Tuesday 21st October:

13.00-13.30 Registration

13.30-13.45 Opening from Jolita Butkeviciene, Director JRC.S, Innovation in Science and Policymaking

13.45-14.00 Opening from Andreea Gulacsi, Director, Policy & External Affairs, CEN-CENELEC

14.00-14.30 State of the art – 3D Bioprinting

14.30-15.15 Set-up the need of standardization – existing standardization activities

15.15-15.45 Keynote lecture

15.45-16.00 Introduction to collaborative thinking sessions

16.00-16.30 Coffee break

16.30-18.00 1st thematic area - Life science

18.00-19.00 Social aperitif

Wednesday 22nd October:

8.30-10.00 2nd thematic area - Bioinks and scaffolds

10.00-10.30 Coffee break

10.30-12.00 3rd thematic area - 3D design and printing parameters

12.00-13.00 Lunch together

13.00-14.30 4th thematic area - Quality/safety assessment and terminology

14.30-15.00 Wrap-up thematic areas

15.00-16.00 Collaborative thinking - discussion

16.00-16.30 What's next

What?

Putting-Science-Into-Standards (PSIS) is one of the main initiatives developed by CEN and CENELEC together with the EC Joint Research Centre (JRC), which aims to facilitate the identification of emerging science and technology areas that could benefit from standardisation.

How is this relevant for the EU?

3D bioprinting is a rapidly evolving field that could revolutionize healthcare and biomedical research. This technology enables the creation of complex 3D structures using living cells and biomaterials (called bioinks), with potential applications in regenerative medicine, in vitro models for drug discovery, disease modelling, and cultivated meat. It has demonstrated its feasibility in laboratory settings, but significant challenges need to be addressed before its translation to clinical applications.

What is the gap?

The 3D printing technology is advanced in the medical device production (TRL 6/7), but the use of living biological materials requires further improvements. According to JRC preliminary findings, the standardisation landscape for 3D bioprinting is still in its infancy, with the only document currently available being the "ASTM F3659-242 Standard Guide for Bioinks Used in Bioprinting". They identified ISO/TC 276 - Biotechnology as being active in this area. There are no technical committees or work started at CEN and CENELEC in this area of activity yet. Standardisation efforts should focus on reliable and well characterised bioinks and cells, on defined printing and post-printing process, but also on vocabulary and terminology.

How? What are possible solutions?

3D bioprinting is a key enabling technology, fitting in the EU priority 2024-2029 of innovation and competitiveness. It relates to the Commission Communication "Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU" (20/03/2024). The standardisation of the 3D bioprinting is also in line with the Horizon Europe program which emphasizes the importance of sustainability to achieve a healthy society, and with the EU Industry 5.0 strategy that highlights the importance of innovation and sustainability. Within the JRC, this project fits in the Portfolio on Strategic technologies.

The objectives of the workshop are:

1. **Facilitate a comprehensive understanding of the standardisation needs across various stakeholders** in the 3D bioprinting domain (researchers, industries, clinicians, and regulators).

2.**Identify the key needs for standardisation in this field,** by bringing together experts from diverse backgrounds.

3. **Establish a network of interested parties** for collaboration, knowledge-sharing, and **facilitate the development of standards that meet the needs of stakeholders**.

Background

The landscape of manufacturing and medicine is undergoing a profound transformation, driven by advancements in additive manufacturing. At the forefront of this evolution is 3D bioprinting, a sophisticated technology that extends the principles of conventional 3D printing into the realm of living biological systems.

3D bioprinting is an additive manufacturing process that utilizes specialized bioinks, often mixed with living cells, to construct natural tissue-like 3D structures layer by layer.

The importance of 3D bioprinting technology reflects on its market size: since bioprinting market is estimated to expand by 17% each year, with over $5.21 billion by 2032. Despite this, 3D bioprinting has a medium-low TRL/MRL. The nascent nature of 3D bioprinting also presents considerable regulatory complexities and challenges in standardisation.

This last is needed to guarantee a compliant final product in terms of quality, safety, and reproducibility.