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) | 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
# Day Two: Wednesday, May 25, 2022

## Development and Impact of Quality Ratings Systems

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<th>Session</th>
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<td>1:00 – 1:05 PM</td>
<td>Welcome &amp; Introduction</td>
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<td>Renu Lal, PharmD, BCACP</td>
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<td>1:05 – 1:30</td>
<td>CDRH’s Case for Quality</td>
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<td>Ron Lear</td>
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<td>Director &amp; Chief Architect</td>
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<td>IP Development &amp; CMMI Products and Services</td>
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<td>Kim Kaplan</td>
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<td>Senior Product Manager</td>
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<td>1:30 – 1:45</td>
<td>The Impact of Quality Ratings Systems: Lessons from other Industries</td>
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<td>Clifford Rossi, PhD</td>
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<td>Executive-in-Residence, Professor of the Practice</td>
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<td>Robert H. Smith School of Business</td>
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<td>University of Maryland</td>
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<td>1:45 – 2:00</td>
<td>An Economic and Risk Analysis of Quality Ratings and Their Effect on Pharmaceutical Product Market Structure</td>
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<td>Clifford Rossi</td>
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<td>2:00 – 2:30</td>
<td>Panel Discussion – Q&amp;A</td>
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<td>Moderator: Neil Stiber, PhD</td>
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<td>Associate Director for Science and Communication</td>
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<td>BREAK</td>
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<td>Ron Lear, Kim Kaplan, Clifford Rossi, Jennifer Maguire and Francisco (Cisco) Vicenty</td>
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<td>Center for Devices and Radiological Health</td>
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</table>
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