

**Title:** Data Science in the pharmaceutical environment: Statistical methodologies for quality by design principles and process monitoring by Raman probe

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**Key objectives:** process development, quality by design, design of experiments, design space, statistical methods, Raman, Spectroscopy, PAT

**Abstract:**

The objective of this presentation was to present selected use cases of statistical methodologies for implementation of the Quality by Design principles in a pharmaceutical environment for vaccine process development. The statisticians contributed to the experimental strategy of process or analytical development by proposing fit for purpose design of experiments, in direct collaboration with scientists and experts.

In the first part of this presentation, we showed how experiments can be optimally designed for the objective of defining the design space of vaccine development and allow a better understanding and optimization of the vaccine production process. Another topic was about image recognition with deep learning algorithm and the analysis of hyperspectral data.

The second part of this presentation is about Raman Process Analytical Technology (PAT). The main objective is to follow the cell culture process and control its quality in real time by analyzing some metabolites every 15 minutes.