ISO/TC 276, BIOTECHNOLOGY

ISO/TC 276 Chair

Dr. Ricardo Gent
Chair, ISO/TC 276

About ISO/TC 276

- Secretariat →
- Scope →
- Participating members →
- Liaisons →

High-profile standards

- ISO 20387:2018 →
- ISO 20395:2019 →
- ISO/TC 276 work programme →

About ISO

- ISO Strategy 2030
- ISO/IEC Directives, Part 1

Message from the Chair

The ISO Vision for 2030 is: "Making lives easier, safer and better." Biotechnology is increasingly central to achieving this vision - not as a technology confined to individual sectors, but as a cross-sectoral enabling platform that is becoming embedded across value chains. Its applications span food and agriculture, healthcare, industrial and chemical production, and environmental solutions, and it is accelerating the development of new processes, products, and materials, including bio-based alternatives to current practices. As biotechnology expands in scope and converges with digitalization and AI, the pace and diversity of innovation continue to increase. Advances in synthetic biology and engineering biology, genetics, and AI-enabled design tools are opening new biological capabilities and novel applications, from advanced biomaterials to emerging concepts such as DNA-based data storage. Standardization is essential to support trust, interoperability, quality and safety, and responsible adoption. Standards can help ensure that the benefits of these transitions are shared widely and that implementation is coordinated and consistent across borders. **ISO/TC 276** is committed to developing globally relevant standards in parallel with technological progress, drawing on input from all stakeholders and addressing the needs of all users through an inclusive and transparent process.

What is the main market trend?

AI-optimized bioprocessing, health care and circular industrial biomanufacturing through standardized, scalable biological systems.

Why are standards important?

Standards foster trust and drive interoperability, quality, safety, and scalability accelerating market readiness while eliminating trade barriers across borders.

Who participates in standards development in this topic?

Experts from industry, science, healthcare, IT, accreditation and certification, and government/regulatory staff.

What are the committee's strategic priorities?

Foundational standards for Organ-on-Chip, provenance and AI integration; and to advance measurement innovation.

How can you get involved?

Speak with your national standards body or one of the extensive range of international liaisons to TC 276.

ISO/TC 276 standards support the following SDGs

iso.org/sdg

Introduction

The evolution of formal strategic planning in ISO Technical Committees is a key measure in supporting the ISO Strategy 2030 vision of making lives easier, safer and better. This document is designed to aid committees and their stakeholders in:

- Identifying benefits and vision of standardization within the committee's field of activity
- Linking benefits to higher strategic imperatives (ISO Strategy 2030, SDGs, London Declaration Action Plan)
- Prioritizing among projects and allocating resources
- Providing transparency and communicating through a format adapted to three key audiences (general public, TMB and other TCs, and internal TC stakeholders)
- Supporting data-driven continuous improvement, including user perspectives where available
- Maintaining strategic flexibility for different market cadences

International standards embody the essential principles of global openness and transparency, consensus and technical coherence. These are safeguarded through its development in ISO Technical committees, representative of all interested parties, supported by a WTO TBT-compliant public enquiry phase.

International standards are developed through a member-driven market-centric process, where any P-member may submit a proposal for new work.

This document represents an important filter through which new work items should be considered by P-members of a committee and shall be referenced in new work item proposals submitted to the committee per clause 2.3.4 of the ISO/IEC Directives, Part 1.

Beginning in 2026, deviations from this strategy shall be rationalized in new work item proposals.

Meeting global needs

To realize our vision, we must develop consensus-based standards that are relevant and respond to current and future challenges. We must focus on getting the right standards to market at the right time, and with the right content and in the right format.

Business environment and future trends

Biotechnology is a transformative, cross-sectoral platform technology that is reshaping industries and innovation ecosystems worldwide, driven by rapid expansion and fueled by digital convergence, sustainability imperatives, health security and geopolitical priorities. Underpinned by advances in engineering biology and synthetic biology, new genomic techniques, and biological computation as well as artificial intelligence (AI) methods among others, biotechnology is enabling applications across health, agriculture and forestry, chemistry, materials science, and environmental technologies including biodiversity monitoring. Because biotechnology cuts across health, agriculture, industry, and digital applications, no single market-size figure fully captures its value. Source-specific estimates place the current global biotechnology market in the trillion-dollar range, while broader assessments suggest multi-trillion-dollar long-term economic impact across sectors. The global bioeconomy, founded on modern biotechnology, is seen as a strategic pillar of industrial policy, health care challenges, and climate resilience.

Current trends include but are not limited to engineering biology/synthetic biology, biomanufacturing and biofoundries, next generation biotherapeutics, organoids and advanced in vitro models, microbiome engineering, digital biotechnology, biobased materials, one health, precision medicine and environmental applications.

What distinguishes biotechnology is not only its market potential, but also its unique capabilities - such as the biological complexity it can harness, its adaptability, and its carbon efficiency - which go beyond the scope of traditional technologies. It enables low-energy, high-precision innovation that operates on renewable carbon and can support circular and regenerative systems.

This innovation wave is being propelled by rapid technological convergence, digital transformation, analytical AI including deep and machine learning, computational biology, automation and digital twins. These tools accelerate R&D cycles, increasing complexity, and enabling new forms of digital-biological integration. At the same time, venture capital and public investments are expanding, and new bioeconomy hubs are emerging globally—from Europe and

North America to Asia-Pacific, Latin America, and Africa. Startups, scaleups, and public-private consortia are now key actors in the biotechnology ecosystem.

However, the dynamic nature of this environment also introduces significant fragmentation risks - across regulatory regimes, data systems, and technical standards. Without harmonized approaches, innovation may become siloed or incompatible across regions and sectors.

In this context, international standardization plays a critical and enabling role. It ensures that biotechnology develops in ways that are safe, reproducible, interoperable, and globally trustworthy. ISO/TC 276 must position itself at the intersection of technical progress, market growth, and public responsibility, helping build the shared infrastructure that allows biotechnology to fulfill its full potential for people, planet, and prosperity.

Benefits of standards and vision for standardization in the field of activity

Standardization in biotechnology plays a unique and transformative role because of the complexity, variability, and high innovation intensity of the field. Biotechnology is a cross-sectoral technology that acts as a catalyst for innovation across a wide range of industries from healthcare, and manufacturing to energy, materials, agriculture, forestry and environmental management, and many more. As a result, standardization in biotechnology does not only serve the biotech sector itself but provides essential infrastructure for the broader transformation toward more sustainable, circular, and innovation-driven economies.

Standards in biotechnology are not just tools of harmonization - they are catalysts for innovation, trust, and responsible growth. By reducing production and transaction costs, enhancing productivity and operational efficiency, and strengthening risk management frameworks, ISO/TC 276 standards create tangible value across all biotechnology stakeholder categories — from industry and regulators to researchers, consumers, and civil society. They improve market access and competitive positioning for organizations of all sizes, including SMEs and innovators in emerging economies, while supporting socio-economic development by enabling technology transfer and building capacity in new and developing bioeconomy sectors. A forward-looking vision for standardization in this field includes digitally integrated, sustainability-aligned, and globally inclusive frameworks that evolve with the pace of science while ensuring interoperability, safety, and public benefit.

In this context, a crucial and often overlooked factor is that biotechnology is no longer just a branch of biology or chemistry, but a technology platform with a comprehensive spectrum that is reshaping numerous areas of science and technology in the whole life science domain and beyond. Its ability to program, repurpose, and optimize living systems is unlocking capabilities that reach far beyond traditional scientific boundaries, enabling innovation in everything from materials design to computing and ecosystem management. Standardization in biotechnology is essential to unlock its innovative power and to navigate and connect diverse scientific and industrial fields safely, reproducibly, and at scale.

Reflections on current publications and their market impacts

ISO/TC 276 has been instrumental in developing standards that enhance the reliability, safety, and interoperability of biotechnological processes and data. These standards have significant implications for various sectors, including but not limited to healthcare, chemicals, agriculture and forestry, and environmental management.

Here are several key publications and their market impacts:

ISO 20387 - General Requirements for Biobanks

Overview: This standard specifies the general requirements for the competence, impartiality, and consistent operation of biobanks.

Market Impact: Standardization in biobanking enhances the quality and reproducibility of biological samples, thereby supporting advancements and translational research.

ISO 21973 - Transportation of Cells for Therapeutic Use

Overview: This standard provides comprehensive requirements for the transportation of cells intended for therapeutic applications, emphasizing the need for maintaining cell integrity throughout the supply chain.

Market Impact: By ensuring incorporation of requirements for transportation service provider and that for the client into transportation, ISO 21973 facilitates the scalability of cell and gene therapies, which are projected to generate substantial revenues in the coming years.

	Analytical Methods Standards (e.g., ISO 20391 series) The ISO 20391-1 and ISO 20391-2 cell counting services, and the upcoming ISO 8934 cell viability series (General Guidance, Experimental design & statistical analysis) Overview: These standards are broadly applicable to the enumeration of cells and the evaluation of cell health, or viability, across biotechnology sectors and cell types. These series of documents provide common terminology, general requirements, as well as guidance for experimental design, statistical analysis and method evaluation. Market Impact: Cell count and cell viability are fundamental measurements for the monitoring and control of biotechnology manufacturing process, pharmaceutical testing, and the release of cell-based therapies. Standardized approaches to establishing appropriate analytical methods and harmonized reporting of cell count and viability data is essential for supporting any cell-based biotechnology application. These standards are therefore widely applicable in academic research, analytic device manufacturing and biomanufacturing industry. **ISO 20691 - Requirements for data formatting and description in the life sciences** Overview: This standard specifies requirements for the consistent formatting and documentation of data and corresponding metadata in the life sciences. It provides guidance on rendering data in the life sciences findable, accessible, interoperable and reusable (F-A-I-R). Market Impact: Ensuring that standardized data formatting and harmonized documentation is an indispensable prerequisite for any data analysis, integration and re-use. This standard is therefore an important building block for the digital transformation in all biotechnology industries as well as for research and development in the domain. **Data Processing and Integration Standards** Overview: ISO/TC 276 is developing standards for data processing, including annotation, analysis, validation, comparability, and integration. Market Impact: Standardized data management and data processing practices are essential for the interoperability of biotechnological systems and for facilitating collaborative research efforts. Moreover, they are indispensable building blocks for the digital transformation of the whole biotechnology industries, including the computational analysis and the exploitation of AI methods. ISO/TC 276 has also expanded its scope to include emerging areas such as nucleic acid- and protein-based biodevices, as well as organoid and organ-on-chip technologies. This expansion reflects the committee's commitment to addressing the evolving needs of the biotechnology sector.
UN Sustainable Development Goals	ISO/TC 276 standards contribute to the following UN SDG Targets: • **SDG 3; Target 3.4** (premature mortality from non-communicable diseases, mental health) — by standardizing methods for next-generation biotherapeutics, biomarkers, and precision medicine tools, ISO/TC 276 standards support the reproducible development and clinical translation of treatments for cancer, rare diseases, and chronic conditions. • **SDG 3; Target 3.8** (universal health coverage, access to medicines and vaccines) — standards for biomanufacturing processes and biosimilar characterization lower barriers to the production of affordable biologics, supporting broader access to life-saving medicines globally. • **SDG 4; Target 4.4** (skills for employment in biotechnology) — standardized terminology, competency frameworks, and laboratory practice standards provide the common language and benchmarks needed for education and workforce development across the biotechnology sector. • **SDG 6; Target 6.3** (water quality, wastewater treatment) — standards for environmental biotechnology methods, including bioremediation and biological water treatment, enable verifiable, reproducible approaches to improving water quality. • **SDG 8; Target 8.2** (economic productivity through innovation and high-value sectors) — ISO/TC 276 standards underpin the scaling of biotechnology from discovery to industrial application, enabling productivity gains in biomanufacturing, agri-biotech, and bio-based industries.

