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Identification of biosimilarity in early process development and clone screening

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Biosimilar development is seeking to identify clones and manufacturing process conditions that are most likely to yield similar quality profiles as the originator product. However, during clone screening and process development, sufficient repetitions of experiments is not feasible in order to perform scientific and statistically sound bioequivalence analysis according to FDA guidelines. Although sample size of biosimilar experiments of a specific clone at a specific process condition is limiting, data is usually rich in redundant critical quality attributes (CQAs). Taking advantage of that situation, we want to present a novel multivariate statistical approach to identify lead clones and optimal process conditions that will later on increase the chance of passing bioequivalence assessment. Moreover, we want to present a successful implementation of a biosimilarity software application that helps operators to identify biosimilar clones and process conditions and even enables them to take counter actions within their process development. This ultimately leads to a more robust and data driven process development of biosimilars.

Biography

Thomas Zahel has completed his PhD in Applied Statistics for Biopharmaceutical Development and Manufacturing at Vienna Technical University, Austria. Since 2014, he is leading an innovation group devloping novel multivariate statistical methods for biosimilarity testing and process validation at the data science and software company Exputec, located in Vienna, Austria.

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