



International Alliance for
Biological Standardization



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Dr Yoji Sato is Head of the Division of Drugs at the Japanese National Institute for Health Sciences (NIHS). Dr Sato's current research area is in quality assurance for new and generic low molecular drugs. Still, he also has extensive experience in regulatory science research on the quality and safety of cell therapy products (CTPs). Until March 2023, he served as Head of the Cell-Based Therapeutic Products Division at the NIHS, where he led a public-private partnership initiative in Japan to validate a variety of test methods for evaluating the tumorigenicity of CTPs in collaboration with the Committee on Nonclinical Safety Evaluation of Pluripotent Stem Cell-Based Therapeutic Products of the Forum for Innovative Regenerative Medicine. He also contributed to establishing Standards for Human Stem Cell Use in Research, which was published in June 2023, as a member of the Standards Initiative Steering Committee of the International Society for Stem Cell Research (ISSCR). In addition, he has published several research papers on the development of NGS-based test methods for viral safety of biologics, including CTPs, and serves as a topic leader for the ICH Q5A(R2) Expert/Implementation Working Group and a member of the Pharmaceutical Affairs Council of the Ministry of Health, Labour and Welfare.