- **SDG 8; Target 8.3** (formalization and growth of MSMEs) — by harmonizing methods and terminology, TC 276 standards lower technical barriers for SMEs and startups entering the biotechnology market, supporting their ability to compete, access finance, and integrate into global value chains.
- **SDG 9; Target 9.5** (scientific research, technological capabilities, innovation) — standards for emerging areas such as synthetic biology, biofoundries, and organoids provide the reproducibility and interoperability infrastructure that enables breakthrough research to be scaled and transferred across institutions and borders.
- **SDG 12; Target 12.4** (environmentally sound management of chemicals and waste) — standards for biological containment, biosafety, and the characterization of bio-based materials support responsible management of biological agents and waste streams in industrial biotechnology.
- **SDG 12; Target 12.2** (sustainable management of natural resources) — standards for bio-based products and biomanufacturing processes support the transition away from fossil-derived materials toward renewable biological resources.
- **SDG 14; Target 14.1** (marine pollution prevention) — standards for environmental monitoring using biological methods, including marine biosensors and biodiversity indicators, support early detection of pollutants and the assessment of biological contamination in marine environments.
- **SDG 15; Target 15.5** (biodiversity, threatened species) — standards for genomic and metagenomic methods support the consistent, comparable monitoring of biodiversity and ecosystem health, enabling evidence-based conservation decisions.
- **SDG 17; Target 17.7** (technology transfer to developing countries) — globally harmonized ISO/TC 276 standards facilitate technology transfer by providing common frameworks that allow developing nations to adopt and apply biotechnology tools without prohibitive technical barriers.

Future standardization within ISO/TC 276's scope could further enhance its positive SDG contributions in several areas. Expanding standards for cell and gene therapy characterization and delivery systems — already an active focus of the committee — could deepen support for SDG Targets 3.4 and 3.8 by improving the reproducibility and accessibility of next-generation biotherapeutics. Further development of organ-on-chip and microphysiological systems standards under SC 2 could reinforce SDG Target 3.4 by accelerating safer, more efficient pathways to clinical translation. Standards addressing bioprinting processes and synthetic nucleic acid production could strengthen contributions to SDG Target 9.5 by providing the reproducibility infrastructure needed to scale emerging biomanufacturing technologies. Broadening biobanking standards to cover low-resource and decentralized settings could support SDG Targets 3.8 and 17.7 by enabling more equitable participation in biotechnology across different national contexts.

ISO's Climate Commitment

The current strategic impact of ISO/TC 276 Biotechnology on sustainability, climate change, and circularity does not lie in the direct reduction of emissions or the introduction of products. Instead, it lies in its fundamental role as a provider of trustworthy, harmonized standards that enable the development, scaling, and adoption of biotechnological innovations in ways that support sustainability by ensuring their safety, interoperability, and trustworthiness.

Biotechnology is itself both affected by and a key response to climate change. Climate-driven pressures — including biodiversity loss, disruption to agricultural systems, increased disease burden, and demand for sustainable materials and energy — are reshaping the priorities of the biotechnology sector and, by extension, the standardization needs of ISO/TC 276. The committee recognizes that these environmental shifts have direct consequences for its work: standards for bioremediation, bio-based materials, environmental genomics, and sustainable biomanufacturing will face growing demand as climate impacts intensify.

At the same time, biotechnology offers meaningful mitigation and adaptation pathways. Standards developed by ISO/TC 276 — across biomanufacturing, synthetic biology, and bio-based processes — provide the reproducibility and safety frameworks that allow climate-relevant biotechnological solutions such as carbon capture, biodegradable materials, and biotechnical recycling to be scaled responsibly. Its role may be indirect, yet it is strategic.

As biotechnology continues to evolve rapidly - particularly in areas such as bioeconomy, health economy, carbon capture, biotechnical recycling or novel sustainable materials - ISO/TC 276 will

	also continue to adapt. In the future, the TC may broaden its scope to more directly support sustainable innovations and contribute to ensuring that emerging bio-based technologies and solutions can be developed and standardized in alignment with global sustainability goals. In this evolving landscape, ISO/TC 276 is positioned not just as a harmonizer of methods, but as a strategic enabler of collaborative, safe, and forward-looking innovation in biotechnology and its many application domains.

All voices heard

We need to ensure that we attract and retain the best experts and enable everyone to participate. We must listen to all voices, both in the development of standards and when making decisions as an organization.

Stakeholder mixture and engagement	ISO/TC 276 membership is open to interested ISO member bodies as participating (P) or observer (O) members. All ISO members may participate in ISO/TC 276 meetings. ISO/TC 276 has a relatively high P-membership and in turn access to a generous body of technical experts including scientists, industry/manufacturers, laboratories, healthcare, IT-staff, accreditation and certification body staff, as well as government and regulatory staff. ISO/TC 276's geographic representation is weighted toward Europe and North America, which account for approximately half of participating members. Asia-Pacific engagement is relatively solid. However, gaps remain: The P-membership of African countries is growing in recent years, but has room for improvement, and Latin American participation is limited relative to the region's growing bioeconomy relevance. Broadening active membership in these regions is important to ensure ISO/TC 276 standards reflect and serve the full global biotechnology landscape. ISO/TC 276 and SC plenary sessions, and WG meetings have been well attended. The latter, in particular, are in general fora in which lively technical debates lead to good work progress. As it is to be expected, some WGs allocated work activities of high impact draw the majority of ISO/TC 276 members, and this impacts on the progress made at other WG meetings at the same time. ISO/TC 276 strives to minimize such conflicts, but this was not always possible during face to face annual meetings. Although the majority of ISO/TC 276 members participate actively in WG meetings, the number of participants who continue to provide input to the ongoing work of a WG in the period between annual meetings is appreciably lower and represented in many instances only a “small” core of experts. While having the work done by a core of experts is not necessarily negative, the non-participation of other members often means that the working result must often undergo a full review and, if appropriate, approval at the next meeting. This can slow down the progress made in ISO/TC 276 work activities.
Developing country perspectives	Developing countries may face both opportunities and systemic challenges in engaging with emerging biotechnology. Applications such as drought-resistant crops, decentralized biomanufacturing, and biological upcycling of waste into valuable products can directly address region-specific needs. At the same time, limitations in technical infrastructure, regulatory frameworks, and institutional support can constrain participation in the development and governance of these technologies. Supporting inclusive innovation ecosystems and knowledge exchange is key to realizing biotechnology’s potential equitably. These dynamics differ from those in industrialized countries, where established R&D ecosystems, mature regulatory frameworks, and deep private investment enable faster adoption and commercialization of biotechnology innovations. Industrialized countries are better positioned to capture early economic value — through intellectual property, high-value exports, and technology licensing — while developing countries risk becoming primarily consumers of technologies they had limited role in shaping. ISO/TC 276 acknowledges that without inclusive standardization the benefits of biotechnology may remain concentrated in developed countries. Therefore, the committee aims to strengthen engagement from developing countries by supporting participation in technical work (e.g. through online participation in its TC, SC and WG meetings), encouraging adaptable and context-appropriate standards, and aligning with capacity-building initiatives through platforms like ISO DEVCO. In concrete terms, ISO/TC 276 can help reduce global asymmetries in the biotechnology sector by promoting interoperable data standards and quality benchmarks for distributed biomanufacturing

(e.g. for enzymes or diagnostics), and safe handling protocols for genetic materials - critical for enabling local innovation ecosystems in health, agriculture, and environmental sectors. By integrating these perspectives, ISO/TC 276 contributes not only to global biotechnology governance, but also to resilience, equity, and innovation in developing countries.

Biotechnology has the potential to significantly contribute to sustainable development in areas such as food security and resilient agriculture, healthcare and diagnostics, or waste valorization and upcycling and bio-based production.

ISO Standards used everywhere

To encourage the widespread use of ISO standards and attract experts to the development process, we must clearly demonstrate the benefits of using ISO standards.

Coordination and cohesion

Demonstrating the benefits of using ISO standards is not just about promoting visibility - it's about embedding ISO/TC 276's work in the daily practices, collaborations, and governance structures of biotechnology. In the context of coordination and cohesion, this means positioning ISO standards as the trusted infrastructure that enables interoperability, accelerates development, and aligns diverse actors.

The current liaison relationships maintained by ISO/TC 276—with both internal ISO technical committees and external organizations—underscore biotechnology's inherently cross-sectoral nature. These liaisons facilitate coordination across adjacent domains such as health, agriculture, data, materials, and quality management, ensuring that biotechnology standards are harmonized with broader industrial, regulatory, and scientific frameworks.

As a 'horizontal' committee, ISO/TC 276 will not develop application-specific ISO deliverables, except where there is a clear gap in standardization efforts and a business demand, and where there is no better suited existing ISO committee that is willing to apply their expertise to the related standards development. There have been multiple instances where a coordination with multiple other TCs or SCs – or even between WGs – was facilitated to pursue cross-cutting new ideas in a coordinated manner and to close existing standardization gaps. For such purposes, ISO/TC 276 has initiated the creation of strong ISO-internal liaison bonds with other ISO committees as well as joint WGs to cover projects with broader scopes – and we will continue to do so.

The implementation and completion of the ISO/TC 276 work program also depend on the effectiveness of ISO/TC 276 liaisons with other organizations. A major advantage of this across-organization participation is that ISO/TC 276's perspective is conveyed to the other committees/groups and, conversely, the perspectives of the other committees/groups are brought to ISO/TC 276, leading to a better and broader understanding of relevant issues and the possibly to agreement on their resolution.

National adoption perspectives

The ultimate impact of ISO/TC 276 standards depends on their translation into national frameworks and their integration into real-world practice—across regulatory agencies, public research systems, clinical settings, and industrial applications. National adoption is not simply a procedural step; it is the gateway to impact.

Concrete examples illustrate how this translation is already occurring in key markets. In Europe, the Vienna Agreement between CEN and ISO provides the primary mechanism for ISO/TC 276 standards to be adopted as EN ISO standards across all CEN member countries, giving them direct relevance to European market access and regulatory compliance. The European Commission's Joint Research Centre has actively contributed to the CEN-CENELEC roadmap for Organ-on-Chip standardization, which explicitly identifies ISO/TC 276/SC 2 as the appropriate international vehicle for global standards development in this area. At the policy level, the European Commission published its proposal for a European Biotech Act in December 2025, now entering the ordinary legislative procedure with adoption anticipated no earlier than 2027; a second act covering the wider biotech ecosystem is expected in 2026. Taken together, these developments signal strong and growing regulatory alignment with the areas in which ISO/TC 276 is active.

