



Version 3 – Updated April 1, 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

Forest "Ray" Ford, Jr., PharmD

CAPT, USPHS, Pharmacist

CDER Small Business and Industry Assistance (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

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

Jennifer Maguire, Nelson Webb, Nuno Matos

3:55 – 4:00

Day One Closing

4:00 PM: Day One Concludes

Day Two: Wednesday, May 25, 2022

Development and Impact of Quality Ratings Systems

1:00 – 1:05 PM

Welcome & Introduction

Forest "Ray" Ford, Jr., PharmD

CAPT, USPHS, Pharmacist

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1:05 – 1:30

CDRH's Case for Quality

Ron Lear

Director & Chief Architect

IP Development & CMMI Products and Services
CMMI

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

Ron Lear, Clifford Rossi, Jennifer Maguire

2:30 – 2:45: BREAK

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 Fox

Senior Director
Quality Assurance External Engagement
Proctor & Gamble

3:25 – 3:55

Panel Discussion – Q&A

Dan Kistner, Erin Fox, Ashley Boam, and

Adam Fisher

OPQ | CDER

3:35 – 3:55

Workshop Closing

4:00 PM: Workshop Concludes