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Quality by Design challenges in Pharma 4.0

The landscape of the pharmaceutical industry is evolving. From what was (and still is) a science-centered discipline, more awareness exists nowadays of the opportunities arising from exploring data-driven methodologies to conduct various key activities. In this regard, Chemometrics has been an old-standing ally of the pharmaceutical industry, allowing for real-time assessment of raw materials, online monitoring of processes, and fast batch release. More recently, artificial intelligence and machine learning (AI/ML) have been increasingly applied in R&D, namely in drug/molecular discovery and formulation development, as well as in Process analysis, for instance through retrospective Quality by Design (rQbD) studies. However, there are open problems on the configuration and use of new methodologies, and more research and debate are needed to bring them to the necessary maturity to be deployed and adopted by the highly regulated pharmaceutical sector. This talk is a contribution to this process. Starting from real (and/or realistic) case studies, new methods for active learning are tested and compared against classic methods. Furthermore, the principles for systematically implementing rQbD are presented, and some preliminary results are shared.

Special/ Invited session

Classification

Mainly application

Keywords

Quality by Design; Design of Experiments; Bayesian Optimization

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