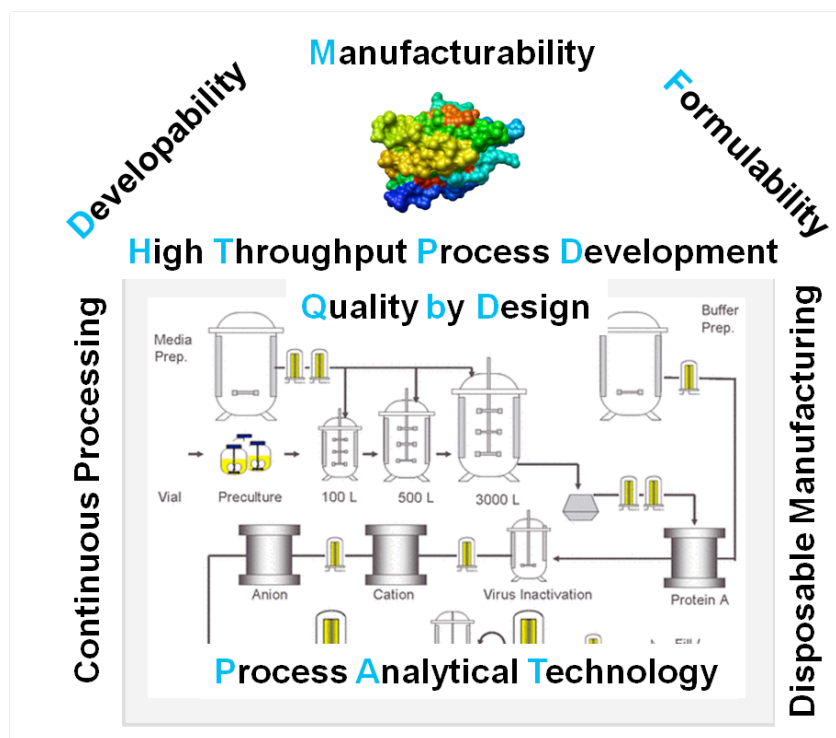




High throughput process development for the purification of biopharmaceuticals – Screening, Analytics and Molecular Understanding

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Modern architecture of biopharmaceutical development and production has seen a rapid change over the past decade and is currently composed by initiatives such as Quality by Design, Process Analytical Technology and early product assessment to mitigate risks during development and manufacture. In the downstream area of biopharmaceutical production, the demand for fast process development with limited material has become everyday life. To meet this demand, high throughput process development (HTPD) strategies for application in downstream process development have been developed. In order to gain maximal benefit from this experimental approach, the analytical methods applied to evaluate the experiments performed require automated performance and a throughput matching the experimental speed. In addition, even though HTS applies low volume set-ups, experimental space should be minimized in terms of feedstock volume needed while at the same time maximising the level of information gained. While the methodology is currently based on statistical data evaluation on the long run a fundamental mechanistic understanding is required. The presentation will give a short overview on and case studies from the application of the HTPD methodology and examples showing its linkage within the current development framework of the biopharmaceutical industry.