Expectations of Field Alert Report (FAR) and Biological Product Deviation Report (BPDR) Submissions

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CDER | U.S. FDA

An Update of Field Alert Reports and Biological Product Deviation Reports
May 24, 2023

Learning Objectives

For Abbreviated and New Drug Application Field Alert Reports (FARs) and CDER Biological Product Deviation Reports (BPDRs, non-blood):

- Identify the type of information CDER expects in a submission.
- Understand key components of these reports .
- Understand the value of specific information about root cause investigations and Corrective Action and Preventative Action (CAPA).
- Understand the correlation between the MedDRA terms when identifying root cause investigations.

Identify the type of information CDER expects in FAR submissions

Identify the type of information FDA expects in a FAR submission

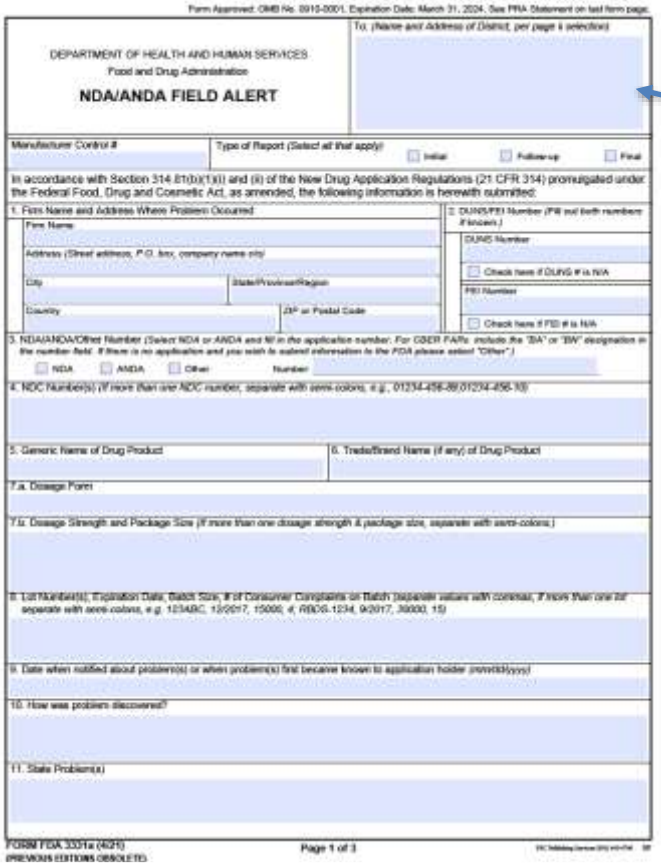
A/NDA Field Alert Report (FAR):

21 CFR 314.81(b)(1) provides the framework for NDA and ANDA applicant holders to provide

- "Information concerning any ***bacteriological contamination***, or any significant ***chemical, physical, or other change or deterioration*** in the ***distributed*** drug product, or any failure of one or more distributed batches of the drug product to meet the ***specification established*** for it in the application."
- "Information concerning any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article."

•*Reporting requirements* -The applicant shall submit information……to the FDA district office that is responsible for the facility involved within 3 working days of receipt by the applicant. The information may be provided by telephone or other rapid communication means, with prompt written follow up."

NDA/ANDA Field Alert



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

NDA/ANDA FIELD ALERT

To: (Name and Address of District, per page 4 selection)

Manufacturer Control #

Type of Report (Select all that apply): Initial | Follow-up | Final

In accordance with Section 314.81(b)(1)(i) and (ii) of the New Drug Application Regulations (21 CFR 314) promulgated under the Federal Food, Drug and Cosmetic Act, as amended, the following information is herewith submitted:

1. Firm Name and Address Where Problem Occurred

Firm Name
Address (Street address, P.O. box, company name c/o)
City | State/Province/Region
Country | ZIP or Postal Code

2. DUNS/FEI Number (Fill out both numbers if known.)

DUNS Number
Check here if DUNS # is N/A
FEI Number
Check here if FEI # is N/A

3. NDA/ANDA/Other Number (Select NDA or ANDA and fill in the application number. For CBER FAPs: include the "BA" or "BW" designation in the number field. If there is no application and you wish to submit information to the FDA please select "Other".)

NDA | ANDA | Other | Number:

4. NDC Number(s): (If more than one NDC number, separate with semi-colons, e.g., 01234-456-89;01234-456-10)

5. Generic Name of Drug Product | 6. Trade/Brand Name (if any) of Drug Product

7.a. Dosage Form

7.b. Dosage Strength and Package Size (If more than one dosage strength & package size, separate with semi-colons.)

8. Lot Number(s); Expiration Date; Batch Size; # of Consumer Complaints on Batch (separate values with commas, if more than one lot separate with semi-colons, e.g. 1234ABC, 12/2017, 15000; 4, RBD5-1234, 9/2017, 30000, 15)

9. Date when notified about problem(s) or when problem(s) first became known to application holder (mm/dd/yyyy)

10. How was problem discovered?

11. State Problem(s)

FORM FDA 3331a (4/21) | Page 1 of 3 | PREVIOUS EDITIONS OBSOLETE

Marketed drugs manufactured domestically

FDA/ORA FIELD ADDRESSES

Select ***one*** primary address by marking the box next to an address below.
When filling out this form in Adobe Reader:
- The selected address automatically will be placed in the upper right area on form page 1, *and*
- its email address will be the "To" addressee in the email generated by the submit button on the last form page.

