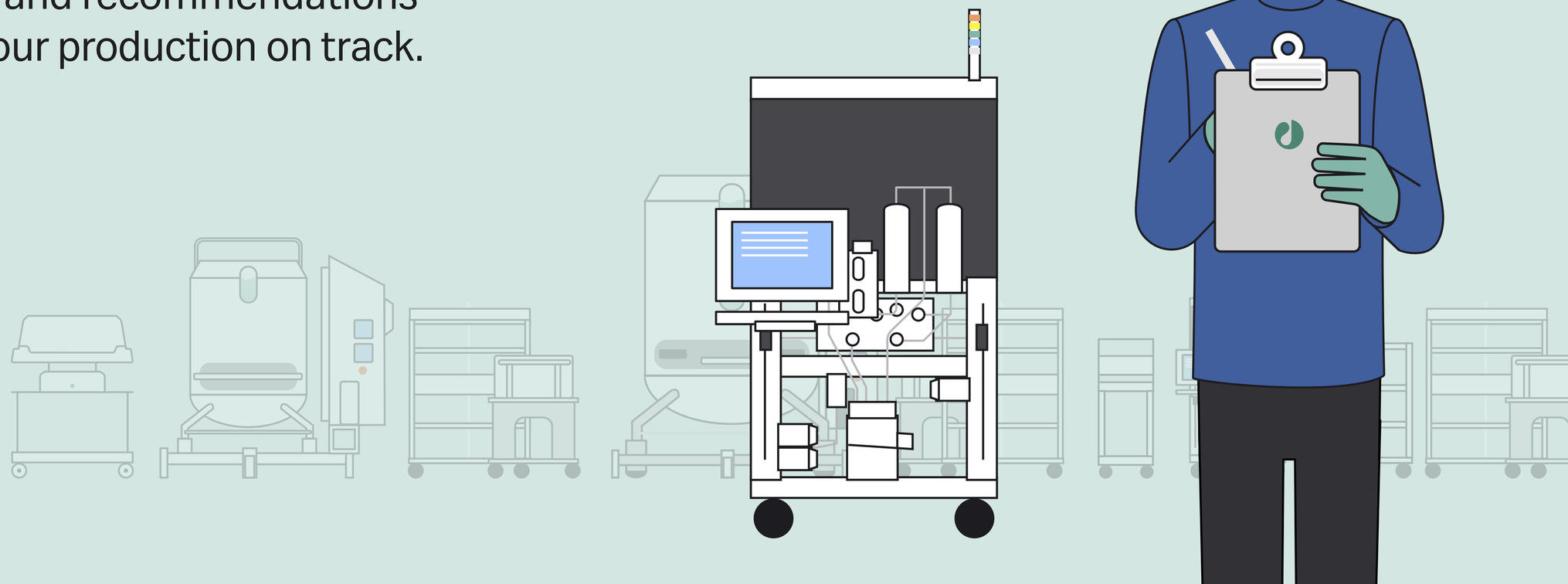
ebook

Building bulletproof bioprocesses with equipment qualification

The latest insights and recommendations to help you keep your production on track.



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Introduction

It goes without saying that you wouldn't build a house without building a strong foundation, and ensuring it stays strong over time. In bioprocessing, your equipment is that foundation—your whole process rests on it. Ongoing qualification throughout the equipment lifecycle is essential for keeping the foundations strong. Without it, processes can drift out of specification, and all of your hard work can be undone. Even the strongest science can crumble if the equipment underpinning it isn't properly qualified.

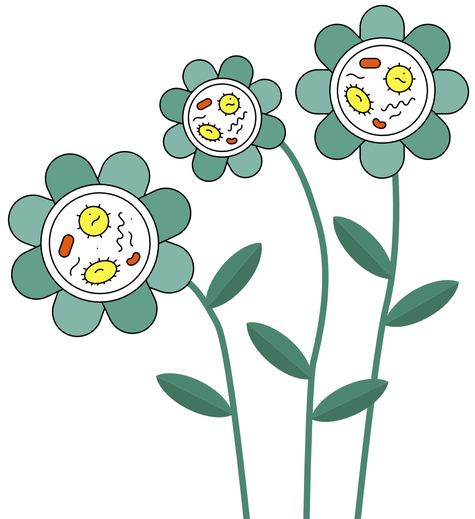
Qualification should be implemented as a recurring activity that provides documented evidence that systems are installed correctly, operate as intended, and perform reliably throughout their lifecycle. Without maintaining proper qualification, you risk failing to comply with regulatory standards and standards and good manufacturing practice (GMP) requirements, as well as quality issues, product recalls, production delays, and serious safety issues.

