
Version 11 – Updated April 11, 2020

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# AGENDA

All times are Eastern (EDT UTC-4)

## Wednesday, April 15, 2020

**8:00 - 8:15: Administrative Announcements** — **Jeff Kelly**

8:15 - 8:30

### Welcome

**Brenda Stodart**
CAPT, USPHS
*Director,* Small Business and Industry Assistance (SBIA)
Division of Drug Information (DDI) | Office of Communications (OCOMM) | CDER

8:30 - 8:50

### Keynote from Office of Generic Drugs (OGD)

**Sally Choe**
*Director*
Office of Generic Drugs (OGD)

8:50 - 9:10

### Keynote from the Office of Pharmaceutical Quality (OPQ)

**Michael Kopcha**
*Director*
Office of Pharmaceutical Quality (OPQ)

## Wednesday, April 15, 2020

9:10 - 9:50

### Product Specific Guidances (PSGs)

This session will provide information on product-specific guidances (PSGs), which identify the methodology for developing generic drugs and generating the evidence needed to support generic approval. It offers an overview on the issuance of PSGs and resources such as the upcoming PSGs for complex generic drug product development webpage.

**Dave Coppersmith**
*Regulatory Counsel*
Office of Generic Drug Policy (OGDP) | OGD

**Myong-Jin Kim**
*Deputy Director*
Division of Quantitative Methods and Modeling (DQMM)
Office of Research and Standards (ORS)
OGD

9:50 - 10:30

### Generic Drug Labeling: Recommendations for High-Quality Submissions

The purpose of the presentation is to provide an overview of the labeling review process and supply recommendations and guidance for ensuring high-quality labeling submissions.
The presentation will also provide strategies to reduce the number of review cycles and share responses to most frequently asked labeling-related questions by industry.

**Rachel Goehe**
*Director*
Division of Labeling Review (DLR)
Office of Regulatory Operations (ORO)
OGD

**Katherine Won**
*CDR* | USPHS
*Deputy Director*
DLR | ORO | OGD

**10:30 - 10:45: BREAK**

10:45 - 11:30

### New Programs and Requirements Under FDARA

**Competitive Generic Therapies (CGT)**
The FDA Reauthorization Act of 2017 created a new pathway by which FDA may, at the request of the applicant, designate a drug with “inadequate generic competition” as a competitive generic therapy (CGT). This presentation will provide an overview of the process that applicants should follow to request designation of a drug as a CGT and the criteria for designating a drug as a CGT. It will also provide information on how FDA implements the statutory provision for a 180-day exclusivity period for certain first approved applicants that submit ANDAs for CGTs.

**Jonathan Hughes**
*Regulatory Counsel*
OGDP | OGD

**Rinku Patel**
LCDR | USPHS
*Acting Team Leader*
Patent and Exclusivity Team
Division of Legal and Regulatory Support (DLRS)
OGDP | OGD

**Post-Approval Notice Requirements**
This session will provide an overview of the marketing status notification requirements for drugs not available for sale within 180 calendar days of approval.

**Andrew Coogan**
LCDR, USPHS
*Regulatory Review Officer*
DLRS |OGDP |OGD

**11:30 - 12:30 PM: LUNCH BREAK**

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## Wednesday, April 15, 2020

12:30 - 1:10 PM

### Pre-ANDA Interactions with the FDA

How to interact with FDA prior to submission on complex products, suggestions and best practices.

**Kris Andre**
*Associate Director for Regulatory Affairs*
ORS | OGD | CDER

1:10 - 2:15

### How to meet FDA's Requirement for Electronic Submission of an ANDA Application and Study Data

**Electronic Submissions Update**
This highly useful presentation covers a wide range of electronic submission topics, including recent updates to the eCTD guidance, how to submit electronically, and address eCTD validations that can result in a technical rejection if study data is not submitted in conformance with the eCTD and Study Data guidance. We will cover frequent questions to the eSub Team, when to use CDER's Next Gen Portal, and CDER's progress to further automate the inbound process to put your submission in the hands of the review office quicker.

**Jonathan Resnick**
Cloud Collaboration Capability Team
Division of Data Management Services and Solutions (DDMSS)
Office of Business Informatics (OBI)
Office of Strategic Programs (OSP) | CDER

**Study Data Technical Rejection Criteria**
Study Data Standards listed in the FDA Data Standards Catalog are required for clinical and nonclinical studies that started after December 17, 2016 (for ANDA, NDA and BLA) or December 17, 2017 (for Commercial IND). Based on the Technical Rejection Criteria for Study Data (TRC) conformance analysis conducted by FDA on submissions that contain study data received by the Agency, FDA updated TRC to provide more clarification. FDA also developed supporting tools to help Industry meet study data requirements, including the Study Data Self-Check Worksheet. These efforts are expected to improve conformance rates over time by making it clearer and easier for Industry to meet FDA's study data requirements.

