



**TITLE: Applying DoE to Bioassays: Faster Optimization, Relevant Performance, Better Decisions**

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**ABSTRACT:** Bioassays are a key analytical technology from basic research to drug discovery in the biopharmaceutical industry. Because these assays are complex and often involve multiple handling steps, optimization should be guided by the intended use (fit-for-purpose assay) and focused on the performance characteristics that matter most for that use—for example precision, accuracy, sensitivity, dynamic range, selectivity, robustness, and throughput.

For process optimization, Design of Experiments (DoE) has long been established as a more powerful strategy than a One-Factor-at-a-Time approach. DoE enables systematic exploration of factors and their interactions, helping teams converge efficiently on settings that improve the targeted performance characteristics within the expected operating window. Despite these advantages, DoE is still not used as broadly as it could be, often due to perceived costs, effort, and complexity.

We will share how implementing DoE as a regular technique for bioassay optimization can be accelerated by (1) aligning experiments to the assay's intended use and critical performance characteristics, (2) identifying and enabling a key user group, and (3) providing JMP-specific training using the JMP DoE platform.

**BRIEF SPEAKER BIO:** Mathematician and physicist by training, with a PhD in quantitative genetics, I build my career as a statistician in the life sciences. At Novartis Vaccines R&D, I provided non-clinical statistical support in close partnership with Clinical Laboratory Sciences, shaping study designs, supporting data interpretation, and enabling fit-for-purpose decisions throughout bioassay development and maintenance.

At UCB, I support biomarker and immunogenicity (ADA) assay development and validation from a statistical perspective. Working side by side with Bioanalytical Sciences and other cross-functional stakeholders, I help define objectives and acceptance criteria, develop robust analysis approaches, and communicate results in a clear, decision-oriented way.