

PROCESS & FORMULATION DEVELOPMENT



Kemwell provides extensive mammalian cell culture based products' development services. The labs have the capability of performing complete process development, process optimization, scale-up, technology-transfers 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. Each customer project is individually customized to match the customer's requirements as per the scope.

Kemwell routinely provides the following development services:

- Upstream and Downstream process Development
- Analytical methods and formulation development (including lyophilized formulations)
- Clone screening and selection
- Cell line stability studies
- Media and cell culture optimization
- Optimizing mfg. processes to improve process time and increase yields/outputs
- Achieving efficient process scale-up
- Reducing of manufacturing costs and time – through process improvements
- 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
- Head to head comparability studies of biosimilars
- Development stability studies
- Preclinical manufacturing capabilities at 5L, 10L and 80L scale

UPSTREAM PROCESS DEVELOPMENT

Kemwell's team of experienced scientists and analysts specialize in mammalian cell culture process development. We use well versed techniques such as design-of-experiments approach for process optimization to reach optimal titer values and generate superior quality products. We strive to develop a robust, efficient, scaled up manufacturing process to deliver consistent product quality.

DOWNSTREAM PROCESS DEVELOPMENT

Kewell's purification process development team develops robust, economical processes for mammalian cell culture products. The design-of-experiments approach for process optimization and process characterization is used in order to achieve optimal yields. Our foremost goal is product quality and we strive to generate superior quality products. A close collaboration with analytical method development scientists ensures in-process testing scheme development.

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™
- ATF-2 perfusion
- CEDEX bioanalyzer
- Cell viability analyser
- AKTA purifier™
- AKTA pilot™
- Cogent TFF systems
- Milistak+Pod filtration system



FORMULATION DEVELOPMENT

Overview

Kemwell offers formulation development services for early and late stage clinical development and commercial products based on target formulation profiles. Formulation development work is carried out collaboratively with analytical development groups to ensure that robust and stability indicating analytical methods are used appropriately during formulation development. Accelerated and real-time stability studies, and varieties of stress stability are employed to deliver the best formulation for your product.

Preformulation Studies

- Evaluation of biophysical characteristics
- Assessment of 'thermodynamic stability'
- Identification of critical factors that impact stability

Formulation Screening Studies

- Formulation screening studies to select optimal formulation for the molecule
- Integrated formulation and analytical method development team to ensure right methods are available for evaluating degradation routes of molecule to enable formulation screening studies

Lyophilization Cycle Development

- Lyophilization cycle development for molecules that may have inherently lower stability in liquid form
- Optimization of each phase of the cycle to ensure an efficient, robust and scalable process



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