WHITE PAPER

# FDA's Quality Management Maturity Program

## Why should CDMOs adhere to the new CDER's Rating System?

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As a Contract Development and Manufacturing Organization (CDMO), at Curia, our primary goal is to produce high-quality pharmaceuticals that meet the needs of our clients and ensure the safety and well-being of the final consumers – patients. To achieve this, it is essential to have an in-depth understanding of the FDA's Quality Management Maturity (QMM) program. The objective of this white paper, is to explore the QMM program and its benefits, including the rating system currently being developed by the FDA's Center for Drug Evaluation and Research (CDER) to incentivize drug manufacturers to achieve QMM. We will also explore the possible challenges that CDMOs will face in achieving high scores and the steps to overcome these challenges, to ensure they deliver high-quality products.

### The FDA's Quality Management Maturity (QMM) Program

The Quality Management Maturity (QMM) program is a comprehensive framework developed by the U.S. Food and Drug Administration (FDA) to assess and improve the quality management systems of drug manufacturers. The QMM program aims to ensure that pharmaceutical products are safe, effective and of high quality for the patients. To achieve this, the program encourages drug manufacturers, including Contract Development and Manufacturing Organizations (CDMOs), to implement robust quality management systems that meet or exceed the FDA's expectations.

Furthermore, the QMM program addresses the critical issue of drug shortages, which can arise due to manufacturing disruptions, quality issues, and supply chain disruptions. When drug shortages occur, patients may face challenges in obtaining the necessary medications to manage their health conditions, potentially

leading to serious complications. By improving the quality and reliability of the patients may face challenges in obtaining the necessary medications to manage their health conditions, potentially leading to serious complications. By improving the quality and reliability of the pharmaceutical supply chain, the QMM program contributes to the prevention of drug shortages, thus safeguarding patients' access to vital treatments.

## The Rating System Proposed by CDER

To incentivize drug manufacturers to achieve QMM at their facilities, the new CDER's rating system program aims to evaluate the maturity of a company's quality management systems across several categories. The rating system will provide a benchmark against which drug manufacturers can measure their own program.

The proposed rating system will be based on a 10-point scale, with higher scores indicating greater compliance with the QMM program's requirements. The FDA plans to use this system to prioritize inspections of drug manufacturers and to provide incentives for them to improve their quality management systems.

According to the proposed program, the FDA will evaluate a company's quality management systems across four categories:

1. Leadership and culture
2. Process and infrastructure
3. Measurement, analysis, and knowledge management
4. Performance and improvement

Each category will be further divided into several subcategories, with each subcategory being assigned a score based on the company's performance. The overall score is then calculated, providing a comprehensive assessment of a company's quality management systems.

## Advantages for CDMOs

By culturing a mature quality management system that meets or exceeds the FDA's expectations, CDMOs can achieve high levels of manufacturing performance, which leads to a robust supply chain, increased customer satisfaction, improved regulatory compliance and reduced errors.

One of the primary advantages of the QMM program for CDMOs is improved efficiency and productivity and avoiding drug shortages. A well-designed quality management system can help CDMOs identify and address quality issues early in the manufacturing process, w1hich can help to prevent costly delays and rework. By proactively identifying and addressing quality issues, CDMOs can improve manufacturing performance through reduced waste and increased utilization.

Another advantage of the QMM program is improved regulatory compliance. While the FDA has always focused on ensuring that drug manufacturers have robust quality management systems in place, this program focuses on the maturity of the systems to prevent quality issues and drug shortages. CDMOs that implement the QMM program and achieve high scores on the FDA's rating system will be better positioned to meet the agency's expectations, which can lead to improved regulatory compliance and fewer regulatory issues.

Finally, investing in the QMM program can help CDMOs to build a reputation for quality and reliability in the pharmaceutical industry. By achieving high scores on the FDA's rating system, consumers will have better knowledge of the manufacturers where their medicines come from, and therefore, CDMOs can differentiate themselves from competitors.

## Challenges in Achieving High Scores in the Rating System

Meeting the new rating system’s criteria can pose challenges for CDMOs, as it necessitates the implementation of new technologies and processes, along with the development of a robust quality culture

across the organization. Some specific challenges that CDMOs may encounter include:

**1.IMPLEMENTING NEW TECHNOLOGIES AND PROCESSES:** To achieve high scores in the rating system, CDMOs must be willing to invest in their quality systems, potentially using new technologies and processes that improve the quality and consistency of their pharmaceutical products. Examples include, investing in new equipment, software, and training programs.

**2.DEVELOPING A QUALITY CULTURE:** A strong quality culture is critical to achieving high scores in the rating system. CDMOs must promote a culture of continuous improvement, where all employees are committed to producing high-quality pharmaceutical products and are willing to identify and address areas for improvement.

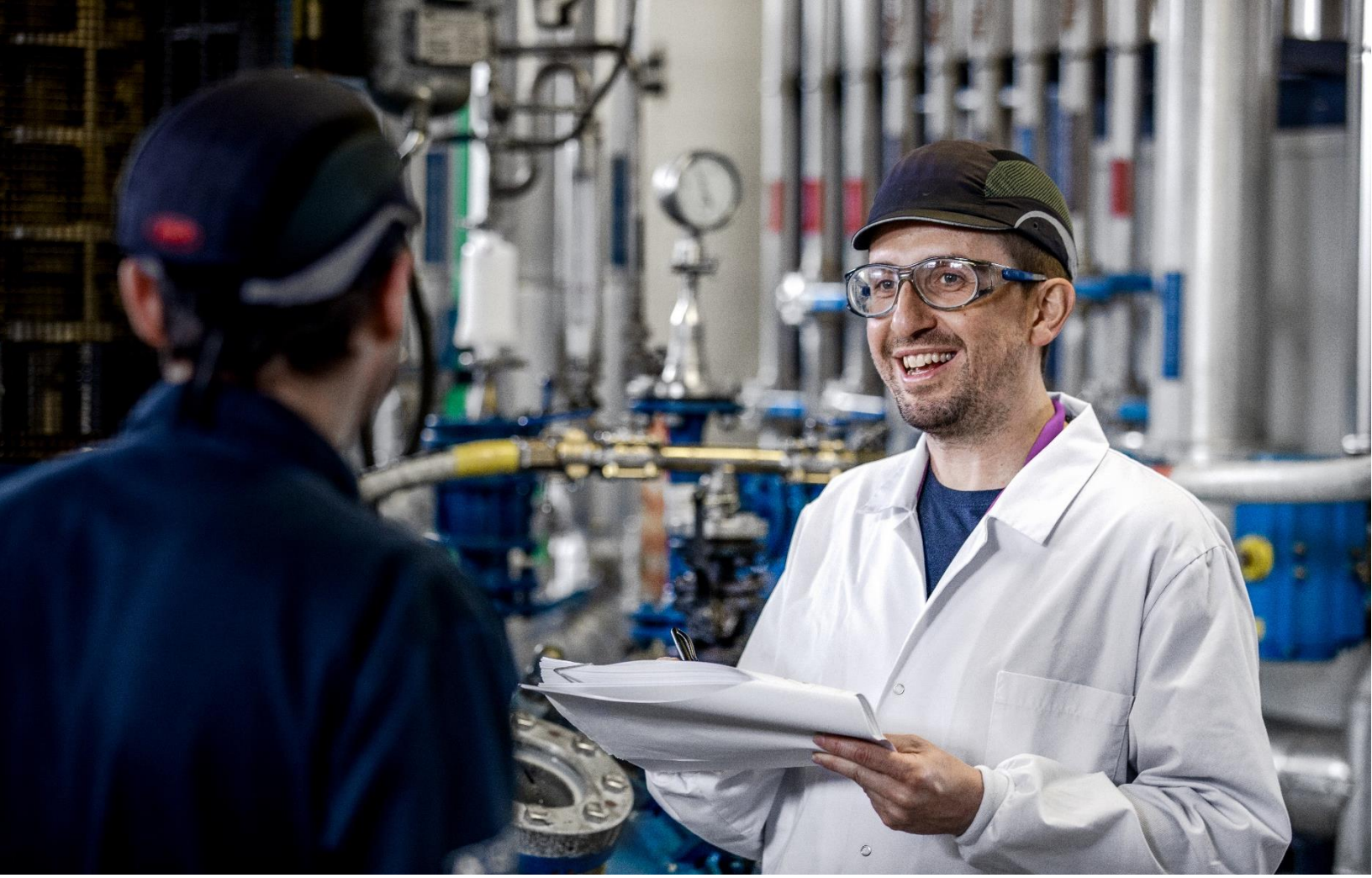
**3.ENSURING COMPLIANCE WITH REGULATORY REQUIREMENTS:** Ensuring compliance with regulatory requirements, including those established by the FDA and other regulatory agencies, is essential for CDMOs to excel in the rating system. This entails conducting regular audits and assessments of their quality management systems to identify areas for improvement.

