

Accelerating vaccines process development and industrialization: can in silico modeling approaches help?

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In a context of increased competition and growing demand to respond to unanswered medical needs, the need of accelerating development programs in the pharma and biopharma industry has become essential.

If from an holistic point of view this requires a de-bottlenecking exercise on the whole development route a product needs to undergo before its approval and launch, from a purely technical point of view, the acceleration concept requires availability of tools that can guide product and process development activities with the aim not only to accelerate experiments, but also to generate valuable data thereof. Process modeling is one of the tools that can help to address the experimentation towards generation of data informative enough to guide decisions while reducing risks and resources, with the final aim to accelerate process development and transfer of the product to the manufacturing facilities.

In this contribution, it is shown how process modeling can help in streamlining the development and transfer of freeze-drying processes in the vaccines industry. Firstly, it will be shown how freeze-drying process models coupled with advanced design of experiments approaches (Model-based Design of Experiments) can be used to design controlled but highly informative experiments which in turn can be used to accelerate product transfer from development to manufacturing environments or to support changes in product manufacturing. Secondly, it will be shown how the model itself offers opportunities to optimize the process for commercial production, enabling the reduction of the time needed for the process while embedding the constraints linked to the product and ensuring its final quality.

About the speaker

Dr. Emanuele Tomba is a Chemical Engineer working in GSK Vaccines in the Technical Research and Development Drug Product department. His main responsibilities concern the development and transfer of Drug Product manufacturing processes. He holds a PhD in process chemometrics and is an expert in process modeling and data analysis. He leads the process modeling Center of Excellence within GSK TRD Drug Product department, supporting projects on a global basis dealing with modeling and simulations of drug product manufacturing processes, including freeze-drying.