

VIRTUAL TRAINING GRPs & TBT AGENDA

Session 1/3

(Aprox. duration 1 hr. 30 min.)

Date 26May20
Time: 10:00 – 11:30 EST
Location: GotoWebinar

TIME (MIN)	AGENDA
5	<p>Welcome Message, Training Objectives & Logistics <i>Sandra Ligia González, Executive Secretary</i></p>
30 + 10 Q&A	<p>Definitions Overview (30 Mins) <i>Presented by: Sandra Ligia González, Executive Secretary & Steven Bipes, AdvaMed</i></p> <ul style="list-style-type: none"> • Industry and Coalition Objectives 1:1 • Regulatory Convergence • Good Regulatory Practices (aka Regulatory Coherence, Regulatory Reform) • The Tier 1 / Tier 2 <p>Q&A (10 Mins) <i>Moderator: Sandra Ligia González, Executive Secretary</i></p>
30 + 10 Q&A	<p>Tier 2 – MedTech Specific Regulatory Convergence and Intl Benchmarks (30 Mins) <i>Presented by: Leticia Fonseca, Executive Secretary, Brazil</i></p> <ul style="list-style-type: none"> • WHO Model Regulatory Framework for Medical Devices and IVDs • IMDRF Documents (incl N47 and N51) • MDSAP (MDSRP) <p>Q&A (10 Mins) <i>Moderator: Sandra Ligia González, Executive Secretary</i></p>
5	<p>Conclusions & Closing Remarks (5 Min) <i>Sandra Ligia González, Executive Secretary</i></p>