Commentary: Alexa Machikas and Elena Kfoury

New body for regenerative medicine launched

18 January 2017 marked the official launch of the international Standards Coordinating Body (SCB), a non-profit organisation which aspires to be a source of knowledge, experience, and leadership for enabling more efficient and successful clinical and commercial development of cellular/gene and regenerative medicine therapies. The SCB expects to facilitate activities such as research, development and education that are the foundation of standards, by helping to coordinate inter-laboratory studies, technical reports and publications, workshops, and other activities. This includes supporting the development of consensus standards within standards organisations. The SCB aims to strengthen the regenerative medicine field by initiating activities to improve product quality, enhance health and safety, strengthen market access, and develop consumer confidence.

Independent initiative

The SCB arose as an independent initiative of the Alliance for Regenerative Medicine's (ARM) Science and Technology committee, which similarly functions as a consortium of stakeholders from throughout the regenerative medicine community. ARM is based in Washington DC. Through discussions with the various regulatory agencies such as the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA), as well as with the US National Institute for Standards and Technology (NIST), a core group of stakeholders identified the crucial need for the development of consensus standards for cell and gene therapy and other regenerative medicine products. This initiative prompted the establishment of the SCB as an independent 501(c)(3) non-profit organisation that is wholly dedicated to the development of consensus standards for the regenerative medicine community.

The SCB is comprised of stakeholders from all parts of the regenerative medicine community: biotechnology and pharmaceutical industry corporations, academic research institutions, professional and accrediting organisations, and federal regulatory agencies. In order to maintain its status as a non-profit organisation, project activities and other operations of the SCB rely on contributions from stakeholder organisations. Additionally, participation in certain projects may incur a minimal cost to support project management and necessary operational needs that are facilitated by the SCB. In return, the stakeholders are provided with a powerful network of knowledge and expertise to facilitate every stage of standards development, from technology development and analytical research activities, through the standards development processes.

In addition to the inclusive aggregate network of stakeholders that comprises the SCB, the organisation also benefits from integral working relationships with the NIST Material Measurement Laboratory, which has been formalised through a memorandum of understanding (MoU). This public-private partnership is consistent with the language that was first described in the *21st Century Cures Act*, passed by the US Congress in 2016, that directs NIST, the FDA, and other US agencies to work cooperatively with industry corporations, standards development organisations, and other stakeholders through the SCB to advance and accelerate standards development. The SCB is also working to formalise similar MoU-sanctioned relationships with the United States Pharmacopeia (USP), the American Association of Blood Banks (AABB), and others.

The SCB operates through four working groups: cell-based drug discovery, cell therapy, gene therapy and gene editing, and tissue engineering. Each working group seeks to identify and prioritise issues that are relevant to the needs and interests of the sector. These issues are then placed through the SCB project process to effectively develop, evaluate and implement standards that will support enabling technologies and infrastructure, clinical development, and commercialisation. Currently, the SCB is working to draft key requirements for a standard that will be further developed within the International Standards Organisation (ISO), on cell transportation and logistics to ensure that cells maintain quality, safety and performance during shipment. A few examples of the standards needs that were identified by stakeholders include minimum requirements for IT infrastructure and transportation, shipment tracking and monitoring protocols, chain of custody requirements, and a centralised logistics management system. The SCB project team working on this project is comprised of representatives from all sectors surrounding the project area, including academic researchers, cell therapy product manufacturers and suppliers, airport field experts, shipping companies, logistics software developers, and government agents for standards development. This project will contribute to the development of an ISO standard for cell transportation and logistics that will have been made possible by the invaluable network of expertise that the SCB comprises.

The SCB is currently managing several other projects across the four working groups that will result in an exciting first year for the organisation. By bringing together product developers, tools and service providers, professional societies, government entities, and academic centres in a pre-competitive forum, the SCB hopes to be an influential leader in the creation of a consistent compliance environment and the adoption of standards that will support the approval of regenerative medicine products. As the participation and activities continue to expand, the SCB aims to be a key influence in standards development both internationally and domestically, through the continued support of dozens of vested stakeholders.

This article was written by Alexa Machikas, operations manager, and Elena Kfoury, president and chief executive, of the SCB. For further information please see www.standardscoordinatingbody.org.