

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	Opening and Housekeeping Message Sandra Ligia González, IACRC
9:05 – 9:10	Welcome Message Carlos Garnica, COFEPRIS
9:10 – 10:10	Health Canada Approach to ISO 13485 (45 min) Moderator: Edgardo Arenas, COFEPRIS Speaker: Frederic Hamelin, Health Canada 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	Auditing Organizations Approach to ISO 13485 (35 min) Moderator: Eamonn Hoxey, AAMI Speaker: Billi Jo Johnson, DEKRA Certification Process of Registrars Auditing Process Audit Reports – Contents, Certificates Q&A (10 min.)
10:55 – 11:00	Closing Remarks Carlos Garnica, COFEPRIS / Sandra Ligia González, IACRC