Qualification involves several key phases:

1. **Installation qualification (IQ)** – Confirms correct setup.
2. **Operational qualification (OQ)** – Verifies functionality under both normal and stress conditions.
3. **Performance qualification (PQ)** – Demonstrates consistent performance in real use.
4. **Requalification (RQ)** – Ensures equipment continues to meet requirements after upgrades, repairs, or relocation.

These initial and ongoing qualification activities are essential, but they're not always easy to stay on top of. Companies can struggle to keep up with the latest best practices in equipment qualification, while facing continuous regulatory updates, technological advances, and pressure to keep costs down. Add in supply chain disruption, and it's easy to see how qualification can quickly become a headache for biomanufacturers, who are often juggling several priorities with limited resources.

In this eBook, we dive into these challenges in more detail, giving you current insights and practical recommendations to help you build an effective equipment qualification strategy.



*Installation and operational qualification (IQOQ)
**Requalification (RQ)

The current challenges of equipment qualification

Evolving regulatory standards

Properly maintaining an instrument's qualified state is now essential for meeting global standards, such as good laboratory practice (GLP), good clinical practice (GCP), GMP, International Council for Harmonisation (ICH) guidelines, ISO 9001, and ISO 13485. It is also crucial for compliance with country-specific regulations such as FDA 21 CFR Part 11 and 21 CFR Parts 210 and 211 in the US, and EudraLex volume 4, Annexes 15 and 11 in Europe.

With the regulatory requirements constantly evolving, any required adjustments to qualification strategies should be considered. For example, USP <665>, a United States Pharmacopeia chapter taking effect in May 2026, introduces mandatory, risk-based standards for characterizing plastic components and systems in pharmaceutical and biopharmaceutical manufacturing. For in-house teams, staying up-to-date on evolving guidance is challenging, while also balancing daily operations. Without specialist support, there is a real risk of falling behind on compliance.

Time and cost pressures

Time and budget pressures are making decisions around equipment qualification critical, with cost efficiency and risk mitigation becoming increasingly important. As a result, facilities are questioning whether qualification should be handled in-house, or if outsourcing is a wiser option.

There's no doubt about it, qualification is complex and demands specialist expertise, rigorous testing, and extensive documentation. While in-house qualification can reduce external spending, it places significant pressure on internal teams who may lack specialist knowledge and are pulled away from their main responsibilities. In contrast, outsourcing can ease time and labor pressures, with trained providers bringing established protocols, dedicated expertise, and streamlined processes. Though this approach comes at a higher financial cost, it can generate faster turnaround times, reduced risk of errors, and improved regulatory compliance. Thus, for companies with mounting time and cost pressures, outsourcing equipment qualification can offer a strategic advantage.

Regulatory agency/ authoroty	European Medicines Agency **(EMA)**	Pharmaceutical Inspectipn Co-operation Scheme **(PIC/S)**	Ministry of Foof & Drug Safety **(MFDS)**	Food and Drug Administration **(FDA)**	Pharmaceuticals and Medical Devices Agency **(PMDA)**	National Medical Products Administration **(NMPA)**
Regional origin	Europe	Global	MFDS	United States	Japan	China

Technological advances

As bioprocessing technologies evolve with the increasing integration of digitization and automation, the expectations around equipment qualification are shifting. Modern systems are dynamic, interconnected, and continuously updated, which means qualification must also be an ongoing process to maintain compliance and mitigate risks.

Finding the capacity in-house to continuously assess, document, and qualify technical updates can be challenging. That's why external partners can be particularly beneficial for equipment qualification, having deeper experience with emerging technologies and applying proven methods to qualify advanced systems more reliably. They can also offer digital tools to make ongoing updates easier to manage, giving you more confidence in your process.

Supply chain disruptions

The rising demand for single-use systems, in addition to geopolitical tensions, and the prolonged aftermath of COVID-19 has strained global supply chains. As a result, manufacturers are experiencing longer lead times, inconsistent vendors, and equipment shortages. These disruptions can stall qualification, leading to downtime and missed deadlines. In some cases, substitute components may need to be sourced, which often requires extra qualification checks, adding further delays. This makes it important to choose the right equipment provider that can ease these pressures, through established supplier networks, reliable equipment, and the right documentation to speed up the qualification process.