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Tel: 718-340-7000
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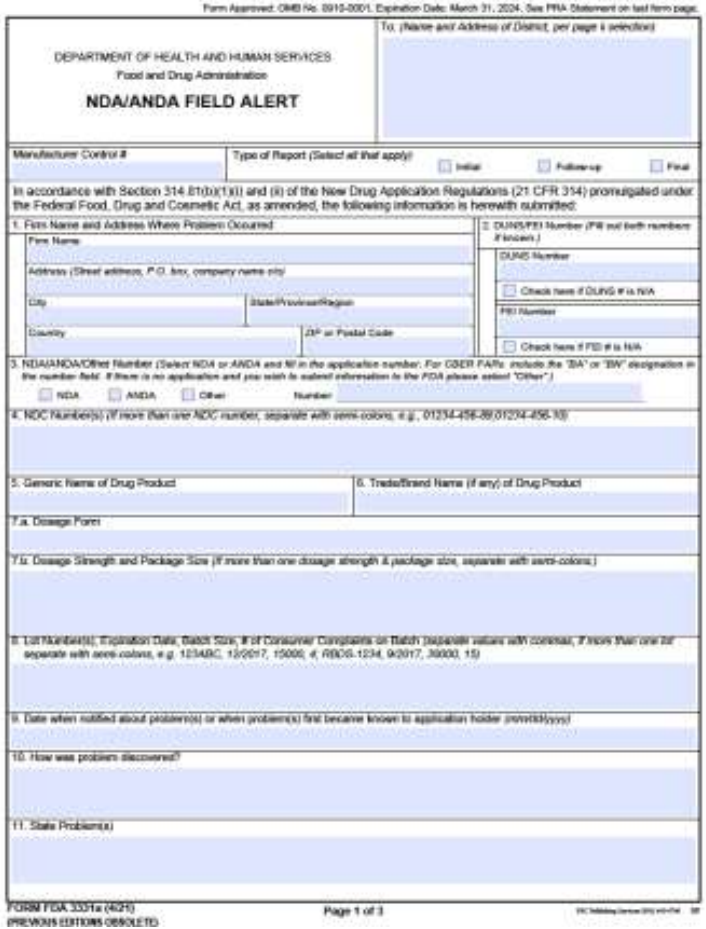
☐ Los Angeles District (LOS-DO)
19701 Fairchild
Irvine, CA 92612-2506
Tel: 949-608-2900
ORALOSFAR@fda.hhs.gov

XML Schema

FAR Submissions of FDA Form 3331a



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FORM FDA 3331a (4/21)
(PREVIOUS EDITIONS OBSOLETE)

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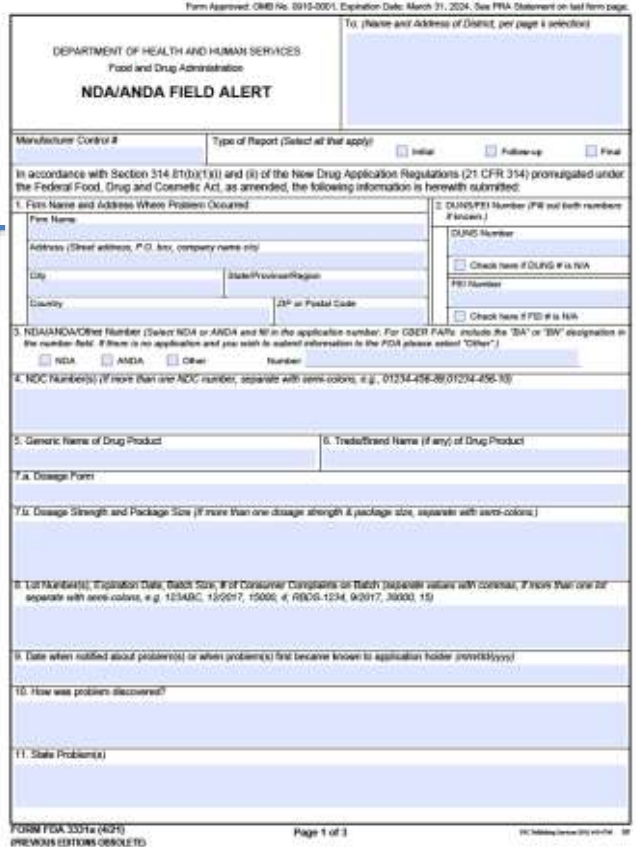
A/NDA applicant holders manufactures or distributes drugs internationally; and their product has a deviation, they are required to submit a FAR through:

<u>International FAR reporting requirements</u> - U.S. Office/Agent (21 CFR 314.50(a)(5)) is responsible for reporting to the FDA District Office where they are registered

Submissions of A/NDA FAR



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FORM FDA 3331a (4/21)
(PREVIOUS EDITIONS OBSOLETE)

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Firm name address of manufacturing finished drug product where the incident occurred

Form FDA 3331a – Structured reporting format

- Manufacturer control number, should be the same number for each FAR initial, follow-up or final, without suffixes or prefixes.
- NDA or ANDA number
- NDC Number – labeler code, product code; https://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm
- Generic name; Brand name
- Dosage strength and package size
- Lot numbers and expiration dates, volume – follow the format provided
- Number of complaints received for that batch
- Date when notified
- How the problem was discovered – feeds into your root cause analysis

FAR Key Reporting Requirements

MedDRA product quality defect code

Detailed description of root cause investigation

Detailed description of Corrective Action and Preventative Action (CAPA)

MedDRA Coding for Product Quality

MedDRA Terminology for Coding

- Medical Dictionary for Regulatory Activities (MedDRA)
  - Standardized medical terminology developed by the International Council for Harmonisation (ICH) of Technical Requirements for Pharmaceuticals for Human Use
- Purpose: To facilitate sharing of regulatory information internationally for drugs, vaccines and combination products.
- MedDRA is a global terminology used by regulatory authorities and industry throughout the regulatory cycle pre-marketing to post-marketing for data entry, retrieval, evaluation, presentation.

