



International Alliance for
Biological Standardization

Europe



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Karen Rule is a Director in Analytical R&D (Biotherapeutics Pharmaceutical Sciences) at Pfizer, based in Massachusetts, USA. She has been with Pfizer for 24 years working in multidisciplinary areas including bioassay/potency development, analytical project lead and currently leads a group that is responsible for analytical regulatory strategy and authoring of analytical sections for the submissions across vaccines, mAbs, gene therapies, ADC and other mAb-like products. Her experience has covered method development, characterization, comparability, control strategy, method validation/transfer and health authority interactions. Over the past few years, Karen has been working with a team at Pfizer to help define the expectations and implement platform analytical procedures for late-stage products.