IDENTIFY AN INDUSTRY STANDARD FOR THE INTAKE OF PRODUCT COMPLAINTS TO ENSURE REGULATORY COMPLIANCE

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By the end of this presentation, you will:

- Become familiar with the recommended minimally required information needed to log a Product Quality Complaint (PQC) into a complaint tracking system and release for investigation.
- Understand the difference between a PQC, a non-PQC, and customer feedback and know how to manage each scenario.
- Become familiar with complaint categorization and suggested timelines for routing of complaint information to the Lead Complaint Investigating Unit for further processing.
This presentation offers guidance based on my perspective and my experience!

- Interpretation of the regulations and guidance available
- My scope is a large, global pharmaceutical company
  - Multiple classes of products (Vaccines, Consumer Care, Rx...)
  - Worldwide manufacturing and packaging sites
  - Rapidly changing environment
TO LEVEL SET, WHY ARE COMPLAINTS IMPORTANT?

- It’s the law!!
  - FDA’s Code of Federal Regulations - CFR 211
- FDA critically reviews PQCs during on-site inspections
  - Focus on decision making, timeliness and depth of investigation
- Represent the ‘voice of the customer’
- Improve our products and packaging
- Foster good customer service
Before we start, let’s define some key terms related to complaint intake for purposes of this presentation...

- **Product Quality Complaint**: Any communication that describes a potential defect related to the identity, strength, quality, or purity of a product after it is released / distributed for use by a customer.

- **Non Product Quality Complaint**: The designation for specific situations where the reported event does not describe a product quality defect.

- **Complaint Priority**: Complaint categorization based on risk to user, product quality and government expectation (High Risk, Standard Risk).

- **Customer Feedback**: Any written, electric or oral communication by a customer, reporter, medical practitioner or distributor that does not allege a product defect but provides a suggestion or opinion on a product. Any question, suggestion, or remark regarding a medical device, which may trigger an improvement in the functionality or quality of the medical device.

- **Date of Company Awareness**: The initial date that Company X is notified of a potential PQC.
Incoming Path for Complaint

- **Call Center or Local Country Office**
  - Global locations
  - Information can come in form of phone, e-mail, letter, brand website, etc.

- **Complaint Handling Unit (CHU)**
  - Global locations
  - Receives complaint information from the call center
  - Logs into appropriate tracking system (multiple systems can complicate situation)
  - Releases to manufacturing/packaging site for investigation
  - Processes some returned complaint samples
    - International
    - Non-High Risk
  - Note: The call center and the CHU can be one in the same

- **Complaint Investigating Unit (CIU)**
  - Lead site responsibility is determined based on defect reported
  - Performs investigation
  - May be responsible for regulatory reporting (typically US release site)
PROCEDURE- PQC INTAKE

- The appropriate Complaint Handling Unit (CHU) must be informed of any incoming potential PQC by the Call Center/Local Country Office within one (1) business day.

- Based on the information received from the Call Center, the CHU must determine if the minimally required information is available to conduct a PQC investigation.
  - Product name
  - Thorough description of the event

Note: The description of a complaint would be considered ‘thorough’ if there was enough information provided to generally determine the defect being reported in order for the complaint to be investigated. For example, a report stating that “product is defective” does not provide enough information to launch a complaint investigation. Conservative judgment is needed to determine whether a thorough description of the event is indeed provided.
PROCEDURE- PQC INTAKE

- If the minimally required information is not available, the CHU must request and attempt to obtain this information from the Call Center within X business days.
  - In these cases, the case should be entered into the complaint tracking system while waiting to obtain the minimally required information.
- When the minimally required information is received, the PQC is referred to the Lead Complaint Investigating Unit and the investigation clock starts.
- If the minimally required information cannot be obtained, the PQC cannot be further investigated.
  - The CHU will document the available details and the reasons not to perform an investigation in the record.
The Call Center should strive to obtain the following additional information about the PQC where possible. **It is important to note that a PQC investigation should proceed even without this information.**

- Date of company awareness
- Batch number
- Availability of complaint sample for return

**Date of Company Awareness**

- Defined as the date that Company X or an agent acting on behalf of Company X became aware of the complaint.
Batch Number

- Every reasonable effort must be made by the Call Center to obtain the batch number. If the batch number cannot be obtained, the reasons why the batch number is not available must be clearly documented in the PQC record by the Call Center, in addition to the number of attempts that were made to obtain the batch number.