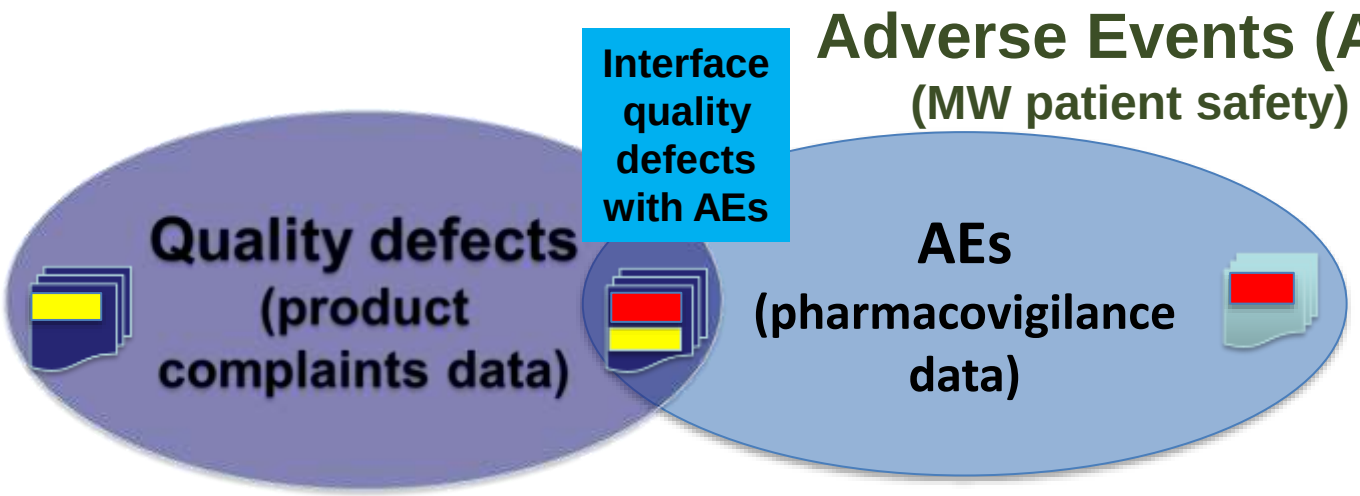
MedDRA Terminology

FDA proposed a 27th System Organ Class (SOC) to MedDRA to incorporate Product Issue

- Terms based on Federal Food Drug and Cosmetic Act (FD&C)
- **C**urrent **G**ood **M**anufacturing **P**ractices
- 21 CFR 210, 211 ensures proper design, monitoring, and control of manufacturing processes and facilities.
- Guarantees that drugs will meet identity, strength, quality, and purity.

MedDRA Allows Intersect between Quality Defects and Adverse Events Data

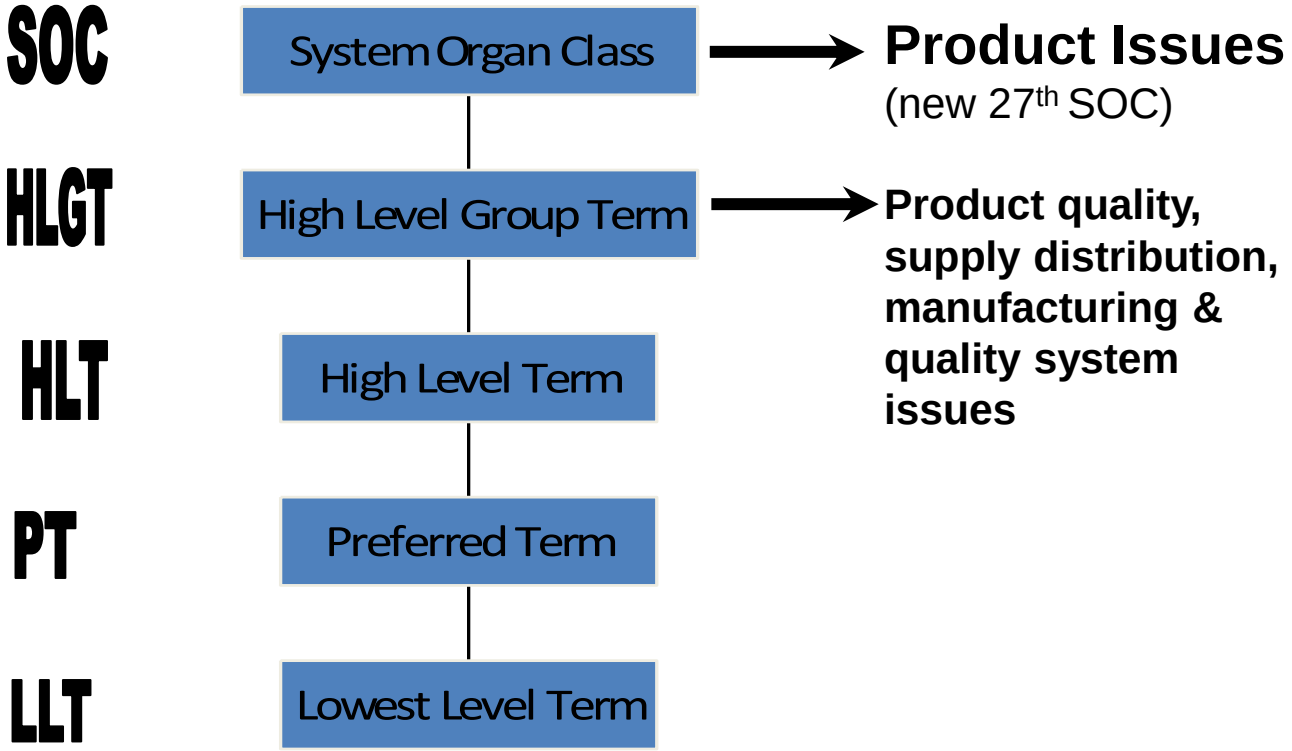
CGMP Failures Product Quality Issues: FAR, BPDR



