

Ensuring quality consistency: Thermo Fisher Scientific's global commitment to quality

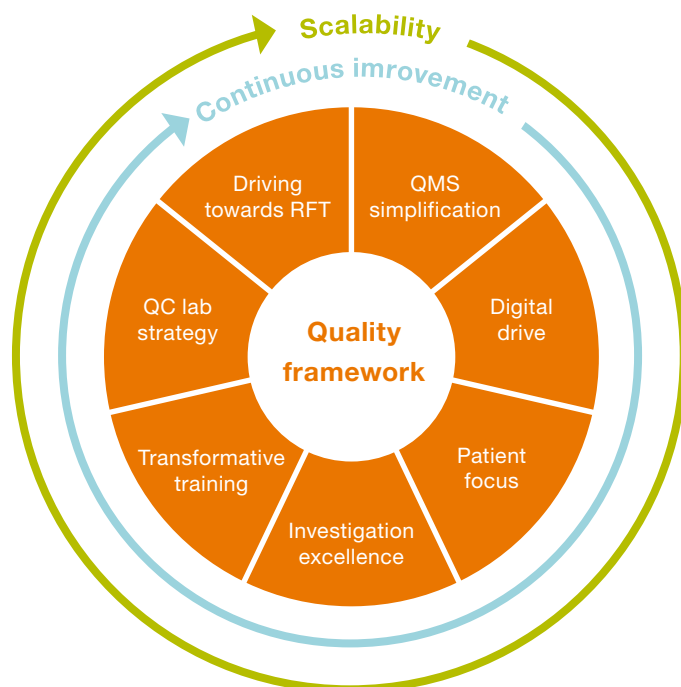
In biopharmaceutical development and manufacturing, quality is critically important to ensuring the safety, efficacy, and consistency of pharmaceutical products. Rigorous adherence to quality standards at every stage of the process, from research and development to manufacturing, is essential to minimizing risks and maximizing therapeutic benefits for patients. In addition, adherence to stringent quality control measures is necessary to comply with regulatory requirements set by authorities like the United States Food and Drug Administration (FDA), European Medicines Agency (EMA), and China National Medical Products Association (NMPA). However, while there are some similarities in the regulatory requirements set by these agencies and others, the implementation and enforcement can differ by country and region, especially for standards related to quality. These variations can create challenges for multinational developers seeking commercialization globally, or in specific regions. Partnering with a CDMO with the global expertise to navigate these differences and with global frameworks in place to standardize quality assurance can alleviate these challenges for developers.

At Thermo Fisher Scientific, we are committed to delivering the highest level of quality throughout the drug development process and have implemented harmonized quality systems standards across all sites in our global network. This means that every site not only complies with regulations that are enforceable by the regulatory agencies of the regions where the drug is manufactured, distributed, and marketed, but also abides by Thermo Fisher Scientific's global quality standards.

Global framework overview for achieving quality management maturity (QMM)

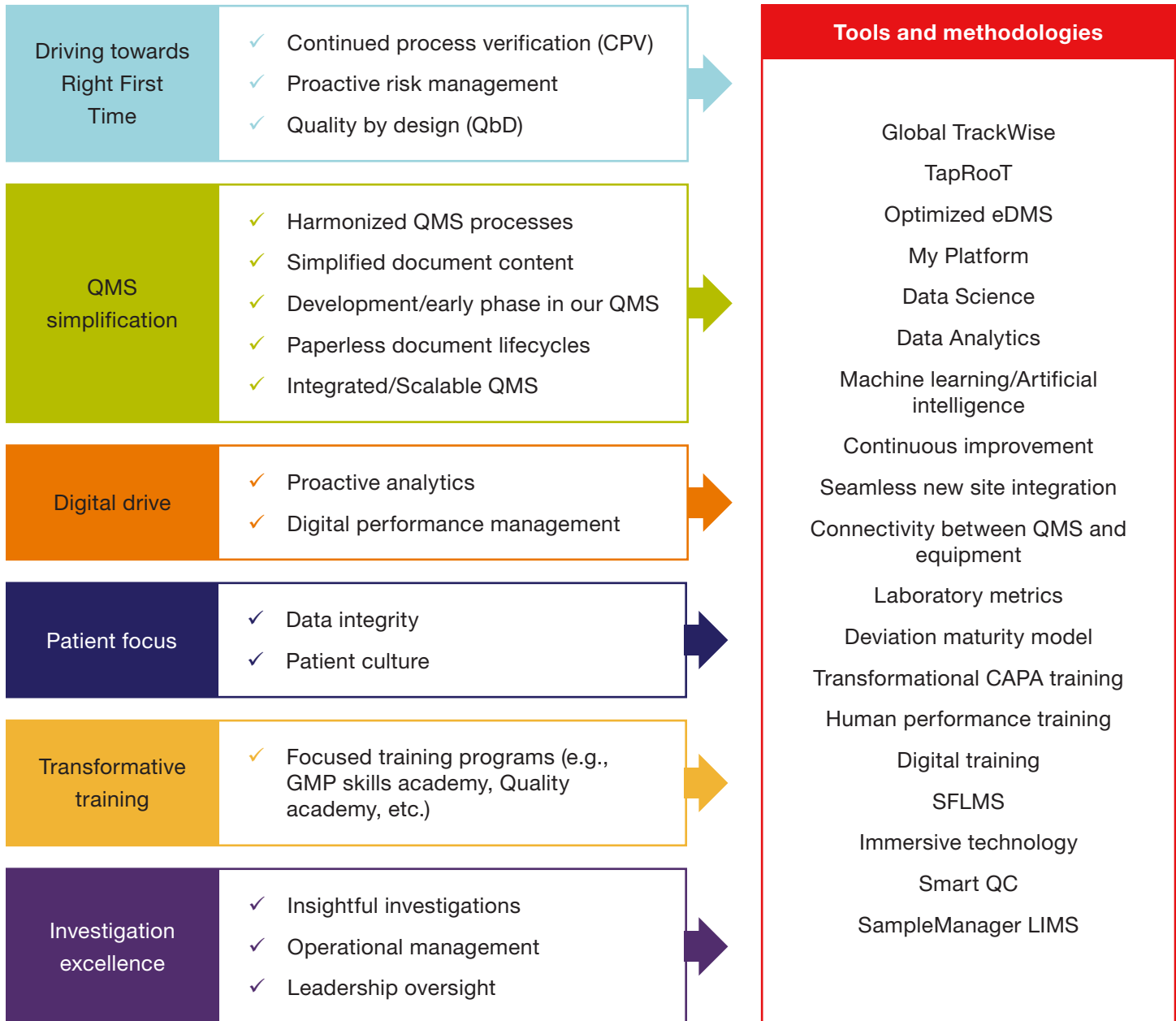
QMM
✓ Invest in people
✓ Organization objectives drive quality
✓ Quality systems shape culture
✓ Focus on innovation and CI
✓ Performance-based QM
✓ Robust metrics program with focus on analytics
✓ Risk management