A comprehensive picture of formal national adoptions, withdrawn conflicting standards, and partial adoptions across all P-member countries is not systematically available in the public domain and

	can be compiled through direct engagement with NSBs. The uptake across countries varies significantly. This variation is influenced by multiple factors, such as national R&D capacities and industrial priorities, regulatory readiness and harmonization agendas, availability of training and awareness-building programs, and incentives and support for early implementation in labs, companies, and public institutions. Supporting the participation of startups and SMEs is vital to ensuring that biotechnology standards are aligned with the full innovation landscape. While ISO/TC 276 can facilitate outreach and inclusion of startups and SMEs, broader structural support—such as cost reduction, streamlined tools, and dedicated funding mechanisms—must come from ISO and its member bodies. By working in concert, the technical committee and ISO governance structures can ensure that biotechnology standards are shaped by and accessible to the full range of innovation actors.
Conformity assessment	ISO/TC 276 currently has one ISO Standard that can be used for conformity assessment, which covers general, personnel, process-specific, quality control and management requirements for biobanks – ISO 20387. The project is based on the structure of ISO/IEC 17025 and developed in close coordination with ISO/CASCO. ISO 20387 enables biobanks to perform in such a way that high quality fit-for-purpose biological material and associated data can be provided to their users.

ISO TC 276 Strategic Objectives

Link to ISO Strategy 2030 priorities	TC Strategic objectives	Proposed actions	Responsibility and priority	Measure of success
Priority 2.1: Deliver ISO standards when the market needs them	To conduct the ISO 20387 Revision	To update and publish ISO 20387 to meet the biobanks' needs	ISO/TC 276/WG2 HIGH	ISO 20387 publication in Q4/2026
Priority 2.1: Deliver ISO standards when the market needs them	To revise biobanking projects based on new ISO 20387	To start the first wave of revisions. To replace dated references to ISO 20387 with undated references, where possible, and update to the current state of science.	ISO/TC 276/WG2 HIGH	Publish ISO 22859, ISO 24651, ISO/TR 22758 in 2027
		To start the second wave of revisions in Q2/2026. To replace dated references to ISO 20387 with undated references, where possible.	ISO/TC 276/WG2 MEDIUM	Publish ISO 21709, ISO 24088-1, ISO 18209-1, ISO 24603 in 2027
		To start the third wave of revisions in Q2/2027. Replace dated references to ISO 20387 with undated references, where possible, and update to the current state of science.	ISO/TC 276/WG2 MEDIUM	Publish ISO 18162, ISO 21899, ISO/TS 23105, ISO/TS 20388 in 2028/2029

Priority 2.1: Deliver ISO standards when the market needs them	To establish a framework of standards to achieve consistency in bioprocessing of cells	To publish ISO standards to meet the needs of stakeholders in bioprocessing of cells and update them as necessary	ISO/TC 276/WG4 HIGH	Publish ISO 23565 in 2027 Publish ISO 21973 in 2027/2028
			ISO/TC 276/WG4 MEDIUM	Publish ISO 24866 and ISO 25950 in 2029 Publish ISO 20399 in 2029/2030 Publish ISO 20404 in 2030/2031
			ISO/TC 276/WG4 HIGH	Publish ISO 20399-4 and ISO 25848 In 2028/2029
Priority 2.1: Deliver ISO standards when the market needs them	To develop standards on the individual processes for cell and cell-related entities	To develop and publish standards by clarifying stakeholders' standardization needs	ISO/TC 276/WG4 MEDIUM	Publish ISO 25347 and ISO 25802 in 2027 Publish ISO 25746 and ISO 26013 in 2028
Priority 2.1: Deliver ISO standards when the market needs them	To develop standards for tracking biological material and data (provenance information model) and for implementation of corresponding interoperability interfaces	To develop further the ISO 23494 series (Provenance information model for biological material and data) and ISO/NP 25999	ISO/TC 276/WG5 HIGH	Publish ISO 23494-1, ISO 23494-2 in 2026, ISO 23494-3 in 2027 Publish ISO 25999 in 2028 Initiate the drafting of ISO 23494-4, ISO 23494-5, ISO 23494-6 in 2026
Priority 1.2: Innovate to meet users' needs	To develop standards for application of AI/ML in biotechnology	To initiate drafting of AI/ML standards in biotechnology	ISO/TC 276/WG5 HIGH	Initiate the drafting of AI/ML standards by 2028

Priority 2.1: Deliver ISO standards when the market needs them	To establish foundational terminology and general requirements for nucleic acid- and protein-based devices	To develop an umbrella ISO deliverable defining terminology, general requirements, and technical considerations for the design, construction, and production of nucleic acid- and protein-based devices	ISO/TC 276/WG6 HIGH	Publish ISO 24031 in 2027
Priority 2.2: Capture future opportunities for international standardization	To develop a series of ISO standards under the umbrella framework to address key technical aspects of nucleic acid- and protein-based devices	To initiate sequential projects covering major layers of the WG6 roadmap — including material specification, construction methodology, performance verification, and application-based evaluation — coordinated with relevant WGs (WG4, WG5, SC1) to ensure interoperability and harmonization	ISO/TC 276/WG6 MEDIUM	Publish ISO 25812 in 2028
Priority 2.1: Deliver ISO standards when the market needs them	To develop a series of organoid standards	To develop and publish standards supporting standardization of organoid terminology, manufacturing, and quality control	ISO/TC 276/WG7 HIGH	Publish ISO 25430-1 in 2027 Publish ISO 25430-2 in 2028
		To develop and publish standards supporting standardized model construction for hepatic and intestinal organoids	ISO/TC 276/WG7 HIGH	Publish ISO 25430 part 3 and 4 in 2028
Priority 2.2: Capture future opportunities for international standardization	To standardize the credibility assessment of computational modelling in biotechnology and the life sciences	To establish a JWG between IEC/TC 62 and ISO/TC 276 to jointly develop IEC 63691-2 *Medical devices — In silico technologies — Part 2: Credibility assessment of first-principles based methods* AND IEC/TR 63691-1 *Medical devices – In silico technologies — Part 1: Terminology and context*	ISO/TC 276 HIGH	JWG establishment based on AWI in 2026 and publish IEC 63691-2 and IEC/TR 63691-1
Priority 2.1: Deliver ISO standards when the market needs them	To develop and maintain a series of ISO standards that support the quantification of gene delivery systems	To complete ISO 16921-1; ISO 16921-2; ISO 16921-3; and additional parts as appropriate to meet the needs of the industry	ISO/TC 276/SC1/WG1 HIGH	Publish ISO 16921 series

Priority 2.1: Deliver ISO standards when the market needs them	To develop a series of ISO standards that address the measurement of key attributes of cells used in biomanufacturing and cell-based assays	To revise as needed cell characterization umbrella standard and cell counting series standards. To publish standards on cell activity such as viability, cell mediated cytotoxicity, and tumorigenicity. Initiate expansion of document series to microbial cell applications	ISO/TC 276/SC1/WG2 HIGH	Publish revision to ISO 20391-1 in 2026 and -2 in 2029 Publish ISO 8934-1 in 2026 Publish ISO 8934-2 in 2028 Publish ISO 26125-1 in 2029 Publish ISO 25824 in 2030
Priority 2.1: Deliver ISO standards when the market needs them	To develop and maintain foundational analytical method standard using PCR or NGS	To revise the ISO 20397 series for NGS, rename all parts from "Massively parallel sequencing" to "NGS"; revise ISO 20395; support the development of related standards using PCR and/or NGS	ISO/TC 276/SC1/WG3 HIGH	Revise the ISO 20397 series; ISO 20395; and ISO 12833
Priority 2.1: Deliver ISO standards when the market needs them	To establish consensus on vocabulary for MPS and OoC	To develop a standard for vocabulary for MPS and OoC	ISO/TC 276/SC2/WG 1 HIGH	Publish ISO 25448 in 2027
Priority 2.1: Deliver ISO standards when the market needs them	To establish a mechanism for developing standards concerning biological components of MPS and OoC	To develop standards providing a framework for development of fit-for-purpose MPSs and OoCs	ISO/TC 276/SC2/WG 2 HIGH	Publish ISO 25693 and ISO 25530 in 2027/2028
		To develop standards for biological components for MPS and OoC having pre-defined context of use for such systems	ISO/TC 276/SC2/WG 2 MEDIUM	Publish ISO 25289 in 2028
Priority 2.1: Deliver ISO standards when the market needs them	To establish foundational standards for experimental design, data reporting, and computational integration in MPS and OoC	To develop ISO deliverables defining minimum information for experimental design and reporting (e.g., reference compounds, metadata, hardware parameters); develop frameworks for data interoperability and computational model documentation; align data structures with WG5 and SC1	ISO/TC 276/SC2/WG 3 HIGH	Publish ISO 25591 in 2027
Priority 2.1: Deliver ISO standards when the market needs them	To develop standards covering engineering of MPS and OoC	To develop an ISO deliverable focussing on flow control together with experts from ISO/TC 48/SC 10	ISO/TC 276/SC2/JWG 4 HIGH	Publish ISO 26086

Annex A ISO/TC 276 Structure and Market Needs

ISO/TC 276/WG 2 "Biobanks and bioresources"

Justification and Market Need for Standardization in the Market Area

Biobanks have traditionally functioned as simple repositories for biological samples. However, they are rapidly evolving into complex and dynamic hubs serving various fields, including human health, animal conservation, agriculture, and microbiology. The transformation of biobanks into such multifaceted entities is driven by multiple factors that necessitate standardization.

- **Human Biobanks**
  The health sector, particularly human biobanks, is witnessing significant advancements propelled by personalized and precision medicine. Tailoring medical treatments according to an individual's genetic makeup requires consistent high-quality samples to support research necessary for therapeutics development. Sophisticated technology and automation are crucial in handling vast collections of samples and data. Additionally, biobanks are instrumental in drug discovery, clinical research, epidemiology, and disease-specific studies, but can also be of value for industry, e.g. IVD developers / manufacturers to support validation studies or AI companies to train AI systems with hiqh-quality data and samples, necessitating standardized practices to maintain sample integrity and foster reliable research and validation outcomes.
- **Animal Biobanks**
  In the realm of animal biobanking, the central role of cryopreserving genetic materials from endangered species underscores the need for standardization in preserving sample viability and efficacy. In addition, high-quality biological material from animals is very important for progressing research for human health (e.g. as parasites, transmissible organisms, study of the life cycle). Moreover, the use of biobanks in veterinary medicine, and livestock research for preserving genetic lines with desirable traits requires meticulous processes. Standardization ensures consistent results across various research and conservation activities, thereby enhancing their contribution to animal health and productivity.
- **Agricultural Biobanks**
  Agricultural biobanks are crucial for addressing global food security challenges and fostering sustainable food systems. They play a pivotal role in climate change adaptation and developing novel crop varieties. The preservation of extensive genetic material is vital for responding to agricultural challenges like new pathogens and environmental shifts. Standardization in sampling and processing ensures the genetic materials retain their potential for future applications and research, enabling biobanks to remain resilient and adaptable to ongoing agricultural demands.
- **Microorganism Biobanks**
  Microorganism biobanks serve cross-industry functions in areas from medical research to food production. They support studies in infectious diseases, the microbiome and synthetic microbial communities, biotherapeutic applications based on bacteriophages, and contribute to industrial biotechnology by supplying microorganisms for the production of crucial microbial products like enzymes, biofuels, and bioplastics. In food fermentation, standardized biobanking ensures the reliability and safety of starter cultures. Establishing uniform standards in the handling and preservation of microorganisms is fundamental not only for consistency but also for innovation and safety.