MedDRA and ICH

- MSSO (Maintenance and Support Services Organization): contracted by ICH with technical and financial oversight by the MedDRA Management Committee, to manage MedDRA versioning, subscriptions and training.
- ICH MedDRA Points to Consider (PtC) working group: developed and maintains guides for harmonized MedDRA coding and data retrieval.
  - Coding standard: *ICH MedDRA® Term Selection PtC,* already contains a section on Medication errors and separately Product quality issues
  - "Companion document" on coding of Product Quality Issues

MedDRA Hierarchy Levels and Quality Issues

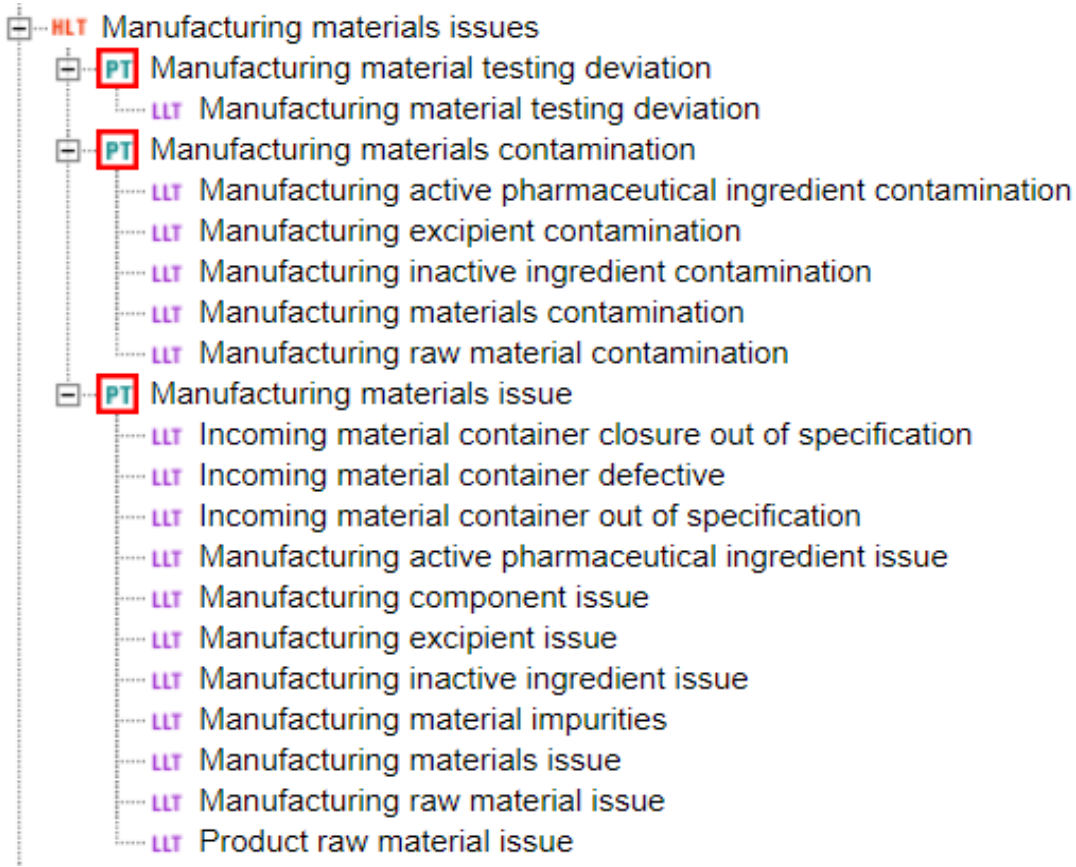


The 27 SOC - Product Issues MedDRA version 26.0

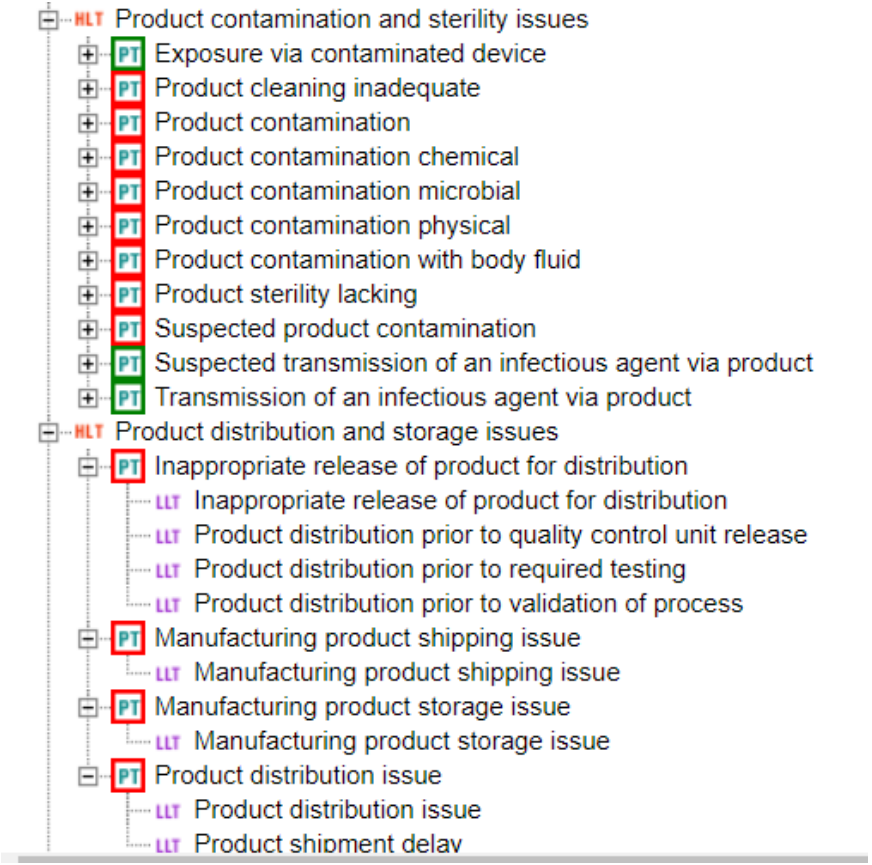
- SOC Product issues
  - HLGT Device issues
  - HLGT Product quality, supply, distribution, manufacturing and quality system issues
    - HLT Counterfeit, falsified and substandard products
    - HLT Manufacturing facilities and equipment issues
    - HLT Manufacturing issues NEC
    - HLT Manufacturing laboratory controls issues
    - HLT Manufacturing materials issues
    - HLT Manufacturing production issues
    - HLT Product contamination and sterility issues
    - HLT Product distribution and storage issues
    - HLT Product label issues
    - HLT Product packaging issues
    - HLT Product physical issues
    - HLT Product quality issues NEC
    - HLT Product supply and availability issues

HLT Manufacturing Laboratory Control Issues

HLT Manufacturing Material Issues



HLT Product Contamination and Sterility
HLT Production Distribution & Storage Issues



Expectations In Root Cause Investigations

Expectations of Root Cause Investigation

- Identify and provide a detailed description of the Failure Mode and Effects Analysis.
- Is the failure a process performance or product quality? How are the system's integrated?
- Is there a trend or signal seen across batches?
- What is the pharmaceutical quality management system's response?
- What is the risk to patients?
- ICH Q9 (R1) Quality Risk Management, May 2023

Corrective Action and Preventative Action (CAPA)

- A detailed plan of the proactive measures used to mitigate the risk is encouraged.
- What metrics are in place such as quantitative, analytical, microbial testing data to ensure that reoccurrence of failure are quickly detected?
- What is the communication plan of the Quality Management System to respond to and communicate failures?

Critical Quality Attributes

Critical Quality Attributes is defined by ICH Q8 (R2) Pharmaceutical Development as physical, chemical, biological or microbiological properties or characteristics that should be within appropriate limit, or distribution to ensure the desired product quality."

Manufacturing defects may affect one or more of the drug quality attributes.

- Identity
- Strength
