

ADAPTIVE COMBINATION OF SSB AND SUB EQUIPMENT TO MASTER COMPLEXITY IN CLINICAL MANUFACTURING IN THE CLINICAL SUPPLY CENTER

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Today's clinical manufacturing of complex monoclonal antibodies under GMP conditions needs to be highly adaptive in order to face the requirements of constant acceleration of processes.

The main challenge of the clinical supply center (CSC) in Penzberg (Germany) is to successfully master the complexity of producing different products in different phases (clinical phase I – III) with different process versions. New products for clinical phase I have different requirements than older products, as well as products in later phases or resupplies. In addition, the actual change to more intensified processes will increase the complexity even more.

The CSC is equipped with a variety of bioreactors in different sizes and types. Stainless steel as well as single use bioreactors, which were installed over the past 25 years. In order to face the main challenge, it is mandatory to create a framework that allows the adaptive combination of standard (SSB) and new technologies (SUB). To realize that, SUBs and SSBs are treated equally. SUBs have the advantage to be used more flexible than SSBs because of less preparation time and an easier adaption to intensified processes (like perfusion modules in the N-1 bioreactor). Furthermore, SUBs can be easily connected to every existing bioreactor type (SSB as well) via hose connections. This all offers the chance to utilize existing bioreactor racks more efficient with less slack time. An adaptive combination is also faster and more favorable than just replacing existing with new equipment. The poster shows the successful implementation of the adaptive combination in the CSC, by adding SUBs with increasing volume to the facility (starting with 250L and ending with 2000L production volume) and apply them for existing and new processes. The intensified usage of SUB equipment shortens the upgrade time to adapt to future needs (e.g. switch to perfusion technology).

With this flexible setup the multi-product-GMP facility in Penzberg is perfectly prepared for actual and upcoming challenges.