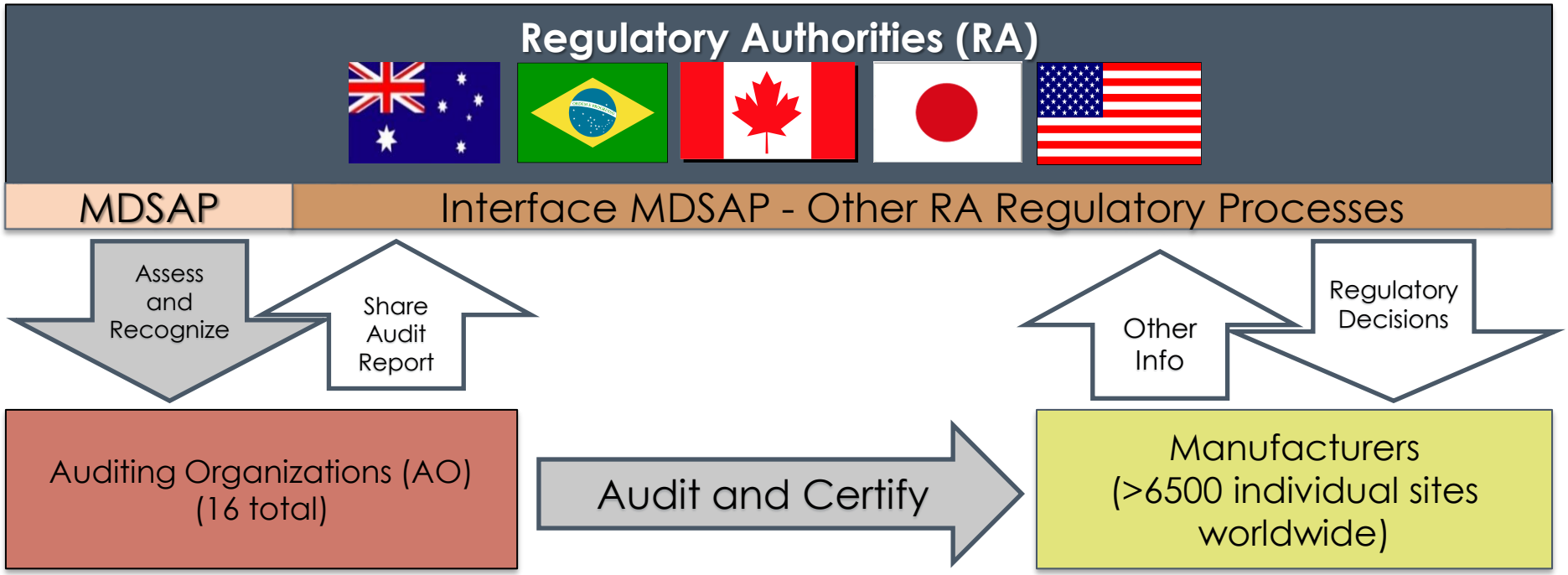
Medical Device Single Audit Program Overview & Update

Michelle Noonan
International Policy Analyst
U.S. Food and Drug Administration
Center for Devices and Radiological Health

Medical Device Single Audit Program (MDSAP)



"The goal of the MDSAP is to provide for more effective, efficient and less burdensome regulatory oversight of the quality management systems of medical device manufacturers." (SOC of MDSAP)