- Purity
- Quality/Performance

Critical Quality Attributes

1) Identity tests

Drug substance and drug product fails to meet established performance specifications:

Manufacturing/formulation

- Starting Material, intermediates and final drug substance
- *FT-NIR, optical rotation USP<781>, melting point, etc.*

Critical Quality Attributes

- 2) Strength
  - Assay, USP or NDA/ANDA methodology should be specified; 90%-110%
  - Content Uniformity
    - (USP <905>)
  - Stability Timepoints
    - Modification to accelerated and Controlled Room Temp should be identified

Critical Quality Attributes

- 3) Purity of drug product – Quantitative data
  - Impurities (ICH Q3A/Q3B)
  - Degradation products (ICH Q3A/Q3B)
  - Residual solvents (ICH Q3C)
  - Chemical or Microbial Contamination Objectionable pathogen, sterility, PCR

Critical Attributes for Drug Quality

- 4) Quality/ Performance
  - Drug Substance
    - Particle sizes and shape within specifications, especially important for solubility
  - Drug product
    - Appropriate drug delivery system
    - Suitable excipients
    - Consistent dissolution rate, .etc

FAR Case Study

- Pharmaceutical Company X manufactures an oncological drug called Fluorouracil Injection, USP lot 55-555 expiration date of Oct. 2024. This sterile liquid was manufactured in a Type I clear vial. At 3-month stability time point the HPLC assay value resulted in 85.0%.
- What type of root cause investigation should the company provide to FDA regarding this OOS result?
- Within 3 working days the company submitted an initial FAR to FDA.

Fluorouracil Injection Root Cause

- The firm performed a retrospective review of their stability data at 0, 3 and 6 month time points.
- They reviewed 0 time: the results were 90.0% within specifications of 90.0% -110.0%. However by 3 months time pt. the product was OOS.
- What type of documentation, data and testing plan should the firm perform?
  - Impurity profile, degradation testing?
  - What knowledge of the Fluorouracil active did they exclude?
- (Hint) Is the packaging and container closure system a factor?

Identify the Type of Information CDER Expects in BPDR Submissions

Biological Product Deviation Reports (BPDRs)

- A manufacturer, who holds a biological product license and has control over the product when a deviation has occurred, must report it to CDER, as required by 21 CFR 600.14 (“Reporting of biological product deviations by licensed manufacturers”).
- The responsible firm must report as soon as possible, but not to exceed ***45 calendar days*** from the date of discovery any information that may affect the product’s safety, purity or potency including:
  - Manufacturing, including testing
  - Processing
  - Packaging
  - Labeling
  - Storage/ Holding
  - Distribution

CBER-Regulated Biologics

What does CBER regulate?

