

Title of the presentation

Impact Ratio - An integral part of Roche's synthetic molecule drug substance technical development

Presenter

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Short biography

Janine Burren has been a nonclinical statistician at F. Hoffmann-La Roche in Basel since 2020. She got her Master's degree in statistics from ETH Zurich in 2016. After a one year cross-industry data science internship, she worked in the statistical consulting group of the Seminar for Statistics at ETH Zurich for two years before joining Roche. At Roche, Janine supports the synthetic molecule technical development and manufacturing with statistics.

Abstract of the presentation

In the last 8 years, the impact ratio has become an integral part of Roche's quality by design based approach in the technical development of synthetic molecule drug substances. The impact ratio is a simple yet powerful mathematical instrument to quantify the practical significance of a process parameter's effect on a critical quality attribute and is used to inform the criticality of process parameters. In this talk we present how the impact ratio in combination with designed experiments is embedded in Roche's drug substance process characterization and decision making process; what considerations and assumptions are made when designing the experiments; what requirements are necessary for the computation of the impact ratio and what visualizations we use to communicate results to chemists, engineers, and health authority regulators. We highlight the benefits the impact ratio has brought to Roche's drug substance process characterization as well as critically discuss the approach with respect to its limitations and improvement opportunities.