

ReadyQMS™

Our Approach

QMS BUILD	
BASICS	Commitment to quality, qualification, and training, documentation management, data, and records management
GROWTH	Risk management, supplier management, oversight, and compliance
PRECLINICAL	GLP oversight of suppliers, management review, and issue management
IND	IND application, trial management, CRO, and CDMO oversight
cGMP	Materials management, facility, manufacturing controls, QC and QA, packaging and labeling, process control, and validation
PHASE II-IV	IND application, trial management, CRO, and CDMO oversight

Phase by Phase QMS

Advarra's ReadyQMS translates the industry standard approach for quality management systems into an agile, fit-for-purpose solution designed to scale with growing organizations.

Grow Confidently and Ensure Cross-Functional, Good Regulatory Practices (GxP)

- Quick-turn quality systems, including templates and tools, focused on critical-to-quality and quality-by-design
- Processes that facilitate the assessment and mitigation of risk, decreasing the potential for costly rework and delays
- Templates that guide proper oversight, improving consistency and increasing confidence in the integrity of the data and results to inform future development decisions
- Access to a cross-functional team of quality experts for ongoing guidance and support

A quality management system (QMS) is a critical business and regulatory imperative for biopharmaceutical companies. An effective QMS plays a vital role in identifying opportunities to manage and mitigate risk, optimize processes, reduce costs, and ultimately drive better business results.

Fit-For-Purpose

Ensure an efficient and compliant progression of your product from preclinical and clinical phases through to approval with a customizable QMS for each step in your journey.