Version 8 – Updated May 12, 2022

CDER's Quality Management Maturity Program 2022 Public Workshop

For files and resources, please visit
The CDER SBIA Webpage

AGENDA

All times are Eastern (EDT UTC-4)
View day one start time on World Clock - *Add the event to your calendar*

Day One: Tuesday, May 24, 2022
CDER's Quality Management Maturity (QMM) Program

1:00 – 1:05 PM

Welcome & Introduction

Renu Lal, PharmD, BCACP
Lieutenant Commander, United States Public Health Service
Team Lead – Division of Drug Information (DDI)
Deputy Director, SBIA
Division of Drug Information (DDI) | Office of Communications (OCOMM) | Center for Drug Evaluation and Research (CDER)

1:05 – 1:20

Vision of CDER's QMM Program

Michael Kopcha, PhD, RPh
Director
Office of Pharmaceutical Quality (OPQ) | CDER

1:20 – 1:35

Drug Shortages: Background and Enduring Solutions

Valerie Jensen, CAPT (Ret.), RPh
Director
Drug Shortage Staff (DSS)
Office of the Center Director (OCD) | CDER

1:35 – 2:00

QMM, Quality Metrics, and ICH Q12: Do They Complement Each Other?

Ashley Boam
Director
Office of Policy for Pharmaceutical Quality (OPPQ)
OPQ | CDER

Day One: Tuesday, May 24, 2022
CDER's Quality Management Maturity (QMM) Program

2:00 – 2:25

Panel Discussion – Q&A

Moderator:
Adam Fisher, PhD
Acting Associate Director of Science and Outreach
OPQ | CDER

Valerie Jensen, Ashley Boam

2:25 – 2:40: BREAK

2:40 – 3:05

QMM Pilots: CDER's Lessons Learned

Jennifer Maguire, PhD
Director
Office of Quality Surveillance (OQS)
OPQ | CDER

3:05 – 3:20

QMM Domestic Pilot: Participant Perspective

Nelson Webb
Director
Corporate Quality Assurance
Proctor & Gamble

3:20 – 3:35

QMM Foreign Pilot: Participant Perspective

Nuno Matos
Corporate Quality Director
Quality Systems Management
Hovione

3:35 – 3:55

Panel Discussion – Q&A

Moderator:
Lyle Canida, Pharm.D.
Acting Associate Director of Science and Outreach
Regulatory Operations Officer | OPQ | CDER

Jennifer Maguire, Nelson Webb, Nuno Matos

3:55 – 4:00

Day One Closing

4:00 PM: Day One Concludes

All times shown are Eastern (EDT UTC-4)

Day Two: Wednesday, May 25, 2022

Development and Impact of Quality Ratings Systems

1:00 – 1:05 PM

Welcome & Introduction

Renu Lal, PharmD, BCACP
Lieutenant Commander, United States Public Health Service
Team Lead – Division of Drug Information (DDI)
Deputy Director, SBIA
Division of Drug Information (DDI) | Office of Communications (OCOMM) | Center for Drug Evaluation and Research (CDER)

1:05 – 1:30

CDRH's Case for Quality

Ron Lear
Director & Chief Architect
IP Development & CMMI Products and Services
CMMI

Kim Kaplan
Senior Product Manager
ISACA

1:30 – 1:45

The Impact of Quality Ratings Systems: Lessons from other Industries

Clifford Rossi, PhD
Executive-in-Residence, Professor of the Practice
Robert H. Smith School of Business
University of Maryland

1:45 – 2:00

An Economic and Risk Analysis of Quality Ratings and Their Effect on Pharmaceutical Product Market Structure

Clifford Rossi

2:00 – 2:30

Panel Discussion – Q&A

Moderator:
Neil Stiber, PhD
Associate Director for Science and Communication
OQS | OPQ | CDER

Ron Lear, Kim Kaplan, Clifford Rossi, Jennifer Maguire and

Francisco (Cisco) Vicenty
Program Manager, Case for Quality
Office of Product Evaluation and Quality
Compliance and Quality Staff
Center for Devices and Radiological Health | FDA

2:30 – 2:45: BREAK

All times shown are Eastern (EDT UTC-4)

Day Two: Wednesday, May 25, 2022

Development and Impact of Quality Ratings Systems

2:45 – 3:05

How QMM Ratings Could Inform Drug Purchasing Organizations

Dan Kistner
Group Senior Vice President
Pharmacy Solutions
Vizient

3:05 – 3:25

Increasing Resilience of the Drug Supply Chain

Erin R. Fox, PharmD, BCPS
Senior Pharmacy Director
University of Utah Health

3:25 – 3:55

Panel Discussion – Q&A

Moderator:
Kristin Phucas
Associate Director for Communication
Office of Policy for Pharmaceutical Quality (OPPQ) | OPQ | CDER

Dan Kistner, Erin Fox, Ashley Boam, and **Adam Fisher**
OPQ | CDER

3:55 – 4:00

Workshop Closing

Michael Kopcha, PhD, RPh
Director
Office of Pharmaceutical Quality (OPQ) | CDER

4:00 PM: Workshop Concludes

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