Other Membership

Observers


European Union


United Kingdom


World Health Organization

Affiliates


Argentina


Israel


South Korea


Singapore

Auditing Organizations

Authorized	Recognized	Application Received
   	          	

MDSAP Overall Numbers

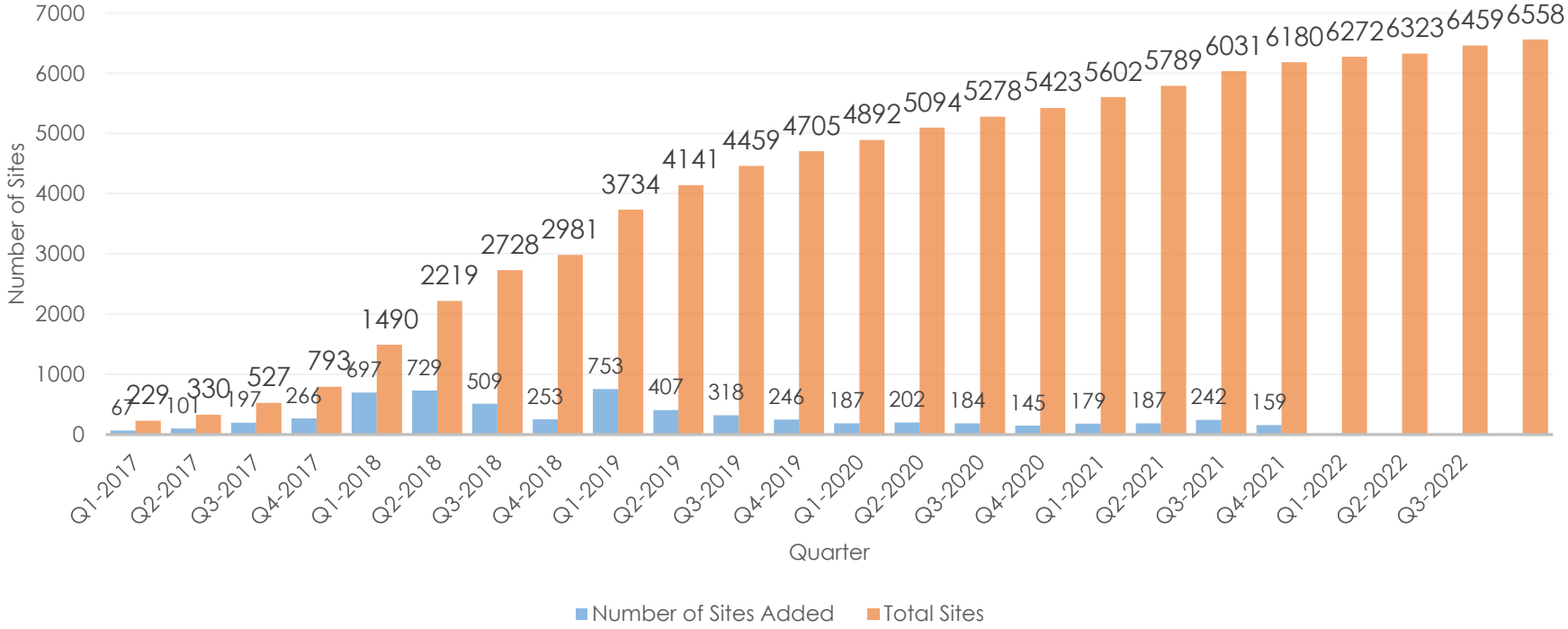
- Facilities: 6,558
- Certificate Holders: 5,090

From 2018-2022

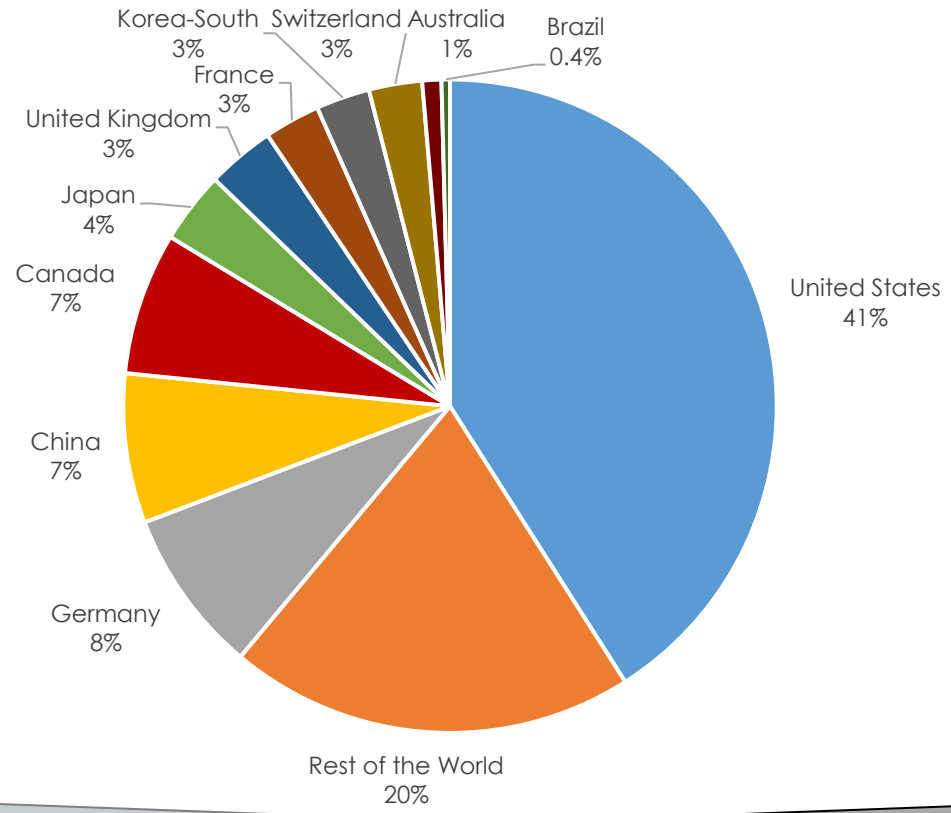
- Audit Reports Submitted: 17,625
- Audit with at least one NC: 10,528 (60%)
- Nonconformances: 37,994
- 5-Day Notice Audit Reports: 165
- Public Threat Flag: 7
- Fraudulent Activity Flag: 1

