

Update on New MedDRA SOC *Product issues*



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Topics

- ▶ Purpose of new System Organ Class (SOC) Product issues
- ▶ Features
- ▶ Contents and structure
- ▶ Impact
- ▶ Intended use

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SOC Product issues

- ▶ 27th SOC implemented in MedDRA Version 19.0 on 1 March 2016
- ▶ Accommodates non-clinical/non-patient related concepts pertaining to products
- ▶ Important concepts as they may affect patient safety
- ▶ Goal of product quality terms in MedDRA is to support recording of product quality issues and any associated adverse events using a single terminology
- ▶ Expert Working Group provided input on structure and contents
 - Representatives from regulatory authorities, industry, MSSO, JMO
 - Expertise in MedDRA and product quality

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Features

- ▶ Same structure and characteristics as other SOC's
 - Content change, not structural change in MedDRA
- ▶ Five level hierarchy (SOC, HLGT, HLT, PT, LLT)
- ▶ 100 character limit for terms
- ▶ 8 digit MedDRA codes
- ▶ Multi-axial links to aid in retrieval and preserve links to patient safety
 - PT *Transmission of an infectious agent via product* (primary link to SOC *Infections and infestations*)

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Contents

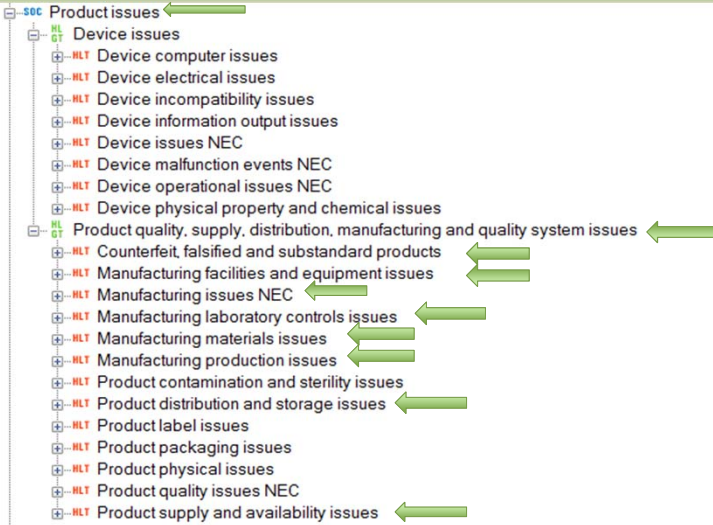
- ▶ Includes terms relevant for issues with
 - Product quality
 - Devices
 - Manufacturing and quality systems
 - Supply and distribution
 - Counterfeit products

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Contents and Structure



← =New

Existing grouping terms
(moved from General disorders SOC)

In MedDRA v19.0
 •5 new PTs in HLG
Device issues
 •8 new PTs in HLG
Product quality, supply, distribution, manufacturing and quality system issues

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Impact on MedDRA Files

- hlgt.asc
- hlgt_hlt.asc
- hlt.asc
- hlt_pt.asc
- intl_ord.asc
- lt.asc
- mdhier.asc
- meddra_history_english.asc
- meddra_release.asc
- pt.asc
- smq_content.asc
- smq_list.asc
- soc.asc
- soc_hlgt.asc

MedDRA files distributed with each release
 • Detail of SOC file displayed

Code	SOC Name	Abbreviation
10005329	Blood and lymphatic system disorders	Blood
10007541	Cardiac disorders	Card
10010331	Congenital, familial and genetic disorders	Cong
10013993	Ear and labyrinth disorders	Ear
10014698	Endocrine disorders	Endo
10015919	Eye disorders	Eye
10017947	Gastrointestinal disorders	Gastr
10018065	General disorders and administration site conditions	Genrl
10019805	Hepatobiliary disorders	Hepat
10021428	Immune system disorders	Immun
10021881	Infections and infestations	Infec
10022117	Injury, poisoning and procedural complications	Inj&P
10022891	Investigations	Inv
10027433	Metabolism and nutrition disorders	Metab
10028395	Musculoskeletal and connective tissue disorders	Musc
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neopl
10029205	Nervous system disorders	Nerv
10036585	Pregnancy, puerperium and perinatal conditions	Preg
10037175	Psychiatric disorders	Psych
10038359	Renal and urinary disorders	Renal
10038604	Reproductive system and breast disorders	Repro
10038738	Respiratory, thoracic and mediastinal disorders	Resp
10040785	Skin and subcutaneous tissue disorders	Skin
10041244	Social circumstances	SocCi
10042613	Surgical and medical procedures	Surg
10047065	Vascular disorders	Vasc
10077536	Product issues	Prod

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Impact on Tools

- ▶ No impact on MSSO's tools
 - Desktop Browser
 - Web-Based Browser,
 - MVAT
 - WebCR
- ▶ Check your tools
 - MSSO Help Desk can provide a demonstration file set with 27 SOCs
 - Demonstration files have four HLTs that lack PTs - sufficient for testing purposes
- ▶ Awareness within organization for locally developed applications
- ▶ Impact on International Order of SOCs
 - Added as last on list

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Impact on Existing Data – Moved to the New SOC

MedDRA Version 18.1

-SOC	General disorders and administration site conditions
-HLT	Administration site reactions
-HLT	Body temperature conditions
-HLT	Complications associated with device
-HLT	Device issues
-HLT	Fatal outcomes
-HLT	General system disorders NEC
-HLT	Product quality issues
-HLT	Product contamination and sterility issues
-PT	Exposure via contaminated device
-PT	Product cleaning inadequate
-PT	Product contamination
-PT	Product contamination chemical
-PT	Product contamination microbial
-PT	Product contamination physical
-PT	Product contamination with body fluid
-PT	Product sterility lacking
-PT	Suspected transmission of an infectious agent via product
-PT	Transmission of an infectious agent via product
-HLT	Product label issues
-HLT	Product packaging issues
-HLT	Product physical issues
-HLT	Product quality issues NEC
-HLT	Therapeutic and nontherapeutic effects (excl toxicity)
-HLT	Tissue disorders NEC

MedDRA Version 19.0

-SOC	Product issues
-HLT	Device issues
-HLT	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
-PT	Exposure via contaminated device
-PT	Product cleaning inadequate
-PT	Product contamination
-PT	Product contamination chemical
-PT	Product contamination microbial
-PT	Product contamination physical
-PT	Product contamination with body fluid
-PT	Product sterility lacking
-PT	Suspected transmission of an infectious agent via product
-PT	Transmission of an infectious agent via product
-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

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Impact on Documents

- ▶ Updates to MSSO documents, e.g., MedDRA Introductory Guide
- ▶ Points to Consider documents
 - Term Selection – edits to Section 3.28 Product quality issues to reference new SOC and HLG
 - Data Retrieval and Presentation – edits to add new SOC in Appendix 6.3 International Order of SOCs
- ▶ Consider updating your own coding and retrieval guidelines, SOPs, procedures documentation

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Intended Use

- ▶ Use of standardized terminology for product quality issues will facilitate data exchange
- ▶ Potential uses of product quality terms, including manufacturing and distribution issues
 - Reporting product defects to regulatory authorities
 - Track and trend quality issues or deviations in organizations' internal databases
- ▶ Encourage use by quality departments in organizations

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Summary

- ▶ Successful implementation so far
- ▶ MedDRA Version 19.0 becomes the current reporting version on 2 May 2016
 - First Monday of second month after release
- ▶ Continued growth based on users' contributions

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Ask