**Heather Crandall**
Cloud Collaboration Capability Team
DDMSS | OBI | OSP

**2:15 - 2:30: BREAK**

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## Wednesday, April 15, 2020

2:30 - 3:10 PM

### ANDA Program Performance Review and Tips

The goal of this session is to show how the ANDA program is doing. There will be updates from pre-ANDA activities to post-approval changes and explanations of program milestones. Interwoven with the statistical review will be tips for applicants

**Ted Sherwood**
*Director*
ORO | OGD

3:10 - 4:40

### Application Case Studies on FDA's Action Letter Timing

The goal of this session is to provide insight into how ANDAs are managed through the evaluation of real situations encountered by the ANDA Program. There will be discussion of the impact of amendments and their timing, the factors that the FDA team considers in making decisions, and lessons learned.

**Ted Sherwood**
*Director*
ORO | OGD

Case Study Presenters:

**Gwendolyn Murphy**

**Dara Nardini**

**Sarah Nguyen**

**Warren Simmons**

**Parth Soni**

**Dustin Derosales**

**4:40: ADJOURN**

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## Thursday, April 16, 2020

**8:10 - 8:20: Administrative Announcements** — **Jeff Kelly**

8:20 - 8:30

### Welcome

**Forest "Ray" Ford, Jr.**
*CAPT* | USPHS
DDI | OCOMM

8:30 - 9:30

### The Importance of Generic Drug Pharmacovigilance

In this session, the Office of Generic Drugs' Clinical Safety Surveillance Staff will describe clinical aspects of premarket safety review; demonstrate data elements and examples of postmarketing generic drug pharmacovigilance; and illustrate cross-Agency collaborative activities that support postmarketing safety surveillance for generic drugs.

**Linda Forsyth**
*Medical Officer*
CSSS | OGD

**Edward Kim**
*Epidemiologist*
CSSS | OGD

**Debbie Catterson**
*Lead Clinical Safety Coordinator*
CSSS | OGD

9:30 - 10:30

### Current Global Generic Drug Landscape

The ICH was founded in 1990 with a mission to achieve greater harmonization worldwide to ensure that safe, effective, and high-quality medicines are developed and registered in the most resource-efficient manner. Harmonization is achieved through the development of ICH Guidelines via a process of scientific consensus with regulatory and industry experts. This session will provide an introduction to the ICH Association as well as an understanding of how ICH's efforts help facilitate global marketing of pharmaceuticals and increased patient access to medicines. Session presentations include:

- Harmonizing Regulatory Science through the International Council for Harmonization (ICH)
- Value of Scientific Harmonization
- FDA Foreign Offices and their Impact on Improving the quality of Generic Drugs
- The State of Pharma Quality for Generics

Moderator: **Iilun C. Murphy**
*Deputy Director*
Clinical and Regulatory Affairs | OGD

**Amanda Roache**
*Operations Research Analyst*
Office of the Center Director (OCD) | CDER

**Lei Zhang**
*Deputy Director*
ORS | OGD

**Mark Abdoo**
*Associate Commissioner*
Global Policy & Strategy

**Raphael Brykman**
*Consumer Safety Officer*

**10:30 - 10:45: BREAK**

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## Thursday, April 16, 2020

10:45 - 11:25 AM

### ICH Q12 Guidance and Emerging Technology Program

**ICH Q12 as it Applies to Generic Drugs**
This is an overview of ICHQ12. This talk will cover aspects of the Guidance that Generic Drug applicants can use effectively. The presentation will provide the generics industry with an overview of this recently finalized guideline and how it applies to ANDA products

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

**Fostering Innovation through Collaboration**
The presentation will discuss how emerging technologies in pharmaceutical development and manufacturing can deliver benefits to both patients and industry. It will also explain the collaborative approach of CDER's Emerging Technology Program and demonstrate how it is supporting the adoption of novel technology utilizing case studies. Finally, the presentation will conclude with sharing opportunities to collaborate with the CDER to advance the scientific understanding of how emerging technologies impact pharmaceutical quality

**Thomas O'Connor**
*Chemist*
Division of Product Quality Research (DPQR)
Office of Testing and Research (OTR)
OPQ

**11:25 - 12:25 PM: LUNCH BREAK**

12:25 - 1:05

### Common CMC (Quality) Issues and How to Avoid Them, Part One

**Common Drug Product Quality Issues and How to Mitigate or Avoid Them**
The objective of this presentation is to discuss and provide guidance in addressing most common quality issues to enhance the ANDA quality data submission, with the intended goal to reduce the overall ANDA approval time. The primary focus of the presentation would be on the ANDA applications related to Solid Oral Drug Products (SODP). The presentation will identify the most common areas of quality gaps in the ANDA submission and then briefly go over the possible resolution of these quality issue by highlighting the use of publicly available MAPPs, guidances and compendia where applicable.

