4 Joint AIC - SILS Conference



Contribution ID: 12

Type: Keynote

Relevance of solid form's curriculum for drug product development: beyond polymorphism of drug substance

Wednesday, 14 September 2022 10:45 (30 minutes)

Appropriate selection of the crystalline form of an Active Pharmaceutical Ingredient (API) is a key decision in developing patient-centered drug products as this influences the safety, efficacy and performance of the pharmaceutical product. On top of these considerations, it is aimed also to facilitate development of robust drug manufacturing processes while guarantying appropriate key quality criterion during the shelf life of the drug product[1]. Advanced characterization tools are needed to analyze the crystalline drug substance in formulated drug products, especially when multicomponent systems and low concentrations are involved. Laboratory and synchrotron-X-ray powder diffraction are seen as complementary techniques among the tools that involve different vibrational spectroscopic techniques and imaging technologies. This presentation will exhibit case studies which illustrate applications of recent improvements of these methods as well as unmet needs and efforts that are deployed to assess and mitigate risks when unpredictable event occurs.

1. R. Hilfiker, M. von Raumer (Eds.). (2019), 'Polymorphism in the Pharmaceutical Industry: Solid Form and Drug Development', Wiley-VCH

Primary author: Dr GRANDEURY, Arnaud (Novartis Pharma AG)

Presenter: Dr GRANDEURY, Arnaud (Novartis Pharma AG)

Session Classification: MS

Track Classification: Crystallographic and Spectroscopic Advanced Tools Applied to Pharmaceuticals