*Data as of 1/30/2023

MDSAP Participating Facilities

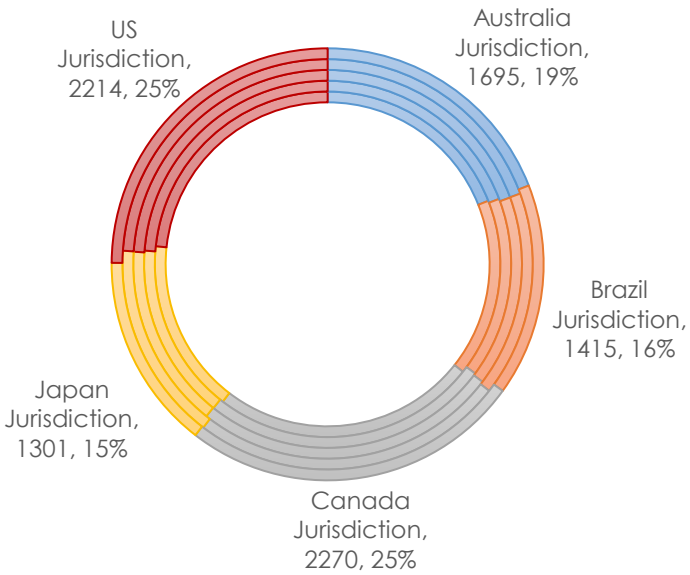


MDSAP Sites by Country



Audit Reports Received by Jurisdiction

Jurisdiction	2018	2019	2020	2021	2022	Total
Australia	1797	2831	3311	3335	1695	**12969**
Brazil	1576	2351	2715	2782	1415	**10839**
Canada	2335	3767	4330	4261	2270	**16963**
Japan	1540	2287	5611	2699	1301	**10438**
US	2205	3511	487	4116	2214	**16133**



MDSAP Participant Where are They?

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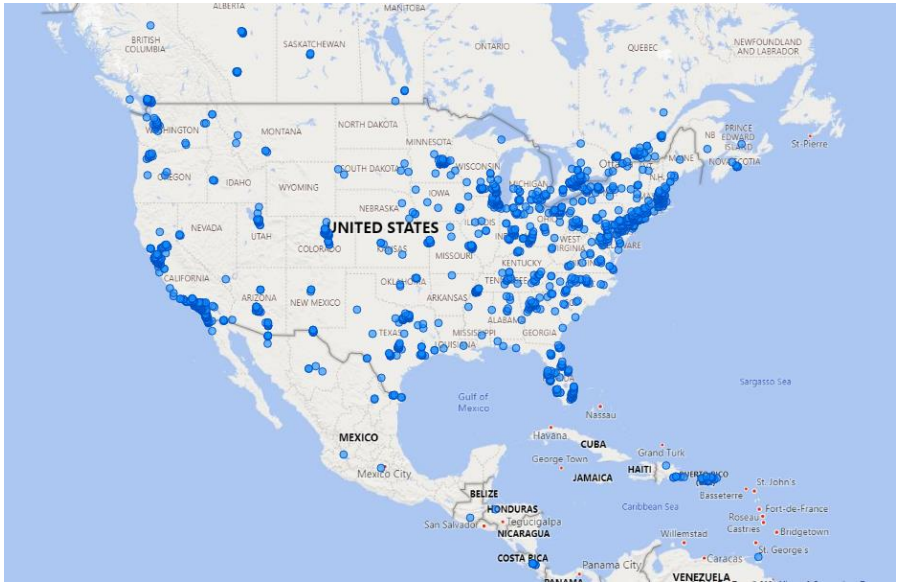

