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** Vesa Vuniqi, **USFDA**
9:10 – 10:00	**Part II** **Moderator:** Sandra Ligia González, **IACRC** **Experience using MDSAP audit model** **Auditing Organization – DEKRA** ***Presenter*** *– Billie Jo Marie Johnson* (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 Patricia Pineda,* **USFDA** *Presented by Auditing Organization –* **DEKRA** *– Billie Jo Marie Johnson* ○ ANMAT ○ ISP ○ INVIMA ○ COFEPRIS
11:50 – 12:00	**Closing Remarks** Patricia Pineda - **USFDA** / Sandra Ligia González - **IACRC**