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# The Role of Quality Management in Modern CRDMOs

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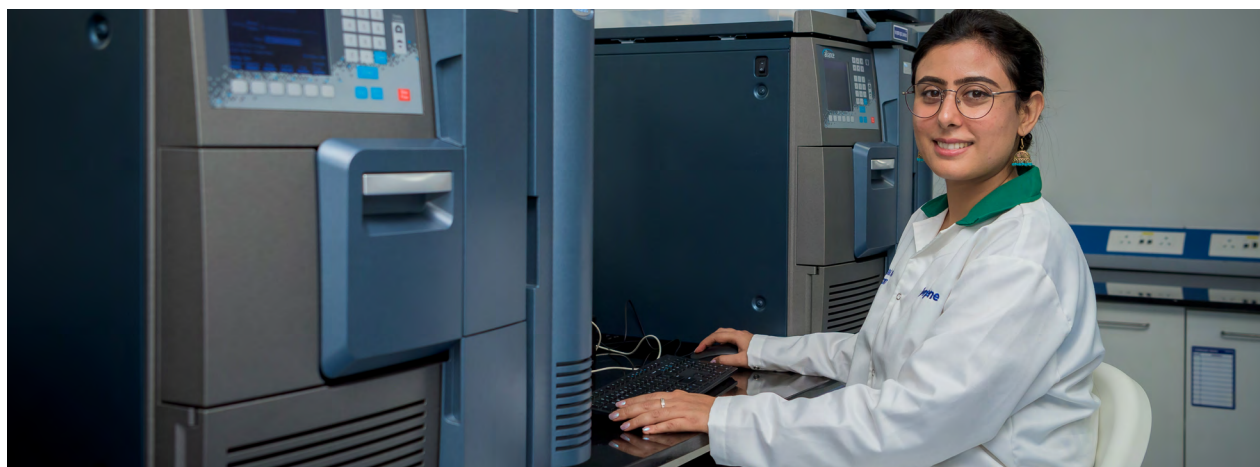
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**Innovation in rProtein A ligand design for manufacturing high-performing affinity chromatography media for implementation in mAb purification platforms.**



In the pharmaceutical and biotechnology industries, quality management is a foundational element that directly influences product safety, efficacy and compliance with regulatory standards. As these industries are heavily regulated, companies must adhere to stringent guidelines to ensure that their products meet the required benchmarks for patient safety and therapeutic effectiveness. Quality management systems (QMS) are therefore critical in guiding organisations through complex processes, from research and development (R&D) to manufacturing and distribution. These systems are designed to establish standardised procedures, minimise risks and ensure that every aspect of production and service meets high-quality standards.

The essence of quality management in these industries lies in its comprehensive approach, covering everything from supplier qualification and process validation to employee training and continuous improvement initiatives. Regulatory bodies such as the US Food and Drug Administration (FDA), the European Medicines Agency (EMA) and other international agencies set the parameters within which these organisations must operate. Compliance with these regulations is non-negotiable and often requires companies to undergo rigorous inspections and audits to verify that their operations meet the required standards.



A robust QMS is not just about meeting regulatory requirements; it is also about fostering a culture of quality that permeates every level of an organisation. This involves ensuring that all employees, from the laboratory to the executive suite, understand the importance of quality in their work. It also means being prepared for unexpected challenges, such as product recalls or regulatory changes, which can have significant impacts on business operations.

In the context of these industry-wide demands, it becomes crucial for companies to not only establish, but also continuously refine their quality management practices. This involves staying ahead of the curve by adopting new technologies, implementing best practices and fostering an environment where quality is everyone's responsibility.

### **'Anytime Audit Ready' philosophy**

Syngene International, a global contract research, development and manufacturing organisation (CRDMO), exemplifies how a robust QMS can be both a compliance necessity and a competitive advantage. By examining Syngene's practices, we can gain insights into how a systematic approach to quality management can be implemented effectively in a highly-regulated CRDMO industry. Syngene operates on the principle of being 'Anytime Audit Ready'; a philosophy that underscores the importance of maintaining high standards of quality consistently, rather than only preparing for specific audits. This proactive stance on quality management is crucial in an industry where regulatory expectations are stringent and constantly evolving.

