

# MEDICAL DEVICE SINGLE AUDIT PROGRAM – MDSAP 2023 FORUM



## Agenda

**Forum Venue:**

[Windsor Plaza Brasília Hotel](#)

SHS Quadra 05 Bloco H, Brasília - Brazil

Thursday, 26 October 2023			
Participants: Regulatory Authorities, Observers, Affiliates, Auditing Organizations & Industry			
Item	Brasília Time	Subject	Presented by
4.1	08:30	Introductions	All
4.2	08:40	Welcome	Anvisa
4.3	08:50	Overview of Agenda	Anvisa
4.4	09:00	MDSAP Introduction	Anvisa
4.5	09:15	Use of MDSAP / Regulatory Updates <ul style="list-style-type: none"> <li>- TGA - Australia</li> <li>- ANVISA - Brazil</li> <li>- Health Canada</li> </ul>	Regulatory Authorities
	10:30	Break	
4.6	10:45	Use of MDSAP / Regulatory Updates <ul style="list-style-type: none"> <li>- PMDA - Japan</li> <li>- FDA – United States</li> <li>- WHO</li> </ul>	Regulatory Authorities
	12:00	Lunch	
4.7	13:30	Regulatory Updates <ul style="list-style-type: none"> <li>- MHRA – United Kingdom</li> <li>- European Union</li> </ul>	MDSAP Official Observers
4.8	14:00	Use of MDSAP by the Affiliates <ul style="list-style-type: none"> <li>- ANMAT - Argentina</li> <li>- Ministry of Health - Israel</li> <li>- HSA - Singapore</li> <li>- MFDS – South Korea</li> </ul>	MDSAP Affiliate Members
	15:15	Break	
4.9	15:30	Medical Devices Regulatory Framework <ul style="list-style-type: none"> <li>- COFEPRIS - Mexico</li> <li>- TFDA - Taiwan</li> </ul>	Regulatory Authorities

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4.10	16:00	State of the Program - MDSAP Updates - Assessment Summary and Scheduling - Audit Report & Master List Data	Regulatory Authorities
4.11	16:30	Q/A	All
4.12	16:45	Summary of Action Items and Overview of Next Day Agenda	Anvisa
4.13	17:00	End of the day (Official photo)	

## Friday, 27 October 2023

Participants: Regulatory Authorities, Observers, Affiliates, Auditing Organizations & Industry.

Item	Brasília Time	Subject	Presented by
5.1	08:30	Welcome	All
5.2	08:40	State of the Program - Quality Management System - AO Acceptance Criteria - Future State	Regulatory Authorities
5.3	09:15	How to validate MDSAP Certificates	Auditing Organizations
5.4	09:45	State of the Medical Device Audit Industry	Auditing Organizations
	10:15	Break	
5.5	10:30	MDSAP Audit experience	Industry (Brazil, Canada, and Japan)
5.6	11:45	Summary of Discussions & Action Items	All
5.7	12:00	Forum End	
	13:30	Reserved Time for RA-Affiliate side discussions	