Title of the presentation:
From Data to Impact: Yield Optimization in Biologics Manufacturing

Presenter:
Alexandre Mösching[1]

Authors in alphabetical order:
Ilmari Ahonen[1], Alexandre Mösching[1], Yiming Peng[1], Christian Schmid[1], Yang Tang[1]

[1] Nonclinical Biostatistics, Product Development, F. Hoffmann-La Roche.

Short biography:
Alexandre Mösching got his PhD in Statistics from the University of Bern (CH) in 2020. In 2022, he joined F. Hoffmann-La Roche in Basel (CH) as a Data Scientist after two years of PostDoc in Statistics at the University of Göttingen (DE). At Roche, Alexandre has supported the manufacturing of multiple drug substances, in particular with the aim of optimizing their yield.

Short summary of the presentation:
Biologics drug substance manufacturing is a complex process which requires close monitoring and data-driven decision making to optimize the production yield in order to ultimately ensure sustained drug access for patients. At Roche, an Advanced Data Analytics team was formed, where statistical expertise and process knowledge join forces to increase, stabilize and forecast the yield. The resulting statistical methods enable process monitoring, process adaptive control on the shop floor, and production scheduling optimization. In this talk, we present the team's operating model, the data landscape, the statistical methods, the resulting applications deployed for end to end yield optimization of drug substance manufacturing at Roche in Basel, and its impact. The use case provides an illustrative example of what it takes to bring a data-driven solution into production.