How to step up your equipment qualification

Having the right equipment qualification strategy is essential to overcoming the current challenges faced in bioprocessing. Here are our top recommendations to help you build a resilient and efficient approach.

1 Follow a lifecycle approach

Qualification should be viewed as a continuous process that runs throughout the entire lifespan of equipment, not just at installation. Installation qualification, operational qualification, performance qualification and requalification should all be considered when building your qualification strategy as part of a structured life cycle approach, which emphasize building quality into processes from the outset and maintaining it over time. By following this approach, you can reduce the risk of failures, improve efficiency, and maintain confidence that your systems are always compliant.

2 Adopt a risk-based approach

Qualification takes expertise, time, and resources. To optimize efficiency, you should take a risk-based approach that focuses on the equipment that has the biggest impact on safety, compliance, or product quality. One way to do this is through failure modes and effects analysis (FMEA). This is a structured approach to map out potential deviations or failures, how likely they are to occur, and what the consequences would be.

You can then score and rank risks to prioritize where to apply the most rigorous qualification testing. This approach avoids wasting time and money on over-qualifying low-risk systems, while making sure high-risk areas are fully covered. It also gives you a clear rationale for your equipment qualification strategy, which is something auditors expect to see.

Risk-based planning also means preparing for the unexpected. Pre-qualification (checking in advance that equipment or parts meet process requirements) and pre-validation (confirming they meet regulatory and performance standards) mean you can switch immediately to an approved alternative if supply chain disruption occurs, avoiding the need to start testing from scratch.

3 Develop robust documentation and standard operating procedures (SOPs)

Strong documentation is the backbone of equipment qualification. Regulators expect every decision, test, and adjustment to be traceable, so without detailed records, even well-executed qualification may fail inspection. Make sure you capture the essentials:

- **Test reports** – To record what was done, the results, and whether acceptance criteria were met.
- **Calibration records** – To prove that measurement tools remain accurate over time.
- **Audit trails** – To log changes to equipment, software, or data.
- **Deviation and corrective action reports** – To show how issues were resolved and prevented from recurring.

Clear, well-written SOPs are also essential. These provide step-by-step instructions for qualification tasks, ensuring consistency across teams and sites, simplifying training, reducing errors, and giving inspectors confidence that activities are carried out properly. Developing robust documentation and SOPs requires applying industry best practices, regulatory knowledge, and practical experience to ensure records are both compliant and workable in real-world settings.

4 Switch to digitized documentation

Forget traditional paper binders. They're slow to update, easy to misplace, and resource-intensive to manage. Digital equipment qualification records offer a faster, more reliable, and more sustainable way to stay compliant. Here are main benefits:

Improved security

Digital records give you greater accuracy and efficiency without the risk of lost information. They remove the need for handwritten edits and manual updates, helping to avoid human error and making it easier to maintain the integrity of your data and documentation. Electronic systems also provide a complete audit trail, so every change is traceable and records are always secure and reliable.

More flexibility

Electronic formats enable you to make multiple approvals simultaneously to reduce approval time, follow execution live from a remote setting or off site and share globally across sites instantaneously for maximum convenience. This flexibility makes it easier to integrate qualification into your workflows.

Time savings

Digital equipment qualification binders make preparing, reviewing, sharing and approving content faster and more straightforward. You are usually able to generate a single PDF that includes the full report, audit trail, and all supporting documents.

Improved sustainability

Switching from paper-based qualification to digital records reduces printing, shipping, and storage needs. This not only cuts costs but also helps reduce waste and CO_2 emissions, supporting your environmental goals.

5 Implement continuous validation

While qualification verifies that the equipment works as intended, validation proves an entire process consistently delivers the expected results throughout its lifecycle. This involves regular calibration, maintenance, requalification, and taking immediate corrective action if deviations occur. By doing so, continuous validation reduces the risk of product defects or contamination. This helps to protect patient safety, strengthen regulatory confidence, and build a comprehensive data record for audits. This data also supports ongoing process improvement and efficiency.

