Short Agenda of 2022 TFDA Medical Devices Regulatory Science Center of Excellence Workshop

<table>
<tr><th>1st Part: August 26 to September 2</th><th>2nd Part: September 2 to September 8</th></tr>
<tr><td>Online Course 1: Medical Device Session
• Definition of the Terms ‘Medical Device’ and ‘In Vitro Diagnostic (IVD) Medical Device’ (GHTF/SG1/N071:2012)
• Basic Scheme of Conformity Assessment Procedure and Classification for Medical Devices (GHTF/SG1/N77&N78)
• Summary of Essential Principles for Medical Devices (IMDRF/GRRP WG/N47)
• Introduction of Case Study: Fingertip Pulse Oximeter</td><td rowspan="2">1st Videoconference (Sep. 2)
Current Harmonization Status of Pre-Market Regulation in Medical Devices</td></tr>
<tr><td>Online Course 2: In Vitro Diagnostic Device Session
• Definition of the Terms ‘Medical Device’ and ‘In Vitro Diagnostic (IVD) Medical Device’ (GHTF/SG1/N071:2012)
• Basic Scheme of Conformity Assessment Procedure and Classification for In Vitro Diagnostic (IVD) Medical Devices (GHTF/SG1/N045&N46)
• Summary of Essential Principles for In Vitro Diagnostic (IVD) Medical Devices (IMDRF/GRRP WG/N47)
• Introduction of Case Study: Dengue Virus Antigen Assay</td><td>2nd Videoconference (Sep. 6)
IVD Case Study of Conformity Assessment: Dengue Virus Antigen Assay</td></tr>
<tr><td>Online Course 3: Optimization Standards Session
• Optimizing Standards for Regulatory Use (IMDRF/Standards WG/N51 FINAL:2018)</td><td rowspan="2">3rd Videoconference (Sep. 6)
MD Case Study of Conformity Assessment: Fingertip Pulse Oximeter</td></tr>
<tr><td>Online Course 4: Digital Health Session
• Trends & Challenges of AI Technology in Digital Health</td><td rowspan="2">4th Videoconference (Sep. 8)
Presentation of Case Studies, Q&A, and Closing</td></tr>
<tr><td>Online Course 5: Medical Device Manufacturing Video
• Continuous Positive Airway Pressure (CPAP) Device</td></tr>
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