Report on the State of Pharmaceutical Quality (RSPQ)

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SBIA Webinar – 24 May 2023

Learning Objectives

- Understand what the Report on the State of Pharmaceutical Quality (RSPQ) is.
- Understand how Postmarket Quality Data are used in the RSPQ.

Agenda

- RSPQ Background
- Use of Postmarket Quality Data in RSPQ
- Examples of Postmarket Quality Data in Prior RSPQ reports

Background on the RSPQ

- Characterizes the state of pharmaceutical quality for human drugs legally marketed in the U.S.
- Provides useful information for the public.
  - Encourage improvements to quality.
  - Insights on future directions in quality surveillance.
- Enables analysis of key factors that impact pharmaceutical quality.

What Does RSPQ Provide?

- Indicators of quality based on analysis of data for site compliance, post-market reporting, and product testing.
- Insights and trends that can be inferred about site quality and product quality.
- All assessments are abstracted to high-level groups, e.g., industry types, product types, countries, etc.
  - No data about individual firms are shared.

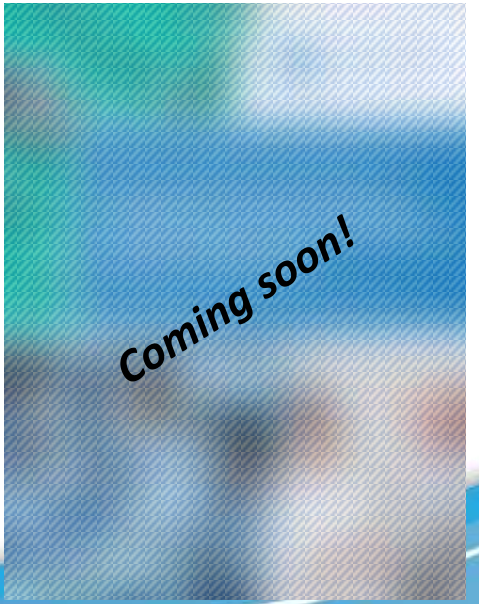
FY2018

FY2019

FY2020

FY2021

FY2022



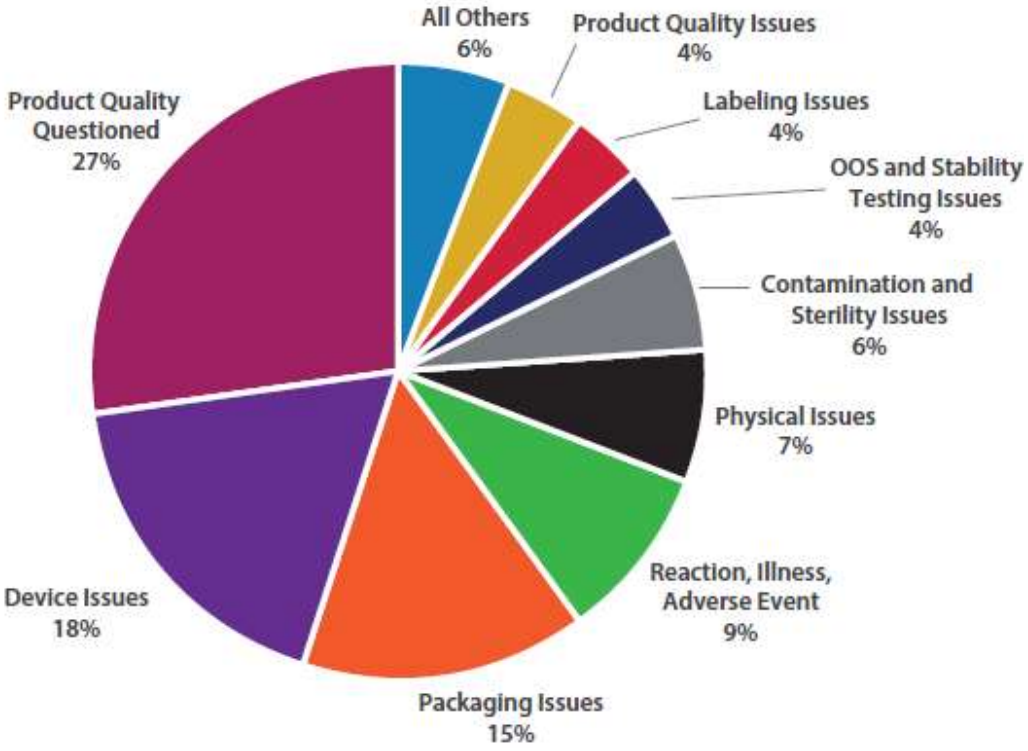
Highlights from the past - FY2020 RSPQ

- Multiple mechanisms for reporting product quality concerns
- Product Quality Defects (PQD) comprised:
  - 11,932 Med Watch (MW) reports
  - **4,308 Field Alert Reports (FAR)**
  - **263 Biological Product Deviation Reports (BPDR)**
  - 253 Consumer Complaints
- Analyzed in context with other data to seek trends

Highlights from the past - FY2020 RSPQ (continued)

- For the purposes of RSPQ, PQD reports are grouped into 20 defect categories.
- For FY2016–FY2020, three defect categories accounted for 60% of all defects reported:
  - Product Quality Questioned
  - Device Issues
  - Packaging Issues

Figure 7. Top Defect Types, PQD Total FY2016–2020



Highlights from the past - FY2021 RSPQ

- Product Quality Defect (PQD) comprised:
  - 11,512 Med Watch (MW) reports
  - **4,115 Field Alert Reports (FAR)**
  - **205 Biological Product Deviation Reports (BPDR)**
  - 273 Consumer Complaints
- Similar to FY2020.
- Rich source of post-market information to understand the state of quality.

Highlights from the past - FY2021 RSPQ (continued)

- Research on FAR Submissions and Site Quality
  - Explored FAR submission rates and the characteristics of the sites to better understand factors that reflect site quality.
  - For FY2018-FY2021
    - 1,143 sites were eligible to submit a FAR.
    - Sites that did not submit FAR tended to be foreign, producing non-sterile products, and have fewer approved applications.

Highlights from the past - FY2021 RSPQ (continued)

- Initial FAR
  - Required when becoming aware of significant quality problems with distributed drug products.
- Follow-up and final FAR
  - Recommended because it indicates completion of an investigation.
  - 97% of sites that submitted an initial FAR submitted at least one follow-up FAR or a final FAR.
- **Submission of FAR is regarded as an attribute of a healthy pharmaceutical quality system.**

Summary

- Reliable data on FAR and BPDR are essential for providing an accurate picture of pharmaceutical quality.
  - Prompt reporting of FAR and BPDR
  - Complete reporting with follow-up and final reports
- The RSPQ presents data, including FAR and BPDR, that are abstracted to high-level groups, e.g., industry types, product types, countries, etc.
  - No data about individual firms are shared.

Challenge Question

- During FY2020 and FY2021 the annual number of FAR and BPDR submitted to FDA was approximately:

A. 10,000 FAR and 1,000 BPDR

B. 4,000 FAR and 200 BPDR

C. 1,000 FAR and 10,000 BPDR

D. 200 FAR and 4,000 BPDR