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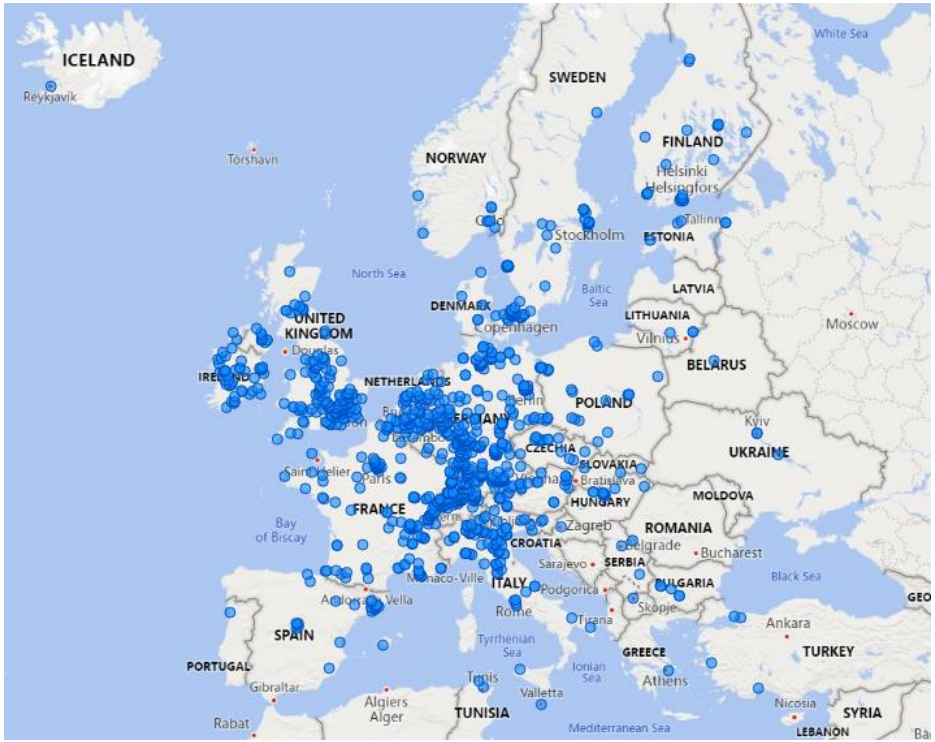

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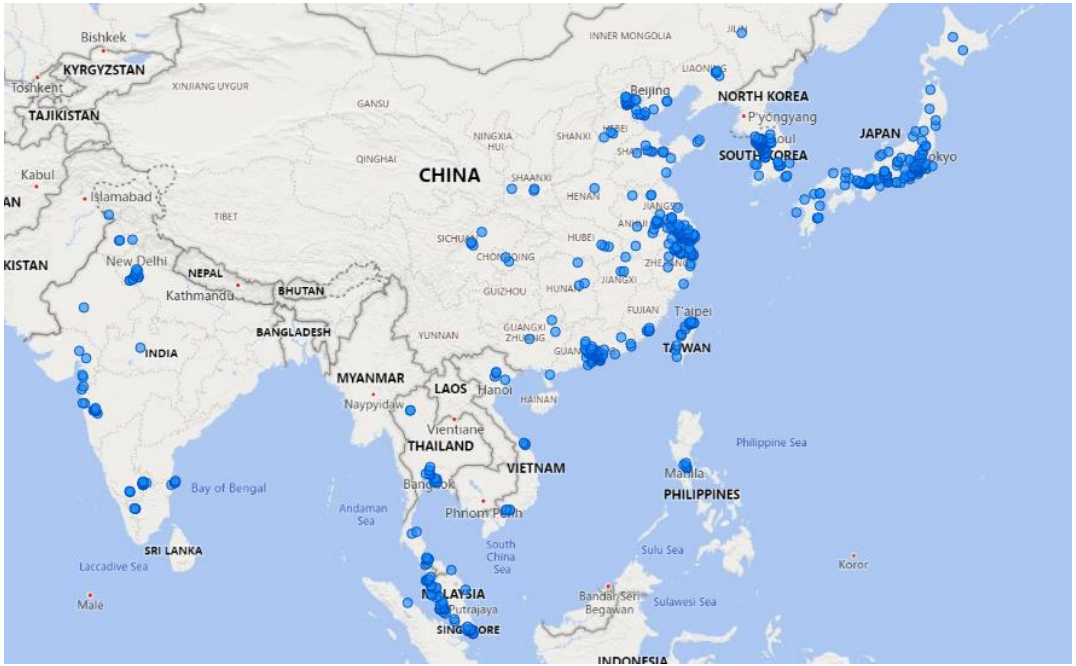
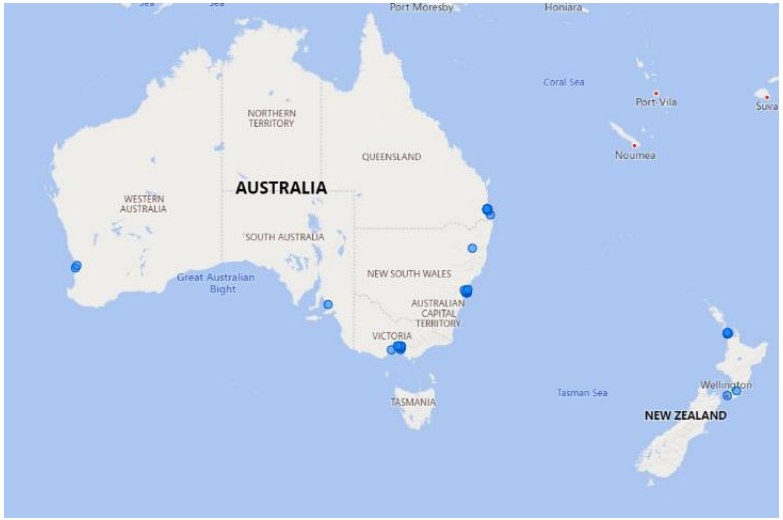




