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TITLE: Predicting and Ranking Formulations in a Sparse Categorical DOE for Potency

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ABSTRACT: Designs of experiments (DOE) with multiple categorical factors are common in non-clinical formulation screening, but the full factorial space grows quickly and is typically sparsely sampled, leaving many factor-level combinations unobserved and complicating analysis. For categorical factors, the design space is discrete: each unique combination of levels defines a distinct formulation point, so interpretation and selection require principled handling of missing combinations and censored outcomes. We report a 65-run D-optimal split-plot DOE (JMP v17) evaluating five categorical excipient classes—buffer (3 levels; hard-to-change), cryoprotectant (6), salt (4), surfactant (4), and amino acids (4)—for their impact on potency under two stress comparisons versus T0 frozen (1 week at 25°C, and 5 freeze–thaw cycles). To translate sparse categorical DOE results into actionable formulation choices, we propose a workflow that (i) explicitly enumerates the discrete formulation space, (ii) uses model-based prediction to handle unobserved combinations under a transparent missing values strategy, and (iii) ranks candidate formulations, yielding the top five factor-level combinations by predicted potency for confirmatory follow-up.

BRIEF SPEAKER BIO: Francisca Galindo Garre is a non-clinical statistician at Johnson & Johnson supporting manufacturing. With experience in applied statistics in the social sciences and biostatistics, she moved into CMC statistics at J&J. She applies design of experiments (DOE) and Bayesian methods to support specification setting and decision-making.