Despite challenges in pinpointing the market size of these niche biobanking fields, the sector demonstrates considerable economic potential. In human health, the global biobanking market was valued to be at least $64.3 billion in 2024, with projections suggesting it could exceed $200 billion by 2034, reflecting a robust compound annual growth rate (CAGR) estimated with a range of 5% to 9% in different reports (see [1], [2], [3]). Similarly, the market for animal genetics, which often includes the value of animal biobanks, was estimated to be at least $6.8 billion in 2024 and is expected to reach $2 billion by 2034, with a CAGR of approximately 7%

[1] Biobanking Market Driving Growth Through Innovation and Expanding Research Applications. ID: 1641, Precedence Research, 2025. https://www.precedenceresearch.com/biobanking-market

[2] Biobanks Market (2025 - 2030). ID GVR-2-68038-564-9, Grand View Research, 2025. https://www.grandviewresearch.com/industry-analysis/biobanks-industry

[3] Biobanking Market Size, Share, Trends and Forecast by Specimen Type, Biobank Type, Application, End-User, and Region, 2025-2033. ID: SR112025A4967, IMARC Group, 2025. https://www.imarcgroup.com/biobanking-market

(see [4], [5], [6], [7]). In agriculture, although the standalone value of agricultural biobanks is complex to isolate, they are integral to the broader agri-biotechnology market, a multi-billion-dollar industry. Microorganism biobanks, while subsumed within larger markets like industrial biotechnology, contribute significantly to sectors valued in the billions. Given these substantial figures and growth trajectories, it becomes vital to have standardized practices. These practices ensure quality and integrity, enhancing the biobanks' contribution to these economically significant fields.

Thus, as the value of a biobank is inherently linked to the quality and integrity of its samples, which necessitates minimizing variability, ISO/TC 276/WG 2 developed standards (including ISO 20387) to provide the framework for consistent operational processes and quality assurance. Standardization efforts facilitate interoperability and collaboration among biobanks, fostering advancements in research and application while ensuring the reliability of results. In conclusion, standardization in biobanking is not only a matter of operational excellence but a necessity to fulfill the growing complex requirements across diverse fields. Standardization drives quality, facilitates innovation, and ensures that the biobanking sector continues to expand its role in scientific, medical, environmental, and industrial advancements.

Scope

ISO/TC 276/WG 2 "Biobanks and bioresources" will elaborate a package of ISO deliverables in the Biobanking field including human, animal, plant and microorganism resources for Research & Development (R&D) aspects, but excluding therapeutics.

Climate and Circularity Relevance

Biobanks play a vital role in promoting sustainability and circular economy principles through efficient resource use and reduced environmental impact. Following ISO 20387, biobanks need to determine environmental concerns in their operations aiming to reduce their environmental footprint. For this purpose, a prime example is the transition from traditional energy-intensive freezers, used to store samples at temperatures like -20°C or -80°C, to innovative methods such as room temperature DNA storage in sealed cans with neutral gas. This technique, developed over 15 years ago and implemented in various institutes, reduces energy consumption and operational costs. Furthermore, by optimizing sample usage, implementing waste reduction protocols, and fostering collaboration among institutions, biobanks can support the efficient use of existing materials, minimizing resource consumption and aligning with circular economy principles.

ISO/TC 276/WG 4 "Bioprocessing for cells and related entities"

Justification and Market Need for Standardization in the Market Area

Standards for cells and related entities (e.g. extracellular vesicles) are essential not only for safety and efficacy of these entities (e.g. therapeutic cells in regenerative medicine) but also for material production applications (e.g. monoclonal antibody production) and *in vitro* evaluation (e.g. drug discovery testing). These standards can contribute to building a robust supply chain and ecosystem that supports sustainable growth and societal integration.

Since cells are prone to changes in their properties during the manufacturing process, standards can contribute in the following aspects to ensure that cells fit for their intended purpose are always manufactured in the same way.

- Standardization of resources to be used and information to be communicated among stakeholders in the process from research to manufacturing and beyond, to ensure similar quality throughout the

---

[4] Animal Genetics Market (2025 - 2033). ID: GVR-3-68038-740-7, Grand View Research, 2025. https://www.grandviewresearch.com/industry-analysis/animal-genetics-market

[5] Animal Genetics Market Size, Share and Trends 2025 to 2034. ID: 4644, Precedence Research, 2025. https://www.precedenceresearch.com/animal-genetics-market

[6] Animal Genetics Market Size, Share & Industry Analysis, By Product & Services (Animal Type, Genetic Material, and Service Type), By End-user (Veterinary Hospitals & Clinics, Research Centers & Institutes, and Others), and Regional Forecast, 2024-2032. Fortune Business Insights, 2025, ID: FBI105584, https://www.fortunebusinessinsights.com/animal-genetics-market-105584

[7] Animal Genetics Market Size, Share, & Industry Analysis Report: By Animal (Poultry, Porcine, Bovine, Canine, and Other Animals), Genetic Material, Genetic Testing Services, and Region – Market Forecast, 2025–2034. ID: PM3975, Polaris Market Research, 2025. https://www.polarismarketresearch.com/industry-analysis/animal-genetics-market

manufacturing process, would make it easier to manufacture similar cells. This will make it easier to produce similar cells.

- Coordination between standards of analytical methods for cells and the above-mentioned standards for processes will facilitate the identification of requirements for process control to produce similar cells. Integrating standardized process monitoring into bioprocesses to support compatibility and improved product outcomes is one way to achieve such coordination.
- In many processes formed by different stakeholders, such as academic-industrial collaboration, supply chains consisting of suppliers and users, standards facilitate the identification of the roles and requirements of each stakeholder.

Biomanufacturing and engineering biology based on microbial cells are important fields in bioprocessing, contributing to manufacturing of materials, drugs, and biologics. As engineering biology can be seen an interdisciplinary field that applies engineering principles to design, build, and optimize biological systems, multiple types of standards, e.g., processes, analytical methods, data, can contribute to its wider implementation.

Backgrounds for expectation of standardization in bioprocessing of cell and related entities include, but are not limited to, the following:

1. Mammalian cells, especially human-derived cells, have become widely used in industry with the widespread use of pluripotent stem cells (embryonic stem cells (ESCs) and induced pluripotent stem cells (iPSCs)). The range of applications of these cells is expanding to include regenerative medicine, cell therapy including the use of transgenic cells, production of bioactive substances such as antibodies. In addition, in parallel with the use of cells, the application of biological entities related to cells (e.g., extracellular vesicles, bacteriophages) is being promoted.
2. According to several reports with titles such as "The Market for Regenerative Medicine" published in 2023, the global market for regenerative medicine is expected to be worth USD 90 - 197 billion in 2030, with a compound annual growth rate (CAGR) from 2023 to 2030 of 15 - 28% [References [8], [9], [10], [11]].
3. The industrial use of these cells and related entities, however, is still in its infancy. Human-derived cells undergo a complex process of identification, laboratory preparation, technology transfer to manufacturing units or institutions, test manufacturing, scale-up, and, if necessary, regulatory approval before they become available for use in society. These processes pose the challenge that, depending on the type of biological entity and the technologies and processes involved, the items required in each combination and the manner in which they are presented will differ.
4. Since therapeutic cells and related entities are generally regulated by legislation in each country, it is necessary to develop standards that will be used as reference documents to support the operation of regulations and regulatory filings, such as processes and records that cannot be defined in regulations, quality control concepts, manufacturing and chain-of-custody frameworks.

[8] Regenerative Medicine Market (2025 - 2030). ID: GVR-1-68038-952-4, Grand View Research, 2025. https://www.grandviewresearch.com/industry-analysis/regenerative-medicine-market#:%7E:text=The%20global%20regenerative%20medicine%20market,medicinal%20strategies%20over%20traditional%20treatment

[9] Regenerative Medicine Market Size, Share, and Trends 2025 to 2034. ID: 1176, Precedence Research, 2025. https://www.precedenceresearch.com/regenerative-medicine-market

[10] Regenerative Medicine Market Size, Share & Trends Analysis Report by Product (Therapeutics, Tools, Banks), Therapeutic Category (Dermatology, Musculoskeletal, Immunology & Inflammation), and Region with Growth Forecasts, 2025-2030. ID: 4375420, Research and Markets, 2025. https://www.researchandmarkets.com/reports/4375420/regenerative-medicine-market-size-share-and?gclid=EAIaIQobChMIj4iertrggQMVbcwWBR1UyA84EAAYASAAEgKE-PD_BwE

[11] Regenerative Medicine Market Size, Share & Industry Analysis, By Product (Cell Therapy, Gene Therapy, Tissue Engineering, and Platelet Rich Plasma), By Application (Orthopedics, Wound Care, Oncology, Rare Diseases, and Others), By End User (Hospitals, Clinics, and Others), and Regional Forecast, 2026-2034. ID: FBI100970, Fortune Business Insights, 2026. https://www.fortunebusinessinsights.com/industry-reports/regenerative-medicine-market-100970

Scope

ISO/TC 276/WG 4 "Bioprocessing for cells and related entities" covers the processes for biotechnology products.

WG 4 standardizes manufacturing and related processes for cells, including development of such processes, for cells used for therapeutic purposes, cells used in *in vitro* evaluation systems for pharmaceuticals, and cells used in material production. Cells can be of mammalian or non-mammalian origin, e.g. insects, microbes. WG 4 standardizes the framework for the supply chain from the manufacturer to the user of cells and processes related to quality control.

Where considerations, and know-how(s) acquired in the development of cell-related standards can be applied, WG 4 develops standards regarding manufacturing and related processes for cell-related entities, including extracellular vesicles, bacteriophages, and so forth.

WG 4 will focus on standards intended to enhance applicability and integration of general bioprocesses. WG 4 will not develop prescriptive procedures or specific conditions for manufacturing unless required by the industry as a whole.

WG 4 collaborates with the SCs and other WGs of TC 276, and with other TCs as needed.

Climate and Circularity Relevance

Standardization in regenerative medicine can significantly contribute to achieving Sustainable Development Goals (SDGs) in the following ways:

- Regarding SDG 3: Good Health and Well-being, standardization contributes to foster a healthier global population. Standardized protocols for manufacturing and quality control support the realization of regenerative medicine and cell therapy through consistent and effective cell production.
- Regarding SDG 9: Industry, Innovation, and Infrastructures, standardization encourages the development of specialized infrastructure for cell manufacturing and processing, further supporting the growth of the regenerative medicine industry.
- Regarding SDG 12: Responsible Consumption and Production, standardization encourages efficient production processes that minimize waste and environmental impact.

Standards for cell therapy manufacturing, cryopreservation, and tissue engineering can reduce waste, can contribute to climate change mitigation in indirect but meaningful ways, e.g., by improving energy efficiency and optimizing resource use.

Standardization in bioprocesses for the generation of sustainable materials and for bioremediation can contribute to achieving SDGs including SDG 6: Clean Water and Sanitation, SDG 9: Industry, Innovation and Infrastructure, SDG 12: Responsible Consumption and Production, SDG 13: Climate Action, SDG 14: Life Under Water, and SDG 15: Life on Land.

Developing country perspective

Standardization in phage therapy can contribute to improve public health in developing countries by offering a cost-effective, accessible, and targeted approach to combatting infectious diseases and antimicrobial resistance. ISO/TC 276 published ISO/TS 20853:2026, *Biotechnology — Bioprocessing — General requirements for the bacteriophage preparation for therapeutic use*.

