



Industry News & Perspectives

ISoOR Gains ILAC Stakeholder Status: Advancing Global Standards in Organoid Biobanking

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The International Society of Organoid Research (ISoOR) has strengthened its role in shaping global standards for organoid biobanking. On September 12, 2025, ISoOR was formally accepted as a Stakeholder member of the International Laboratory Accreditation Cooperation (ILAC), the world's leading authority on laboratory and inspection-body accreditation. Achieved just six months after the launch of the ISoOR-ISOB International Standard for Organoid Biobanking at the society's March 2025 congress in Shanghai, this membership provides ISoOR with a platform to contribute to international accreditation discussions, align its standards with globally recognized frameworks, and support the long-term goal of establishing organoid biobanking as a robust, reproducible, and trusted platform for clinical and commercial applications.

Organoids - self-organizing, three-dimensional structures derived from stem cells that recapitulate the architecture and function of human organs - have transformed disease modeling, drug

screening, and regenerative medicine. Yet their widespread adoption has been limited by the absence of universally accepted biobanking and quality control standards. ISoOR's entry into ILAC directly addresses this gap by aligning the field with the same rigorous accreditation framework that underpins confidence in millions of laboratory results worldwide every day.

The Origins and Evolution of ILAC: From 1977 Vision to 2025 Global Authority The International Laboratory Accreditation Cooperation traces its roots to a pivotal conference held in Copenhagen, Denmark, from October 24-28, 1977. At that time, rapid growth in international trade exposed a critical problem: differing national calibration and testing standards forced exporters to undergo costly, redundant assessments in every market. Representatives from 15 countries gathered to advocate for mutual recognition of accredited test results, laying the philosophical and practical foundation for what would become ILAC.

In 1996, ILAC transitioned from an informal network into a formal international cooperation with a charter focused on peer evaluation and harmonized accreditation practices. The defining moment arrived on January 31, 2001, when 36 accreditation bodies from 28 economies signed the inaugural ILAC Mutual Recognition Arrangement (MRA) in Washington, D.C. This multilateral agreement created the principle of “accredited once, accepted everywhere.”

The MRA has since expanded in scope and depth:

- October 2012 – inclusion of inspection bodies (ISO/IEC 17020)
- May 2019 – proficiency testing providers (ISO/IEC 17043)
- May 2020 – reference material producers (ISO 17034)

As of November 2025, the ILAC MRA comprises 121 signatories from 122 economies, covering more than 114,600 accredited laboratories, 15,600 inspection bodies, 700 proficiency testing providers, and 300 reference material producers. The arrangement directly supports World Trade Organization (WTO) objectives by eliminating technical barriers to trade and is recognized by regulators in fields ranging from food safety and environmental monitoring to medical diagnostics and advanced therapeutics.

Importantly, ILAC itself does not accredit laboratories or conformity assessment bodies (CABs). That responsibility lies with its Full Member accreditation bodies, which operate under the peer-evaluated discipline of the MRA. National or regional bodies (e.g., UKAS in the UK, A2LA in the US, SAC in Singapore) perform the actual accreditations, while ILAC ensures their competence through rigorous evaluation against ISO/IEC 17011 and supplementary requirements.

ISoOR’s Strategic Roadmap Toward Global Alignment

ISoOR is actively working to align its organoid biobanking standards with international accreditation frameworks. In March 2025, the society unveiled ISoORISOB – the world’s first dedicated international standard for organoid biobanking – which builds on ISO 20387:2019 (general biobanking) and addresses organoid-specific challenges, including long-term viability, genetic fidelity, phenotypic stability, ethical provenance, and data interoperability.

To guide its long-term development toward potential regional and international recognition, ISoOR has outlined a **multi-year roadmap**, which includes:

1. Internalization of ISO/IEC 17011 requirements

conducting a gap analysis focused on impartiality, conflict-of-interest mitigation, and structural separation of commercial and accreditation functions.

2. Deployment of a Quality Management System (QMS)

developing publicly available documentation, appointing an independent Quality Manager, and establishing governance structures to ensure accreditation decisions are insulated from revenue-generating activities.

3. Legal and governance restructuring

updating statutes, financial safeguards, and governance policies to reinforce impartiality and transparency.