- Biological products, including blood and blood products, blood derivatives, vaccines, allergenics, gene therapies, cellular therapies, and xenotransplantation.
- Human cells and tissue products (HCT/Ps) that are intended for implantation, transplantation, infusion, or transfer into a human recipient. This may include bone, ligament, skin, dura mater, heart valve, cornea, hematopoietic stem/progenitor cells derived from peripheral and cord blood, manipulated autologous chondrocytes, epithelial cells on a synthetic matrix, and semen or other reproductive tissue.
- Medical devices involved in the collection, processing, testing, screening, manufacture and administration of blood, blood components, and human tissue and cellular products.
- HIV test kits used to screen donor blood, blood components and tissue and cellular products (HCT/Ps), and products used to diagnose, treat, and monitor persons with HIV and AIDS.
- Certain drug products, including blood bags with anti-coagulant, and plasma volume expander.

CDER-Regulated Biologics

- Biologics transferred to CDER from CBER on June 30, 2003.

The therapeutic biological products include:

- Monoclonal antibodies for in-vivo use
- Cytokines, growth factors, enzymes, immunomodulators; and thrombolytics
- Proteins intended for therapeutic use that are extracted from animals or microorganisms, including recombinant versions of these products (except clotting factors)
- Other non-vaccine therapeutic immunotherapies

- All Biologics are required to file BPDR for any product deviations per 21CFR 600.14, and these will be reviewed by either CBER or CDER per the assigned jurisdiction

Biologics Definition

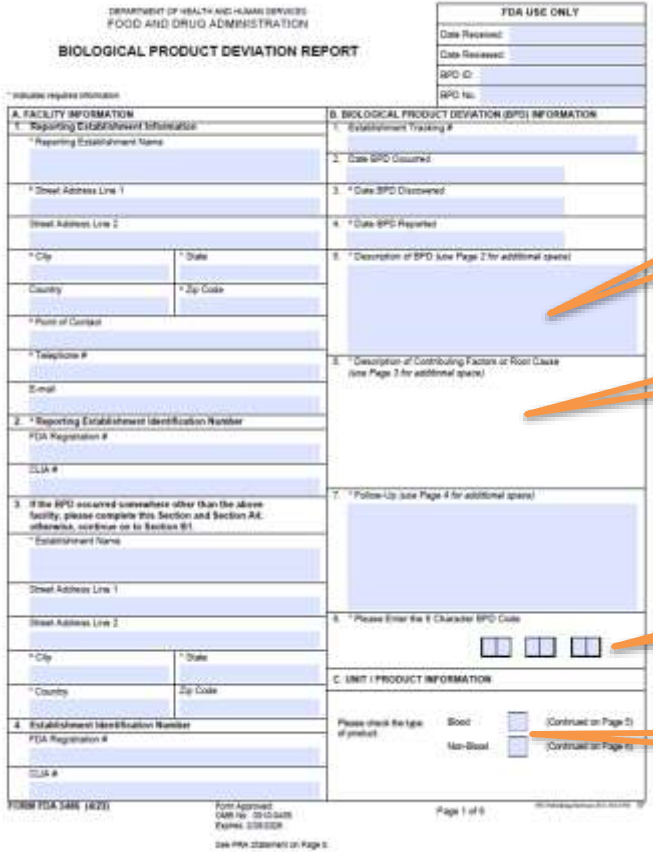
- Re-defined Biologic product by BPCI (2009) and transitioned on March 23, 2020.
- Biologics Definition:

The BPCI Act clarified the statutory authority under which these protein products will be regulated by amending the statutory definition of a "biological product" in the PHS Act to include a "protein (except any chemically synthesized polypeptide)," and describing procedures for submission of a marketing application for these protein products. The Further Consolidated Appropriations Act, 2020, enacted on December 20, 2019, further amended the definition of a "biological product" in the PHS Act to remove the parenthetical "(except any chemically synthesized polypeptide)" from the statutory category of "protein," meaning that such chemically synthesized products are now within the definition of "biological product" and subject to the statutory transition. This legislative change only affects chemically synthesized products that fall within the interpretation of "protein" (see updated Preliminary List below); this legislative change does not affect "peptides" (i.e., polymers composed of 40 or fewer amino acids).

Biological Product Deviation Reports (BPDRs)

- FDA has developed FORM FDA 3486, a standardized reporting format that may be submitted in paper form by mail. FORM FDA 3486 is used to report biological product deviations.
  - https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM061463.pdf
- CBER Submission: Electronic Submission of Biological Product Deviation Reports (eBPDR)
  - BPDRs can be submitted electronically via the Internet (for CBER submission only)
  - A valid Registration or CLIA (Clinical Laboratory Improvement Amendment) Number is required to use this eBPDR system at CBER. If firm does not have a valid Registration Number, they should contact the local FDA district office to obtain a Registration Number from the appropriate Registration Monitor (Blood, Device, or Drug).
- CDER Submission: separate from eBPDR system and via e-mail or paper submissions

FORM FDA 3486



DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

BIOLOGICAL PRODUCT DEVIATION REPORT

FDA USE ONLY
Date Received:
Date Received:
BPD ID:
BPD No.

