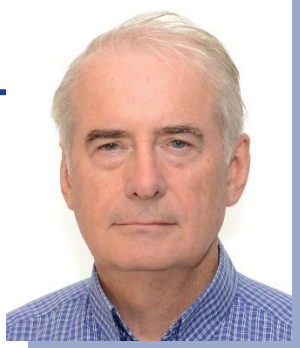
International Alliance for
Biological Standardization



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Andrew Lennard is in the Global Regulatory Affairs CMC team at Amgen and is based in the UK. Within CMC Regulatory Affairs, he is part of the External Engagement and Advocacy team with responsibilities in advancing innovations to accelerate CMC in product development. Andrew has over 18 years' experience in CMC Regulatory Affairs, with a special interest in control strategy and using prior knowledge, in which he has participated at the EMA workshops on Prior Knowledge, and on CMC acceleration in Breakthrough/PRIME. He is also an active member of EFPIA, leading several initiatives relating to CMC acceleration, including 'Stability' for which Andrew is the EFPIA topic lead on the Expert Working Group for the ICH Q1revision of the stability guidelines, and as part of the ICH Q6 Specifications revision EFPIA Support team. Andrew presented on case studies for approaches to a Patient-centric Specification at the 3rd IABS workshop (2023). Prior to Regulatory Affairs, Andrew was a Principal Scientist in drug discovery for large pharma and small biotech start-up companies and holds a PhD from the University of Cambridge (UK).