Setting impurity specifications for biologicals

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The presentation will look at the role of impurities in complex biological molecules. Typically, there are no therapeutic benefits to be derived from impurities. Therefore, all impurities should be removed or controlled to the extent possible to meet product specifications, good manufacturing practices (GMP), or other quality or safety-based criteria and drug products should contain no higher levels of residual impurities than can be supported by safety data and/or process capability. The focus will then switch to regulatory requirements for impurities that are enshrined in ICH Q3A / ICH Q3B and ICH Q6B; as well as other related impurity guidance for residual solvents (ICH Q3C), residual elemental impurities (ICH Q3D) and residual mutagenic impurities (ICH M7).

The presentation will then focus on the typical types of impurities in biological molecules before looking at an assessment of the process capability (Cpk) and impurity purging capability of the process. Then the focus will switch to allowable safety margins and the typical risk assessments that are needed to support the safety margins, before providing some concluding remarks.

Speaker Biography

Dr. Elder has 40 years of service within the pharmaceutical industry, with Sterling, Syntex and for the last 23 years with GSK. He is now an independent CMC consultant with broad based experience in formulation and analytical method development. Dr. Elder obtained his PhD in crystallography from the University of Edinburgh. Dr. Elder is a visiting professor at King's College, London. He is a Fellow of the RSC and chartered chemist and scientist. He is a member of the British Pharmacopoeia. He is the immediate past chairman of JPAG (Joint Pharmaceutical Analysis Group). He is a member of the Editorial Advisory Board for the Journal of Pharmaceutical Sciences. He has published over 131 papers in international journals and has given 17 webinars and over 138 presentations at international symposia. He has co-edited a book on the Analytical Characterization and Separation of Oligonucleotides and their Impurities and on ICH Quality Guidelines.

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