle management of the OWBA system. If no abnormalities or deviations are observed over several review periods, the frequency of the reviews can be extended, such as moving to an annual review.

5.0

Case study: early results obtained with an OWBA using an enzyme activity-based method

5.1 Introduction and methodology

This case study presents findings from the installation of an OWBA in a pharmaceutical PW distribution system (Figure 3). The objective of the study was to assess the capability of an enzyme activity-based method to provide near-real-time monitoring of microbial growth in the system.

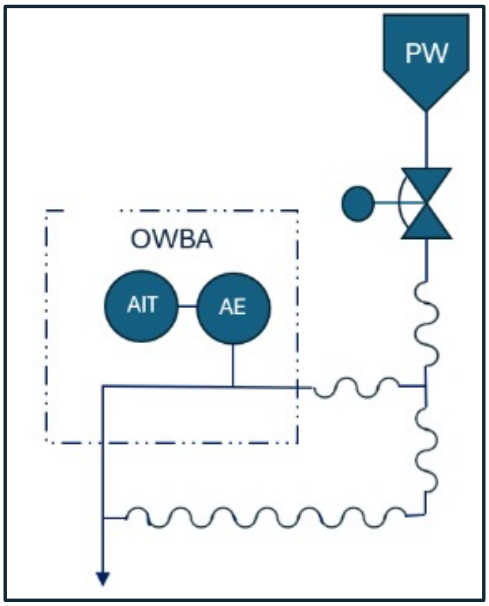
The analysis aimed to evaluate how the OWBA trends correlate with sanitization cycles and conventional CFU-based measurements, offering insights into the water system performance, associated contamination control and supporting future decisions on operational optimization.

The study followed the principles of the 10-step phased roadmap for OWBA implementation described in this paper.

Data was collected and controlled in accordance with the safe harbor principle. The OWBA system was used solely for monitoring and did not influence water production or distribution. All activities complied with user requirements for PW and adhere to regulations set by the relevant pharmacopeias (Ph. Eur., USP, JP).

The method employed is based on the reaction between a phosphate-activated enzyme, a housekeeping enzyme naturally located on the membrane surface of low-nutrient living microorganisms and a substrate. A filter inside the OWBA unit catches microorganisms, which are then saturated with substrate. The enzyme splits the molecule, generating a fluorescent signal proportional to the amount of enzymes present, measured by a detector. This follows the principle of the Michaelis-Menten correlation, assuming steady state, giving linearity of product produced in the measurement timeframe. The system automatically checks the data for linearity by plotting it against time using an algorithm.

