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Tremendous Impact of the Very New and Promising OMARS DOE in Pharma Industry for Quicker Access to New Vaccines

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In the past, screening (which process parameters are impactful) and optimisation (optimise the response variable or the critical quality attribute, CQA) were 2 distinct phases performed by 2 designs of experiments (DoE). Then, the definitive screening designs (DSDs) published approximately 10 years ago attracted a lot of attention from both statisticians and non-statisticians, espcially in the pharma industry. The idea is to combine screening and optimisation in a single step. This allows to reduce the total number of experiments and the research development time with a substantial gain in the budget.

Recently, a new type of DoE called OMARS for orthogonal minimally aliased response surface has been published. These OMARS DoEs outperform DSDs in many criteria. Firstly, the orthogonality criteria where the independence between main effects is fulfilled, and also between main effects and interaction terms. Secondly, the projection property where OMARS designs are able to estimate a response surface model (main effects, interactions, quadratic terms) from the remaining significant parameters. OMARSs also outperform DSDs in presence of categorical factors.

In this presentation, we will assess the impact of the new OMARS DoEs in the pharma industry. A case study will be used with fermentations on Ambr system for vaccine development (with 6 process parameters and multiple response variables) where the OMARS DoE allows to cut at least by 2 the total number of experiments. Finally, it will be shown that the OMARS substantially accelerates the R&D process and shortens the time-to-market of future drugs and vacccines.

Keywords

Design of Experiments, OMARS, Definitive Screening Designs

Classification

Mainly application

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