CRED Understanding Digital Health and Electronic Products

Thursday 1st September 2022

Programme

Time	Activity
08:30	**Registration Opens**
09:00	**Chairperson's Introduction** Welcome from TOPRA Overview of the session
09:10	**Electrical and Electronic Devices – Part 1** • Definition and understanding of "active" devices and electrically powered devices • Development considerations for electrical and electronic devices • Understanding manufacturing and finished device testing aspects of electrical and electronic devices • Software used in electromechanical devices • Regulatory perspective on these type of electronic devices
09:50	**Break**
10:00	**Electrical and electronic Devices – Part 2** • Electrical safety and electrical disturbance testing • Standards, requirements, and country deviations • Linkage to risk management and life cycle management • Describing additional considerations for usability and information supplied to the user for prescription and OTC devices • Regulatory perspective for requesting technical information
10:50	**Question and Answer; Panel Discussion**
11:00	**Workshop: Electronic and Electrical Devices**
12:00	**Case study Feedback and Discussion**
12:30	**Lunch**

Day 2

Time	Activity

13:30	**Software as a Medical Device**
	Explanation of software integrated in medical devices and stand-alone software applications
	• Software Development Life Cycle (SDLC) Management
	• Manging software changes/versions
	• Software documentation including:
	  ○ Software requirements and detailed specifications
	  ○ Design architecture
	  ○ Verification and validation
	  ○ Hazard analysis
	  ○ Traceability matrix
	Managing software applications or "Apps"

14:15	**Break**
14:30	**Software as a Medical Device (con.)** Explanation of software integrated in medical devices and stand-alone software applications • Software of Unknown Provenance (SOUP) • Configuration management and Software Unit • Linking to risk management and usability • Cybersecurity and networked applications/devices
15:30	**Question and Answer; Panel Discussion**
16:00	**Workshop: Software Documentation**
16:45	**Case study Feedback and Discussion**
17:00	**Chairperson's conclusion**
17:15	**Close**

Delegates will be encouraged to ask questions throughout the day so as to ensure the meeting is as interactive as possible.