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SS-19: Safety Challenges and Emerging Risks of the Future Healthcare and Medtech Industry

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Description

Artificial Intelligence, Internet of Things, Quantum Computing, Robotics and Virtual/Augmented Reality are transforming society and key sectors of the economy, including the Healthcare and MedTech industries. These technological innovations spread rapidly and generate strong market enthusiasm, mesmerized by the benefits, while potential risks often receive less attention.

The Healthcare and MedTech sectors experience frequent innovation and are subject to extensive regulation. Before a medical product or device is approved for its intended use, its benefits and risks must be carefully analyzed and weighed, which is particularly relevant when technical innovations are introduced for the first time. Sometimes the new risks are difficult to assess and pose challenges for current approaches to designing safe and secure medical products/devices. Additionally, complex and time-consuming studies are often required, which causes delays of the approval process and disruptions for investors and manufacturers' business.

Multiple stakeholders participate in this process, each contributing distinct perspectives and expectations. While regulatory bodies emphasise legal compliance, industry focuses on market opportunities, and clinicians are interested in the product's use. The Healthcare and MedTech communities are deeply involved in these discussions and there is no unanimous consensus.

The objective of the special session is to brings together experts from academia, industry, regulatory bodies, standardization organizations and professionals, to discuss the future of the Healthcare and MedTech sectors in face of the introduced technical innovations and the emerging risks.

Topics of Interest

- How can regulatory and standardization processes follow the fast pace of this rapid innovation?
- How research and innovation can be safely transferred to Healthcare and MedTech industry?
- What is the role of risk analysis methods in identifying and evaluating emerging risks?
- How to weigh benefits in face of partially unknown risks of the new technologies?
- Are new technologies increasing the vulnerability of medical devices to cyber-attacks?
- Shall new technologies be allowed for high-risk class medical devices?
- Can safety know-how of other high-tech domains be transferred to MedTech industry?