



## Workshop on ISO 13485 Certification

Date: 26 May 2022

Time: 9:00 – 11:00 (Mexico City)

Language: English/Spanish (Simultaneous Interpretation)

Platform: Zoom

TIME	AGENDA
9:00 – 9:05	<b>Opening and Housekeeping Message</b> Sandra Ligia González, IACRC
9:05 – 9:10	<b>Welcome Message</b> Carlos Garnica, COFEPRIS
9:10 – 10:10	<b>Health Canada Approach to ISO 13485 (45 min)</b> <b>Moderator: Edgardo Arenas o Julieta Arévalo, TBC, COFEPRIS</b> <b>Speaker: Frederic Hamelin, Health Canada</b>  ISO 13485 in the Regulatory Approval Process Certification Process of Registrars Auditing Model Audit Reports – Review Process Listing of Registrars – Availability and Update Process  Q&A (15 min.)
10:10 – 10:55	<b>Auditing Organizations Approach to ISO 13485 (35 min)</b> <b>Moderator: Eamonn Hoxey, AAMI</b> <b>Speaker: Billi Jo Johnson, DEKRA</b>  Certification Process of Registrars Auditing Process Audit Reports – Contents, Certificates  Q&A (10 min.)
10:55 – 11:00	<b>Closing Remarks</b> Carlos Garnica, COFEPRIS / Sandra Ligia González, IACRC