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Identification and quantification of individual Host Cell Proteins (HCP's) in biosimilars and comparison with originator using SWATH mass spectrometry

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Regulatory requirements for biosimilars include process related impurities including (HCP) which should be identified, characterized as appropriate, quantified, and compared with the reference products. Here we present a HCP analysis method based on a SWATH (Sequential Windowed Acquisition of All Theoretical Fragment Ion Mass Spectra) LC-MS workflow that is fast, sensitive and provides reproducible identification and absolute quantification of individual HCP's in the purified drug substance. The workflow is generic for vaccines, mAbs (monoclonal antibodies), small therapeutic proteins and protein biopharmaceuticals. We will present this new method for accurate and absolute HCP quantification, and parameters critical for method validation, including reproducibility, linearity, LOD/LOQ and measurement range. Case examples will be shown including comparison between biosimilar and originator product.

Biography

Thomas Kofoed holds a PhD in Chemistry from the University of Southern Denmark, Denmark. He is the Co-Founder and Chief Executive Officer of Alphalyse and has been responsible for general management of Alphalyse since its inception in 2002. He has more than 20 years of experience from the Biotech industry, and previous posts as Head of Proteomics at ACE BioSciences A/S, Denmark, Associated Professor at Copenhagen University, Denmark and Senior Scientist at PNA Diagnostics AS, Denmark.

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