

## Scale-up of mammalian cell culture process

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Due to a nature of the investment in biopharmaceutical industries, i.e., long-term and high financial commitment, small-scale set-up is preferably used for the process development. Typically, biopharmaceutical process consists of cell culture, protein purification, formulation and lyophilization. Most of the feasibility works, i.e., characterization of MCB/MWCB, characterization of protein, formulation development and stability testing method development, can be accomplished with the small-scale set-up. In addition, materials required to support the pre-clinical and Phase I clinical trial could be produced with the small-scale set-up. Then, Phase II clinical trial requires sizable quantity of material, and the process needs to be scaled up either to a pilot scale or a full manufacturing scale. There is the other reason that the process needs to be scaled up. That is, when the market demand increases and exceeds the manufacturing capacity, the current licensed process needs to be scaled up.

Key process parameters that should be reviewed for scaling up the mammalian cell culture process are presented. In addition, impact of scale-up on currently licensed process is discussed.