

Cell Line Engineering Services

WuXi AppTec offers a full portfolio of cell line development, cell banking, cell bank characterization, and storage solutions. With this single-source approach, we assist our global partners in shortening the cycle time to clinical trials and help speed products to the market.

WuXi AppTec is a global leader in providing discovery, testing and manufacturing services for the pharmaceutical, biotechnology and medical device industries. Research-driven and customer-focused, with operations in China and the U.S., WuXi AppTec offers a broad and integrated portfolio of services designed to assist our customers with cost-effective and efficient outsourcing solutions.

Cell Line Development

WuXi AppTec offers comprehensive cell line development services include gene cloning, vector construction, reagent generation by microbial, baculovirus/insect cell or mammalian transient expression, stable cell line creation, process and medium development. Cell line development starts when clients provide the cDNA and transfection vector for subsequent molecular cloning. After transfection into a client-specified protein expression cell line (e.g., CHO, NS0), WuXi AppTec will work with the client to determine the appropriate number of clones to analyze based on the client's time and budget restrictions in order to find high-expressing product clones.



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Identification and selection of high-producing stable clones can be subjected to additional rounds of subcloning or further analysis such as short (10 generations) or long (>30 generations) stability studies and product analysis/characterization. The top selected clone(s) can be transitioned to WuXi AppTec's cell culture process development team for media and cell culture optimization studies as well as GMP cell banking and cell line characterization activities. Completed cell banks can be stored in WuXi AppTec's cGMP cell storage facility. For cell line development activities involving monoclonal antibodies (MAB), WuXi AppTec also offers hybridoma development services and molecular cloning of the light and heavy chains (including humanization and codon optimization activities) into a client-specified mammalian cell culture expression system (e.g., CHO).

The Cell Line Development and Reagent Generation team is led by Dr. ChiChang Lee. Dr. Lee has over 17 years' experience in cell line development, including the generation of production cell lines to support several BLA submissions and NME filings.

Cell Banking and Storage

The cell bank facility at WuXi AppTec, with five individually monitored GMP cell banking suites, offers clients an opportunity to manufacture cell banks grown to their specifications, under exacting standards and QA oversight, in a highly monitored, secure and controlled environment. All work is performed in ultra-clean tissue culture suites by gowned, highly skilled personnel. Many different species of mammalian or insect cell banks – ranging in size from 10 to 800 vials – can be manufactured GMP using a variety of media types. Cell culture methods for both adherent and suspension cells include T-flasks, cell factories, roller bottles and shaker and spinner flasks.



All cell banks are strictly segregated and produced on a campaign basis (i.e., one cell bank is produced within each suite at a time). Validated changeover and cleaning procedures, requiring Quality Assurance release of each suite prior to use, ensures cell line integrity and minimizes adverse events and contamination. Cells are frozen at a controlled rate to minimize freeze-related trauma and can be stored long term at one or two of the WuXi AppTec sites in highly controlled and regulated GMP storage facilities. Various levels of segregation can be reserved for your cell bank within the vapor phase of liquid nitrogen.



Supporting Testing Services

WuXi AppTec provides GLP and GMP cell line characterization, lot release and stability testing programs for various biological products at every phase of clinical development through commercialization. All GMP assays undergo stringent validation programs as defined by International Conference of Harmonization (ICH) or worldwide Pharmacopoeia documents. We understand the importance of turnaround times and work closely with clients to meet their specific needs.

For more information on WuXi AppTec's services please contact:

U.S.
+1 (651) 675 2000 • +1 (888) 794 0077
info@wuxiapptec.com

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www.wuxiapptec.com