Regulatory Education for Industry (REdI)

Pharmaceutical Quality Symposium 2016

DoubleTree
Silver Spring, MD
July 20 & 21, 2016

FDA

Pharmaceutical Quality Symposium Agenda

WEDNESDAY, JULY 20

7:30am — **Registration Opens**

8:50 - 9:00am — **Welcome**

Forum Welcome and opening remarks.

Brenda Stodart, PharmD
Captain, United States Public Health Service
Program Director
CDER Small Business and Industry Assistance (CDER SBIA)
Division of Drug Information (DDI)
Office of Communications (OCOMM)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

9:00 - 9:30am — **KEYNOTE**

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

9:30 - 9:50am — **Introduction to the Office of Process and Facilities (OPF)**

The Office of Process & Facilities (OPF) is one of the eight sub-offices in the Office of Pharmaceutical Quality (OPQ). OPF's roles and responsibilities span assessment of manufacturing processes and facilities for BLAs, ANDAs, and NDAs; management of the pre-approval inspection program for new applications and supplemental applications and assessment of microbial controls and sterility assurance aspects of regulatory submissions. This presentation provides a high level overview of the structure, function and vision of OPF.

Robert Iser, MS
Acting Director
Office of Process and Facilities (OPF)
OPQ | CDER | FDA

9:50 - 10:10am — **Current Thinking on Microbiological Controls for Nonsterile Drug Products**

Nonsterile drug products have important considerations for microbiological control during all steps of the manufacturing process. This talk will outline the relative microbiological risks of different nonsterile dosage forms, and will outline FDA's thinking on considerations for nonsterile product development, critical manufacturing controls, and finished product testing strategies.

Erika A. Pfeiler, PhD
Microbiologist & Acting Quality Assessment Lead
Division of Microbiology Assessment
OPF | OPQ | CDER | FDA

10:10 - 10:25am — **BREAK**

10:25 - 10:45am — **Aseptic Processing of Biological Products: Current Regulatory Issues**

This presentation will discuss the microbiology quality assessment of Biologic License Application drug product section. Common deficiencies seen in BLA submissions will be included in the discussion.

Candace Gomez-Broughton, PhD
Microbiologist
Division of Microbiology Assessment
OPF | OPQ | CDER | FDA

10:45 - 11:15am — **Microbiological Assessment Considerations Panel – Question and Answers**

Robert Iser, MS
Erika A. Pfeiler, PhD
Candace Gomez-Broughton, PhD

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11:15 - 11:35am

Recommendations for Manufacturing Process Information in Prescription Drug Applications

Patients expect their medicines to be quality products that are readily available when needed. Robust and well-controlled manufacturing processes in accordance with the principles of ICH Q8, Q9 and Q10 help achieve these expectations. This presentation will address the expected level of information for the Agency to assess whether or not the product meets its quality attributes consistently and is "manufactureable" over product lifecycle. It will focus on leveraging product and process knowledge through process development activities to support the operation of the commercial process.

Akm Khairuzzaman, PhD
Branch Chief (Acting)
Branch I, Division I,
OPF | OPQ | CDER | FDA

11:35 - 11:55am

Manufacturing Process: Common Deficiencies and Recommendations for Information Request Responses

The goal of the CMC review of ANDAs is to ensure that the generic product is pharmaceutical equivalent to the reference listed drug (RLD) and that sponsors have adequate methods and controls in place for the manufacture, processing, and packaging of a drug. This presentation will include a discussion of some commonly seen deficiencies related to manufacturing process development and scale up of solid oral dosage forms that would be presented in the context of FDA's expectation for process related information to be provided in an ANDA submission.

Ubrani Venkataram, PhD
Branch Chief (Acting)
Division of Process Assessment II
OPF | OPQ | CDER | FDA

11:55 - 1:10pm

Networking Lunch at the Savor Restaurant (Guest Pays for Own Food & Beverage)

1:10 - 1:30pm

Manufacturing Process Considerations for Immediate & Modified Release Products

This talk will provide an overview of common manufacturing processes and risk assessment and mitigation strategies for oral immediate release (IR) and modified release (MR) products.

Rakhi B. Shah, MS, PhD
Quality Assessment Lead (Acting)
Division of Process Assessment-I
OPF | OPQ | CDER | FDA

1:30 - 1:50pm

Manufacturing Process Considerations for Lyophilized Products

The aim of this presentation is to discuss the current regulatory understanding and considerations in the field of pharmaceutical lyophilization. Every year the agency receives numerous new and abbreviated drug applications employing the lyophilization process. These applications vary in length of discussion on lyophilization process development. It is critical that the process development of lyophilized products is well thought through by keeping the product life cycle in mind.