6 Integrate simulation and modeling

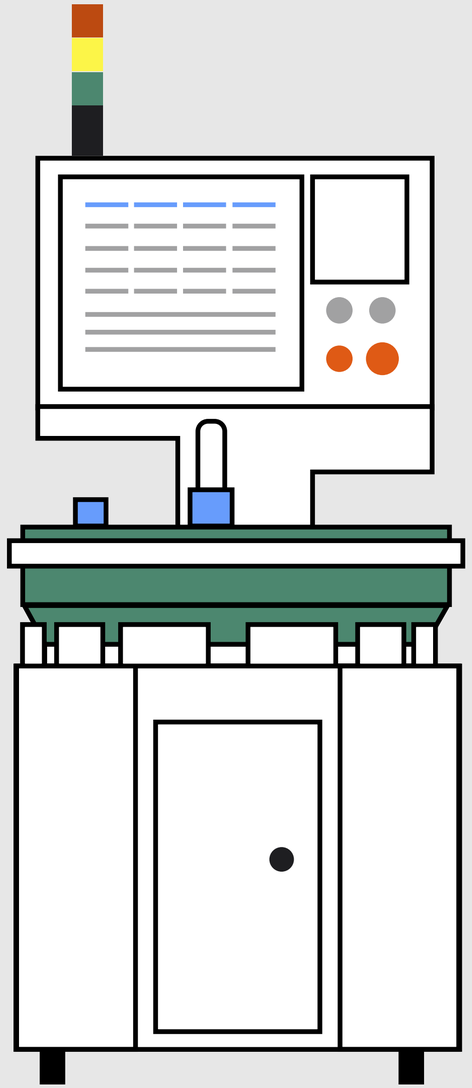
When integrated carefully, simulation and modeling can reduce risk, shorten timelines, and provide valuable insights into system behavior across the lifecycle. Digital technologies including digital twins and predictive analytics allow you to simulate how equipment will perform under different conditions, helping you identify risks and optimize processes before issues occur.

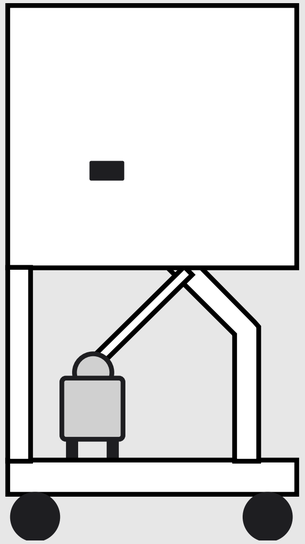
By testing scenarios virtually, you can predict qualification outcomes more accurately and avoid disruptions once systems are in use. It's important, however, to remember that these tools must also be qualified themselves to prove they reflect real-world performance reliably.

7 Seek support from your supplier

When it comes to qualification, don't overlook the value of your equipment supplier. As the designers and manufacturers of the systems, they have detailed knowledge of system design and function that is hard to replicate in-house. Many also bring deep regulatory expertise and keep up with the latest FDA, EMA, and GMP requirements, and can provide proprietary documentation such as validation support files and regulatory support files. These are tailored to the equipment and usually include test procedures, acceptance criteria, and supporting evidence that regulators expect to see.

Beyond documentation, suppliers can also deliver training for your teams, share best practices, and provide hands-on technical support to resolve issues quickly during qualification or production. Drawing on this expertise can help you speed up qualification, reduce the risk of errors, and be better prepared for audits. It also eases the burden on your internal teams, freeing up valuable time so they can focus on other priorities.





Conclusions

Equipment qualification is the bedrock of reliable and compliant biomanufacturing. It ensures that manufacturing equipment operates correctly, meets regulatory standards, and delivers consistent results. When qualification is overlooked or poorly managed, the consequences can be serious—from wasted resources and production delays to failed inspections and product recalls.

But companies are facing challenges that make qualification more complex, such as evolving regulations, rising time and cost pressures, rapid advances in digital technologies, and ongoing supply chain disruptions. The good news is that these challenges can be managed with the right qualification strategy. Planning around risk and maintaining clear documentation help reduce delays, ensure product quality, and strengthen compliance. Moving to digital records and adopting continuous validation make it easier to stay inspection-ready, while tools like modeling and simulation can help predict issues before they affect production. Working closely with suppliers also provides valuable expertise and support that eases pressure on internal teams.

Find out more about how we can support you here.

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