ISO/TC 276/WG 5 "Data Processing and Integration"

Justification and Market Need for Standardization in the Market Area

Emerging biotechnology and advanced biomanufacturing generate large, complex, and high-dimensional datasets from a wide variety of methods and processes. Data and metadata standards are essential for enabling automated data collection, analysis, and integration. These standards include both consistent data formats (supporting syntactic interoperability) and standardized metadata that document context, provenance, reproducibility, relevance, credibility, and accuracy (semantic interoperability).

After raw data are generated and information about biological materials is collected, the data typically undergo multiple processing and integration steps. These may involve converting raw signals into numerical values, performing transformations such as image processing or parameter extraction, reducing and compressing data, storing it, and ensuring its quality. At each processing step, the data must be described within its environmental, experimental and technical context. This contextual information enables researchers to group related datasets, compare results across similar experiments or workflows, link different data types associated with the same sample or conditions, and build computational models that integrate results from multiple methods for prediction. Much like assembling a jigsaw puzzle, each component requires well-defined and compatible interfaces. Therefore, consistent and durable standards for data and metadata across all stages of processing and computational analysis are crucial.

As biotechnology for both health and non-health sectors advances rapidly, establishing holistic and stable data and metadata standards becomes increasingly important. These standards must support every stage of data processing and integration — across existing, emerging, and future technologies. In addition, they must enable smooth connections between sequential processing steps (vertical integration) and support the integration of processed data generated by different methodological and technological approaches (horizontal integration). Achieving this requires both broad, technology-agnostic standards and complementary technology-specific standards that ensure components fit together seamlessly.

Artificial intelligence (AI) based methods, such as large language models (LLMs) and machine-learning (ML) algorithms, are rapidly becoming integral to biotechnology and biomedical R&D. Their ability to automate data processing workflows, detect patterns, generate hypotheses, accelerate discovery, and optimize biotechnological production depends directly on the quality, structure, and contextual richness of the data they use. Consistent and interoperable data is required for establishing and feeding AI methods as well as for validating, refining and filtering their outputs. Standardized, interoperable data and corresponding metadata are therefore essential. Without them, AI systems used in biotechnology cannot reliably integrate results from different sources, compare experiments and workflows, or avoid errors caused by missing context.

AI is considered a transformative force in biotechnology, revolutionizing biotechnological R&D, production, drug design, diagnostics development, and personalized medicine. Consequently, AI is also driving significant economic growth across biotechnology and pharmaceuticals. The global AI market, valued at USD 233.46 billion in 2024, is projected to reach USD 1,771.62 billion by 2032, with a compound annual growth rate (CAGR) of 29.2%. Within the pharmaceutical and biotechnology sectors, the AI market was valued at USD 1.8 billion in 2023 and is expected to grow to USD 13.1 billion by 2034, reflecting an 18.8% CAGR. As AI-enabled methods become central to drug development and biomanufacturing, they are poised to generate substantial economic impact across the life sciences.

Biotechnology data and metadata standards form the foundation for trustworthy data processing and AI applications by ensuring consistent high-quality data inputs from analytical methods (see ISO/TC 276/SC 1) and engineered systems (see ISO/TC 276/SC 2, ISO/TC 276/WG 6, and ISO/TC 276/WG 7). Such standards also are a prerequisite for bioprocessing workflows and their documentation (ISO/TC 276/WG 4) as well as for metadata recordings in biobanks (ISO/TC 276/WG 2). Moreover, they also support rigorous validation of outputs from data processing as well as AI methods, and enable models to operate within appropriate biological and experimental contexts.

Scope

ISO/TC 276/WG 5 “Data Processing and Integration” aims to develop standards for findable, accessible, interoperable and reusable (FAIR) data across the biotechnology and life science domains to enhance comparability, traceability and integration of data. WG 5 also aims to enable harmonized data processing in these domains.

Within this main focus WG 5 draft standards and other ISO deliverables for:

- Data and model formats and their interoperability;
- Descriptive metadata (including domain-specific terminologies and ontologies);
- Linked data and corresponding data relations, as well as data models;
- Data provenance;
- Data processing, structuring, sharing and storing;
- Application and validation of artificial intelligence (AI) and machine learning (ML) methods in the domain;
- Quality management of processed data and models;
- other topics related to data processing and integration.

WG 5 will build on existing community standards and develop standards where required and where gaps are identified. WG 5 will coordinate its work with relevant technical committees and standardization initiatives. This includes coordination with all working groups of ISO/TC 276 and ISO/TC 276/SC 1.

Climate and Circularity Relevance

Even though data-intensive processes need substantial computational resources, including hardware for servers, data centers, federated data storage in the cloud and computational analysis, digital technologies also significantly help to save resources as processes can be simulated beforehand and only promising ones actually have to be implemented. This especially applies for highly complex and costly methods, such as in developing biotechnological production processes, pre-clinical drug development or toxicological screening, where simulation techniques help to reduce the number – or even partially replace – laboratory and animal testing with all their biological and material resources. The standards developed in ISO/TC 276/WG 5 enhance the interoperability of data and metadata supporting computational analysis and simulations. They also render obtained data reusable, reducing the need for extensive experimental setups to reproduce similar data again and again. So, the standards developed directly support circular transformation and helps saving natural resources.

ISO/TC 276/WG 6 "Nucleic acid- and protein-based devices"

Justification and Market Need for Standardization in the Market Area

The rapid convergence of biotechnology, materials science, and information technology has positioned nucleic acid- and protein-based devices as a strategically vital domain within the global bioeconomy. These devices — constructed wholly or partly from biological molecules such as DNA, RNA, or proteins — translate biological functions into measurable, controllable, or computational outputs. Applications span biosensors, sequencing platforms, DNA data storage, bioelectronic interfaces, and biological molecule-based analytical systems used across research, industrial, and environmental sectors.

Despite strong market growth, the absence of harmonized terminology, quality criteria, and performance benchmarks hinders comparability, reproducibility, and interoperability. Current reliance on disparate methods and proprietary practices creates fragmentation in material quality, design validation, and safety assessment — increasing innovation costs, impeding regulatory acceptance, and limiting international collaboration.

Standardization led by WG 6 is therefore essential to establish a common technical language and framework for the design, construction, and production of nucleic acid- and protein-based devices, thereby ensuring interoperability between biological and non-biological components in hybrid or bio-digital systems. Furthermore, it serves to harmonize requirements for biological material sourcing, modification, and performance verification, which in turn supports industrial translation and market access by reducing technical barriers and enabling certification pathways grounded in biotechnology principles.

As bio-devices increasingly underpin critical applications in diagnostics, environmental sensing, sustainable manufacturing, and bio-computing, global markets require trustworthy and scalable reference frameworks. WG 6 addresses this need by focusing on the biological foundations and construction principles of these devices — areas not covered by existing committees on medical, electronic, or nanotechnological devices. By providing these baseline standards, WG 6 will support both innovation and market maturity in this fast-growing sector.

Scope

ISO/TC 276/WG 6 "Nucleic acid- and protein-based devices" aims to develop standards in the field of nucleic acid- and protein-based devices, including requirements and terminology for their construction (e.g. design, development, integration) and production.

WG 6 will also develop standards for natural and modified biological material (i.e., nucleic acids, proteins) to be used as device parts and/or elements.

WG 6 will cooperate with relevant ISO/TCs and ISO/TC 276/WGs where overlapping standardization is needed. The work of WG 6 will be based on the development trends of biological research and industry.

WG 6 excludes standardization of medical devices or medical products.

WG 6 will build on existing community standards and develop standards where gaps and needs are identified.

Climate and Circularity Relevance

The standardization of nucleic acid- and protein-based devices contributes indirectly yet significantly to climate action and circular economy goals by enabling a new class of low-energy, high-precision, and renewable biological technologies.

- **Sustainable material basis**: Bio-devices constructed from renewable biological materials — DNA, RNA, and proteins — produced through carbon-efficient biomanufacturing processes. They can be biodegradable or recyclable, reducing electronic waste and supporting circular material flows.
- **Enabling green innovation**: Standardized frameworks will accelerate the deployment of bio-devices for environmental monitoring (such as biosensors for pollution detection, carbon capture verification, or bio-based energy systems) supporting climate resilience and sustainable industrial transitions.
- **Circular bioeconomy integration**: By ensuring interoperability and quality across biological components, WG 6 standards facilitate the reuse of biological resources and promote data-driven, regenerative biomanufacturing systems. This aligns with the ISO London Declaration on Climate Change and relevant UN Sustainable Development Goals (e.g., SDG 9, 12, and 13).
- **Responsible innovation infrastructure**: The establishment of harmonized standards also supports responsible innovation governance, helping to ensure that emerging bio-digital systems are designed with safety, sustainability, and long-term environmental impact in mind from the outset.

ISO/TC 276/WG 7 “Organoids”

Justification and Market Need for Standardization in the Market Area

Organoid technology, an emerging and promising frontier in biotechnology, is reshaping paradigms in biomedical research, drug development, and toxicity testing. This technology utilizes stem cells or tissue-derived cells to form self-organizing three-dimensional (3D) structures in vitro that recapitulate key structural and functional features, as well as complex cellular interactions, of human organs. This capability provides a new platform for research and testing that more accurately models human physiology. Thus, organoid technology serves as a vital bridge, connecting fundamental research — such as engineering biology — with critical translational applications including preclinical studies, precision medicine, and safety assessment.

Currently, regulatory authorities and the scientific community worldwide are actively fostering the development and implementation of new approach methodology (NAMs) to enable more human-relevant and precise scientific assessment. These efforts are establishing organoid technology as an integral and increasingly central component within the biomedical innovation and translation pipeline.

The application of organoid technology has rapidly expanded into the following key domains:

- Drug Discovery and Development: Serving as more physiologically-relevant in vitro models, organoids are employed for high-throughput screening of drug candidates, efficacy evaluation, and toxicity prediction. This approach holds significant potential to reduce R&D costs and timelines while decreasing reliance on animal testing during the preclinical phase.
- Precision and Regenerative Medicine: Patient-derived organoids enable disease modeling and personalized drug sensitivity testing, thereby informing the development of targeted therapeutic strategies. They also serve as a vital platform for exploring possibilities in cell therapy and tissue regeneration.
- Research on Disease Mechanisms: Organoids provide novel, dynamic model systems for investigating the pathogenesis of complex diseases — such as cancer, genetic disorders, and infectious diseases — as well as gene-environment interactions.
- Toxicology and Safety Assessment: In the safety evaluation of environmental toxins, cosmetics, and chemicals, organoids can generate organ-specific toxicity data (e.g., for liver, kidney, or nervous system) with enhanced physiological relevance.

Currently, there is a lack of globally harmonized standards for establishment of organoid culture protocols, characterization methods, functional assessment criteria, and quality control parameters. This lack of standardization compromises the comparability, reproducibility, and integration of research outcomes.

Consequently, it undermines data interoperability and hinders the technology's translation into industrial and clinical applications. Such fragmentation also poses obstacles to regulatory review, potentially diminishing the reliability of decisions based on organoid data.

Therefore, standardization is essential to unlock the full potential of organoid technology and to align with the evolving global scientific and regulatory consensus. The development of dedicated standards covering critical aspects — such as harmonized terminology, quality control frameworks, core characterization methods, and application guidelines — will systematically enhance the technology's credibility and fitness for purpose.

