The PPQ Readiness Guide

Discover the six questions every late-stage biotech should answer before commercial manufacturing



Guide

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Preparing for Commercial Success Starts Long Before PPQ

Process Performance Qualification (PPQ) is where years of development decisions are put to the test. By the time a programme reaches PPQ, much of the work that determines success has already happened. Process development, analytical strategy, technology transfer, quality systems and supply chain planning all influence whether validation proceeds smoothly, or whether costly delays emerge at the final stage.

For cell and gene therapy developers, the stakes are particularly high. Manufacturing processes are inherently complex, regulatory expectations continue to evolve and commercial launch timelines leave little room for error.

Successful PPQ isn't simply about completing validation batches. It's about demonstrating that your manufacturing process is robust, reproducible and capable of reliably supplying patients long after launch.

This guide highlights the critical areas organisations should assess before entering PPQ and shares practical considerations that can help reduce risk as programmes transition from clinical phases into commercial manufacturing.

Why PPQ Programmes Get Delayed

Most PPQ delays aren't caused by the validation exercise itself. They occur because issues that developed earlier in the programme aren't identified until commercial manufacturing begins.

Common challenges in the industry include:

- Manufacturing processes that perform differently at commercial scale
- Incomplete technology transfer between organisations or facilities
- Analytical methods that are not sufficiently mature
- Documentation gaps discovered during validation planning
- Quality systems that aren't fully aligned with commercial expectations
- Supply chain vulnerabilities affecting manufacturing continuity
- Limited cross-functional alignment across Manufacturing, Quality, Regulatory Affairs and Supply Chain

Many of these risks can be mitigated through earlier planning and a structured commercial readiness strategy.



Expert Insight

"Clients that begin preparing for PPQ well before validation activities are typically better positioned to avoid delays and maintain launch timelines." – **Jason Brown, Principal Validation Specialist**

6 Questions to Ask Before PPQ

1. Is your manufacturing process ready for commercial scale?

A process that performs well during clinical manufacturing may behave differently once commercial-scale production begins.

Before PPQ, organisations should have confidence that process variability is understood, critical process parameters have been characterised, and manufacturing performance is predictable.

Ask yourself:

- Have critical process parameters been fully characterised, with the impact to critical quality attributes well known?
- Has a design space been established to define the boundaries of the manufacturing process?
- Has commercial-scale performance been demonstrated?
- Is process variability understood?
- Can manufacturing consistently meet quality specifications?

2. Has technology transfer been completed successfully?

Successful technology transfer is about much more than documentation.
Critical process knowledge, operational experience and manufacturing expertise must be transferred effectively to ensure process consistency during PPQ.

Ask yourself:

- Has manufacturing knowledge been transferred effectively?
- Are process risks clearly documented?
- Have knowledge gaps been identified and addressed?
- Are all teams aligned on process execution?



Expert Insight

"A comprehensive technology transfer establishes the essential knowledge transfer from development to GMP, sets the baseline for full-scale process performance and operability, and helps establish an expected product quality profile. A successful technology transfer represents a major milestone in preparation for PPQ."

– Jason Brown, Principal Validation Specialist

3. Are your analytical methods ready?

Reliable analytical methods are essential for demonstrating process consistency and product quality throughout validation.

Late-stage programmes should ensure analytical methods are appropriately validated or qualified before PPQ begins.

Ask yourself:

- Are analytical methods appropriately validated?
- Are acceptance criteria clearly defined?
- Can testing support commercial manufacturing timelines?
- Are laboratories fully prepared?

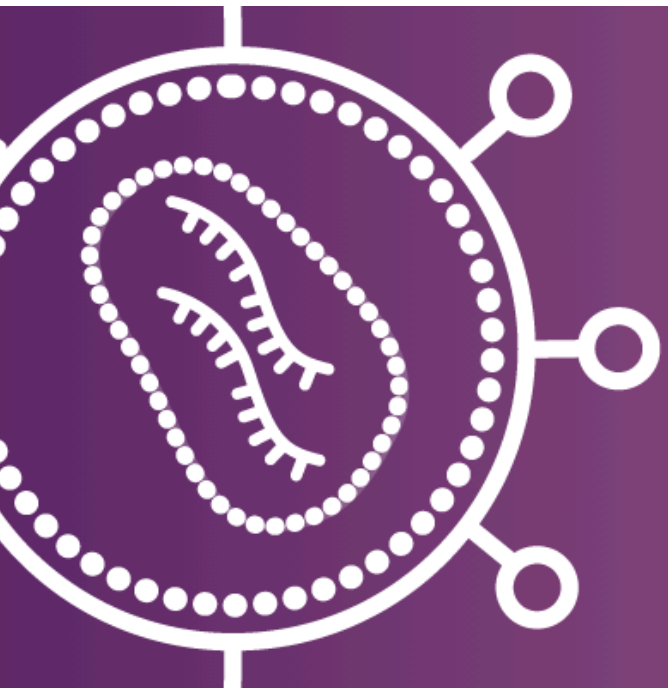
4. Are your quality systems inspection ready?

