Kemwell’s biopharmaceutical labs have the capability of performing complete process development, process optimization, scale-up, technology transfer and process characterization. Moreover, our scientists have demonstrated the capability to design and execute development work to meet defined product quality attributes. Kemwell’s integrated cross-functional project teams comprise of process and analytical development scientists who work closely together leading to excellent product and process understanding.

UPSTREAM DEVELOPMENT

Overview
■ Mammalian cell culture process development for recombinant proteins and monoclonal antibodies
■ Experienced development scientists who understand the complex dependence of cell culture parameters on product quality attributes
■ Well-equipped labs to perform process development and process characterization studies

Lab infrastructure
■ Biosafety cabinets and Laminar Air Flow Units for aseptic work
■ Access controlled cell bank (research cell banks and working cell banks) storage facility
■ CO₂ incubators for shake flask experiments
■ Bioreactors
  - 5L and 10L glass bioreactors
  - 80L SS bioreactor
  - WAVE bioreactor™
■ Metabolite analyzer
■ Cell viability analyzer
■ Perfusion (provision for addition)
DOWNSTREAM DEVELOPMENT

Overview
- Purification process development for recombinant therapeutic proteins and monoclonal antibodies
- Well-designed purification process schemes with clearly established capabilities for each process step
- Close collaboration with analytical method development scientists to develop in-process testing schemes

Lab infrastructure
- ÄKTA purifier™
- ÄKTA pilot™
- Cogent TFF systems
- Milistak+Pod filtration system

PROCESS CHARACTERIZATION
- Establishment of scale-down models
- Univariate and multivariate DoE studies
- Studies to define critical and key process parameters, establishment of design space, etc.
- Control strategy

ABOUT KEMWELL
Kemwell is a 100% CDMO, servicing pharmaceutical and biopharmaceutical organizations worldwide for over 30 years. Kemwell’s biopharmaceutical facilities are located in Bangalore, India, and were built with technical guidance from Boehringer Ingelheim, providing our customers with state-of-the-art technology along with the benefit of cost-effective manufacturing.

To get customized solutions for your project, get in touch with us today.