Advanced Biosafety and Analytical Testing Solutions by WuXi Biologics

WuXi Biologics
Global Solution Provider

Biosafety Testing Solutions

Certified by Global Regulatory Agencies
- Audits passed from global clients with zero critical findings
- EU QP audits passed more than 30 times
- Passed inspections from FDA, EMA, PMDA, NMPA, and Health Canada

Viral Clearance Studies
- Experience with over 1400 IND and BLA-enabled Viral Clearance Studies
- TAT (Turn Around Time): IND study: 2 months; BLA study: 3 months
- **In-house database** for study design, and in-house high-titer, high-purity virus for purification

Cell Bank Characterization (CHO, HEK293)
- Experience with over 2500 Cell Bank Characterization
- TAT: 11 weeks for MCB, less than 9 weeks for WCB, and 11 weeks for EOPC
- **Next-Generation Sequencing (NGS)** -based genetic stability testing

Unprocessed Bulk Harvest Testing
- 5500+ UPB lot release testing for clinical and commercial batches
- TAT: 6 weeks for clinical UPB release testing, 35 days for commercial UPB release
- Full-panel tests for UPB release compliant with global standards (EP, USP, ChP, JP) and GMP requirements

Analytical and QC Testing Solutions

Bioassay Development (ELISA-based 2 months; cell-based 3 months)
- Bioassay method development for various modalities
- Proprietary bioassays reveal difficult-to-detect efficacy and safety attributes of ADCs immune regulatory biologics
- Reagent and bioassay cell line development

Forensics (1 week)
- Large commercial and in-house database for root cause identification and analysis
- Comprehensive PS80 control strategy

Product Characterization (1 month)
- Primary and higher-order structural characterization using sequence and charge variant analysis, host cell protein identification with mass spectrometry (HCP-MS), and functional assays;

Release and Stability Study (1-2 months)
- Full-panel of non-GMP and GMP methods available
- Characterization and investigation analysis

HCP Analysis
- Coverage of 70–90% with 2D Western blot and complete, process-specific HCP assay development in as little as 9 months with enhanced coverage

Testing of ADCs
- Full spectrum of analytical methods for ADC molecules in over 100 ADC projects and over 100 cell-based assays
- Comprehensive structural characterization of ADCs with various types of linkers and payloads
- Over 15 high-resolution MS methods

12月6日(金) PDA年会に伴い
バイオセーフティー、AS/QC試験セミナーを開催致します！

2024年12月6日(金) 18:00-20:00 (20:00-21:00 ディナー・ビュッフェ)
会場：**グリーンパレスマツヤ、孔雀1** (東京都江戸川区松島1-38-1)
*PDA会場タワーホール船堀からセミナー会場へのシャトルバスをご用意しております

セミナー演題の一部
- 次世代シーケンシング技術：動物試験の代替と製造工程への新しい適用例
- 連続生産プロセスにおけるウイルスクリアランス試験：課題とその解決策
- 高度な分析技術を活用したADC等バイオコンジュゲート製品開発成功への道

企業ブースも
出展しております

セミナー詳細とご登録は
QRコードをスキャンして下さい

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