International Alliance for
Biological Standardization

Globally Harmonized Specifications: Current State and Future Opportunities
January 10-12, 2023
Kunstmuseum, Basel, Switzerland

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Mats Welin holds a position as a Senior expert at the Medical Products Agency in Sweden, working with quality assessment of human and veterinary biologics and normative work within this field with a focus on vaccines and monoclonal antibodies.
He is a pharmacist by training and has been employed at the agency since 1988.
Since 1996 he is the Swedish delegate of CHMPs sub group on biologics, the Biologics working party (BWP) and has been heavily involved in writing of new guidelines as well as in EMA-Industry workshop on setting specifications, making use of prior knowledge in regulatory submissions and quality expectations in relation to accelerated approvals.
He was a member of EMEA PAT team dealing with QbD related topics from 2003 as one of the BWP representatives to cover biological aspects in the field.
He also was a delegate of the Quality implementation working group (Q-IWG) of the ICH during its existence to work with introduction of the Q8-Q10 concepts.
He is frequent speaker at conferences on Quality by Design, process validation, setting of specifications and on general aspects in relation to biological medicinal products.