Commercial manufacturing requires more than regulatory compliance.

Quality systems should support consistent execution, effective change management and continual inspection readiness.

Ask yourself:

- Can your Quality System guide you through the complete lifecycle of your product?
- Has your Quality System developed during your journey as a company?
- Are your Quality events under control and closed out in a timely manner?
- Has your Quality System been audited?



TOP TIPS

Expert Insight

"A robust Quality System is needed to ensure products produced are of suitable quality, safety and efficacy. Reviewing the quality system periodically ensures the system remains fit for purpose through the journey of the company's growth and the journey of product development."

– Sipi Dhaliwal, Head of Quality

5. Is your supply chain commercially prepared?

Commercial success depends on reliable manufacturing continuity.

Raw materials, suppliers, inventory strategies and manufacturing capacity should all be aligned before PPQ starts.

Ask yourself:

- Are critical suppliers qualified?
- Is raw material availability secure?
- Is manufacturing capacity sufficient?
- Are contingency plans in place?

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"A strong collaborative partnership with your suppliers is key to ensure a robust supply chain and the appropriate inventory levels at all stages of the product life cycle."

– **Amanda Collett, Head of Supply Chain**

6. Is your manufacturing partner ready for the next stage?

PPQ represents the beginning of commercial manufacturing - not the end. As programmes mature, manufacturing partners should be able to support process optimisation, lifecycle management, increasing demand and future regulatory submissions.

Ask yourself:

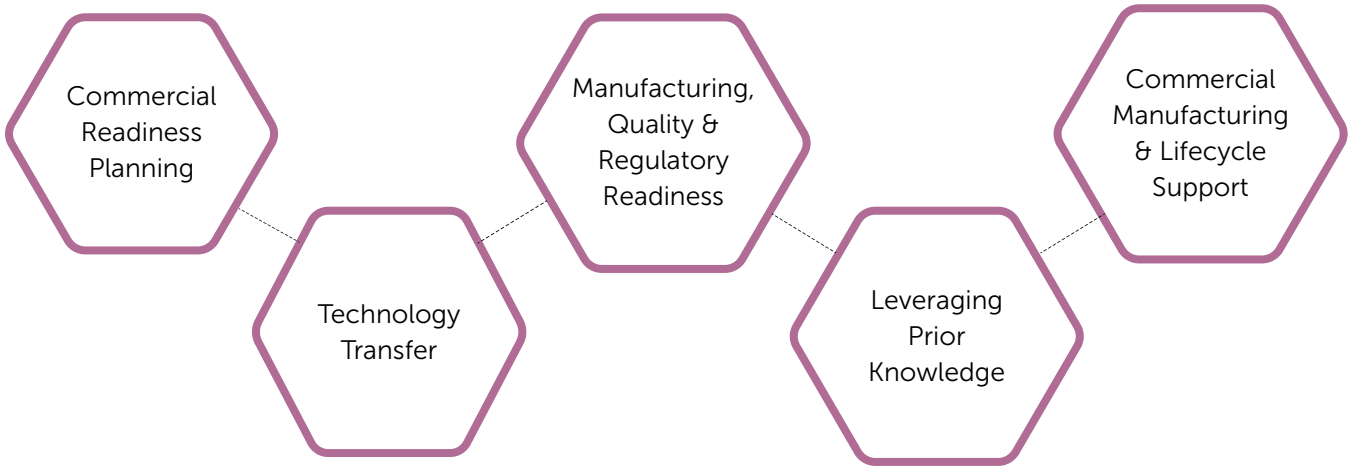
- Can your partner support commercial launch?
- Do they have experience with late-stage programmes?
- Can they support lifecycle management?
- Are they equipped for global commercial supply?

