

INTRODUCTION OF INTENSIFIED PROCESSES INTO THE CLINICAL SUPPLY CENTER

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The requirements for the production of monoclonal antibodies have changed significantly over the past few years. High titer processes and flexible utilization of single use and stainless steel equipment are currently state of the art in bioprocessing. The new goal is to manufacture the same or even more product within a shorter production time while maintaining the same level of product quality.

New, intensified and connected processes in the upstream and downstream departments introduced with new technologies are making these visions come true.

Implementing new technologies especially under GMP conditions poses a lot of challenges.

Suitability of established analytical methods needs to be demonstrated (e.g. cell count).

Work flows and new standard operating procedures need to be in place for the high volume media and buffer preparations required for intensified processes.

Finally, new and existing equipment needs to be integrated into the GMP production area with a special focus on safety, i.e. ensuring that the building remains structurally sound, e.g. floor load capacity.

The first intensified drug substance batches comprising new technologies were successfully produced in a 1000 L - 2000 L scale in the clinical supply center at Roche in Penzberg. This presentation aims to illustrate opportunities and challenges of process intensification and connected processing in a clinical supply setting, and how to deal with it in a GMP environment.

The start of the new intensified processes in a commercial facility is only a heartbeat away.