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## **Computational Fluid Dynamics, Sophisticated Marketing Tool or Reliable Method for Pharma- and Biotech Processes**

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Numerical methods such as Finite Element Analysis (FEA) or Computational Fluid Dynamics (CFD) are considered to be well established technologies in industrial design and engineering. While the methodology of numerical simulation is fully recognized in conventional industry (e.g. automotive, aviation, construction, machinery) even (especially) for critical application, pharma-industry and biotechnology have just started to carefully consider numerical simulation methods as valueable tool to create a sound understanding of their processes. The high level of regulation in this specific industry as well as the strong drive for evidence based validation (verification) may have contributed to the fact that numerical simulation methods are hardly applied in pharma industry and biotech.

The paper in hand shall demonstrate on typical applications how the CFD approach can be applied to design and optimize processes, to create additional knowledge about specific process interactions, to provide better understanding about correlations between process parameters and product quality, to supply a sound data base for process validation and thus to increase process flexibility.

In four different references various aspects of the CFD methodology are discussed. The operational performance of a fermenter is presented with specific focus on gas distribution (oxygen) depending on mixer and vessel design and on shear stress exposure of the cell culture. Also, a stirred and heated storage vessel for thermal sensitive emulsions is investigated. Especially the temperature distribution within the products related to the temperature of the heating jacket and stirrer parameters shall be analysed. A third application considers a very specific freeze technology for protein-buffer-solutions. The freeze and thaw process is analysed by CFD under specific consideration of temperature induced concentration shifts in the protein-buffer. Finally a standard vessel-agitator set-up is discussed and strategies for process optimizations are presented based on CFD. Based on this specific problem it shall be demonstrated how CFD can support process-upscaling from lab to industrial size.