

DGMP Advisory Committee

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AdvaMed

- Advanced Medical Technology Association (“AdvaMed”) represents hundreds of manufacturers of medical devices that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatment.
- Members range from the smallest to the largest medical technology innovators and companies.
- Thank you for the opportunity to present today on this very important topic. We intend to provide written comments to the docket once we have had time to evaluate proposed rule in detail.

Topics to be Covered

- Importance of international voluntary consensus standards
- Benefits of Transition from QSR to ISO13485
- Points for Implementation
 - Avoiding “13485 Plus”
 - Sufficient transition period
 - Roll Out
 - Inspections
 - Role of Risk

Importance of Voluntary International Consensus Standards

- Use of international voluntary consensus standards to meet regulatory requirements has many benefits, including
 - furthers efforts to harmonize global medical technology regulations
 - introduces efficiencies for both FDA & the medical device industry by reducing duplication
 - minimizes unnecessary costs and delays in patient access to innovative new devices.

Importance of International Voluntary Consensus Standards Cont'd.

- Open process encourages participation by a broad group of stakeholder experts in development of standards, ensuring high level of quality.
- OMB Circular A-119 and National Technology Transfer and Advancement Act of 1995 direct U.S. government agencies to use standards developed or adopted by voluntary consensus standards bodies rather than government-unique standards, except where inconsistent with applicable law or otherwise impractical.
- Reduces barriers to trade

Benefits of Transition from QSR to ISO13485

- AdvaMed strongly supports the proposed transition.
- Promotion of global harmonization and reduction of burden while ensuring patient safety and public health
 - 2016 version very much aligned with QSR
 - Standard widely accepted throughout the globe
 - Many within industry already follow the standard.

Benefits of Transition from QSR to ISO13485, Cont'd.

- MDSAP based on standard.
- Eliminates need to maintain multiple quality systems.
- Sets a great example to encourage other jurisdictions to adopt standard and not impose their own country-unique quality systems requirements.

Points for Implementation: Avoiding “13485 Plus”

- To gain full benefits of transition, importance of avoiding “13485 plus” type approach.

Points for Implementation: Sufficient Transition Period

- Need sufficiently long transition period to avoid disruption.
- Recommend at least two-year transition period.
- Transition more challenging for small companies and/or companies only selling in the United States.
- Transition needs to take into account how long it takes to rewrite quality systems and hire needed experts.
- Companies could choose to immediately implement.

Points for Implementation: Roll Out

- Need for clear roll out, including transition timeframes.
- Training of both industry and FDA inspectional cadre
 - AdvaMed happy to partner with FDA to assist with training.
- Both industry and FDA will need clear understanding of any requirements that are above and beyond QSR, e.g., role of risk
- Clarification that other provisions, e.g., Parts 803 and 806 continue to apply for those that may be less familiar with regulatory scheme.

Points for Implementation: Inspections

- Clarify that while need to abide by standard, certification not required as having to pay for a certification could be costly to small companies.
- Importance of harmonizing how FDA conducts inspections with other inspectors, e.g., notified bodies.
- We would like to understand how FDA intends to leverage existing ISO13485 certifications.
 - What value may be conferred to those that hold existing certificates?

Points for Implementation: Role of Risk

- ISO13485 places a much greater emphasis on risk throughout a product's lifecycle than QSR
- For instance, design and development is a potential challenge for implementation, especially with linkages to risk management.

Conclusion and Thank you

- We very much support the proposed transition.
- We look forward to collaborating with FDA and other stakeholders on implementation.
- Thank you for the opportunity to present today.