FACING THE CHALLENGES – A MINIATURIZED PLATFORM FOR INTEGRATED PROCESS DEVELOPMENT OF PRODUCTS FROM MICROBIAL HOSTS

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The recent developments within the biopharmaceutical market change the demands and requirements that have to be addressed. The venture of biosimilars and biobetters based on the off-patent situation enhances the need for acceleration of process development with high flexibility for new products. The trend toward PAT and continuous processing raises the need for better process understanding and integrated process development which challenges both - up and downstream processing. Bacterial systems offer high advantages and flexibility for high yield overexpression but often end up in very complex processes during product recovery. Often overexpression in E.coli is therefore limited to soluble fractions which means a severe limitation and restricts the opportunity to succeed. This talk present a HTS platform to evaluate the entire process of proteins expressed in E. coli as inclusion bodies – directly connecting DoE screening in upstream development to the subsequent downstream process including cell disruption, IB preparation and protein capture. This fast and material saving platform method provides a high-quality evaluation of fermentation screenings and reduces the initial barrier and reservation for IB processes opening potential for new products. As additional benefit you will generate valuable knowledge and gain better understanding of your process on the way.