Coalición Interamericana de Convergencia Regulatoria
SECTOR DE TECNOLOGÍA MÉDICA

Coalizão Interamericana de Convergência Regulatória
SETOR DE TECNOLOGIA MÉDICA

Inter-American Coalition for Regulatory Convergence
MEDICAL TECHNOLOGY SECTOR

POLICY SESSION WITH REGULATORS – US FDA
AGENDA

(Duration Aprox. 1hr., 30 min.)

Date: 15 June 2020
Time: 10:00 – 11:30 EST
Location: GotoWebinar

TIME (min)	AGENDA
5	**Introductions & Session Objectives** *Facilitated by: Steven Bipes, Vice President – Global Strategy & Analysis, AdvaMed*
60	**Presentation by U.S. Food and Drug Administration** *Presented by: Patricia Pineda, International Regulatory Analyst* • FDA Latin America Office • Overview of IMDRF Structure, WGs, and Priorities • FDA Medical Device Division (CDRH) & LatAm Activities • Overview of FDA Engagement with IMDRF and use of international standards for medical device regulatory convergence (FDA Standards & Conformity Program/Policy) • MDSAP & ISO13485
20	**Q&A** *Facilitated by: Sandra Ligia González, Executive Secretary*
5	**Conclusions and Closing Remarks** *Facilitated by: Steven Bipes*