Public Meeting on Standardized Data for Pharmaceutical Quality/Chemistry Manufacturing and Control (PQ/CMC)

October 19, 2018
Great Rooms B & C
Food and Drug Administration

Eventbrite Registration website: [PQ/CMC Public Meeting]

Online Webinar and Call-in information:

Adobe Connect Web and Audio: https://collaboration.fda.gov/pqcmc/
Alternate Dial-up for audio: 301-796-7777, meeting ID #665129

Web Attendees will be in listen-only mode. Questions entered via Adobe Connect.

Agenda

8:00-9:00am **Registration**

9:00-9:10 am **Welcome and Opening Remarks**

Bryan Spells
Operations Research Analyst
Office of Strategic Programs (OSP),
Center for Drug Evaluation and Research (CDER),
U.S. Food and Drug Administration (FDA)

9:10-11:00am **Session 1: PQ/CMC Standardization activities at FDA**

This session will focus on the activities to date for creation of a standardized representation of the PQ/CMC data elements and associated vocabularies. Furthermore, FDA will present an in-depth discussion of the range of activities stimulated by industry input including revisions to the PQ/CMC draft standard and various efforts at harmonization with other related standardization initiatives. Following these talks will be and end-of-session question and answer panel with FDA panelists. **Please hold questions until the end-of-session panel.**

Background and Overview of PQ/CMC Standardization Activities

Mary Ann Slack
Director
Office of Strategic Programs (OSP)
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration (FDA)

Public Comment and Harmonization Activities

Norman Schmuff
Associate Director for Science
Office of Process and Facilities
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration (FDA)

FDA Presenter Panel: Session presenters jointly respond to questions about PQ/CMC Standardization activities at FDA

Moderator:

Norman Schmuff, OPQ, CDER, FDA

Joining the Panel:

Frank Holcombe Jr.
Advisor
Office of Lifecycle Products
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration (FDA)

Norman Gregory
Chemist
Office of New Animal Drug Evaluation (ONADE)
Center for Veterinary Medicine (CVM)
U.S. Food and Drug Administration (FDA)

11:00-11:15am Break

11:15-11:45pm Session 2: Industry Perspectives

This session (with an intervening lunch break) will focus on industry perspectives on the PQ/CMC standardization effort. Views on the potentials and challenges of PQ/CMC data standardization in regulatory submissions will be discussed as well as direct comments and recommendations for the PQ/CMC standardization effort. Following these talks will be and end-of-session question and answer panel with the industry panelists. **Please hold questions until the end-of-session panel.**

Business Case for Structured Submissions
Genentech, Member of the Roche Group

Charles Morgan
Regulatory Group Director & IDMP-MDA PT Lead
Pharma Technical Regulatory,
Genentech

Rodrigo Palacios
Global Head for Business Systems,
Pharma Technical Regulatory,
F. Hoffman-La Roche Ltd

11:45-1:00pm Lunch Break

1:00-2:30pm Session 2 (continued): Industry Perspectives

PQ/CMC Standardized Data Approaches and the Impact on Global Harmonization
Pharmaceutical Research and Manufacturers of America (PhRMA)

Andy Chu
Director, Global Safety & Regulatory Sciences
Regulatory Systems Strategy – Regulatory Quality & Operations
Biogen

John Groskoph
Executive Director New Products CMC
Global Chemistry Manufacturing & Controls
Pfizer

Standardized Data for Pharmaceutical Quality/Chemistry Manufacturing and Control
Plasma Protein Therapeutics Association (PPTA)

Christopher Leonienco
Senior Manager, Regulatory Operations at
Emergent BioSolutions, Inc.
(Member company of PPTA)

Industry Presenter Panel: Session presenters jointly respond to questions about Industry Perspectives on PQ/CMC Standardization

Moderator:
Norman Schmuff, OPQ, CDER, FDA

2:30-2:50pm Open Public Comment

2:50-3:00pm Closing Remarks