Revision of ISO 13485
DIS2

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Regulators

Exceptionally important that the level of harmonization be maintain or further convergence be obtained for such Regulatory programs as the Medical Device Single Audit Program (MDSAP), as well as the ease of implementation by the manufacturers.

Key Issues for Regulators

- The numbering system must be reviewed and revised throughout to ensure there is meaningful numbering for audits. Must align with the GHTF Nonconformance Grading document N19. Realize that for regulatory audits NC will be graded at a level of X.X.X – therefore any delineation down from that has limits utilization. Clause numbers that are “deeper” than X.X.X.X should be eliminated.

Key Issues for Regulators

Example: Change Title 6.4 Work Environment to "Work Environment and Contamination" in order to remove subclause numbers 6.4.1.1 to 6.4.1.4 these numbers are too delineate. No distinctions are needed to this level as they do not separate different concepts. This level of numbering will be meaningless and at best cumbersome for auditors to use. Renumber and re-title

Key Issues for Regulators

Change:

6.4 Work Environment and Contamination

6.4.1 Work Environment [instead of 6.4.1 General and ***remove 6.4.1.1 – 6.4.1.3***]

6.4.2 Contamination

6.4.3 Particular requirements for sterile devices

Key Issues for Regulators

- GHTF Definition should be adopted wherever available since these have been negotiated definitions between many regulatory authorities already. Having new definitions within ISO 13485 does not help and only adds differences for manufacturers to comply with that are not necessary.

Key Issues for Regulators

- Definitions such as:
  - Authorized Representative
  - Importer
  - Label
  - Labelling

Key Issues for Regulators

- 4.1.4 The organization shall manage these quality management system processes in accordance with the requirements of this International Standard and applicable regulatory requirements.

Changes to be made to these processes shall be:

a) evaluated for their impact on the quality management system

Key Issues for Regulators

- Outside the scope of the standard as this encroaches on continual improvement and business impacts outside the scope of this regulatory standard. Further there are not necessarily tools and techniques known as current practices for such evaluation as compared to tools for evaluation of impact on products and manufacturing processes.

Key Issues for Regulators

- Should not use “purchased product” as this connotes the exchange of money and that is not always the case, for example when one facility with one QMS supplies a portion of the finished device to another sister facility with a different QMS – they often do not purchase it by it is supplied product under internal agreements or arrangements. All supplied product – purchased or not – should follow these control requirements.

Key Issues for Regulators

- Traceability to the end user in all cases is onerous, costly and over burdensome. Goes way beyond regulatory requirements. Most regulators only require traceability to the first person outside of the manufacturers control unless it is a high risk implantable device. Even for implantable devices not all are required to be traced to the end user. Cost burden to industry to comply with this requirement outweighs the benefit.

Key Issues for Regulators

"In defining the records required for traceability, the organization shall include records of all components, materials and work environment conditions…"

- Requirement is too onerous and goes way beyond regulatory requirements. The record keeping burden is so high and in many cases impossible to enforce beyond the initial consignee or first person outside the control of the manufacturer.

Key Issues for Regulators

- Requirements for measurements of the quality management system processes are to onerous and outside the scope of most regulatory authorities. Regulatory authorities have jurisdictions over the product the process that design, manufacture, distribute the process. This requirements is continual improvement for the QMS and not just effectiveness and suitability.

Key Issues for Regulators

- Just an example of some of the major concerns Regulatory Authorities have with the ISO 13485 DIS2
- Very important that manufacturers pay close attention to this standards and its revision in June before is becomes a Final Draft International Standard where NO technical changes are allowed!

Conclusion

Thank you for you attention and involvement in this very important process.