

BIOPHARMA & BIOTHERAPEUTICS

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David P Elder

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Stability, storage and cold chain supply of biologics

The presentation will look at a comparison of biologicals vs. small molecules, highlighting some of the key challenges inherent with biological molecules. Before looking at the main degradation pathways for therapeutic proteins (taken as an exemplar of complex biological molecules) and reviewing the stability challenges facing biological development organizations. The presentation will then focus on the “Cold Chain” challenge, highlighting that over half of the top 50 biological drugs in the world require cold chain, i.e. refrigerated storage and distribution due to stability concerns. Cold chain storage and transportation, and some of the challenges and regulatory considerations will then be reviewed, focusing on global good distribution practice (GDP) requirements before providing concluding remarks to complete the presentation.

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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