Signs your manufaturing partner is commercially ready

- Proven experience supporting PPQ and commercial launches
- Robust quality systems and inspection-ready operations
- Capacity and supply chain strategies to support long-term supply
- Expertise in lifecycle management, regulatory submissions and post-approval changes

How OXB helps its clients prepare for PPQ Readiness

Preparing for PPQ requires more than technical expertise. Success depends on effective planning, robust process and analytical development, strong quality systems and alignment across Manufacturing, Quality, Regulatory and Supply Chain functions. With experience supporting 100+ programmes, 100+ regulatory submissions and 7 PPQ campaigns, our teams help clients navigate the transition from Phase III development through to commercial supply.



1. Commercial Readiness Planning

Moving from Phase III into commercial manufacture is a critical transition. Manufacturing decisions made during late-stage development can directly influence PPQ success, regulatory timelines and future commercial supply.

OXB helps clients understand the dependencies between process development, analytical development, technology transfer and PPQ activities, enabling the creation of a clear project roadmap and identification of the critical path to commercialisation. Our approach can be tailored to programme-specific requirements, timelines and regulatory strategies.

2. Technology Transfer

A successful technology transfer is fundamental to PPQ readiness. Critical process knowledge, operational expertise and manufacturing experience must be effectively communicated to ensure process consistency during PPQ.

OXB works alongside client teams to identify knowledge gaps, assess technical risks and support effective transfer of manufacturing know-how. Our cross-functional teams bring together Development, GMP Manufacturing, Quality and Regulatory expertise to help establish a strong foundation for validation and commercial manufacture.

3. Manufacturing, Quality & Regulatory Readiness

PPQ requires confidence that the manufacturing process is sufficiently understood, controlled and reproducible. OXB supports process validation planning, analytical readiness, quality system alignment and regulatory strategy development to help prepare programmes for successful PPQ execution.

Our teams have supported 100+ regulatory submissions and understand how regulatory expectations may vary across products, jurisdictions and development pathways, helping clients make informed decisions throughout programme development.

4. Leveraging Prior Knowledge

Where platform manufacturing data or analytical assays are available, assessing how this existing knowledge can be applied to your programme may help inform development strategies and reduce unnecessary product-specific activities.

OXB can support the assessment of platform manufacturing data and platform analytical assays to identify opportunities to leverage pre-existing data and prior knowledge where appropriate. This can help you determine where product-specific studies are required, where existing knowledge may provide useful support and how development activities can be structured efficiently.

5. Commercial Manufacturing & Lifecycle Support

PPQ is not the end of the journey. Commercial success depends on maintaining process control, supporting continued process verification and adapting to evolving commercial requirements.

OXB supports clients beyond PPQ and initial launch with commercial manufacturing, lifecycle management, process optimisation and supply-chain planning. Having supported **7 PPQ campaigns** and programmes through to commercialisation, we help clients build manufacturing strategies that can evolve alongside product demand and regulatory requirements.

Key Takeaway

PPQ isn't simply a regulatory milestone - it's a measure of how effectively an organisation has prepared for commercial manufacturing.

By taking a structured approach to process readiness, technology transfer, quality, analytical strategy and supply planning, organisations can reduce risk, improve execution and move towards commercial launch with greater confidence.



PPQ Readiness Checklist

Are You Ready for PPQ?
Use this checklist as a starting point for assessing your commercial manufacturing readiness.

Manufacturing Process

- [ ] Manufacturing process finalised
- [ ] Critical process parameters understood
- [ ] Commercial-scale process demonstrated
- [ ] Process performance consistent

Technology Transfer

- [ ] Manufacturing knowledge transferred
- [ ] Documentation complete
- [ ] Risks identified and mitigated

Validation & Quality

- [ ] PPQ protocol approved
- [ ] Analytical methods ready
- [ ] Quality systems inspection ready
- [ ] Documentation complete

Commercial Readiness

- [ ] Commercial manufacturing capacity confirmed
- [ ] Supply chain established
- [ ] Raw material strategy in place
- [ ] Commercial launch plan aligned

Ready to discuss your PPQ Strategy?

Reach out to OXB:
partnering@oxb.com

OXB

Whether you're preparing for technology transfer, planning PPQ or scaling for commercial manufacture, OXB works with clients to support every stage of the journey, from late-stage development through to commercial supply.



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