Inter-American

Coalition for Regulatory Convergence

MEDICAL TECHNOLOGY SECTOR

SAVE THE DATE

The United States Food and Drug Administration (FDA) with the support of the Medical Device Regulatory Convergence Project invites you to join us at:

Medical Devices Webinar Series

ISO 13485 and MDSAP

Coalición Interamericana de Convergencia Regulatoria
Coalizão Interamericana de Convergência Regulatória
Inter-American Coalition for Regulatory Convergence

Medical Devices Webinar Series

Part I
ISO 13485 and MDSAP Audit Model

Date: 02 June 21
Time: 9:00 – 12:00 CT
Platform: Zoom

Objective: Explain how medical devices inspections are conducted using the MDSAP model based on the ISO 13485, and how agencies may align to ISO 13485

TIME	AGENDA – Part I
9:00 – 9:05	**Medical Devices Webinar Series Opening: Housekeeping message** Sandra Ligia González, Technical Secretariat, **IACRC**
9:05 – 9:10	**Welcome Message** **FDA**
9:10 – 11:55	**MDSAP audit model TBD** **FDA** (60 min.) **AO Assessment Program** **FDA** (30min.) **ANVISA'S Experience** **ANVISA** (30 min.) **USFDA's Transition from CFR820 to ISO13485** **FDA** – *Melissa Torres* (15 min.) Questions 30 min
11:55 – 12:00	**Closing Remarks** ***FDA** / Sandra Ligia González - **IACRC***

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Medical Devices Webinar Series

Part II
MDSAP Inspections

Date: 10 June 2021
Time: 9:00 – 12:00 CT
Platform: Zoom

Objective: Present how an MDSAP audit is conducted and a case study to explain the audit model based on ISO 13485.

TIME	AGENDA – Part II
9:00 – 9:05	**Medical Devices Webinar Series Opening: Housekeeping message** Sandra Ligia González, Technical Secretariat, **IACRC**
9:05 – 9:10	**Welcome Message** **FDA**
9:10 – 10:00	**Experience using MDSAP audit model** **AO** (30 min.) Questions (20 min.)
10:00 – 11:50	**Case Study:** **Different approaches by the participating regulatory agencies vis a vis an MDSAP audit to highlight the similarities and identify areas of opportunity for alignment** *Facilitated by* ***FDA*** *Presented by* ***AO*** ○ **ANMAT** ○ **ISP** ○ **INVIMA** ○ **COFEPRIS** ○ **DIGEMID**
11:50 – 12:00	**Closing Remarks** ***FDA*** */ Sandra Ligia González -* ***IACRC***

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Medical Devices Webinar Series

Part III
Leveraging MDSAP audits outcomes

Date: 17 June 2021
Time: 9:00 – 12:00 CT
Platform: Zoom

Objective: Explain the MDSAP audit model, present the opportunities to leverage on MDSAP audit outcomes and provide the experience of an Affiliate Member on the process to become one and the benefits obtained.

TIME	AGENDA – Part III
9:00 – 9:05	**Medical Devices Webinar Series Opening: Housekeeping message** Sandra Ligia González, Technical Secretariat, **IACRC**
9:05 – 9:10	**Welcome Message** **FDA**
9:10 – 11:50	**ANVISA'S use of MDSAP Documents** ***ANVISA*** (30 min.) **FDA's use of MDSAP Documents** ***FDA*** (30 min.) **ANMAT's Experience as an Affiliate Member** ***ANMAT*** (30 min.) **Opportunities to leverage MDSAP outcomes** ***MDSAP*** (30 min.) Open Discussion (40 min.)
11:50 – 12:00	**Closing Remarks** ***FDA /' Sandra Ligia González - IACRC***