**4.ENSURING CONSISTENT QUALITY ACROSS MULTIPLE SITES:** CDMOs often have multiple sites across the globe, which makes it challenging to maintain consistency in quality across all locations. This can result in a lower rating score if there is a discrepancy in quality between them.

To overcome this challenge, CDMOs should ensure that all sites follow the same quality standards, procedures, and policies. They can achieve this by implementing a quality management system that is consistent across all sites. Regular audits and inspections can also be conducted to ensure that all sites are adhering to the same standards.

**5.BALANCING THE REQUIREMENTS OF THE RATING SYSTEM WITH CLIENTS' NEEDS:** One of the biggest challenges CDMOs will probably face is the need to balance the requirements of the rating system with the needs of their clients. CDMOs often work with multiple clients, each with their own unique requirements and specifications. Adhering to the new rating system may require CDMOs to make changes to their processes that could impact their ability to meet their clients' needs.

**6.ENSURING CONTINUOUS IMPROVEMENT OF AND INVESTMENT IN QUALITY SYSTEMS:** Leadership at CDMO show involvement in Quality Systems by staying informed through routine management reviews and ensuring that risks are addressed at the correct level. Additionally, leadership should ensure that investments are made into the quality systems that that is commiserate to the risk assessed.



## Steps to Overcome Challenges and Achieve High Scores

To overcome these challenges and achieve high scores in the rating system, CDMOs will be required to take several steps, including:

1. ASSESS CURRENT STATUS OF QUALITY SYSTEMS: While the FDA has not indicated how the data will be compiled, The CDMOs should be prepared to discuss and provide justification for the current status of the quality system.

2. CONDUCT A GAP ANALYSIS: Conducting a gap analysis of the company's current quality management systems and processes can help identify areas that require improvement. This will involve a thorough review of all aspects of the manufacturing process, Including process control, facility and equipment, materials management, and laboratory control.

3. DEVELOP AN IMPLEMENTATION PLAN: Once the gaps have been identified, CDMOs will need to develop and implement a detailed action plan, with specific timelines and measurable goals. This process may involve upgrading equipment, revising standard operating procedures, and improving training programs for employees. It may also involve hiring additional staff or engaging external consultants to provide expertise and guidance.

4. MONITOR AND EVALUATE PROGRESS: CDMOs should monitor and evaluate their progress regularly to ensure that they are on track to meet the rating system's requirements. This can involve conducting internal audits and inspections to identify any areas that need improvement.

5. CONTINUOUSLY IMPROVE: CDMOs should continuously improve their quality management systems to maintain a high rating score. This can involve investing in new technologies, implementing best practices, and staying up-to-date with regulatory changes.

## Conclusion

In conclusion, the FDA's Quality Management Maturity (QMM) program and the rating system proposed by CDER are important initiatives that aim to ensure the quality of pharmaceuticals and prevent drug shortages. By investing in quality management systems, prioritizing investments, and continuously improving processes, CDMOs can achieve a high rating score and meet the requirements of the rating system. Ultimately, these efforts will benefit not only the pharmaceutical industry but also the patients who rely on these medications. Through the implementation of quality management systems and adherence to the rating system, CDMOs can produce high-quality pharmaceutical products that meet the needs and expectations of patients.

At Curia, our core values and operational model align closely with the FDA's Quality Management Maturity (QMM) program and the proposed rating system. Curia operates under global quality processes that prioritize not only inspectional compliance but also proactive improvements throughout our network, utilizing leading indicators for quality performance. Investment in quality improvement is a continuous focus at Curia, encompassing initiatives such as global quality IT system investments, risk-based internal audit programs, preventative maintenance schedules to prevent failures before they occur, and robust CAPA planning and execution. These measures provide increased assurance of compliance, ensure timely and accurate product delivery, and emphasize our commitment to delivering the highest quality pharmaceuticals.

## ABOUT CURIA

Curia is a Contract Development and Manufacturing Organization with over 30 years of experience, an integrated network of 29 global sites and over 3,500 employees partnering with customers to make treatments broadly accessible to patients. Our biologics and small molecule offering spans discovery through commercialization, with integrated regulatory and analytical capabilities. Our scientific and process experts and state-of-the-art facilities deliver best-in-class experience across drug substance and drug product manufacturing. From curiosity to cure, we deliver every step to accelerate and sustain life-changing therapeutics.

*Learn more at curiaglobal.com*

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