4. Operational rollout of the ISoOR-ISOB accreditation scheme

piloting processes for assessor training, surveillance, complaints, and appeals.

5. Engagement with Asia Pacific Accreditation Cooperation (APAC) and ILAC

submission of relevant documentation and standards for feedback and alignment; ILAC Stakeholder membership, achieved in September 2025, marks an initial step in this ongoing process.

6. Commitment to continuous improvement

implementing regular audits, stakeholder workshops, and transparent reporting to refine processes over time.

Each of these steps is part of a **long-term initiative**; full international recognition and potential accreditation remain future objectives. ILAC Stakeholder membership provides ISoOR with a platform for early participation in global accreditation discussions and alignment with best practices, supporting the society's ongoing development.

Understanding ILAC Membership Categories and the Path to MRA Signatory Status

ILAC membership is structured in four categories (full criteria: <https://ilac.org/ilacmembership/membership-criteria/>):

- Stakeholder (ISoOR's current status): For international, regional, or national organizations with legitimate interests in accreditation (e.g., laboratory associations, regulators, industry bodies). No peer evaluation required; application via email to the ILAC Secretariat.
- Associate: Developing accreditation bodies operating schemes and demonstrating conformity with relevant standards.
- Full Member (MRA Signatory): Mature accreditation bodies successfully peer-evaluated

against ISO/IEC 17011 and capable of accrediting CABs to ISO/IEC 17025, 15189, 17020, 17043, and/or 17034.

- Recognised Regional Cooperation Bodies (e.g., APAC, EA, IAAC): Regional groups whose own MRAs are evaluated and recognized by ILAC.

Acceptance as a Full Member and MRA signatory is contingent on a rigorous peer evaluation process conducted by senior staff from established accreditation bodies. Evaluations include:

- Headquarters office assessment for ISO/IEC 17011 conformity
- Witnessing of the applicant body's assessors performing actual accreditations at CAB sites
- Verification that accredited CABs meet the relevant technical standards with sufficient depth

Regional bodies such as APAC typically conduct these evaluations under delegated ILAC authority, although direct ILAC evaluation is available for bodies without regional affiliation.

The Peer Evaluation Process: Ensuring Global Confidence The ILAC MRA's credibility rests on an intensive, transparent evaluation cycle governed by publications such as IAF/ILAC A-series documents. Key commitments of every MRA signatory include:

- Maintenance of conformity with the current version of ISO/IEC 17011 and supplementary requirements
- Accreditation of laboratories to ISO/IEC 17025 and/or ISO 15189
- Accreditation of inspection bodies to ISO/IEC 17020
- Accreditation of proficiency testing providers to ISO/IEC 17043

- Accreditation of reference material producers to ISO 17034
- Immediate notification to peers of significant changes (name, legal status, key personnel, scope, etc.)
- Designation of a liaison officer for consistent communication

Annual reports and four-year re-evaluations ensure ongoing compliance, preserving the phrase “accredited once, accepted everywhere.”

Stakeholder members like ISoOR play a vital complementary role

Shaping standards, providing technical input, and preparing the ground for future accreditation schemes (such as ISoOR-ISOB-based organoid biobank accreditation) that can eventually be operated by Full Member bodies under the ILAC MRA umbrella.

Looking Forward: From Stakeholder to Potential Accreditation Body ISoOR’s Stakeholder membership is explicitly the first phase of a longer-term vision: to evolve into a recognized accreditation body for organoid biobanking worldwide. With ISoOR-ISOB already adopted by leading institutions and the society’s governance now demonstrably ISO/IEC 17011-aligned, the path toward Associate and ultimately Full Member status within APAC and ILAC is clearly mapped.

When that milestone is reached, an organoid biobank accredited under the ISoORISOB scheme by an ILAC MRA signatory will carry the same international weight as any ISO/IEC 17025-accredited testing laboratory – a transformative prospect for drug developers, regulators, and clinicians relying on organoid data.

As ILAC prepares its own transition to the Global Accreditation Cooperation in 2026, the inclusion of a forward-looking organization like ISoOR illustrates how accreditation infrastructure is adapting to the next generation of biomedical technologies. For the organoid community, September 12, 2025, will be remembered as the day the field formally entered the global accreditation ecosystem.

