Physikalisch-Technische Bundesanstalt
National Metrology Institute

PTB Medicine Event 2022

The Future of Regulation in Medical Devices

The digital transformation of the healthcare sector has been an important driver for improving a broad range of outcomes, including innovative medical products. Artificial intelligence (AI), especially machine learning (ML), are opening up new frontiers in medicine but are also leading to unprecedented challenges associated with regulating their use. New regulatory approaches supporting the introduction of new technologies are needed: The parallel development of technology and regulation under real-world conditions, for example, takes a practical approach to realising policy goals.

Metrology can make a valuable contribution to regulation. Quality metrics and reference data developed by metrology for example can support an objective and impartial evaluation of algorithms and thus strengthen the social acceptance of the use of AI.

This workshop will discuss the role of metrology in supporting modern approaches to regulation that are compatible with current software development processes. The focus will be on the requirements that Regulations (EU) 2017/745 on medical devices, (EU) 2017/746 on *in vitro* diagnostic medical devices, and the proposed European Regulation on establishing harmonised rules for artificial intelligence (Artificial Intelligence Act) are setting for medical devices with a high software content (especially AI).

Key questions on the role of metrology are:

- How will emerging technologies be regulated in the future?
- How can metrology contribute to clear guidelines and procedural instructions for medical devices with a high software content in order to check the quality of the data and the (AI) procedures?
- How can metrology be efficiently integrated into agile regulation methods?

04 November 2022

10:00 Welcome & Introduction

10:15 Stephen Gilbert, TU Dresden
Daniel Truhn, University Hospital Aachen
Artificial intelligence / machine learning-based software as medical device:
- the challenges of regulating complex device systems
- De-biased synthetic image data, as a training, test and metrology platform

11:00 Steffen Buchholz, Bundesministerium für Gesundheit
Regulatory challenges of AI in medical devices - the view of the German Federal Ministry of Health.

11:30 Christoph Hoeschen, Universität Magdeburg
Methods and applications of artificial intelligence in diagnostic radiology and radiotherapy - possibilities, framework conditions and pitfalls.

12:00 Lunch Break

13:00 Dirk Schlesinger, TÜV-Verband
Regulation of AI as a source of competitive advantage – some practical considerations.

13:30 Guillaume Avrin, GMED & LNE
Evaluation of artificial intelligence at LNE and feedback on medical devices.

14:00 Claudia Reinel, DIN e.V.
Improving legislation: How standardization supports and relieves federal rulemaking.

14:30 Coffee Break

15:00 Hans Rabus, Physikalisch-Techniche Bundesanstalt
The Quality Infrastructure 'Digital' initiative: Introduction of the use case metrology for artificial intelligence in medicine (M4AIM).

15:30 Panel Discussion

16:00 End

PTB Berlin, Charlottenburg, Hermann von Helmholtz Lecture Hall

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