

CRED Understanding Digital Health and Electronic Products



Day 1

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 <ul style="list-style-type: none">• 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 <ul style="list-style-type: none">• 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	Close

Day 2

Time	Activity
08:30	Registration Opens
09:00	Chairperson's Introduction Overview of the session Review of information from the first session day
09:30	Software as a Medical Device Explanation of software integrated in medical devices and stand-alone software applications <ul style="list-style-type: none">• Software Development Life Cycle (SDLC) Management• Managing software changes/versions• Software documentation including:<ul style="list-style-type: none">○ Software requirements and detailed specifications○ Design architecture○ Verification and validation○ Hazard analysis○ Traceability matrix• Managing software applications or "Apps"
10:15	Break
10:30	Software as a Medical Device (con.) Explanation of software integrated in medical devices and stand-alone software applications <ul style="list-style-type: none">• Software of Unknown Provenance (SOUP)• Configuration management and Software Unit• Linking to risk management and usability• Cybersecurity and networked applications/devices
11:30	Question and Answer; Panel Discussion
12:00	Workshop: Software Documentation
12:45	Case study Feedback and Discussion
13:00	Chairperson's conclusion
13:15	Close

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