Global Medical Technology Alliance
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The Future of the Medical Device Single Audit Program

IMDRF Stakeholder Day
Tuesday, March 19, 2019
Moscow, Russia

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Outline

- Background
- Value of the MDSAP
- Opportunities within the current model
- Recommendations for the future
- GMTA support for the MDSAP

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Background

- Goal of regulatory convergence since GHTF
- Program initiated in 2012
- Began as a pilot with 4 IMDRF members:

  Australia, Brazil, Canada, U.S.
- Expanded to include Japan, EU/WHO (observers)
- Health Canada mandates MDSAP in 2019

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Value of MDSAP

- Regulators
  - Efficient and flexible use of resources
  - Alignment of global regulatory requirements
- Industry
  - Single audit in place of multiple inspections
  - Audits announced and planned with manufacturer
- Patients
  - Timely access to safe and effective medical devices
  - Confidence in high-quality devices

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Opportunities Within the Current Model

- Leverage efficiencies to reduce audit duration
- Continue AO training to promote consistency
- Reinforce goal of minimizing repeat inspections
- Continued stakeholder education and promotion of MDSAP

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Recommendations for the Future

- Further leverage MDSAP audits
  - Acceptance of MDSAP in whole
  - Reduce local review to “essential” requirements only
- Update companion documents and AO training to reflect learnings
- Continued refinement of current audit grading system

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GMTA Supports the MDSAP

GMTA applauds IMDRF for:

- Building on the strong foundational work of the GHTF
- Initiating the MDSAP
- Advancing harmonization based on a fundamental regulatory activity