

Title The international Organ-on-Chip Standardization Roadmap – Towards a global Standard

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Organs-on-Chips (OoC) are microfluidic devices that contain small samples of healthy or diseased tissue cultured in controlled micro-environments that mimic natural cells environments. This technology has great potential in applications such as drug screening, personalized medicine, toxicology and medical devices, as it provides information and data more representative of physiological and pathological conditions. There has been substantial innovation and investment in recent years, resulting in many experimental systems and products.

However, it has proven difficult to carry out comparative scale studies to demonstrate their value. One major barrier has been the lack of harmonization of terminology, methods and practices required to advance this field, which makes it difficult for researchers to develop OoCs that can easily be industrialized.

Over the last 2 years, a group of 120 experts have convened under the umbrella of the ISO Focus Group Organ-on-Chip (FG OoC) to develop a roadmap for Organ-on-Chip standardization. The roadmap links to existing standards and makes key recommendations covering minimum reporting requirements for inputs, key technical aspects, and requirements for experimental design and data management across application domains and regulatory frameworks. The FG OoC identified existing standards for biological inputs of OoC models (e.g. 2D coatings to culture cells and biophysical/biochemical cell culture conditions). Additionally, standards relevant to the engineering and hardware setup processes of OoC systems and scientific applications of OoC are described in the roadmap.

This roadmap is a significant milestone and sets the stage for future developments and standardization initiatives involving a broad range of international stakeholders.

The presentation will outline the need, progress, and recommendations so far, and invite comments and contributions from the lab automation and screening community for the next phase of development.

[1] <https://www.cencenelec.eu/media/publication-july-2024-fg-ooc-roadmap.pdf>  
(retrieved 6<sup>th</sup> Sept. 2024)