* Indicates required information

A. FACILITY INFORMATION
1. Reporting Establishment Information
* Reporting Establishment Name
* Street Address Line 1
Street Address Line 2
* City
* State
Country
* Zip Code
* Point of Contact
* Telephone #
E-mail
2. * Reporting Establishment Identification Number
FDA Registration #
CLIA #
3. If the BPD occurred somewhere other than the above facility, please complete this Section and Section A4; otherwise, continue on to Section B1
* Establishment Name
Street Address Line 1
Street Address Line 2
* City
* State
* Country
Zip Code
4. Establishment Identification Number
FDA Registration #
CLIA #

B. BIOLOGICAL PRODUCT DEVIATION (BPD) INFORMATION
1. Establishment Tracking #
2. Date BPD Occurred
3. * Date BPD Discovered
4. * Date BPD Reported
5. * Description of BPD (use Page 2 for additional space)
6. * Description of Contributing Factors or Root Cause (use Page 3 for additional space)
7. * Follow-Up (use Page 4 for additional space)
8. * Please Enter the 6 Character BPD Code

C. UNIT / PRODUCT INFORMATION
Please check the type of product:
Blood (Continued on Page 5)
Non-Blood (Continued on Page 6)

FORM FDA 3486 (8/21)
Form Approved:
OMB No. 0910-0458
Expires: 2/28/2024
See PRA statement on Page 6.
Page 1 of 6

Description of the deviation

Initial Investigation description

Defect Code

Blood (CBER) or Non-Blood (CBER and CDER) product designation

BPD Code Categories for Non-Blood Products

The BPD Code is made up of three levels.

The first level (XX) identifies the system affected in which there was a breakdown or failure, which resulted in the distribution of an unsuitable product. Use the appropriate guidance document for determining the system affected.

BPD Code |__XX__| - |_____| - |_____|

Summary of Product Codes by Type of Product

For blood products the systems include:	For non-blood products the systems include:	For HCT/Ps the systems include:
DS - Donor Screening	IM - Incoming Material Specifications	DE - Donor Eligibility
DD - Donor Deferral	PC - Process Controls	DS - Donor Screening
BC - Blood Collection	TE - Testing	DT - Donor Testing
CP - Component Preparation	LA - Labeling	FA - Facilities
VT - Transfusion-Transmitted Infection Testing	PS - Product Specifications	EC - Environmental Controls and Monitoring
RT - Routine Testing	QC - Quality Control and Distribution	EQ - Equipment
LA - Labeling		SR - Supplies and Reagents
QC - Quality Control and Distribution		RE - Recovery
		PC - Processing and Process Controls
		LC - Labeling Controls
		ST - Storage
		SD - Receipt, Pre-Distribution, Shipment and Distribution

6-Character BPD Code Example

PS-53-** Stability testing failed
- PS-53-01 Other
- PS-53-02 Potency
- PS-53-03 Preservative
- PS-53-04 Container closure integrity
- PS-53-05 Chemical analysis/purity
- PS-53-06 Moisture
- PS-53-07 pH
- PS-53-08 Appearance

†PS-54-** Administration set, or device constituent part (packaged with product) did not meet specifications
- PS-54-01 Other
- PS-54-02 Incorrect or missing label
- PS-54-04 Expired

QC--** QUALITY CONTROL AND DISTRIBUTION**

QC-60-** Miscellaneous
- QC-60-01 Other

QC-61-** Product distributed inappropriately
- QC-61-01 Other
- QC-61-02 Product distributed prior to completion of required testing
- QC-61-03 Product distributed prior to CBER approval of a PAS
- QC-61-04 Product distributed less than 30 days after submission of CBE-30 or prior to submission of CBE-30
- QC-61-05 Product distributed prior to validation of process
- QC-61-06 Outdated product distributed
- QC-61-07 Product distributed prior to record review or release by the quality control unit

QC-62-** Shipping and storage
- QC-62-01 Other
- QC-62-02 Product shipped at incorrect temperature
- QC-62-03 Product stored at incorrect temperature
- QC-62-04 No documentation product was shipped or stored at appropriate temperature

QC-63-** Product identified as unacceptable, and not quarantined
- QC-63-01 Other

QC-64-** Packing
- QC-64-01 Other
- QC-64-02 Vial missing
- QC-64-03 Packaged incorrectly
- †QC-64-04 Broken or cracked vial/syringe/container/device constituent part
- QC-64-05 Improper orientation (e.g., sideways)

FORM FDA 3486 (Cont.)

Biological Product Deviation Report

B5. DESCRIPTION OF BPD *(continued)*

Detailed Description of the Deviation

Biological Product Deviation Report

B6. DESCRIPTION OF CONTRIBUTING FACTORS OR ROOT CAUSE *(continued)*

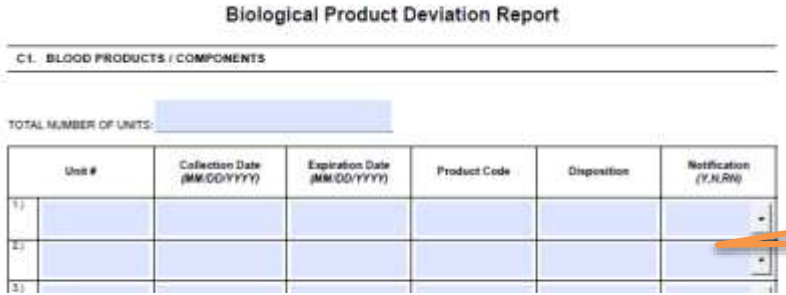
Detailed description of the investigation, root cause analysis, CAPA…etc.

Biological Product Deviation Report

B7. FOLLOW-UP *(continued)*

Details of follow-up information and whether additional reports are planned to be submitted

FORM FDA 3486 (Cont.)



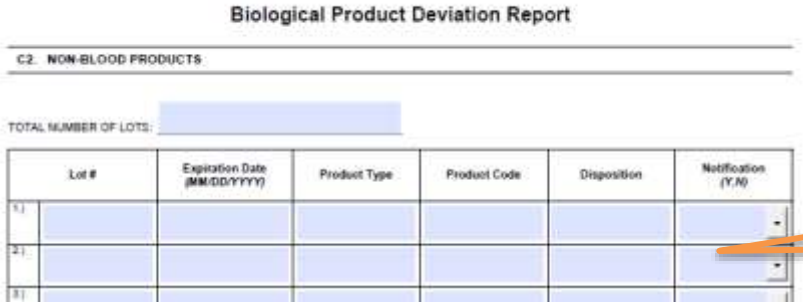
Biological Product Deviation Report

C1. BLOOD PRODUCTS / COMPONENTS

TOTAL NUMBER OF UNITS:

	Unit #	Collection Date (MM/DD/YYYY)	Expiration Date (MM/DD/YYYY)	Product Code	Disposition	Notification (Y,N,RN)
1.						
2.						
3.						