Kumar Janoria, PhD
Chemist
Division of Process Assessment – III
Branch VII
OPF | OPQ | CDER | FDA

1:50 - 2:20pm

Manufacturing Process Assessment Considerations Panel

Akm Khairuzzaman, PhD
Ubrani Venkataram, PhD
Rakhi B. Shah, MS, PhD

2:20 - 2:35pm

BREAK

2:35 – 2:55pm

Current Submissions Expectations for Facility Information

The presentation will discuss the Agency's current expectations for facility information needed to perform a facility review to support a drug application. The goals of the facility review and a general overview of the considerations for a risk-based quality assessment will be provided. Framing submission expectations to be aligned with statutory and regulatory requirements, an overview of commonly seen deficiencies that may impact the facility review will be presented.

Quallyna Porte, MBA
Quality Assessment Lead (Acting)
Division of Inspectional Assessment
OPF | OPQ | CDER | FDA

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2:55 - 3:15pm	**Lifecycle Facility Assessment** This presentation will discuss the goals of a Pre-Approval Inspection as well as guiding principles for the Pharmaceutical Quality System to ensure continual improvement over the lifecycle of the product. **Christina Capacci-Daniel, PhD** *Quality Assessment Lead (Acting), Division of Inspectional Assessment, OPF | OPQ | CDER | FDA* 
3:15 - 3:45pm	**Facility Assessment Considerations Panel** Q&A **Kumar Janoria, PhD** **Quallyna Porte, MBA** **Christina Capacci-Daniel, PhD**
3:45pm	**DAY 1 ADJOURNMENT**
3:45 - 7:00pm	**Networking Opportunity: NETWORKING OPPORTUNITY IN THE SAVOR LOUNGE**

The Savor lounge offers a comfortable atmosphere to network with peers. Please come and enjoy!

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THURSDAY, JULY 21

7:30am — **Registration Opens – Pinnacle Grand Ballroom**

8:50 - 9:00am — **Welcome**

Welcome and overview of CDER SBIA

Brenda Stodart, PharmD
Captain, United States Public Health Service
Program Director
CDER Small Business and Industry Assistance (CDER SBIA)
DDI | OCOMM | CDER | FDA

9:00 – 9:30am — **Points to Consider for the CMC Review of Therapeutic Biologics**

Topics will focus on the general distinction between biologics and small molecule therapeutics. An overview of the types of products reviewed by the Office of Biotechnology Products (OBP) will be discussed along with the analytical methods used to characterize biologics. Finally, the presentation will focus on aspects of the CMC review and points to consider when submitting early Phase 1 IND applications.

Willie Wilson III, PhD
Chemist
Division of Biotechnology Research and Review I
Office of Biotechnology Products (OBP)
OPQ | CDER | FDA

9:30 - 9:50am — **Analytical Procedures and Method Validation**

Lucinda Buhse will give the FDA perspective on method validation and the importance of developing robust methods suitable for their intended use. Additionally, she will discuss the new FDA Guidance on Analytical Procedures and Methods Validation and give examples of frequent deficiencies found during FDA laboratory method verification.

Lucinda (Cindy) Buhse, PhD
Director
Office of Testing and Research (OTR)
OPQ | CDER | FDA

9:50 - 10:10am — **Hot Topics – Drug Substance Review in CDER**

This presentation will provide an introduction to the Office of New Drug Products (ONDP), cover drug substance operational updates and review initiatives. We will also discuss what you need to know about starting material selection.

M. Scott Furness, PhD
Deputy Director
Office of New Drug Products (ONDP)
OPQ | CDER | FDA

10:10 - 10:25am — **BREAK**

10:25 - 10:45am — **Evolving Regulatory Landscape for Emerging Technology: Continuous Manufacturing**

Office of Pharmaceutical Quality (OPQ) supports modernization of pharmaceutical development and manufacturing. Therefore, OPQ encourages the adoption emerging pharmaceutical technology that has potential to enhance the process capability and therefore product quality. Because emerging technologies, by definition, will generally be unfamiliar, in both industrial and regulatory contexts, OPQ established the Emerging Technology Team (ETT) to facilitate the identification and implementation of emerging technology. Regulatory considerations of continuous manufacturing will be highlighted to illustrate FDA progress in the emerging technology area.