“Quality management maturity is the state attained when drug manufacturers have consistent, reliable, and robust business processes to achieve quality objectives and promote continual improvement.”



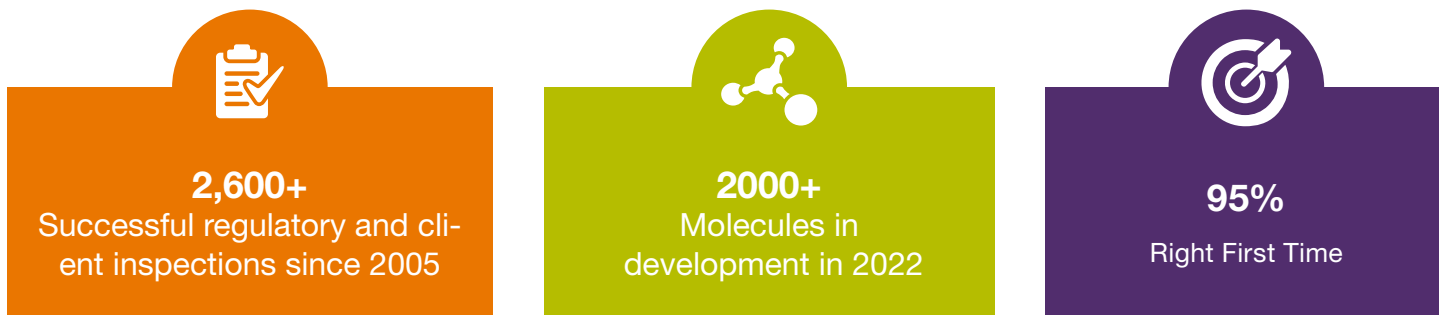
Quality framework initiatives, tools, and methodologies

To ensure consistent quality across all sites in our global network, our quality teams employ the same initiatives, tools, and methodologies regardless of location. In addition, site quality directors report directly to our global quality team, and not to the site general manager.



Continuous improvement through experience

Our unparalleled experience puts us at the forefront of innovation and ensures we are always providing the highest level of quality standards to our customers, driven by continuous improvement.



Our global commitment

Thermo Fisher Scientific is dedicated to maintaining the highest level of quality standards across the entire drug development process. We achieve this through various initiatives, including globally tracked risk and performance monitoring. We also develop site-specific maturity plans that are performance-based, ensuring continuous improvement. Our business processes are designed to drive ongoing enhancements, while our alignment with Quality Management Review further reinforces our commitment to quality. Additionally, we invest in a diverse pool of talent and actively promote a quality culture within the organization. Our customer-centric approach, combined with a data-driven mindset, enables us to deliver industry leading quality to our customers, reliably and consistently.

 Visit [patheon.com](https://www.patheon.com) to learn more about our global network of pharma services sites

¹ Quality Management Maturity: Essential for Stable U.S. Supply Chains of Quality Pharmaceuticals | FDA, 2022