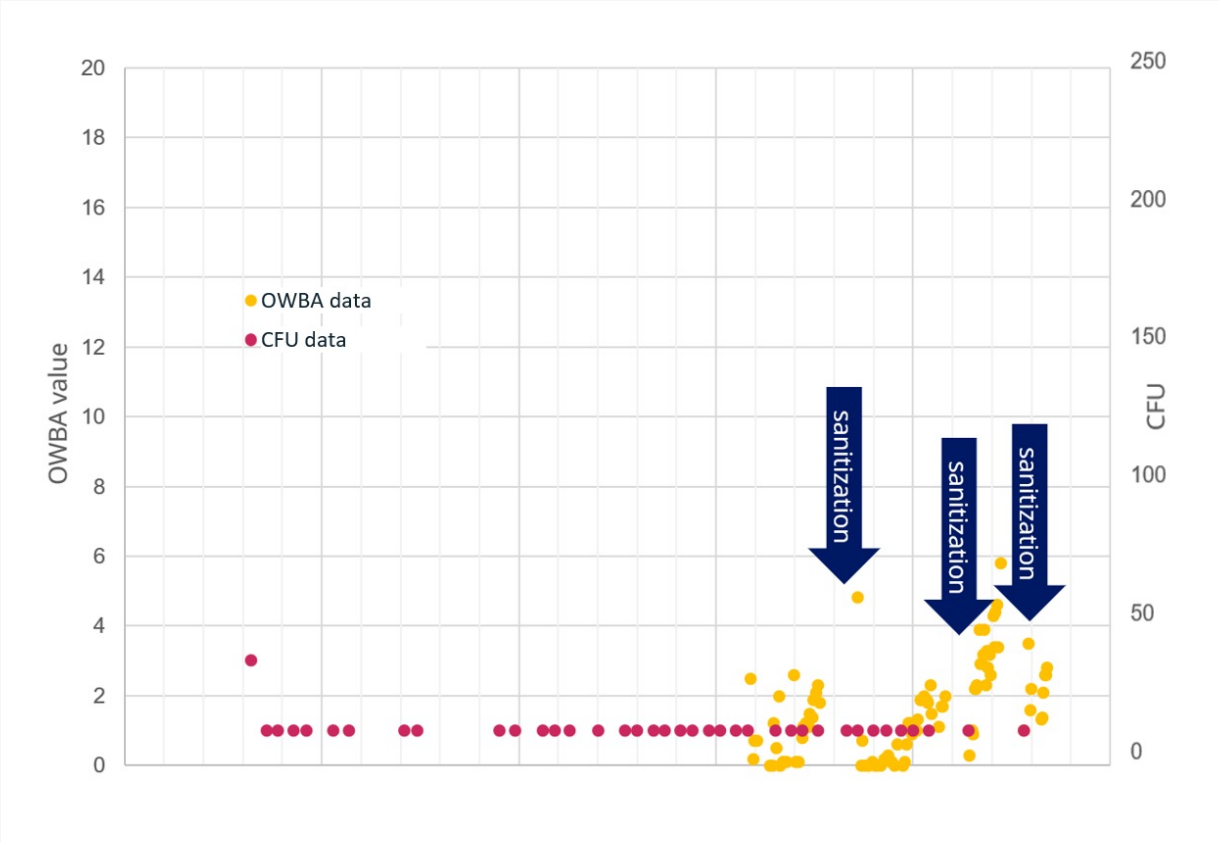
Figure 3: General diagram of OWBA set-up on site



