



Version 5 – Updated April 21, 2022

# CDER's Quality Management Maturity Program 2022 Public Workshop

For files and resources, please visit  
[The CDER SBIA Webpage](https://www.fda.gov/CDERSBIAWebinars)

## 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*

*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 – 1:30

**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 R. Fox, PharmD, BCPS**

*Senior Pharmacy Director*  
University of Utah Health

3:25 – 3:55

### Panel Discussion – Q&A

**Dan Kistner, Erin Fox, Ashley Boam, and**

**Adam Fisher**

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3:55 – 4:00

### Workshop Closing

**4:00 PM: Workshop Concludes**