Medical Devices Webinar
Utilization of voluntary consensus standards

Date: December 7, 2021
Time: 9:00 – 11:30 CT
Platform: Zoom

Objective: Provide USFDA's experience in developing and applying consensus standards while making regulatory decisions that promote safety and effectiveness of medical devices.

TIME	AGENDA
9:00 – 9:05	**Medical Devices Webinar Series Opening: Housekeeping message** Sandra Ligia González, Technical Secretariat, IACRC
9:05 – 9:10	**Welcome Message** USFDA - Katie Serrano, Director, Latin America Office
9:10 – 11:25	**Moderator** USFDA- Vesa Vuniqi, International Relations Specialist **Why Consensus Standards? How Device Manufacturers and Regulators Benefit from International Consensus Standards** (25 min) USFDA- Scott Colburn **FDA's Standards and Conformity Assessment Program: Promoting the Use of Regulatory-Ready Consensus Standards** (45 min) USFDA- Donna Walsh **Standards in Device Regulatory Review** USFDA – Donna Walsh Break (5 min) **The Accreditation Scheme for Conformity Assessment (ASCA) Program: Putting Standards to Work in Conformity Assessment** (15 min) USFDA – Scott Colburn **Call to Action: Getting Involved in Standards Development** (20min) USFDA – Scott Colburn **Questions and Answers Session** (25 min)
11:25 – 11:30	**Closing Remarks** FDA/IACRC