

## Systems-based Pharmaceutics and gPROMS Formulated Products

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This seminar will firstly introduce the concept of Systems-based Pharmaceutics (SbP), a holistic model-based approach that considers both drug substance and drug product manufacture as well as drug product performance.

This approach was defined by Eli Lilly, Pfizer and PSE with the aim of (i) reducing iterations between drug product design and manufacturing process design, and (ii) being able to assess variability in product performance as a result of common cause variability in manufacturing (raw material and process conditions) and patient-to-patient variability. Secondly, SbP will be compared with QbD. It will be shown that its aims are the same, but the approach is significantly different to the prevailing method based on statistical techniques. Consequently SbP can also be thought of as QbD 2.0.

The second half of this talk will focus on industrial case studies from AZ, Lilly and Pfizer illustrating the value of mechanistic model-based approaches and the concept of SbP. The final part of this talk will introduce a PSE product gPROMS Formulated Products, which makes implementation of the SbP approach accessible to a wider range of stakeholders.