



BREAKTHROUGH INNOVATIONS SESSION

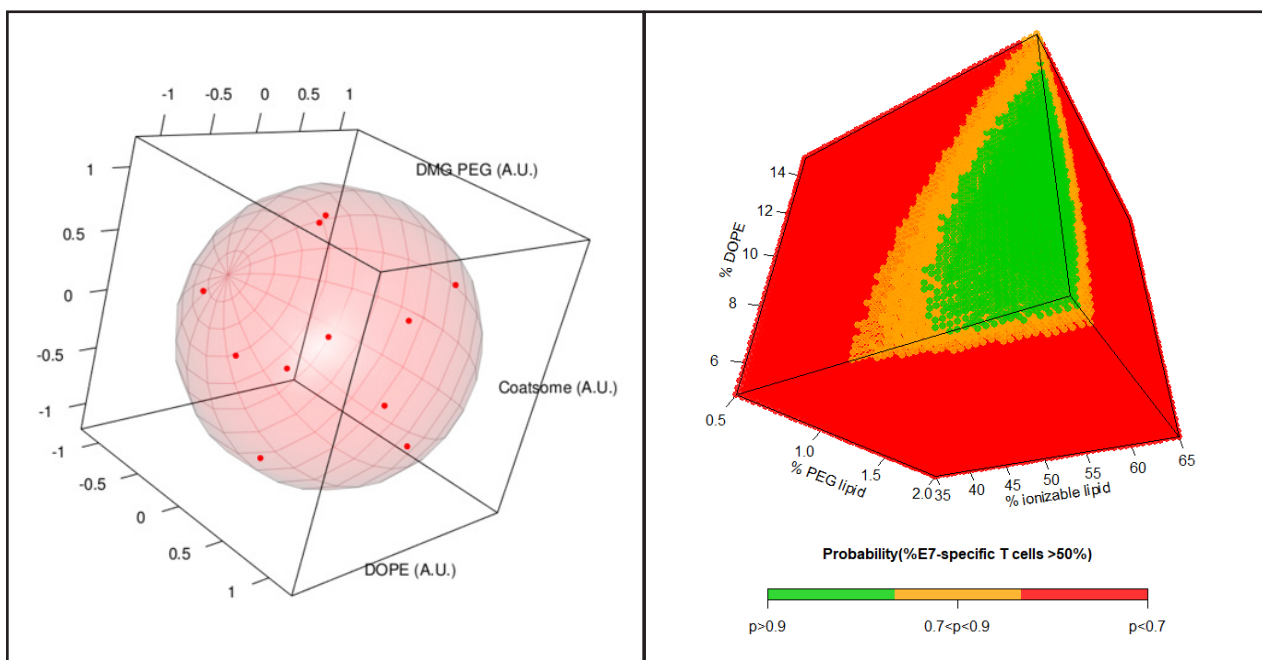
EASYQBD

CYBERNANO

easyQBD: a Quality by Design SaaS Platform. Application to the development of lipid nanoparticles for mRNA delivery

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The transfer of mRNA by lipid nanoparticles has become an important issue in recent years not only for anti-COVID-19 applications but also for the development of new treatments against cancer. eTheRNA, UMCU, Karolinska Institutet and CYBERNANO are collaborating on this subject and in particular on the optimization of the formulation of a lipid nanocarrier capable of inducing an acceptable immune response. The question is to determine the values of three Critical Material Attributes making it possible to obtain an acceptable probability of an immune response (Critical Quality Attribute) of at least 50%. For this purpose, the easyQBD service platform was used to implement the good development practice: Quality by Design (ICHQ8-Q11) and to respond effectively to this problem while reducing experimental costs. A Roquemore's Hybrid design composed of 11 different experiments was applied in triplicate to a panel of mice. All the statistical analysis was performed in a Bayesian framework both for the selection of relevant variables, the model identification and the validation of the model predictions. A quality region (in green in Figure below) has been identified in which the corresponding formulations have more than 90% chance of satisfying the expected performance on the immune response. Validation tests on a formulation selected in this area corroborated the model's predictions. In addition to this result, this study also demonstrates the effectiveness of the Quality by Design easyQBD platform to support the development of innovative pharmaceuticals.



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