Sau (Larry) Lee, PhD
Associate Director for Science
Team Leader for Botanical Review Team
Chair for OPQ Emerging Technology Team
Immediate Office
OPQ | CDER | FDA

10:45 - 11:15am — **Panel Discussion**

Q&A

Willie Wilson III, PhD
Lucinda (Cindy) Buhse, PhD
M. Scott Furness, PhD
Sau (Larry) Lee, PhD

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11:15 - 11:35am

Complex Drug Substances

The presentation will cover issues regarding review of CMC portions of complex drug substances in ANDAs.

Kshitij A. Patkar, PhD
Review Chemist
Division of Process Assessment – III
OPF | OPQ | CDER | FDA

Risk-Based CMC Review/Quality Informatics in Knowledge Management

Office of Pharmaceutical Quality (OPQ) has implemented risk-based review approaches to enhance the efficiency and effectiveness of the quality assessment of Abbreviated New Drug Application (ANDAs). This approach was later extended to New Drug Applications (NDAs). Failure Modes, Effects and Criticality Analysis (FMECA) risk algorithms are currently used as a tool to prospectively identify low, medium and high quality risk areas to better allocate review efforts, commensurate with inherent product failure risks associated with critical quality attributes. To complement this initial risk assessment, approaches to effectively capture risk mitigation using structured knowledge descriptors of formulation design, process design, and measurement control strategy are under development. The integration of initial risk assessment based upon inherent risks, with structured knowledge descriptors to capture risk mitigation, shows promise in effectively capturing drug product risks across OPQ's repertoire of approved drug products.

Andre Raw, PhD
Acting Senior Science and Policy Advisor
Office of Lifecycle Drug Products (OLDP)
OPQ | CDER | FDA

11:55 - 1:10pm **Networking Lunch at the Savor Restaurant** **(Guest Pays for Own Food & Beverage)**

1:10 - 1:30pm

Application of process capability in pharmaceutical manufacturing

This presentation will define process capability and performance, discuss the role of statistical process control, and then finally examine a few case studies of process capability applications.

Alex Viehmann
Branch Chief (Acting)
Quality Intelligence Branch
Office of Surveillance (OS)
OPQ | CDER | FDA

1:30 - 1:50pm

Panel Discussion

Kshitij A. Patkar, PhD
Andre Raw, PhD
Alex Viehmann

1:50 - 2:20pm

Post-Approval Change Management with sANDA Examples and Case Studies

The presentation will focus on post-approval changes and risk-based reporting categories. Use of appropriate regulations and guidances will be discussed in this context. Following an overview of the supplement review process for generic drugs, examples and case studies relating to Abbreviated New Drug Application supplements (sANDAs) will be discussed, in addition to commonly observed deficiencies and how to avoid them.

Niles Ron, PhD, MBA
Branch Chief (Acting)
Division of Post-Marketing Activities-II,
Office of Lifecycle Drug Products (OLDP)
OPQ | CDER | FDA

2:20 - 2:35pm **BREAK**

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2:35 - 2:55pm

Biopharmaceutics Review – Current Practices and Expectations

The Division of Biopharmaceutics (DBP) is a fairly new division under ONDP/OPQ which serves both the new drug and the generic drug development review process. This presentation will describe the current structure of DBP and what aspects of the submissions are reviewed by DBP. It will also describe what is expected in the submissions both at the pre- and post-approval levels to reduce the time for approval from biopharmaceutics perspective.

Tapash Ghosh, PhD
Branch Chief (Acting)
Division of Biopharmaceutics
Office of New Drug Products (ONDP)
OPQ | CDER | FDA

2:55 - 3:15pm

Practical Implementation of ICH Q3D: Guideline on Elemental Impurities

ICH Q3D currently applies to new drug applications in ICH regions, and is expected to apply to existing marketed products in the US in January of 2018. This presentation will provide an overview of ICH Q3D, with an emphasis on product risk assessment and control of elemental impurities. It will highlight some training material that has been made available on the ICH Website, and will discuss some additional considerations for implementation.

John Kauffman, PhD
Division of Pharmaceutical Analysis (DPA)
Office of Testing and Research (OTR)
OPQ | CDER | FDA

3:15 - 3:45pm

Proper CMC Submission-ANDA and Content of CMC Section

Topics include - Introduction, Submission Quality, Regional Administrative Information, and Document Summaries

Nashed Samaan, PhD
Senior Chemist Reviewer
Division of Immediate Release Products II
OLDP | OPQ | CDER | FDA

3:45 - 4:05pm

Panel Discussion

Q&A

Niles Ron, PhD, MBA
John Kaufman, PhD
Tapash Ghosh, PhD
Nashed Samaan, PhD

4:05pm

SYMPOSIUM ADJOURNMENT