PROOF OF CONCEPT: MODEL PREDICTIVE CONTROL OF BIOPROCESSES

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One of the major challenges in the (bio)pharma industry is to reduce time from early stage to manufacturing for a new drug/new treatment. To improve in this field, scientific based development (Quality by Design, QbD) was established. New technologies such, as Process Analytical Technologies (PAT), are widely established in the process development– according to the PAT Guideline (2004).

As of today, a number of PAT applications are established in development and manufacturing - including advanced analyzers such as RAMAN, NIR, Fluorescence – just to name a few.

In contrast, the advantages of Design of Experiment (DoE) including the resulting process models are mainly deployed in the development stage, but not yet applied in the manufacturing stage.

The focus of this Proof of Concept is to elaborate and showcase the applicability of DoE based mathematical models to improve manufacturing processes by a closed loop process control.

THE ADVANTAGES OF APPLYING THIS TECHNOLOGY ARE THE FOLLOWING:

- Better handling of (raw material) variations → improved quality of productsPlant status at a glance.
- Better handling of (raw material) variations → reduction of out of specification products / less drug shortages
- Improved yield → reduction of costs for drugs
- Improved flexibility → better market supply/ less drug shortages

ZETA GmbH is currently in close exchange with the US Food &Drug Administration (FDA) who is looking for innovative approaches to manufacturing that address both technical and regulatory challenges in their Emerging Technology Program (ETT). ZETA's proposal on a model predictive control has officially been accepted in the ETT Program.

REFERENCES:

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