CRED Understanding Digital Health and Electronic Products

Time	Activity
09:00	**Registration Opens/Coffee**
09:30	**Chairperson's Introduction** Welcome from TOPRA Overview of the day
09:40	**Electrical and Electronic Devices – Part 1** • Definition and understanding of "active" devices and electrical devices • Development considerations for electrical and electronic devices • Understanding manufacturing and testing aspects of these type of devices • Software used in electromechanical devices • Regulatory agency perspective on these type of devices
10:15	**Tea/ coffee break**
10:30	**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 • Expectation of Notified Body perspective for technical information
11:15	**Question and Answer; Panel Discussion**
11:30	**Workshop: Electronic and Electrical Devices**
12:15	**Case study Feedback and Discussion**
12:30	**Lunch**
13:30	**Software as a Device** Explanation of software integrated in medical devices and stand-alone software applications • Software Development Life Cycle Management and manging software changes/versions • Software documentation including architecture, verification, validation,

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	hazard analysis, and traceability • Software of Unknown Provenance (SOUP), configuration management, and version control • Linking to risk management and usability • Cybersecurity and networked applications/devices
15:30	**Question and Answer; Panel Discussion**
16:00	**Workshop: Software Documentation -** *Tea / coffee to be taken in syndicate groups*
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.