



Product Quality and Device Terms

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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

Product Quality Terms

- 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

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
 - Initially suspended pending completion of Device Working Group task
 - Needle and syringe terms now placed in device hierarchy



Device Terms



Device Terms – Who, Why, and What?

- Existing device terms in MedDRA are used by subscribers
- In response to users' requests, MSSO is reviewing device terms in MedDRA
- External references
 - FDA Center for Devices and Radiological Health (CDRH)
 - Patient problem codes (events/procedure in patient)
 - Device problem codes (refer to device itself)
 - International Organization for Standardization/ Technical Committee 210 (ISO/TC 210)



Patient Problem Terms

- MSSO reviewed Patient Problem Terms with CDRH experts
- Implemented those that fit MedDRA rules and conventions
- Created self-explanatory device terms to avoid confusion with patient terms
- 60 terms added to MedDRA in versions 11.0 and 11.1

Goals of Device Problem Terms Review

- Provide intuitive hierarchical groupings
- Realign existing PT/LLT device terms
- Develop device term acceptance/evaluation criteria
- Draft user guidance for Term Selection PTC document



MedDRA Device Working Group

- Recommended by Expert Panel members and self-nominated
- 8 companies
- JMO
- MSSO

Review Timeline

- Started in October 2008
- Completed in May 2009
- Hierarchy to be posted as complex change proposal June 2009
- MSSO to implement approved proposals in v13.0 (March 2009)

Current Hierarchy

- Three HLTs under HLG *Procedural and device related injuries and complications NEC* in SOC *Injury, poisoning and procedural complications*
 - HLT *Device component findings*
 - PT *Device breakage, PT Device electrical finding*
 - HLT *Device malfunction events*
 - PT *Cardiac pacemaker malfunction, PT Oversensing*
 - HLT *Device related complications*
 - PT *Medical device pain, PT Device related infection*

Proposed Hierarchy

- Replaced by two new HLGTS in SOC
General disorders and administration site conditions
 - HLGTT *Complications associated with device*
 - HLGTT *Device issues*
 - HLGTT *Product quality issues (existing)*

Proposed Hierarchy Details

- HLTG *Complications associated with device*
 - HLT *Breast complications associated with device*
 - HLT *Cardiac complications associated with device*
 - HLT *Complications associated with device NEC*
 - HLT *Eye complications associated with device*
 - HLT *Reproductive complications associated with device*
 - HLT *Respiratory complications associated with device*
 - HLT *Vascular complications associated with device*

Proposed Hierarchy Details (cont)

- HLTGT *Device issues*
 - HLT *Device computer issues*
 - HLT *Device electrical issues*
 - HLT *Device incompatibility issues*
 - HLT *Device information output issues*
 - HLT *Device issues NEC*
 - HLT *Device malfunction events NEC*
 - HLT *Device operational issues NEC*
 - HLT *Device physical property and chemical issues*

Device Terms Considerations

- Proposed hierarchy is framework for additional device concepts – added through Change Request process
- Terms represent event concepts, not device types
 - Specific terms for device types, e.g., IUD, IOL will generally not be accepted in future
- Product quality terms include devices
 - If existing product quality term covers concept, a separate device term will not be added, e.g., PT *Product contamination microbial*



Thank You

Q&A