

Insights into the world of a CMC statistician for Biologics

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This presentation provides insights into the life of a CMC (Chemistry, Manufacturing, and Controls) statistician in the pharmaceutical industry, elucidating statistical questions and their solutions through various examples. These examples range from the concrete implementation of an ICH Q14 guideline on the development of analytical methods with DoE (design of experiment) to examples from the field of process modeling and unplanned data. Different model types are explained in practical examples.