Manufacturing Strategy for Pre-clinical and Clinical Development of Biopharmaceuticals

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Manufacturing processes for Biopharmaceuticals should be validated and be able to comply with GMP requirements. The process must be robust to ensure that any manufacturing changes made to scale-up production do not change the way the drug performs. Equally important is that validated procedures and analytical methods are in place to ensure that the manufacturing process is able to inactivate or remove adventitious agents such as viruses from the final product before clinical testing in humans. It is also essential to develop and validate analytical methods for carrying out preclinical animal testing, tox/ADME studies and human serum samples from the clinical trial.
Manufacturing Strategy should define appropriate level of GMP readiness for each of the following three key components: 1) Bioprocess technology for manufacturing process and analytical methods; 2) Regulatory compliance and QA/ QC system; 3) GMP manufacturing facility including process equipments and trained personnel. Detailed discussion of appropriate manufacturing strategy for preclinical, clinical and commercial manufacturing will be presented.