Standardization serves to enhance the reproducibility and reliability of organoid models, thereby providing a robust foundation for research and development decisions. It also establishes recognized scientific benchmarks for regulatory evaluation, fostering regulatory confidence. Furthermore, by reducing resource waste associated with inconsistent practices, standardization supports the development of a more efficient and sustainable innovation ecosystem.

Scope

ISO/TC 276/WG 7 "Organoids" aims to develop standards in the field of organoids. WG 7 will work on organoid-related standardization projects that do not require a more specialized working group to lead or coordinate the project development.

WG 7 will cooperate with relevant ISO/TCs and ISO/TC 276/WGs where overlapping standardization is needed. The work of WG 7 will be based on development trends of biological research and industry.

WG 7 will build on existing standards and will develop standards to address identified gaps and needs, following a fit-for-purpose principle.

WG 7 excludes standardization of medical products.

Climate and Circularity Relevance

Standardization of organoid technology, by establishing reproducible and reliable in vitro human models, systematically enhances research and development efficiency. In particular, it can significantly reduce the drug development cycle, thereby greatly saving R&D costs. It reduces the consumption of reagents, consumables, and energy associated with experimental failures and inconsistent operations, thereby lowering the technology's inherent environmental footprint.

In drug discovery and toxicity testing, standardized organoid models will decrease reliance on animal experiments and primary human tissues, advancing a more scientifically robust and resource-efficient research paradigm. Furthermore, standardized protocols improve the comparability and reusability of experimental data. Coupled with unified quality management standards, this avoids redundant experiments and conserves valuable research resources.

Within industrial biotechnology and novel materials safety assessment, the adoption of standardized organoids for early-stage biocompatibility screening facilitates the upfront identification of potential hazards. This prevents harmful substances from entering downstream production processes or the environment, thereby supporting green manufacturing and sustainable design principles.

ISO/TC 276/SC 1 "Analytical methods"

Justification and Market Need for Standardization in the Market Area

Robust analytical methods underpin the advancement of biotechnology by accelerating research and development, supporting the transition to more sustainable biomanufacturing, and strengthening consumer and regulatory confidence. Measurements of biotechnology processes and products are inherently complex and, in the absence of standards, can vary significantly across laboratories, instruments, and methodologies. Establishing reproducible and traceable standards for analytical methods and assays is therefore essential to ensure comparability and reliability of data, which in turn accelerates innovation and translation across biotechnology sectors. In addition, for advanced biomanufacturing, knowledge-directed characterization helps understand and define the reproducibility of the product while quality-directed characterization provides product release specifications to demonstrate the consistency and quality of the product.

High-quality, standardized analytical data enable innovation and knowledge creation, including through the convergence of biotechnology and artificial intelligence (AI). Standardized methods improve data interoperability and reproducibility, which are critical for AI and machine learning applications that rely on large, high-quality datasets. Such integration further enhances predictive modelling, process optimization, and innovation in health, agriculture, and industrial biotechnology.

Standardized analytical methods also accelerate commercialization of biotechnology products and reduce friction in global trade. They ensure product safety, efficacy, and quality, especially for emerging therapeutic modalities such as cell and gene therapies, and support the implementation of process analytical technologies that improve process control and reduce cost of goods. In industrial biotechnology, harmonized assays for enzyme activity or fermentation outputs enable process transfer across facilities and suppliers worldwide, promoting supply chain resilience and efficiency. Standardization similarly fosters the adoption of new analytical technologies, such as advanced sequencing, high-resolution microscopy, and cytometry, by providing confidence in performance and measurement traceability.

Internationally harmonized analytical standards contribute directly to public health, safety, and biosecurity. Reliable analytical data are essential for applications such as pandemic response (e.g., high confidence molecular or metagenomic pathogen detection or correct dosing of therapeutics), food security (e.g., somatic cell counting in milk), synthetic biology oversight (e.g., high-confidence screening of synthetic nucleic acids), and drug and chemical toxicity testing (e.g., high-throughput screening for drug discovery). These standards also support regulatory harmonization and global market access by providing a common technical foundation for demonstrating product quality and safety.

To meet the evolving needs of emerging biotechnologies, SC1: Analytical Methods continuously assesses and prioritizes standardization needs through broad stakeholder engagement across sectors. SC1 maintains a coordinated portfolio of standards addressing:

- Biological entities (e.g., cells, proteins, nucleic acids);
- Attributes (e.g., identity, quantity, purity, stability);
- Commonly used analytical tools and methods and measurement platforms; and
- Specific application areas.

This modular and integrated approach enables the use of SC1 standards across a range of biotechnology domains, supporting innovation, sustainability, and global harmonization of biotechnology measurement practices.

Scope

Standardization of analytical methods to enable accurate, reproducible, and robust measurements and analysis of biologically relevant molecules and entities, such as:

- Nucleic acids
- Proteins,
- Cells,
- Gene delivery systems

Climate and Circularity Relevance

Analytical methods and standards play a critical role in advancing biotechnology that supports climate and circularity objectives. They provide the reliable measurement foundation needed to assess, optimize, and validate sustainable biomanufacturing processes and bio-based products.

Analytical methods contribute to climate and circularity goals by:

- Enabling quantification of sustainability metrics – Standardized, high precision analytical methods generate reliable data for evaluating the resource efficiency of biotechnological processes.
- Supporting innovation in bio-based products – Accurate and harmonized measurements enable validation and certification of bio-based materials that replace or complement fossil-based alternatives, helping reduce overall carbon footprint.
- Facilitating sustainable bioresource management – Analytical techniques for measuring biomass yield, conversion efficiency, and byproduct formation drive advances in sustainable biomanufacturing.
- Optimizing process efficiency and resource utilization – Real-time analytical monitoring of cellular responses, metabolites, enzymes, and residual biomass enables more accurate process control, reduces waste, and enhances recovery of valuable co-products.

- Enabling technologies for environmental protection and safety – Analytical tools support bioremediation efforts and ensure environmental and product safety through reliable toxicity and performance assessments; support monitoring eDNA/bioproducts released into the environment.

Together, these analytical capabilities ensure that biotechnology innovation proceeds responsibly — advancing climate resilience, resource circularity, and environmental stewardship.

Strategic planning for the next 5 years

Standardized analytic methods form the foundation for trustworthy biological measurements across biotechnology domains. This 5-year strategic plan defines a roadmap for analytical-method standardization that underpins biotechnology innovation, enables the convergence of biotechnology and other emerging technologies, such as artificial intelligence and automation, as well as strengthens biosecurity and sustainability.

Strategic Imperatives

Analytical-method standards must address multiple considerations that shape the broader biotechnology ecosystem:

- Biotechnology innovation and translation: Enable high-quality and reproducible measurements to ensure product quality, comparability, and consistency for emerging therapeutics and novel biotechnology applications across sectors; drive toward mechanistic and functional understanding of biological processes via predictive and prescriptive analytics
- Digital convergence: Support the rise of AI-driven biotechnology through interoperable, traceable, and high-quality biological data that facilitate data integration, modelling, and automation.
- Advanced manufacturing: Strengthen Manufacturing 4.0 through robust process analytical technologies (PAT), supporting automation, process control, and continuous manufacturing
- Sustainability: Enable innovation aligned with climate and circular-bioeconomy goals by providing reliable analytical data to assess resource efficiency, bioproduct performance, and environmental impact.
- Safety and security: Ensure biosecurity, data integrity, and responsible innovation through standards that support safe use of biotechnology and reliable bio-surveillance measurements.

Strategic Goals

To achieve these imperatives, SC1 will:

- Advance measurement innovation – Develop standards that promote advances in analytical instrumentation, methods, and data interpretation to improve sensitivity, accuracy, precision, and throughput; development of new approaches to understanding biological measurement uncertainty so that sources of variability can be controlled.
- Ensure measurement rigor and data quality – Produce analytical standards that enable traceable, reproducible, and AI-ready biological data, supporting digital transformation across biotechnology sectors.
- Provide foundational analytical capabilities – Establish standards that underpin applications, including those covered by other ISO/TC 276 Subcommittees and Working Groups, such as biobanking, bioprocessing, engineering biology, and emerging platforms including organoids and microphysiological systems (MPS).
- Align analytical and digital-data standards – Strengthen coordination between analytical-method standards and digital-data, metadata, and AI-governance standards to ensure interoperability and responsible data use.
- Integrate sustainability and safety frameworks – Where appropriate, link analytical data outputs with life cycle assessment (LCA), clinical evaluation, and biosecurity frameworks to support responsible innovation and global harmonization.

ISO/TC 276/SC 1/WG 1 “Gene delivery”

Justification and Market Need for Standardization in the Market Area

Modern and emerging biotechnology is underpinned by the ability to manipulate the genes and genomes within living systems. Gene delivery is a process by which foreign nucleic acid is introduced to host cells through mechanical, chemical, and biological means. The field is developing an increasing number of gene delivery systems or encapsulated and/or protected genes that can be delivered to a targeted site in vivo or ex vivo. Examples of gene delivery systems include viral vector-based gene therapy for curing retinal dystrophy, spinal muscular atrophy, and severe forms for haemophilia A. Standards to harmonize measurement terminology and assay performance requirements to quantify and characterize gene delivery systems are needed to improve comparability and reproducibility in analytical measurements. Standardization of analytical methods for characterizing gene delivery systems is critical for supporting this rapidly growing biotechnology sector.

The global viral vector production market size is estimated to be USD 7.5-8.2 billion in 2025, and depend on the source, is projected to reach USD 28-56 billion by 2034. Another example is lipid nanoparticular-based delivery systems such as mRNA-based vaccines. The global mRNA therapeutics market size was valued at USD 54 billion in 2024 and is expected to expand at a compound annual growth rate (CAGR) of 3.4-17% from 2025 to 2030. Many other gene delivery systems are under development for various health and non-health applications and as tools for advancing broader biotechnology.

Genome editing technology, a specific type of gene delivery technology, is a fast-growing and rapidly advancing global bioscience field with applications in many biotechnology sectors. Genome editing is used to modify the nucleic acids of a genetic code, which can be composed of DNA or RNA, in a site-specific manner. Modifications can include insertion, deletion or alteration of nucleic acids. The technology operates via biochemical principles generally applicable to every kind of cell. Examples of areas for which genome editing technology applications will have global significance include human cell-based therapeutics, agriculture, microbial-based therapeutics, synthetic biology and biomanufacturing. The global genome editing market was valued at USD 9.3 billion in 2024 and is projected to reach USD 40 billion by 2033. registering a CAGR of 15-17%.

Recognizing the rapidly growing field of gene delivery systems, WG1 will focus on developing a package of foundational ISO deliverables to enable more accurate, reproducible, robust, and comparable measurement and analysis of gene delivery systems. When appropriate, WG1 will coordinate with other Technical Committees, Subcommittees, and/or Working Groups to jointly develop sector-specific standards.

Scope

ISO/TC 276/SC 1/WG 1 “Gene delivery” will initially develop ISO deliverables to provide common understanding, guides, and analytical methods for characterizing emerging biotechnology tools in a sector and application agonistic manner.

This WG will focus on horizontal ISO deliverables and, when applicable, vertical / particular ISO documents for industry sectors.