The ILAC-IAF Merger: Birth of the Global Accreditation Cooperation and Its Implications for ISoOR

In a parallel development that amplifies the timing and strategic value of ISoOR’s ILAC Stakeholder status, the accreditation landscape is undergoing its most profound structural change in decades. On October 24, 2024, following unanimous approval at their respective annual meetings in Vancouver, **the International Accreditation Forum (IAF)** and ILAC formally initiated the merger process, culminating in the incorporation of the **Global Accreditation Cooperation Incorporated (GAC)** as a legal entity in New Zealand. Provisionally set to become operational on January 1, 2026, the GAC represents the fusion of IAF – the global association for certification body accreditation since 1993 – and ILAC, creating a unified, single international organization overseeing all aspects of conformity assessment accreditation.

This merger, years in the making, addresses longstanding fragmentation in the global accreditation ecosystem. IAF has historically focused on management systems, product certification, and personnel certification (e.g., ISO/IEC 17021 for management systems certification bodies), while ILAC has specialized in laboratory, inspection, proficiency testing, and reference material accreditation. The resulting GAC will integrate the **IAF Multilateral Recognition Arrangement (MLA)** and ILAC MRA into a single

GAC Mutual Recognition Arrangement (MRA), streamlining peer evaluation, signatory status, and global acceptance of accredited results across all scopes. As outlined in the joint IAF/ILAC Constitution and General Rules approved in 2024, the GAC aims to enhance efficiency, reduce duplication, and strengthen advocacy for accreditation's role in sustainable development goals, WTO compliance, and emerging technologies like biotechnology.

The relevance of this merger to the broader accreditation community cannot be overstated. By consolidating operations, GAC will foster a more cohesive voice in international forums, such as the WTO Technical Barriers to Trade Committee and ISO technical committees. It promises operational synergies: unified peer evaluations, shared resources for digital transformation (e.g., traceability in analytical chemistry via CITAC), and a single MRA Mark to replace the IAF MLA and ILAC MRA logos by 2029. Regulators and specifiers are encouraged to update references to "ILAC/IAF accreditation" with "GAC accreditation" post-transition, ensuring seamless continuity. The provisional January 2026 launch date allows for a phased handover, with both organizations continuing parallel operations through 2025 to minimize disruption.

For ISoOR, the merger is strategically timely. As a new ILAC Stakeholder, the society enters the accreditation ecosystem at a moment of structural renewal, positioning itself to participate in and benefit from GAC's unified framework.

The merger may influence ISoOR in several ways:

- **Enhanced global advocacy:** GAC's unified platform amplifies Stakeholder voices like ISoOR's in shaping future standards, including potential extensions to biotech-specific scopes (e.g., ISO/TC 276 for biotechnology). ISoOR could contribute to initiatives such as digital

traceability for organoid data, aligning with GAC's focus on emerging risks like AI-driven lab automation.

- **Early engagement in a consolidated accreditation ecosystem:** Being part of GAC's Stakeholder network allows ISoOR to observe, participate, and align its organoid biobanking standards with global best practices, positioning the society for future regional or international recognition.

While these developments are prospective, the merger provides ISoOR with an early opportunity to engage with a consolidated global accreditation framework, helping to inform its ongoing development of organoid biobanking standards and eventual alignment with regional and international accreditation practices.

Overall, the ILAC-IAF fusion via GAC is a boon for ISoOR, transforming its timely Stakeholder entry into a launchpad for leadership in biotech accreditation. By embedding organoid standards into a unified global MRA, ISoOR not only safeguards the field's reproducibility but also positions it as a pillar of the next accreditation era - one where miniature organs inform therapies trusted across borders.

Conclusion

ISoOR's acceptance as an ILAC Stakeholder represents a strategic milestone in the society's long-term plan to advance global standards for organoid biobanking. While this membership does not confer accreditation authority, it provides a platform for engagement with the international accreditation ecosystem and alignment with best practices. Looking ahead, ISoOR's transition into a recognized accreditation body seeks to eventually achieve MRA signatory status, positioning organoid biobank accreditation for international recognition, reproducibility, and trust in clinical and research applications.