

1. National Regulatory Agencies, i.e. FDA, EMA, MHRA, PMDA

Working with national regulatory agencies involves understanding their expectations for compliance, data integrity and quality management systems (QMS). While similar, each agency has nuanced requirements and by staying aligned with their frameworks, this ensures that development, manufacturing and distribution activities meeting their expectations, are in control and audit-ready.

2. ICH Guidelines & Other Supporting Data for Characterisation and Comparability

ICH guidelines provide internationally harmonised technical guidance across regions. They set out agency expectations in areas such as quality risk management, product development, validation, stability, etc. These frameworks enable consistent interpretation & application of regulatory expectations across different territories for biopharmaceutical development & operations.

3. Quality Technical Agreements (QTAs)

QTAs define responsibilities between sponsors and service providers. They formalise how compliance with Quality Management Systems (QMS) and its related documentation will be controlled and managed, and which parties have responsibility. Well-structured QTAs support consistency, promote accountability and ensures that quality obligations are traceable and clearly understood by all parties involved.

4. Facility Compliance

Facility compliance involves routine inspection readiness, documentation practices & system validation. It ensures that manufacturing environments meet applicable regulatory and GMP standards. An effective Quality Management System (QMS) promotes continuous improvement and keeps operations aligned with evolving expectations and audit findings.

5. Material Standards

Raw materials must meet defined standards, including pharmacopoeial compliance, consistent quality & validated supply chains. Robust material control underpins product reliability and traceability. For cellular therapies, where input variability is inherent, strict standards are especially vital to ensure safety & efficacy and are especially critical for cellular therapies.



6. Pre-Approval Inspection (PAI)

A PAI evaluates production facility readiness for commercial distribution. It includes assessments of quality systems, data integrity management and validation status. Proactive auditing and consistent documentation are essential for demonstrating control to regulatory agencies and is a critical stage prior to commercial production.

7. Pharmacopoeia Requirements

Pharmacopoeias vary by country, i.e. US, British, Japanese pharmacopoeia, etc.. However, all define quality expectation and standards for raw materials excipients & finished products. Meeting these requirements ensures consistency, traceability & compliance across the supply chain. Adherence is essential for demonstrating product integrity and supports audit readiness and regulatory approval in both clinical and commercial settings.