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EXCiPACT

FDA CONFERENCE

May 14, 2019
Hanover Marriott| Whippany, New Jersey

INDUSTRY & FDA VIEWS ON OUTSOURCING AND AUDITS

https://www.eventbrite.com/e/2019-njpqca-fda-conference-registration-55838455323

Excellent presentations! Q&A and individual conversations with industry, FDA speakers & other industry members.

Great Conference! I wish I knew about you earlier.

Presentations were very helpful and informative.

Overall the agenda was meaningful and thoughtful! I plan to attend future conferences.

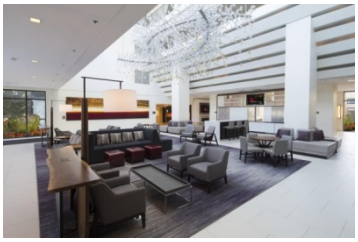
Recent NJPQCA FDA Conference Events

Event/Hotel Location

Hanover Marriott
1401 Rt. 10 E
Whippany, NJ 07981
(for directions, see next page…)

Overnight Reservations

Rooms filling up quickly!
Call (973) 538-8811 and use code: NJPQCA
for the reduced rate of $199.00 (excluding tax)



Event Cost

- $375.00 – Members/Non-Members if registered by May 01
- $400.00 – Members/Non-members if registered after May 01
- $300.00 – Group rate (3 and more from same company; per registrant)
- $175.00 – Government employees

Register at…

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Event Information

#NJPQCA

NJPQCA

8:00 – 8:30 AM

WELCOME COFFEE AND REGISTRATION

8:30 – 8:45 AM

Sonande Shah
Associate Director
BMS

Michael Spangler
Principal Consultant,
Spangler Consulting LLC

8:45- 9:00 AM

Diana Amador-Toro
Central Region (CER), Regional Food and Drug Director (RFDD), **FDA**

Focus on current FDA organization, 2018 and past overview and past 483s, 2019 priorities

Diana Amador-Toro serves as the Central Region's food and drug director in the Food and Drug Administration's (FDA) Office of Regulatory Affairs (ORA). She is responsible for more than 700 field employees in seven districts and three laboratories. She has served as the chair of the Field Drug Committee and as the drug program manager for ORA since 2008. Ms. Amador-Toro also served seven years as the district director in New Jersey, six years as the director of investigations, and four years as the science branch director in the San Juan District Office. She was the first pre-approval manager in the field and held positions as drug specialist and investigator. Ms. Amador-Toro has more than 33 years of field experience in investigations and compliance activities. She has contributed to guidance documents of FDA and the International Conference on Harmonization and has conducted international training on good manufacturing practices and pharmaceutical quality training in Argentina, Estonia, and England, among other countries.

9:00 – 9:45 AM

Elisabeth Corbett
Regulatory Affairs Director,
Merck

A Regulatory Perspective on Implementation of ICH Q3D: Impacts and Challenges- CMOs and Suppliers

Elisabeth Corbett is Director, CMC, in Global Regulatory Sciences-Biologics at Merck, West Point, PA. She has served as a global submission lead in post-approval oncology since joining Merck in 2018 following six years in Regulatory CMC at Bristol-Myers Squibb. She joined Bristol-Myers Squibb as an engineer in Process R&D in 2001. In 2008, she relocated to Texas and served in Quality roles before returning to CMC Regulatory at BMS where she supported CMC lifecycle management of small and large molecule products as well as of early development assets. She served as the regulatory lead for the implementation of ICH Q3D at BMS, authored a September 2018 Pharmaceutical Technology article related to the regulatory challenges presented by ICH Q3D and presented at the 2016 PQRI conference on the topic. She holds a B.S. in Chemical Engineering and Biology from Carnegie Mellon University and a M.B.A from New York University.

9:45 – 10:00 AM

MORNING BREAK AND NETWORKING

10:00 -10:45 AM

Maya Davis,
Compliance Officer
FDA

Focus on harmonization with EU and other markets, issues with outsourcing, impact, challenges – A FDA Perspective

Maya Davis began with FDA in 2009 as a Drug Investigator in New England District after completing her Ph.D. in Pharmacology from Yale University with a preclinical neuroscience focus. She conducted inspections of human and veterinary drug manufacturers and compounding facilities as an Investigator and later as Drug Specialist and Pre-Approval Manager in 2014. She became a Compliance Officer in 2015, recommending compliance actions for domestic and foreign pharmaceutical manufacturers and compounding facilities. Maya is responsible for outreach to boards of pharmacy in the New England area and currently serves on the Massachusetts Board of Pharmacy Advisory Committee as a CGMP expert in aseptic processing. Most recently, Maya has also served on the Mutual Reliance Inspection Review Team reviewing and classifying inspection reports from foreign regulatory partners.