5.2 Data collection and results

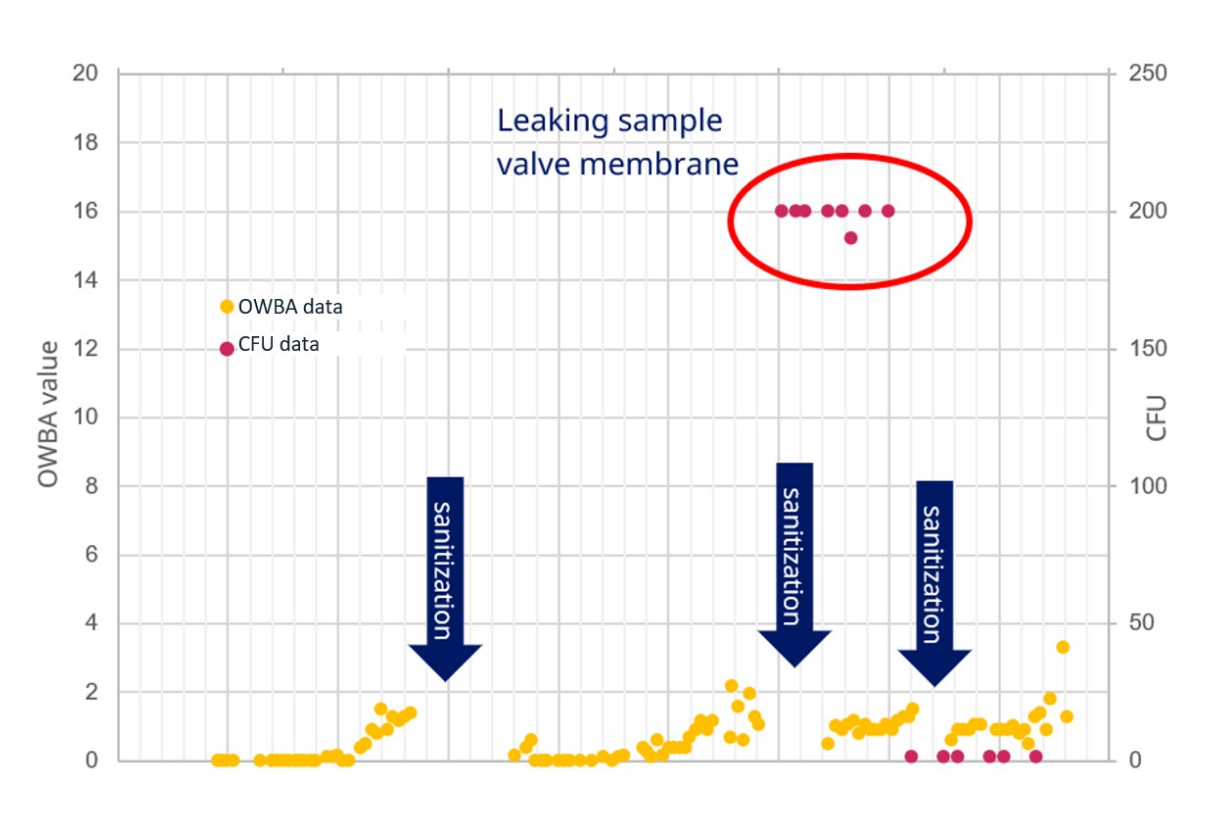
A trend was observed in the OWBA data from the early testing phase, closely related to sanitization cycles. In Figure 4, covering the PW distribution system, visual analysis shows values gradually increase and then drop to 0 after sanitization. This trend was noticeable because the equipment was located after a longer, more complicated pipeline, further from the sanitization point. Biofilm as well as planktonic growth are more inclined to appear in the distribution system, leading to high OWBA values.

Figure 4: Early testing OWBA values from a distribution skid showcasing a distinct pattern due to sanitization



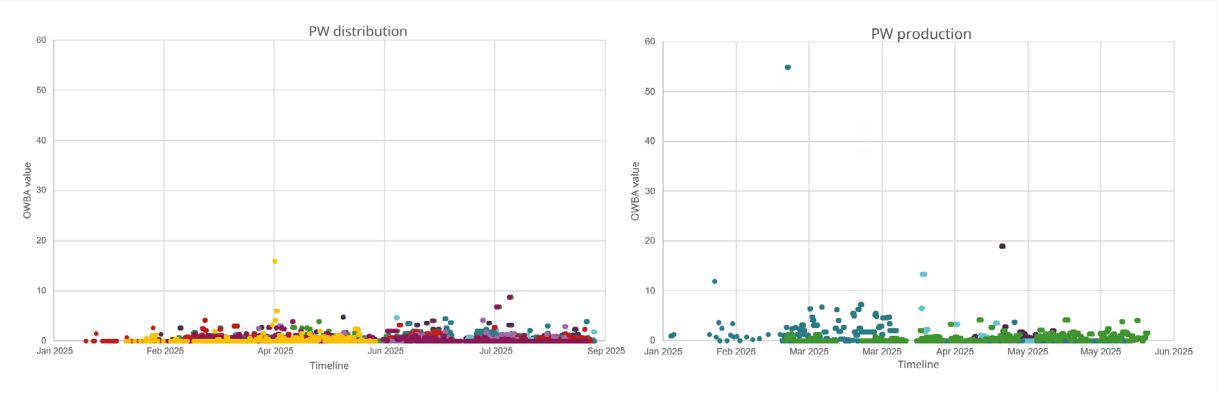
From the early testing data, the OWBA trend could also give insight into peculiar CFU values. In the case presented in Figure 5, CFU points reached the maximum loss on drying (LOD) of 200 for an extended period. Meanwhile, the OWBA data appeared unaffected. The high CFU measurements were discovered to be caused by growth inside the sample point membrane itself, rather than from the system. Here, the OWBA helped identify the true source of the bioburden: the contamination was confined to the sample point membrane, not the water system itself, despite what the CFU results suggested.

