

Introduction to Quality Management Maturity (QMM)

Meet the future of pharmaceutical excellence with our "Introduction to Quality Management Maturity (QMM)" course. Uncover the FDA's groundbreaking initiative, learn the 5 critical practice areas, and position yourself to revolutionize quality culture in your organization—be a trailblazer in the evolution of pharmaceutical quality.

In 2024, FDA will be rolling out the initiative Quality Management Maturity (QMM). The purpose of the QMM initiative is to foster a strong quality culture and minimise risks to product availability hereby assuring reliable market supply of medicines.

This course will give you a thorough introduction to the QMM initiative. To begin with you will learn what QMM is and why FDA has decided to roll out this initiative.

You will be introduced to the learnings from the pilot projects being conducted in close collaboration with the pharma industry.

Furthermore, you will be presented for the 5 practice areas that FDA will assess to conclude on the maturity of the manufacturing site:

1. Management Commitment to Quality
2. Business Continuity
3. Advanced Pharmaceutical Quality System
4. Technical Excellence
5. Employee Engagement and Empowerment

At the end we will discuss how you can work with QMM in your own organization and what the benefits will be.

Some of the benefits outlined by FDA are:

- reduced inspection frequency
- increased regulatory flexibility for post approval changes
- improved supply chain oversight

The course language is English.

At the course you will meet:

Erik Steffensen, Managing Partner and Principal Consultant, Spot-on Pharma Consulting

Course facts

FORMAT

1 day

PRICE THIS YEAR

5,350 DKK excl. VAT

Sign-up dates

Hillerød	Hillerød
16. apr. 2024	29. okt. 2024

Do you have questions about this course?

Kontakt

Kursuskoordinator
Andreas Goldschadt
+45 48 20 62 63
ag@pharmakon.dk

Target group

- QA professionals and specialists working with manufacturing of marketed products
- QA managers working with manufacturing of marketed products
- Project managers that will work with implementing QMM.

Your benefits

- You will gain a profound understanding of QMM and why FDA is introducing this initiative
- You will understand the 5 critical practice areas FDA will use to assess the maturity level
- You can implement the work with QMM and quality culture in own organisation.

Your company's benefits

- Employee understands what QMM is and know the timeline for rollout
- Employee can train colleagues in QMM and hereby broaden the QMM knowledge base in own organisation
- Employee can increase regulatory flexibility and improve supply chain oversight, ultimately enhancing the overall operational excellence of the company.

Course agenda

The course covers the following topics, among other:

- What is QMM?
- Why is FDA introducing QMM?
- What were the learnings of the QMM pilot projects in 2020-2022?
- What are the 5 practice areas that will be part of the QMM initiative being rolled out in 2024?
- How can you work with QMM and quality culture in own organisation?

The course will be a combination of interactive lectures and group work.

Sign up online at

www.pharmakon.dk