10:45 -11:30 AM

A BMS perspective on holistic view of contract manufacturers

Himanshu Patel
Drug Product MS&T Lead, Third Party
BMS

Himanshu has been with BMS for 4 years and is responsible for the technical stewardship of the portfolio of commercial BMS products manufactured in the Americas both internal and external sites. His team in the Pharma MS&T organization actively manages products thru their life cycle and leads efforts to reduce commercial product supply risk, through execution of best practice in Technical Transfers, Product Robustness assessment and Improvement, Deviation resolution

Gerry Keaney
Operations Quality Director
BMS

Gerry Keaney joined BMS in 2013 at Mt Vernon as Site Quality Director. In his current role, he has Quality responsibly for Pharma External Manufacturing virtual plant teams in North America and Canada. The team also provide Quality support for activities associated with the transfer of products between internal sites and CMO's. Prior to joining BMS Gerry worked for Pfizer as Quality Director with responsibility for sites in Copenhagen and Cluj Romania.

Event Information

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NJPQCA

11:30 AM – 12:00 PM

QUESTIONS & ANSWERS

12:00 PM – 1:00 PM

LUNCH

1:00 – 2:30 PM

The EXCiPACT GMP Certification Scheme – from an idea to global reality

Dale Carter
Head of Quality
Evonik

Dale Carter is the Head of Quality for the Business Line Silica in the Region Americas for Evonik Industries. He is responsible for product quality and compliance with IPEC/PQG GMPs for the manufacturing of Silica products at facilities in Tennessee, Maryland, Pennsylvania, Alabama, and New York. Dale is a Board member of EXCiPACT and a member of the NSF Joint Committee for Pharmaceutical Excipients that wrote the ANSI/NSF/IPEC/363 Good Manufacturing Practices for Pharmaceutical Excipients. He is a Past Chair of International Pharmaceutical Excipient Council of the Americas and currently serves as Vice Chair Membership. Dale received an MS in Chemistry from North Carolina State University and a BS in Chemistry from Davidson College. He is an ASQ Certified Quality Auditor. Prior to joining Evonik/IM Huber Dale worked for Pfizer, The Coca-Cola Company, and Archer Daniels Midland Company.

The benefits of EXCiPACT Certification to Croda's customers

Iain Moore
Global Head of Quality Assurance
Croda

Dr. Iain Moore is Global Head of Quality Assurance, Croda, a manufacturer of speciality and performance chemicals based in the United Kingdom. He has worked for Croda for 31 years, and for more than 25 years in various quality roles, including overseeing two UK regulatory inspections. He has contributed to the publication of European and US National Standards as well as many IPEC Guides. He was project leader for the development and delivery of the EXCiPACT Certification Scheme, and stood as its first President, and has latterly returned to the Board. He is also chair of the EFfCI (European Federation for Cosmetic Ingredients) GMP Committee which oversees the EFfCI GMP Guide and standard for Cosmetic Ingredients.

2:30 – 2:45 PM

AFTERNOON BREAK AND NETWORKING

2:45 – 3:00 PM

Acceptance of Third Party audits with special preference to pharmaceutical excipients

Invited Speaker
CDER
FDA

3:00 – 4:30 PM

Utilization of Excipient GMP Certification Audit Reports by Pharmaceutical Companies

David Klug
Officer and Past Chair
IPEC Americas

David Klug is an Officer and Past Chair of IPEC-Americas. He served on the Global Steering Committee and GMP Annex Team that developed the EXCiPACT Certification Standards for Pharmaceutical Excipient Suppliers and presently serves as EXCiPACT asbl full member representative for IPEC-Americas. Mr. Klug is an industry representative on the NSF Joint Committee for Pharmaceutical Excipients that developed and maintains NSF/IPEC/ANSI 363 Good Manufacturing Practices (GMP) for Pharmaceutical Excipients. He has participated in the development of IPEC Guides published since 2001. Mr. Klug holds an M.S. degree in Chemistry from the University of Missouri - Columbia.

4:30 – 5:00 PM

QUESTIONS & ANSWERS