

## Quality Based Approach for Efficient Biologics Manufacturing

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**Abstract :** To improve the manufacturing efficiency of biologics, such as antibody drugs, a quality engineering framework was designed. Within this framework, critical steps and parameters in the manufacturing process were studied. Identification of these critical steps and critical parameters allows a deeper understanding of manufacturing capabilities, and suggests to process development department process control standards based on actual manufacturing capabilities as part of a PDCA (plan-do-check-act) cycle. This cycle can be applied to each manufacturing process so that it can be standardized, reducing the time needed to establish each new process.

**Keywords :** antibody drugs, biologics, manufacturing efficiency, PDCA cycle, quality engineering

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