



TITLE: Process Characterization and associated DoEs considerations in R&D/CMC

SPEAKER: C.Leveder⁽¹⁾

COAUTHORS: C.Bennett⁽¹⁾, G.Cesaraccio ⁽²⁾,E.Gbaje ^{(3,]} V.Taillefer^{(1]} , Y.Van Haelst⁽¹⁾

⁽¹⁾Sanofi R&D/ Global CMC Development/Data Sciences-Statistics

⁽²⁾Aixial on behalf of Sanofi

^{(3]} Efor-CVO on behalf of Sanofi

ABSTRACT: Process Characterization (PC) is critical in biopharmaceutical development to understand how manufacturing process parameters impact product quality and performance. This presentation shares Sanofi's main practices for applying Design of Experiments (DoE) methodologies in R&D/CMC process characterization studies, with two primary objectives: establishing Proven Acceptable Ranges (PARs) for key process parameters and evaluating impact severity through Impact Ratios to identify Critical Process Parameters (CPPs).

We provide an overview of our methodology for designing and analyzing Designs of Experiments, addressing key aspects and challenges including model selection, strategies for handling block factors, Impact Ratio calculation using different formulae, and Proven Acceptable Range (PAR) determination in various contexts.

Our approaches are illustrated through concrete examples drawn from recent programs.

This work was funded by Sanofi.

Authors conflict of interest disclosures :

Caroline L  veder, Chelsey Bennett, Vincent Taillefer and Yannick Van Haelst are employees of Sanofi and may hold shares and/or stock options in the company. Ga  lle Cesaraccio is an employee of Aixial and Ejiro Gbaje is an employee of Efor-CVO. These companies were contracted by Sanofi for this work.

BRIEF SPEAKER BIO: Caroline Leveder joined Sanofi in 2006, following several years of experience in other companies.

She initially worked as a CMC statistician in R&D for chemical and pharmaceutical development, before moving to the Vaccines division as an industrial statistician for manufacturing development.

For the past seven years, Caroline has managed a team of CMC statisticians in R&D for biotherapeutics. In this role, she has actively contributed to several projects on small-scale model justification and on process characterization.