

## CELL CULTURE MANUFACTURING OF ACCELERATED PROJECTS – LESSONS FROM LIFE IN THE FAST LANE

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**Key Words:** Breakthrough Therapies, Accelerated development, Process Performance Qualification, Cell Culture, Flexible Manufacturing

The possibility of promising molecules receiving Breakthrough Therapy Designation (BTD) early in their clinical lifecycle encourages accelerated development strategies to decrease approval timelines. The speed that these projects move through the pipeline has required Genentech's manufacturing organization to push the limits of their manufacturing flexibility in order to support a streamlined approach to scale-up.

Recent accelerated development product manufacturing presented several new operational, logistical and technical challenges which required creative solutions to overcome, in order to achieve tight in-process control while maintaining agility. This poster will discuss the lessons learned by the manufacturing site while executing that Cell Culture manufacturing campaign, including

The benefits and challenges associated with:

- Process qualification with limited small scale data
- Operating within a narrow design space
- Leveraging a clinical facility for process qualification activities
- Supporting new strategies in an existing facility