Post-Market Reports (FAR/BPDR) Site Dossiers

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Post-Market Reports
An Update on Field Alert Reports (FAR) and Biological Product Deviation Reports (BPDR)
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Learning Objective

- Understand how FDA considers FAR and BPDR information in Site Dossiers.

Overview

- Site Dossier
- How FARs and BPDRs are used in Site Dossiers
- Considerations for FARs and BPDRs

Site Dossier

- Internal – Confidential – process for assessing and review of the state of control of the Pharmaceutical Quality Systems
- Communicate with FDA offices and field operations about possible areas of focus and aid decision making with respect to creating an inspection strategy plan

Site Dossier

Includes, but is not limited to:

- Registration information
- Drug Product Listing
- FDA Facility inspection history
- Foreign Regulatory Agencies inspectional outcomes
- Product Quality Defect Reports (e.g., FAR, BPDR, MW, consumer complaints)
- Quality Metrics data (if available)

How FAR and BPDR are used in Site Dossiers?

Assess the robustness and effectiveness of Pharmaceutical Quality Systems.

- Is there a robust Quality Unit?
- Is the firm complying with reporting requirements?
- Is the firm conducting thorough investigations and implementing effective CAPAs?
- What is the state of control for each of the Six Systems (Quality, Laboratory, Production, Facilities and Equipment, Materials, & Packaging and Labeling)?

Things to consider

- Adequate Investigations address root cause(s)
  - Thorough, Timely, Unbiased, Well-documented, Scientifically Sound
- CAPA effectiveness check (when appropriate)
- Evaluate the risk to product quality as a surrogate of potential harm to patients, regardless if the batch(es) has been released or not
- Evaluate the risk to other batches manufactured, regardless if the batch(es) has been released or not
- Evaluate if the process continues to perform in a validated state or if there is need to implement changes and revalidate the process
- Evaluate the impact on the stability of the quality attributes of the drug products

Summary

- FDA uses information from FAR and BPDR to understand the maturity and robustness of the Pharmaceutical Quality Systems to assist FDA offices and field investigators developing an inspection strategic plan using a science-based risk management approach.

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Questions?

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