Climate and Circularity Relevance

Analytical methods provide the reliable measurement foundation needed to assess, optimize, and validate sustainable biomanufacturing processes and bio-based products using gene delivery systems, genome editing, and related technology.

ISO/TC 276/SC 1/WG 2 “Cell characterization”

Justification and Market Need for Standardization in the Market Area

Cells (human, microbial, or other biological systems) are at the core of biotechnology innovation, powering applications from advanced therapeutics and regenerative medicine to industrial biomanufacturing, synthetic biology, and environmental biosolutions. However, variability in cell characterization, culture conditions, and performance metrics remains a major barrier to reproducibility, scalability, and regulatory confidence. Standardization of analytical methods for cell identity, purity, potency, viability, and function is critical to ensure data comparability across laboratories and sectors. These standards will accelerate product development, reduce time-to-market, and enhance safety and efficacy evaluations for cell-based products. The standards will also support the wider cell-based assay sector for drug and toxin toxicity testing, which is reliant on analytical methods that evaluate cell response to substances. Market demand is rising sharply as industries adopt cell-based production systems and cell-based assays, and as regulatory frameworks increasingly emphasize quality-by-design and data integrity. Harmonized cell characterization standards also support AI-driven biological design by providing high-quality, interoperable data, strengthening the bioeconomy, promoting international trade, and reinforcing biosecurity and ethical oversight in the use of living systems.

Market Size:

- Cell therapy (incl. autologous & allogeneic cell-based therapeutics): the broader cell & gene therapy market higher (e.g., ~$25 billion in 2025 with longer-term projections up to $117 billion by 2034 for combined cell & gene therapies).
- Synthetic biology (including engineered microbes, cell-based platforms, biomaterials): analysts cluster in the $14–20 billion (2024–2025) base today and ~$42–64 billion by 2030–2032, depending on the report and forecast horizon. (Example estimates: Grand View ~USD $16.2 billion (2024) → $42.1 billion by 2030; other firms project larger or faster growth).
- Microbial / microbiome manufacturing (probiotics, live biotherapeutics, microbial CDMOs): Market size (representative estimates): projections vary by narrow vs. broad definitions: microbiome/microbiome-manufacturing estimates include ~$27 billion (2024) growing to ~$130 billion by 2034 in long-range forecasts for a broad manufacturing market.
- Cell-based assays: Cell measurements are critical for drug development and chemical toxicity testing with a global market size projected to rise from ~$18 billion in 2024 to ~$40 billion in 2034. Cell-based measurements are also foundational for the growing area of advanced microphysiological systems, organ-on-a-chip and organoids, supporting both starting material characterization for the biological components of these systems as well as endpoint analysis of cellular response.

Scope

ISO/TC 276/SC 1/WG 2 “Cell characterization” will develop a package of ISO deliverables to enable more accurate, reproducible, and robust measurement and analysis of cells, including human, mammalian, and microbial systems.

This WG will develop horizontal ISO deliverables and, when applicable, vertical / particular ISO documents for industry sectors, such as cellular therapeutic products. The work programme will include specific attributes, such as cell counting, cell viability, cell line authentication, as well as impurity measurements.

SC 1/WG 2 will also focus on common methods for cell characterization, including but not limited to cytometry, spectroscopy, and microscopy.

Climate and Circularity Relevance

Analytical methods provide the reliable measurement foundation needed to assess, optimize, and validate sustainable biomanufacturing processes and bio-based products using cells (e.g., human, microbial) and cell free systems. Cell characterization includes measurements that support biomanufacturing process analytical technology for improving biomass yield, conversion efficiency, scalability, and byproduct formation, and reducing batch failures. These analytical technologies drive advances in sustainable bio manufacturing and are critical for reducing waste and optimizing processes. Additionally, cell characterization analytical methods are critical for cell-based assays that are used to support bioremediation efforts and ensure environmental and product safety through reliable toxicity and performance assessments.

ISO/TC 276/SC 1/WG 3 “Nucleic acid characterization”

Justification and Market Need for Standardization in the Market Area

Nucleic acids play essential roles in all cells and viruses. Nucleic acid technology, including the ability to read, write, and edit sequences, underpins modern biotechnology, from clinical diagnostics, therapeutics, agriculture, new bioengineering and biomanufacturing capabilities, and enabling new technologies for addressing other pressing society challenges, such as climate. The global market for DNA sequencing alone is valued at USD 14.88 billion in 2024 and is projected to reach a value of USD 48.22 billion by 2030 at a compound annual growth rate of 14.9-21.66 % over the forecast period.

The nucleic acid synthesis market is projected to grow significantly, with estimates for the global DNA synthesis market valued at USD 10.5 billion in 2025 and reaching USD 24.7 billion by 2030. Growth is driven by applications in genomics, synthetic and engineering biology, precision/personalized medicine, and therapeutics, with a compound annual growth rate (CAGR) typically ranging from 15% to 19%.

Recognizing the broad and pervasive application of nucleic acid-based technologies, WG 3 will focus on developing a package of foundational ISO deliverables to enable more accurate, reproducible, and robust measurement and analysis of nucleic acids in a sector-agnostic manner. When appropriate, WG 3 will coordinate with other Technical Committees, Subcommittees, and/or Working Groups to jointly develop sector-specific standards.

Scope

ISO/TC 276/SC 1/WG 3 “Nucleic acid characterization” will initially focus on the following package of ISO deliverables, including regular review and revision for this rapidly evolving technology.

SC 1/WG 3 will continue to identify emerging standard opportunities, including RNA quantification, gene expression, and issues related to sampling and detection limits.

Climate and Circularity Relevance

Nucleic acid characterization plays a critical role in understanding climate change, ecosystem dynamics, biodiversity, and environmental adaptation. High-confidence eDNA measurements, for example, enable tracking species distribution, monitoring invasive species, and assessing biodiversity loss. Nucleic acid analyses can also reveal environmental stress through changes in gene expression or epigenetic patterns, as well as provide insights into DNA degradation over time. In addition, nucleic acid characterization supports synthetic biology applications aimed at developing climate-related solutions. In addition, analytical methods provide the reliable measurement foundation needed to assess, optimize, and validate sustainable biomanufacturing processes and bio-based products using nucleic acids.

ISO/TC 276/SC 2 "Microphysiological systems and Organ-on-Chip"

Justification and Market Need for Standardization in the Market Area

Microphysiological systems (MPS) and Organ-on-Chip (OoC) represents a rapidly growing and innovative field, with numerous academic research groups and established companies operating worldwide.

According to several reports with titles such as “Organ-on-Chip Market” published in 2024 and 2025, the global market size for OoC is expected to be worth USD 900 – 1500 million in 2030, with a CAGR of 30 – 35% from 2025 to 2030 [12], [13], [14].

The rapid world-wide expansion of MPS and OoC technologies has highlighted a critical need for international standards to ensure trust, interoperability, and scalability. The current scarcity in standards impedes both implementation and innovation of the technology — for example, by affecting the reproducibility and comparability of results, which in turn makes it challenging for businesses and regulatory bodies to actively utilize the data, and by hampering the interoperability of various MPS and OoC components and systems, thereby hindering expansion of functionality and scalable production. Current market adoption is constrained by fragmented approaches in device design (particularly including size, geometry and interfaces), biological substrates and their sourcing, data quality (reliability, repeatability, reproducibility), and qualification protocols. This inconsistency creates barriers to cross-border collaboration, technology adoption, industrial implementation and is in the way of regulatory acceptance.

Standardization will provide aligned terminology, reference frameworks, and validation pathways that will reduce duplication of efforts, enhance reproducibility of results, and accelerate translational uptake. By enabling comparability and interoperability across platforms and aligning with regulatory bodies, a dedicated standardization committee can address the urgent demand for robust, transparent, and globally-recognized benchmarks, thereby unlocking market growth, investor confidence, and broader adoption in pharmaceutical, chemical, and cosmetics industries. MPS and OoC systems typically run in dedicated, controlled environments and by means of external peripheral systems (e.g., electrical, pneumatic, optical), whose use and interfacing may in turn be covered by existing or future standards developed in collateral working groups.

---

[12] Organ-on-a-Chip Market (2025 - 2030). ID: GVR-68040-148-6, Grand View Research, 2024. https://www.grandviewresearch.com/industry-analysis/organ-on-a-chip-market-report

[13] Organ on a Chip Market Size to Expect USD 3242.34 Mn by 2034. ID: 5358, Towards Healthcare, 2025. https://www.towardshealthcare.com/insights/organ-on-a-chip-market-sizing

[14] Organ-on-chip Market Size & Share Analysis - Growth Trends and Forecast (2026 - 2031). Mordor Intelligence, 2025. https://www.mordorintelligence.com/industry-reports/organs-on-chips-market

To address the challenges mentioned above and promote the advancement of MPS and OoC technology, ISO/TC 276 established Subcommittee 2 “Microphysiological systems and Organ-on-Chip” (ISO/TC 276/SC2) with the following objectives:

- standardizing the interaction between biological and technological components within MPS and OoC systems,
- bringing experts together from the fields of biological sciences and technology to ensure a holistic approach to standardization,
- monitoring relevant developments of standards within other TCs and working groups, and
- providing targeted input to ensure the coherence and effectiveness of MPS and OoC standards.

Given that MPS and OoC is still a new and innovative field, there will be a significant number of standards developed in the coming years. Therefore, it is essential to establish a robust platform to coordinate the development of these standards, ensure consistency between them, and foster the evolution of the field.

Scope

Standardization in the field of Microphysiological Systems (MPS) and Organ-on-Chip (OoC) that includes the following topics:

- Terminology, stakeholder environment, interdependencies in MPS and OoC
- Biological components in MPS and OoC
- Engineering in MPS and OoC, including manufacturing and designing
- Experimental design, data processing and integration of MPS and OoC studies
- Characterisation of materials and processes

ISO/TC 276/SC 2 MPS and OoC has a specific focus for MPS and OoC as a hybrid system consisting of biological components and technical components and the interaction between the two.

ISO/TC 276/SC 2 will work closely with related working groups within ISO/TC 276 and related (technical) committees, e.g. ISO/TC 48 and ISO/TC 212, in order to identify standardization needs and gaps, and collaborate with other organisations to avoid duplications and overlapping standardization activities.

Climate and Circularity Relevance

MPS and OoC technologies represent not only a breakthrough in biomedical innovation but also a strategic lever for climate and circularity goals. By reducing and eventually replacing animal testing in the future, these systems contribute to cutting the resource- and carbon-intensive processes associated with animal feeding, housing, transport, and disposal. The miniaturized, data-rich MPS and OoC devices and platforms require significantly fewer biological components, reagents and consumables with respect to comparable laboratory practices, directly lowering emissions and waste across the drug discovery and safety testing pipeline. Standardized systems and protocols can lead to more efficient lab setups, reducing energy consumption in experimental workflows. In addition, their predictive accuracy accelerates development cycles and reduces costly late-stage failures, ensuring that R&D resources are used more efficiently and lead to a smaller environmental footprint. Data harmonization is also important for climate-related health studies. Consistent terminology enables better integration of data across studies, including those investigating climate-related health impacts (e.g., pollution, heat stress, vector-borne diseases).