Figure 5: Early testing OWBA and CFU trends for a distribution skid in PW distribution showing how a leaking sample membrane affects the two trends



The overview of all collected data during the period of the case study (eight months) is shown in Figure 6. Based on this data, initial limits have been proposed by multiplying the standard deviation for each piece of equipment by five. For the PW distribution system, a warning limit was set at five and an alarm limit at 10. For PW production, the warning limit was set at eight and the alarm at 13. These limits are expected to be reviewed and refined as additional data becomes available following performance verification.

Figure 6: Overview of all data collected in distribution loops and in production loops



Note: Each dot color represents a separate PW loop.

5.3 Conclusion of the case study and next steps

The results collected from this early testing and pre-performance verification provide a solid basis for the future implementation of OWBA. The OWBA trend was compared to the trend obtained from CFU values, and subsequently directly associated with events across the facility. The variety of situations described provides useful insight into the credibility of OWBA data, as well as the status of the actual system. The data suggests that OWBA could be used as part of the CCS for PW, providing near-real-time data as the basis for optimized sanitization cycles instead of the current fixed schedule that are not data driven.

The next step for this specific case will be to compare the pre-performance verification and post-performance verification measurements, to ensure the validity of the measurements and to perform a test without sanitization on an unreleased water loop system to get more data on the dynamics of bioburden with the equipment.

6.0

Conclusion

The implementation of OWBA for process monitoring is already underway. As the industry moves toward real-time monitoring, OWBAs facilitate a shift from reactive to proactive water system management, unlocking more efficient and safer operations. The proven benefits in cost and resource optimization, sustainability and contamination control provide a compelling rationale for their use alongside traditional methods, supporting both operational efficiency and robust CCSs.

Adopting a phased implementation approach not only reduces the immediate burden of validation but also minimizes disruption to existing systems, enabling organizations to collect the necessary data for a smoother transition to GMP use for product release testing. Real-world examples from pioneering organizations demonstrate that using OWBA for process monitoring will ease broader adoption across the industry as more data is gathered. This momentum underscores the readiness of the industry to embrace OWBA technology, paving the way for future regulatory acceptance and full GMP application.

Glossary

Process monitoring as described in this paper refers to the continuous or routine observation and measurement of water quality parameters, specifically microbial contamination, to ensure the water used in drug manufacturing remains safe, clean and compliant with regulatory standards.

Safe harbor principle or safe haven principle, as described in industry best practice (e.g. BioPhorum, International Society for Pharmaceutical Engineering (ISPE)), refers to the period during which a new technology is operated in parallel with existing validated methods, and data generated is not used for regulatory or quality actions until the technology is fully validated. While not formally defined in regulatory guidance, this approach is consistent with the risk-based, innovation-supportive frameworks outlined in ICH Q9 and ICH Q10.

Term	Definition
CCS	Contamination control strategy
CFU	Colony-forming unit
COTS	Commercial off-the-shelf
CSV	Computer system validation
DCS	Distributed control system
FAT	Factory acceptance test
GMP	Good manufacturing practice
IOQ	Installation and operational qualification
IQ	Installation qualification
LOD	Limit of detection
OQ	Operational qualification

Term	Definition
OWBA	Online water bioburden analyzer
PLC	Programmable logic controller
POC	Proof of concept
PQ	Performance qualification
PW	Purified water
QC	Quality control
RTRT	Real-time release testing
SAT	Site acceptance test
SLA	Service level agreement
URS	User requirements specification
WFI	Water for injection

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