



Product Quality Terms in MedDRA

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Product Quality Terms – Who?

- FDA requested the addition of product quality terms into MedDRA
- Allows FDA to use a single coding system for adverse events and product quality issues
 - Currently CDER, CBER and CFSAN use MedDRA in their postmarketing safety systems



Product Quality Terms – Why?

- FDA:
 - Requires manufacturers to report contamination, packaging issues, other product quality issues
 - Solicits voluntary reports from lay and medical community



Why Product “QUALITY”?

- FDA sees quality as important information to capture
- “Product” refers to any product regulated by FDA (e.g., drugs, device, food, etc.)
- To address concerns about the word “quality”, FDA provided a Concept Description for Introductory Guide



Product Quality Description

- “Product quality” = abnormalities introduced during product
 - Manufacturing
 - Labeling (physical label)
 - Packaging
 - Shipping
 - Handling
 - Storage



Product Quality Terms – How and When?

- FDA provided list of terms, including potential grouping terms, for MSSO to consider
- MedDRA Expert Panel provided input
- Most of the proposed terms were added to MedDRA Version 12.0



Expert Panel Review

- Generally favorable to FDA proposal
- Some issues over meaning of “product” (medicinal vs. devices)
- Concern about overlap with some existing medication error terms
- Recommended to be addressed in Term Selection PTC document
- Each term should be distinct and self-explanatory to MedDRA Version 12.0



Product Quality Terms (cont)

- New HLGT *Product quality issues* in SOC *General disorders and administration site conditions*
- Five new HLTs:
 - HLT *Product contamination and sterility issues*
 - HLT *Product label issues*
 - HLT *Product packaging issues*
 - HLT *Product physical issues*
 - HLT *Product quality issues NEC*
- 139 new PT/LLT terms added
- 24 Existing PT/LLT terms moved to product quality HLTs



MedDRA Introductory Guide

- Appendix B (Concept Descriptions)

Closure	Compounding	Compounding issue	Coring	Crystal formation
Dissolution	Gel Formation	Label	Precipitate	Product coating incomplete
Product colour issue	Product odour abnormal	Product taste abnormal	Product quality issues	Seal
Sedimentation	Solubility			



MedDRA Introductory Guide (cont)

- Examples of concept descriptions
 - **Coring:** A small piece of the stopper is sometimes sheared off (known as coring); an example could be after a needle is inserted through the stopper of a medication vial
 - **Product coating incomplete:** Refers to the outer coating of a product when it does not entirely cover the product and can appear blotchy, splattered or speckled



Issues to Monitor/Resolve

- Potentially confusing terms
 - E.g., PT *Product expiration date issue* (new term) vs. PT *Expired drug administered* (medication error)
- Placement of device quality terms
 - Suspended pending completion of Device Working Group task



Browser Demonstration – Product Quality Terms



Thank You

Q&A