



## Medical Devices Webinar

**Date: June 1, 2023**

**Time: 9:00 – 11:30 Central America Time (11-1:30pm EDT)**

**Platform: Zoom**

**Objective:** Provide an overview of the requirements and FDA’s review considerations for establishing shelf life, product performance, and use-life of medical devices.

TIME	AGENDA
<b>9:00 – 9:05</b> 11:00-11:05 (EDT)	<b>Medical Devices Webinar Series Opening: Housekeeping message</b> Sandra Ligia González, Technical Secretariat, IACRC
<b>9:05 – 9:10</b> 11:05-11:10 (EDT)	<b>Welcome Message</b> FDA – Katherine Serrano, Regional Director Latin America Office
<b>9:10 – 11:25</b> 11:10-13:25 (EDT)	<b>Moderator: FDA Vesa Vuniqi, International Relations Specialist</b>  <b>Conducting Package Stability and Performance Validation for Terminally Sterilized Single-Use Medical Devices (40 min)</b> Steven Turttil  <b>Assessing device performance for the labelled shelf-life (30min)</b> Limin Sun  <b>Establishing Use-Life for Reusable Medical Devices (30min)</b> Steven Turttil  <b>Questions &amp; Answers Session (35 min)</b>
<b>11:25 – 12:30</b> 13:25-13:30 (EDT)	<b>Closing Remarks</b> FDA/IACRC