

## 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	<b>Medical Devices Webinar Series Opening: Housekeeping message</b> <i>Sandra Ligia González, Technical Secretariat, IACRC</i>
9:05 – 9:10	<b>Welcome Message</b> <i>Katherine Serrano, USFDA</i>
9:10 – 11:50	<b>Part III</b> <b>Moderator:</b> Patricia Pineda, USFDA  <b>ANVISA’S use of MDSAP Documents</b> Thiago Cunha, <b>ANVISA</b> (30 min.)  <b>USFDA’s use of MDSAP Documents</b> LCDR Kenneth Chen, <b>USFDA</b> (30 min.)  <b>ANMAT’s Experience as an Affiliate Member</b> Marcela Rizzo, <b>ANMAT</b> (30 min.)  <b>Opportunities to leverage MDSAP outcomes</b> Vesa Vuniqi, <b>USFDA</b> (30 min.)  Open Discussion (40 min.)
11:50 – 12:00	<b>Closing Remarks</b> <i>Melissa Torres USFDA / Sandra Ligia González - IACRC</i>

## Medical Devices Webinar Series

### Part IV Regulators Only Recap and Feedback Session

**Date:** 24 June 2021  
**Time:** 9:00 – 11:00 CT  
**Platform:** Zoom FDA

**Objective:** Open Discussion to recap, discuss and define next steps.

TIME	AGENDA – Part IV
9:00 – 9:05	<b>Medical Devices Webinar Series Opening: Housekeeping message</b> Patricia Pineda, FDA
9:05 – 9:10	<b>Welcome Message</b> Vesa Vuniqi, FDA
9:10 – 10:50	<b>Open Discussion (90 min)</b> <i>Facilitated by Patricia Pineda FDA / ANVISA</i> <ul style="list-style-type: none"><li>○ ANMAT</li><li>○ ISP</li><li>○ INVIMA</li><li>○ COFEPRIS</li><li>○ DIGEMID</li></ul>
10:50 – 11:00	<b>Closing Remarks</b> <i>Katherine Serrano FDA / ANVISA</i>