AdvaMedDx

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Proposed IMDRF IVD Market Authorization Table of Contents—Industry Perspective

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Overview

- Background
- Considerations
- Next Steps

Background

- IMDRF Issues IVD Market Authorization Table of Contents (TOC) for Comments (late Nov. 2013)
  - Industry supports goals of IMDRF Regulated Product Submission (RPS) efforts
  - Appreciates opportunity to participate as members in RPS WG
  - However, this detailed TOC document has generated numerous questions and concerns
  - Short time frame for review (Jan 17 deadline)

Considerations

- Significant non-harmonized jurisdictional elements—more appropriate for separate country-specific guidance
- Risk-based submission elements not articulated in document itself—requirements irrespective of product complexity, novelty, or risk-based classification
- Laundry list of requirements well beyond a TOC
  - Overly granular; can be condensed and still capture necessary elements
  - Contains proprietary/confidential data elements and information outside of product submission

Considerations

- Clear communication and transparency as important
- Industry has important contributions and can assist with constructive comments and lend expertise
- Encourage thoughtful consideration of comments of industry in US and globally
  - Integrate necessary revisions for clarity and improved harmonization
  - Work collaboratively through issues for successful implementation
- Welcome early helpful dialogue and technical input

Proposed Next Steps

- Additional dialogue on document and implementation plans with industry
- Leverage better use of available standards and existing harmonization documents (e.g., EP checklist, IVD STED, IVD Clinical Performance Studies)
- Outline risk-based implementation in the document
- Focus on core harmonized requirements
  - Cross reference or create separate country-specific guidance if needed
- Provide opportunity for industry review and comment on all related documents