Beyond efficiency gains, MPS and OoC align closely with circular economy principles. MPS and OoC devices are largely produced out of glass, various forms of polymers and metals, which are sufficiently distinct materials that can in principle be systematically sorted and recycled. Their modular and reusable designs reduce dependency on single-use plastics, while ongoing developments in biologically sourced and recyclable materials enhance sustainability of the platforms themselves. Although recycling is currently not envisioned let alone enforced among the various constraints for material choice in MPS and OoC manufacturing, guidelines oriented toward recycling and circularity (e.g., reusability of devices, which is at the moment limited at best) could inform future standards, with a foreseeable impact on waste proportional to technology adoption. In addition, by minimizing biomedical waste and enabling personalized, data-driven medicine, MPS and OoC devices help close loops in healthcare innovation, ensuring fewer wasted treatments and reduced resource demand over product lifecycles. Establishing clear terminology for reusable and recyclable components will further support waste reduction, enable consistent lifecycle assessments for environmental impact reporting, and facilitate sustainable material selection—particularly in microfluidic device design, where material choice and device reuse are key to minimizing environmental impact.

Standardization in MPS and OoC can significantly contribute to achieving Sustainable Development Goals (SDGs) in the following ways:

- Regarding SDG 3: Good Health and Well-being, standardization can accelerate drug development, since reliable and reproducible OoC systems help identify effective drugs faster and more safely.
- Regarding SDG 6: Clean Water and Sanitation, OoC technology can be used to assess the safety of water and sanitation systems by modelling the impact of pollutants on human organs.
- Regarding SDG 9: Industry, Innovation, and Infrastructure, standardization helps establishment of innovation ecosystem, by fostering interoperability and scalability, encouraging industrial investment and infrastructure development.
- Regarding SDG 12: Responsible Consumption and Production, standardization helps reduction in animal testing, since OoC devices replicate human physiology better than animal models, supporting the 3R's (Replacement, Reduction, Refinement) in research. In addition, terminology plays a foundational role in enabling sustainable manufacturing practices, transparent supply chains, eco-design of biotech systems

Standardization in MPS and OoC can indirectly contribute to mitigating climate change by accelerating the development of environmentally friendly products and reducing the need for animal testing, which has significant environmental impacts.

Strategic planning for the next 5 years

Over the next five years, the strategic priorities of ISO/TC 276/SC2 will focus on creating a foundation of standards that both reflect scientific innovation and meet industry and regulatory requirements. Introducing standards in this relatively young but rapidly maturing field is timely also in consideration of the absence to date of dominating manufacturers of devices which might be in the position of imposing de facto standards. In the short term, the emphasis will be on establishing a unified vocabulary, setting baseline quality criteria, and defining reference materials and models to ensure reproducibility of experimental data. It is considered timely also to align with regulators for what concerns e.g. terminology and definitions and relative scope of standards and regulations. Mid-term actions will expand to guidelines for regulatory science integration, data sharing frameworks, and qualification protocols for specific organ models, strengthening alignment with health authorities and international partners. Longer-term planning will support scalability through modular and interoperable system standards, sustainability considerations in materials, manufacturing, reusability and recyclability, and proactive adaptation to emerging applications such as multi-organ platforms and personalized medicine. This staged approach will ensure that standardization keeps pace with technological progress, promotes technological adoption, and actively shapes a sustainable, trustworthy global market for MPS and OoC technologies.

ISO/TC 276/SC 2/WG 1 "Terminology"

Justification and Market Need for Standardization in the Market Area

- **Rapid Growth and Complexity of the Field**

  MPS and OoC technologies are interdisciplinary, combining biology, engineering, and data science. As the field grows, so does the diversity of terminology, which can lead to confusion and miscommunication among stakeholders such as researchers, manufacturers, regulators, clinicians, investors.

  Standardized terminology ensures clarity and consistency, which is essential for collaboration and innovation. This is now addressed in the new standard ISO 25448, *Microphysiological systems and Organ-on-Chip systems — Vocabulary* (under development).

- **Align terminology in International Standards**

  WG1 is tasked with identifying and aligning existing national and international standards, guidelines, and definitions. The goal is to create a unified vocabulary that supports:

  — Regulatory compliance
  — Cross-border research and development
  — Technology transfer
  — Intellectual property protection

This alignment is especially important in biotechnology, where terminological discrepancies can lead to delays in product development or approval.

- **Support for Other Standardization Efforts**

  Terminology standardization underpins the work of other ISO/TC 276/SC 2 working groups, such as ISO/TC 276/SC2/WG2, WG3 and JWG4.

  Without a shared vocabulary, these groups risk inconsistent documentation and interpretation, which could compromise the reliability and reproducibility of standards.

- **Market and Regulatory Demand**

  The biotechnology and microfluidics industries are increasingly regulated. Standardized terminology helps:

  - Facilitate regulatory approval by aligning with global standards
  - Improve product labeling and documentation
  - Enhance interoperability between devices and systems
  - This is particularly relevant for healthcare applications, where precision and safety are paramount.

Scope

ISO/TC 276/SC2/WG1 “Terminology” will work on terminology related to MPS and OOC.

Climate and Circularity Relevance

See ISO/TC 276/SC 2.

ISO/TC 276/SC 2/WG 2 “Biological components in MPS and OoC”

Justification and Market Need for Standardization in the Market Area

Increase in physiologically-relevant cell sources and exploration of context of use are the biological component-related growth drivers for the field of MPS and OoC.

Standards relating to the following items support this growth drivers to work consistently:

- reliable cell sources supported by appropriate quality control and sufficient information, and
- framework for fitting MPS and OoC to the intended context of use.

Given that the rapid progress in bioscience and biotechnology, timely standardization for biological components with pre-defined context of use also contributes to the growth of the field.

Scope

ISO/TC 276/SC 2/WG 2 “Biological components in MPS and OoC” focuses on the identification of standards for biological components in MPS and OoC models. Biological inputs include aspects related to cell source, biomaterials (3D matrices and 2D coatings) to culture cells and biophysical/biochemical cell culture conditions. WG2 will focus on functional aspects for MPS and OoC.

General standardization work items related to biological parts can be covered by either ISO/TC 276/WG 2 Biobanks and bioresources or ISO/TC 276/WG 4 Bioprocessing for cells and related entities. Furthermore, the SC2/WG2 experts focusing on biological topics involved in ISO/TC 276/WG 2 or ISO/TC 276/WG 4 will add a unique OoC perspective to the standards that are being developed in ISO/TC 276.

Climate and Circularity Relevance

See ISO/TC 276/SC 2.

ISO/TC 276/SC 2/WG 3 “Experimental design, data processing and integration of MPS and OoC studies”

Justification and Market Need for Standardization in the Market Area

The MPS and OoC field is rapidly advancing but remains hindered by a lack of standardized approaches to experimental design, data handling, and computational integration. Current practices vary widely across laboratories and manufacturers, with no unified method for reporting biological, hardware, or analytical data. This absence of common data formats and metadata standards limits reproducibility, comparability, and cross-platform validation—particularly for industrial and regulatory users who require traceable, qualified, and interoperable data to inform decision-making. Without systematic documentation of hardware characteristics, biomarker read-outs, or kinetic data, the broader adaptation and qualification of OoC systems are impeded.

Standardization in experimental design, data management, and computational modelling is therefore essential to unlock the full potential of MPS and OoC technologies. A clear framework for designing, executing, and reporting experiments will improve reproducibility and reduce the threshold for technology adoption across research and industrial settings. Harmonized standards will also support the creation of centralized databases that integrate biological and technical data, enabling the use of machine learning and artificial intelligence to identify optimal chip designs and predictive models. The integration of digital-twin and computational modelling approaches—underpinned by robust standards for coding practices, data security, and model qualification will further enhance the predictive accuracy and translational value of MPS and OoC systems.

From a market perspective, the absence of qualified, standardized assays has slowed industrial uptake, as end-users face uncertainty regarding applicability, reproducibility, and regulatory relevance. Establishing internationally harmonized standards will ensure that all relevant experimental and computational information is captured consistently, enabling reproducible results across laboratories and fostering confidence among regulators, pharmaceutical companies, and technology developers. Ultimately, standardized experimental and data frameworks will accelerate innovation, promote clinical translation, and strengthen the competitiveness of the global MPS/OoC market by transforming these technologies into reliable and scalable tools for drug development, disease modelling, and precision medicine.

Scope

WG 3 focuses on general requirements and considerations for MPS and OoC projects related to experimental design and setup, execution of biological experiments using OoC or MPS. It includes the following topics:

- Experimental design, including considerations for reference compounds and monitoring
- hardware parameters;
- Data management and reporting;
- Data interoperability and integration;
- Computational analysis/modelling, including considerations for translation to humans.

WG 3 works closely with ISO/ TC276/SC1 Analytical methods and WG 5 Data processing and integration, on topics on data processing and integration for MPS and OoC, such as:

- processes relating to the standardisation of the production and technical operation of the
- hardware, which are required to run a biological OoC/MPS experiment;
- reporting data from biological experiments and providing templates for specific applications; or
- Organ-on-Chips.

Climate and Circularity Relevance

See ISO/TC 276/SC 2.

ISO/TC 276/SC 2/JWG 4 “Engineering”

Justification and Market Need for Standardization in the Market Area

The MPS/OoC market is highly interdisciplinary. Development of a new product requires the understanding of significant and often nuanced interdependencies between technical aspects from the fields of biology engineering and material science. In highly interdisciplinary markets there is often a strong need for specific standards to ease communication between the disciplines and thereby reduce friction between market actors. The MPS/OoC market is no exception and, as it grows, we see an increasing recognition of that fact from multi-stakeholder focus groups and from surveys of experts.

The need for clear communication must be carefully balanced against the need for market innovation. The field of MPS/OoC is still relatively young and its growth is highly innovation-driven. Standards that help ensure clear communication and device interoperability must therefore not be overly restrictive to innovation. Standardized testing/reporting protocols are an option which can facilitate clear communication without a significant impact on design freedom. In particular, standardized protocols for measuring device and material properties tell producers how to perform a test without going so far as to state that a given test must be run. These standards also make no comment on which test outcome is “correct”. Standardized reporting guidelines then allow users and integrators to pick the right components for their specific application. Also, as the field continues to evolve, there is an opportunity to develop standardized templates that could be adopted by manufacturers. Following appropriate review and approval, these templates could eventually be incorporated into the ISO standard, thereby facilitating testing practices that may not yet exist today but could become common in the future.

While some testing/reporting standards exist in adjacent multidisciplinary domains (i.e. ISO 10993 for biological evaluation of medical devices) these domains have significantly different needs, both in terms of technical design aspects (i.e. the surface area to volume ratio and the inclusion of microflows in MPS/OoC) and regulatory aspects (the regulation of MPS/OoC devices is a topic of active development). Therefore, there is a strong need for MPS/OoC specific standards, but also much prior work to draw inspiration from.

Scope

JWG 4 is a joint working group with TC 48/ WG 3 Microfluidic Devices. It is centered on topics related to OoC/MPS specific engineering. Specifically seeking to ease challenges associated with the selection of components and materials when designing new systems. The main focus will be on component intercompatibility and measurement/reporting of performance metrics.

Topics include:

- Material properties
- Compatibility with incubator conditions
- Compatibility with existing cell-culture workflows
- Production, fabrication and manufacturing methods;
- Sensors;
- Actuators;
- Modularity/integration (i.e. fluidic connector compatibility)
- System Reliability (i.e. sterilization, leakage, and contamination)

Climate and Circularity Relevance

See ISO/TC 276/SC 2.