**Simin Hassannejad Tabasi**
*Product Quality Assessor*
Division of Modified and Immediate Release Products 1
OPQ

**Common CMC Issues for Manufacturing Process and Facility Reviews**
OPQ's Office of Pharmaceutical Manufacturing Assessment (OPMA), performs a holistic evaluation of pharmaceutical manufacturing by integrating the assessment of the manufacturing process, facilities, and pre-approval inspection. OPMA's integration of these activities ensures that quality is built into the manufacturing process and facility over the product's life cycle. This presentation will discuss the key elements of process and facility review, commonly seen deficiencies for various dosage forms and considerations for information to be included in the submission.

**Pei-I Chu**
*Branch Chief*
Division of Pharmaceutical Manufacturing
Office of Pharmaceutical Manufacturing Assessment (OPMA)
OPQ

## Thursday, April 16, 2020

1:05 - 1:45 PM

### Common CMC (Quality) Issues and How to Avoid Them, Part Two

**Emerging Topics and Trends in Recent Inspections and How They Can Affect Application Approval**
This is a presentation of inspectional findings, utilizing text analytics tools, on emerging topics and most frequently cited 483 observations and citations to CFRs. The presentation will discuss ways to identify potential risk areas within your application supply chain prior to it becoming an issue of approvability of the application.

**Tsedenia Woldehanna**
*Consumer Safety Officer*
Office of Pharmaceutical Surveillance (OPS
OPQ

**Facility Submission Expectations in View of the 356H Form**
The talk will discuss the agency's expectation of information that needs to be provided in the 356 H form in order to avoid errors and to prevent delay of approval of applications.

**Rose Xu**
*Quality Assessment Lead (Acting)*
Division of Pharmaceutical Manufacturing IV
OPMA | OPQ

**1:45 - 2:00: BREAK**

2:00 - 2:40

### Generic Combination Products

**Combination Product Assessment for ANDAs**
The purpose of combination product assessment for an ANDA is to ensure that the generic form is therapeutically equivalent to its reference listed drug (RLD) – that is - the generic combination product produces the same clinical effect and safety profile as the RLD under the conditions specified in the product labeling and can be freely substituted for its RLD. It is our intent that this presentation will enhance transparency in the regulatory process and help applicants understand FDA's general expectations while preparing Quality related sections of ANDA submission for combination products.

**Ashish Rastogi**
*Quality Assessment Lead (Acting)*
Branch III
Division of Liquid Based Products – 1
Office of Lifecycle Drug Products (OLDP)
OPQ

**Regulatory Update on Generic Combination Products**
At the conclusion of this session, participants will have an increased awareness of the dynamic global regulatory environment and key challenges the Agency and the industry together encounter. Participants will also benefit from the sharing of best-practices and lessons learned regarding combination product CGMP and PMSR requirements

**Steven Hertz**
*Consumer Safety Officer*
Division of Pharmaceutical Manufacturing IV
OPMA | OPQ

## Thursday, April 16, 2020

2:40 – 3:20 PM

### Facility Readiness and Related Issues

**Applying GMPs to the Quality Assessment of the Applications**
This presentation will provide seamless integration of review, inspection, surveillance and research across the product lifecycle. The commercial manufacturing process can consistently produce a quality product over lifecycle.

**Aditi Thakur**
*Chemist*
*Product Quality Assessor*
Division of Pharmaceutical Manufacturing III
OPMA | OPQ

**Compliance Trends and Guidance while Engaging Manufacturers**
The talk will provide information on enforcement trends. It will highlight Issues to consider when selecting manufacturers to avoid surprises.
The talk will emphasize the importance of selecting the right manufacturers who can perform good process validation/development work and who use Quality risk management tools and quality agreements to effectively manage and enable changes as they occur.

**Tara Gooen Bizjak**
*Regulatory Officer*
*CDR* | USPHS
Office of Manufacturing Quality (OMQ)
Office of Compliance (OC)

3:20 – 3:25

### Closing Remarks

**Brenda Stodart**

**3:25 PM: ADJOURN**

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