- Why is this important?
Batch Number

- Regulatory agency expectation
- Knowledge of a batch number is a key input to execution of a robust complaint investigation. Without a batch number, the following inputs to a complaint investigation cannot be performed:
  - Batch record review
  - Retention sample examination
  - Review of relevant test results
  - Deviation review
  - Process change review
- Enables execution of batch specific complaint trending
- Knowledge of a batch number leads to a more robust Field Alert (FAR) or Biological Product Deviation Report (BPDR)
- If a batch number cannot be obtained, the Call Center must document the reasons why this information is not available
Returned Complaint Sample

- Every reasonable effort must be made by the Call Center to obtain the returned complaint sample. If the returned complaint sample cannot be obtained, the reasons for this must be clearly documented in the PQC record by the Call Center, in addition to the number of attempts that were made to obtain the batch number.
- Why is this important?
OBTAINING A COMPLAINT SAMPLE

 Returned Complaint Sample

- Regulatory agency expectation
- Evaluation and/or analysis of the returned complaint sample is a key input to execution of a robust complaint investigation
- Substantiate reported defect
- Analyze and identify extraneous matter
- Analyze glass breakage/fracture patterns
- Evaluation and/or analysis of the returned complaint sample leads to a more robust Field Alert (FAR) or Biological Product Deviation Report (BPDR)
- If a returned complaint sample cannot be returned, the Call Center must document the reasons why this cannot be completed
PROCEDURE- PQC INTAKE

VERY IMPORTANT- All PQC's are assumed to be legitimate and investigated accordingly.

The designation of ‘Non-PQC’ is reserved for specific situations where the reported event does not describe a product quality defect (e.g. Customer contacts Company X to ask about proper storage of the product or customer expresses dissatisfaction with the general design of a package). These are also referred to as customer feedback.

The designation of ‘Non-PQC’ can also apply to a situation where a customer reports a quality defect in error (e.g. A consumer reports a bottle of tablets was underfilled but then calls back to report that the missing tablets were found and thus the bottle was never underfilled).
PROCEDURE- DATA ENTRY

- The CHU enters PQC information received from the Call Center into a complaints management database.
- Upon receipt of PQC information from the Call Center, the CHU will determine the following:
  - Complaint Category
  - Complaint Priority
    - High Risk, Standard Risk
  - Date of Company Awareness
  - Lead Complaint Investigating Unit
  - Investigation Due Date
  - Sample Availability
PROCEDURE - PQC PRIORITIZATION

- As part of data entry, the CHU must categorize each complaint record according to priority.
  - High Risk, Standard Risk
HIGH RISK COMPLAINTS

- Reported defect meets any one of the following criteria:
  - Represents a health/safety risk to the patient
  - May result in patient use of wrong product, expired or adulterated product
  - May require regulatory notification (including recall)
  - Represents a critical manufacturing/packaging defect
Examples of High Risk Complaints:

- Alleged Contamination or Extraneous Matter in Product
- Alleged Mix
  - Product A contained in carton for Product B
- Overfilled unit dosing packaging (e.g. blister)
- Child Resistant Closure not functioning as intended
- Damaged, incomplete, or missing primary seal on tablet/capsule bottles or tamper-evident band
- Sterile Solution or oral suspension containing precipitation or a particulate or foreign matter
- Cracked primary container—vial, syringe or oral/ocular dosing tube
• Standard Risk
  • Reported defect that:
    • Does not meet the criteria of High Risk, and....
    • Will not impact usability of product OR
    • May render the product unfit for use, but will be noticed by the customer
Examples of Standard Risk Complaints:

- Taste irregularity
- Chipped tablet
- Damaged vial flip cap
- Appearance of package
- Underfilled bottle/tablets
Once the minimally required information about a PQC is obtained from the Call Center, the CHU must forward the initial PQC details to the Lead Complaint Investigating Unit according to the following timelines:

- High risk complaints- within one (1) business day.
- Standard risk complaints- within three (3) business days.
- Timely notification is critical to initiate the investigation cycle and evaluate the need for regulatory reporting.

Feedback is required if the Lead Complaint Investigating Unit alters the PQC prioritization or downgrades the record based on the results of their ongoing investigation.
**PROCEDURE - ROUTING AND ASSIGNING DUE DATES**

- Investigation due dates for PQC investigations are assigned as follows:
  - 30 calendar days for high risk complaints
  - 60 calendar days for standard risk complaints

- The CHU must track each PQC until the PQC is acknowledged by the Lead Complaint Investigating Unit.
  - Acknowledgements take place electronically
  - CHU must monitor records created to ensure that they have been acknowledged.
Call Center activity is often outsourced

- Primarily on-the-job training
- Reminder training conducted periodically to emphasizing key points, such as importance of batch number and complaint sample return

Work closely with Call Center

- Ensures that key information about the defect is obtained at the time of the customer contact
PAIN POINTS

- Global process
  - Multiple hand-offs
  - Supply chains are constantly changing
  - Communication can be a challenge; sometimes difficult to reach wider audience with key messages

- Sample return
  - Clearing customs

- Divestitures, Tollers, Business Partners
  - Process becomes more complex as manufacturing is outsourced