Impacted units/lots for Blood products (CBER only)



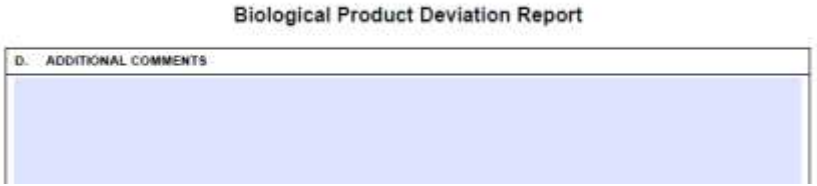
Biological Product Deviation Report

C2. NON-BLOOD PRODUCTS

TOTAL NUMBER OF LOTS:

	Lot #	Expiration Date (MM/DD/YYYY)	Product Type	Product Code	Disposition	Notification (Y,N)
1.						
2.						
3.						

Impacted units/lots for Non-Blood products (CBER and CDER)



Biological Product Deviation Report

D. ADDITIONAL COMMENTS

Most Common Reporting Errors from FORM FDA 3486 in CDER BPDR Program

- Listing multiple applications and/or products under one form
- Reporting to the incorrect center or office
- Having the reporting firm information that does not match our data
- Having the wrong/inappropriate problem firm
- Inappropriate defect code
- Did not refer to general instructions while preparing for the report submission
- Refer to CDER BPDR website for submission recommendation to CDER BPDR program

https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/cder-biological-product-deviations

CDER BPDR Submission Recommendations

- One BPDR must be submitted per Biological License Application (BLA) product impacted by the deviation;
- Wherever possible list BLA application information during reporting;
- Multiple lots of the same BLA product impacted by the same deviation be reported in one BPDR;
- Multiple complaints with similar root cause for one BLA product be reported in one BPDR provided that these complaints were received within 45 calendar days from the date of discovery;
- Wherever possible, indicate in the initial report whether additional follow-up or final reports are expected.
- Electronic submission to CDER DQRS Reports mailbox is preferred: CDERDQRSREPORTS@fda.hhs.gov;
- Custom reports attached to FDA FORM 3486 or any submissions without FDA FORM 3486 is discouraged.

How to Avoid Information Request(s) After BPDR Submission

- Provide as much information of the description of the deviation that includes defect and scope assessment.
- Provide Root Cause Analysis for clear and logical investigation. Include details for appropriate actions to prevent recurrence.
- Provide any Corrective Action and Preventative Action (CAPA) plans that are designed based on the root cause identified.
- Provide BLA and relevant product information.
- Select the best representation of the defect code from the current BPD code list.
- Provide information accurately per the general instructions for BPDR submission.
- Provide relevant data in the report to allow appropriate assessment and/or product quality evaluation.
- Provide information to all fields in the FORM FDA 3486.
- Avoid custom reports attached to the end of the form.
- Adhere to the commitments stated in the initial report.

Summary

- When a product quality deviation occurs, the manufacturer and applicant holder should initiate a retrospective root cause analysis of the failure mode. It should be implemented based on a pre-defined protocol that includes affected lots and a sampling strategy for testing.
- This plan should outline critical control points of the manufacturing process and demonstrate performance of the drug or biological product.
- When conducting a root cause analysis of a product or performance issue, the traceback of the causality should begin at the lowest level where the failure occurred.

Summary

- When a deviation occurs, three working days are required for the submission of a FAR by the A/NDA applicant holders; and 45 days for a BPDR by the BLA applicant holder for biologics.
- The use of FDA forms 3331a for FARs and 3486 for biologicals are encouraged.
- These reports should include complete and accurate assessment of the detailed root cause investigations and Corrective Action and Preventative Action (CAPA) Plans.

Challenge question #1

Q: Is there always a causal relationship between product quality deviations and adverse events?

Answer to Challenge Question #1

Challenge Question #2

Q: What is the value of having a standardized format for reporting drug product quality reports?

Answer to Challenge Question #2

References for FAR

- 3331a FDA form and instructions: https://www.fda.gov/about-fda/reports-manuals-forms/forms
- Field Alert Report Guidance: https://www.fda.gov/drugs/surveillance/field-alert-reports
- Field Alert Report From: Questions and Answers https://www.fda.gov/drugs/surveillance/field-alert-report-form-questions-and-answers
- Field Alert Report Submission – Questions and Answers- Guidance for Industry July 2021
- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/field-alert-report-submission-questions-and-answers-guidance-industry

References for BPDR

CDER BPDR website:

https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/cder-biological-product-deviations

FDA Guidance for Industry on Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other than Blood and Blood Components:

http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/General/UCM163923.pdf.

FORM FDA 3486:

https://www.fda.gov/media/70604/download

Deviation Codes:

https://www.fda.gov/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/biological-product-deviation-reporting-and-hctp-deviation-reporting-deviation-codes

Non-Blood Product Codes:

https://www.fda.gov/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/biological-product-deviation-reporting-and-hctp-deviation-reporting-non-blood-product-codes

Postmarketing Safety Reporting for Combination Products Guidance for Industry and FDA Staff:

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarketing-safety-reporting-combination-products

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Thank you!


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