Instead of reacting to audits, Syngene has embedded a culture of quality throughout its operations, ensuring that its practices meet or exceed regulatory requirements at all times.

At the core of Syngene's quality management strategy is its own QMS, a dynamic framework that supports ongoing improvements and adaptations in response to both regulatory changes and operational feedback. This system is designed to ensure that all processes, from research and development to manufacturing, are conducted in accordance with stringent quality standards. The QMS is supported by a set of Standard Operating Procedures (SOPs) that cover critical processes across the organisation. These SOPs are not static documents; they are regularly updated to reflect new regulatory requirements, technological advancements and industry best practices. However, the effectiveness of any QMS or SOP depends heavily on the competence of the workforce executing them.

Recognising this, Syngene places a strong emphasis on Syngene's quality management approach. These audits are designed to be as rigorous as external regulatory inspections, ensuring that the company is always prepared for formal audits. Over the past three years, this rigorous internal audit process has contributed to the successful completion of over 200 audits. Internal audits serve multiple purposes: they verify compliance with existing protocols, identify areas for improvement, and ensure that the organisation maintains a state of continuous readiness. By detecting and addressing potential issues early, Syngene can mitigate risks and maintain its high standards of quality.

## Leveraging digital tools

In recent years, Syngene has embraced digital transformation as a means of enhancing its quality management practices. By transitioning to a paperless environment, the company has reduced the risk of human error and improved the traceability of quality-related data. Digital tools such as TrackWise and the Electronic Document Management System (EDMS) have been integrated into their operations, providing real-time oversight and enabling quick responses to emerging issues. This digital transformation is reflective of a broader industry trend towards greater efficiency and accuracy in quality management.

Syngene's Learning Management System (LMS) is another digital tool that supports its commitment to quality. The LMS facilitates ongoing employee education, ensuring that staff members stay up-to-date on the latest protocols and best practices. In an industry where regulations are frequently updated, this systematised approach to training is essential for maintaining compliance and fostering a culture of continuous improvement.



## Integrated quality management

In addition to these internal mechanisms, Syngene has implemented Quality Improvement Plans (QIPs) to drive systematic enhancements across its operations. These plans focus on reducing errors, improving efficiency, and ensuring that quality is maintained at every stage of the production process. One initiative, in particular, is the 'right first time' approach, which aims to minimise mistakes in laboratory work. This methodology highlights the importance of precision and accuracy in pharmaceutical and biotechnology operations, where even small errors can have significant consequences.

Another key aspect of Syngene's quality management strategy is the decentralisation of responsibility. The company empowers line leaders to take ownership of quality within their specific areas of operation. This approach ensures that quality is not confined to a single department, but is a shared responsibility across the organisation. By embedding accountability at all levels, Syngene promotes a culture where quality is integral to all processes and decisions.

Syngene's investment in infrastructure has also played a critical role in supporting its quality management efforts. The company has developed state-of-the-art facilities equipped with advanced technology to meet the demands of modern pharmaceutical and biotechnology research and manufacturing.

These investments are not just about compliance; they are about ensuring that the company can handle complex projects and consistently deliver high-quality results. Regulatory approvals are a testament to the effectiveness of Syngene's quality management practices. The company's facilities have been inspected and approved by major global regulatory bodies, including the US FDA, EMA and PMDA. These approvals reflect Syngene's adherence to global standards and its ability to meet the rigorous demands of international regulators. However, maintaining these approvals requires continuous vigilance and adaptation to evolving regulatory requirements.

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While Syngene International's approach to quality management is tailored to its specific operational needs, the underlying principles are broadly applicable across the pharmaceutical and biotechnology industries. The emphasis on continuous improvement, digital transformation and decentralised accountability provides a robust framework for ensuring compliance with global standards. As regulatory expectations rise and the complexity of operations increases, the insights gained from Syngene's experience will be valuable for other organisations looking to enhance their quality management practices.

Quality management is not merely a set of procedures, but a comprehensive strategy that encompasses every aspect of an organisation's operations. It requires a commitment to excellence, a willingness to invest in the necessary infrastructure and technology and an understanding that quality is everyone's responsibility. By fostering a culture of quality, organisations can not only meet regulatory requirements, but also achieve greater efficiency, innovation and competitiveness in a challenging and rapidly-changing industry landscape.



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