The Future of the Medical Device Single Audit Program

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

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