CDER SMALL BUSINESS AND INDUSTRY ASSISTANCE (SBIA)

WEBINARS

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Post-Market Reports
An Update on Field Alert Reports (FAR) and Biological Product Deviation Reports (BPDR)
May 24, 2023
9:00 AM – 2:00 PM (ET)

Time	Presentation	Speaker
9:00 AM	**SBIA Welcome and Overview**	**Forest "Ray" Ford, PharmD, BCPS** *Captain, United States Public Health Service* Pharmacist Division of Drug Information (DDI) Office of Communications (OCOMM) Center for Drug Evaluation and Research (CDER)|FDA
9:10 AM	**Introductory Remarks and Welcome**	**Jennifer Maguire, PhD** *Director* Office of Quality Surveillance (OQS) Office of Pharmaceutical Quality (OPQ) CDER | FDA
9:20 AM	**FAR and BPDR Regulatory Background and Framework**	**Melissa Furness** *Biologist* Division of Internal Policies and Procedures (DIPP) Office of Policy for Pharmaceutical Quality (OPPQ) OPQ | CDER | FDA

What is an FAR/BPDR and how is it different from a consumer complaint/MedWatch (MW)?
Overview of 21 CFR 314 and 600

- Why are these reports required and what is the value for the Agency and Industry by reporting them (reference preamble)?
- What are the reporting requirements and who is responsible for reporting?
- How does a firm report?
    - What happens if they are not reported?

Question and Answer (Q&A)

10:10 AM **Expectations of FAR and BPDR Submissions**

Elise Murphy
Supervisory, Consumer Safety Officer
Division of Quality Intelligence II (DQI II)
OQS | OPQ | CDER | FDA

What type of information is FDA seeking in the submission of an FAR/BPDR?
Overview of FAR, BPDR assessments

- Expectations: Root Cause Analysis (RCA)and Corrective and Preventive Actions (CAPA)
- Assessment/MedDRA/Primary Defect Coding
- Final Post-Market Reports - why are they important?
- Case Study
- Follow-up

Question and Answer (Q&A)

11:10 AM **Modernizing the Post-Market Product Quality**

Alex Viehmann
Division Director
DQI II | OQS | OPQ | CDER | FDA

Reporting Program Through the Application of Advanced Analytics

Nandini Rakala, PhD
Visiting Associate
DQI II | OQS | OPQ | CDER) | FDA

Question and Answer (Q&A)

12:10 PM **Break**

12:25 PM **How Are Post-Market Reports Utilized by FDA?**

Report on the State of Pharmaceutical Quality

Neil Stiber, PhD
Associate Director for Science and Communication
OQS | OPQ | CDER | FDA

How are FARs/BPDRs utilized within Site Selection Model (SSM)
John Wan
Supervisor
OQS | OPQ | CDER | FDA

Pre-approval Decisions – [Pre -Approval Inspection (PAI) and Pre-License Inspection (PLI)]
Derek Smith, PhD
Deputy Director
Division of Pharmaceutical Manufacturing Assessment IV (DPMA IV)
Office of Pharmaceutical Manufacturing Assessment (OPMA)
OPQ | CDER | FDA

Pharmaceutical Quality System (PQS) assessments
Alex Viehmann
Division Director
DQI II | OQS | OPQ | CDER | FDA

Site Dossiers
Milva Melendez
Supervisory Consumer Safety Officer
DQI II | OQS | OPQ | CDER | FDA

Question and Answer (Q&A) Panel

1:50 PM **Closing Remarks**
Jennifer Maguire, PhD

1:55 PM **SBIA Closing**
Forest "Ray" Ford

2:00 PM **Adjournment**