2022 Accomplishments

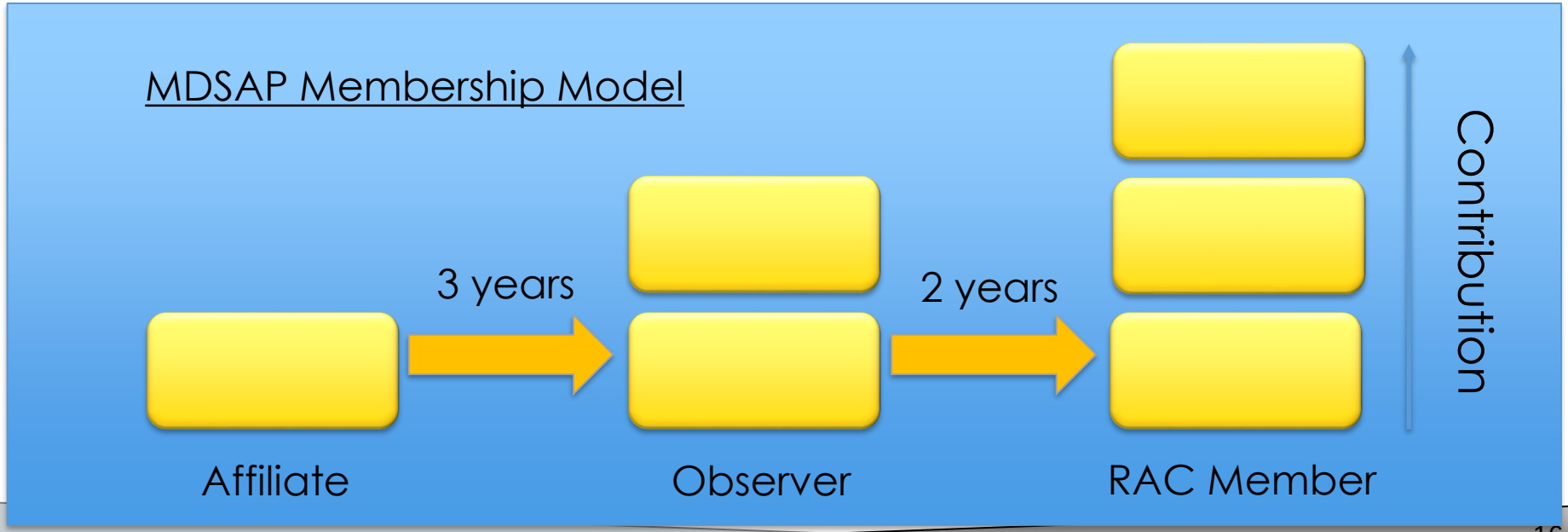
- 24 Assessments of Auditing Organizations
- 2,397 Audit Reports Submitted
- 528 New MDSAP Sites
- Transition of the MDSAP IT Portal from PAHO to FDA
- Mid-Year and End of Year Annual Forum
- Addition of Israel as Affiliate Member

2023 Activities

- Improve documentation of nonconformities in audit reports
- Launch Pilot to permit hybrid/remote audit practices in a post-pandemic world
- 2023 Annual Forum(s)
- Publish MDSAP Roles & Responsibilities Document (*completed 1/6/2023*)

Features of the New Criteria

- Escalation rule from Affiliate to Observer, Observer to RAC Member
- Clarification of expected contribution per each membership category



Questions?

https://www.fda.gov/medical-devices/cdrh-international-programs/medical-device-single-audit-program-mdsap


MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM