Lot Release Programs

Speeding product release with rapid, reliable safety testing

ILLUSTRATION:
Typical non-enveloped virus

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WuXi AppTec

High-Quality, Rapid Lot Release for Biologics and Raw Materials

Regulatory guidelines dictate that testing be conducted to confirm safety and consistency in the incoming raw materials and outgoing product. WuXi AppTec's expertise, years of experience, and uniquely broad menu of services provides manufacturers with a "single-source solution" to support their quality (QA and QC) programs including:

ASSAY DEVELOPMENT

Having developed over 1500 assays in a wide variety of disciplines (microbiology, virology, analytical, molecular biology, cell biology, in-life), WuXi AppTec's team of scientists is uniquely suited to assist your assay development efforts. All facets of assay development are considered including cost-effectiveness, ease-of-use, development of acceptance criteria, and designing the assay to meet the eventual – and appropriate – validation parameters, such as robustness, reproducibility, specificity, and sensitivity.

ASSAY TECHNICAL TRANSFER

WuXi AppTec has years of experience in transferring client protocols or SOPs. We consult with the client on many aspects of the transfer process – including instrumentation or technology to be used, detection methods, raw materials and other assay components – to ensure comparability before moving to the next phase of assay transfer or development.

ASSAY QUALIFICATION & VALIDATION

Phase-appropriate product specific/test matrix qualification and assay validation protocols are available. Assays can be performed according to GLP or GMP regulations, depending on the stage of product development (e.g., for Phase I, II or III clinical trials or for commercialization). WuXi AppTec's years of successfully testing products throughout these stages allows us to guide clients regarding the level of testing or validation required.

LOT RELEASE PROGRAM ASSAYS

WuXi AppTec's lot release program offers routine assays (GLP or GMP) for these standard stages in the manufacturing process:

Raw Materials Testing

General *in vitro* virus screen
9 CFR virus screens for animal-derived raw materials
Mycoplasma (USP/EP, PTC & TD-PCR)
Sterility or microbial enumeration
Analytical assays for identity assessment
PCR- and infectivity-based assays to detect potential viral contaminants

In-Process Testing

Residual DNA
DNA sizing
Host cell protein
Product titer assays
Other process residuals (e.g., BSA, Protein A)
Analytical assays (identity, purity, concentration)
Potency assays (including cell-based assays)
Sterility or microbial enumeration

Unprocessed Bulk Product Testing

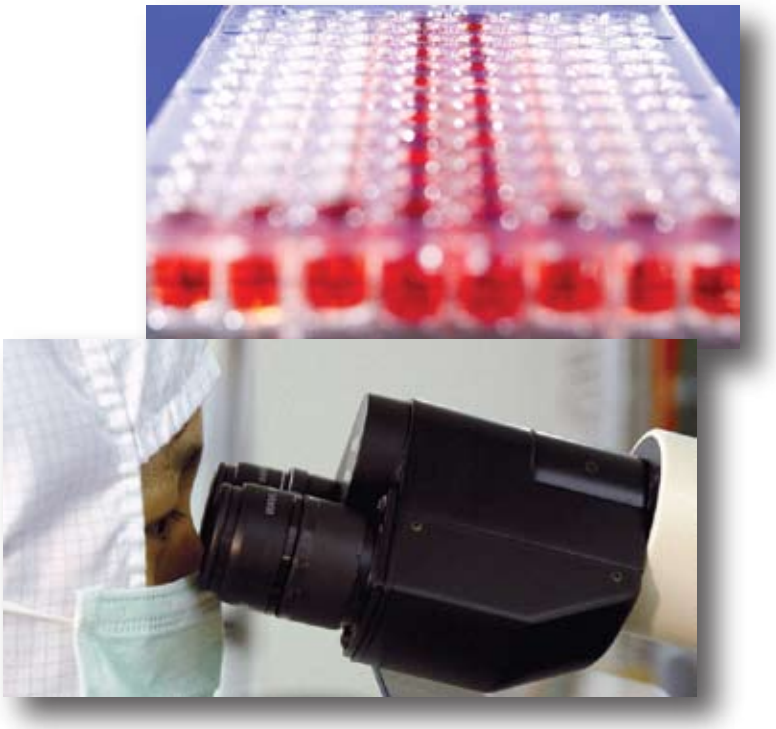
In vitro virus screen
In vivo virus screen
Mycoplasma (USP/EP, PTC & TD-PCR)
Sterility or microbial enumeration
Quantitative EM
Product titer assays
Analytical assays (identity, purity, concentration)
Potency assays (including cell-based assays)

Purified Bulk Product Testing

Residual DNA
DNA sizing
Host cell protein
Other process residuals (e.g., BSA, Protein A)
Potency assays (including cell-based assays)
Analytical assays (identity, purity, concentration)
Sterility
Pyrogenicity
Endotoxin

Final Product Testing

Sterility
Pyrogenicity
Endotoxin
General safety



QUALITY

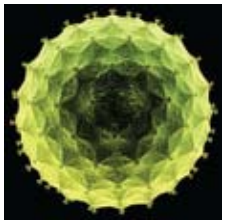
WuXi AppTec's testing programs have been audited and accepted by regulatory authorities worldwide and all U.S.-based facilities have received ISO 17025 certification. In addition, GMP certification from the EMA and TGA have been granted for specific commercial lot release programs. The Quality Assurance team at WuXi AppTec conducts a review of raw data and reports for 100% of tests involved in GLP or GMP biologics lot release programs.

TIMELINESS

WuXi AppTec understands the need for timely lot release testing. Thousands of lots are tested each year that meet the agreed upon timelines for report or Certificate of Analysis delivery. A robust operational excellence/continuous improvement program features LEAN techniques to ensure our operations perform efficiently. Capacity analysis is performed to determine where resources are required (facilities, suites, labs, equipment, personnel) to meet your expectations.

PROJECT MANAGEMENT

Highly trained project managers are assigned to coordinate qualifications/validations, schedules, shipments, preliminary results and other project needs. In addition, a web-based utility is available for clients to track samples during the testing process. This online tool allows our clients 24/7 access to view the status of assays from the time the samples arrive to the time the reports are delivered. On-line test ordering is also available.



Lot Release Programs

WuXi AppTec has over 20 years of experience with safety testing programs designed to rapidly enter clinical trial phases or to expedite commercial product lot release.

EXPERIENCE

- Thousands of commercial product lots have been tested and released using our virus and mycoplasma detection assays.
- WuXi AppTec's testing programs have been audited and accepted by regulatory agencies worldwide.
- Comprehensive release programs – that include safety, potency and analytical assays – have been conducted for hundreds of different products.
- WuXi AppTec has developed and validated a wide variety of analytical, *in vivo*, and *in vitro* methods for lot release, including PCR detection assays for viruses and mycoplasma.
- Extensive experience in customer-specific assays, including GMP testing with C of A reports.

PROGRAM FEATURES

- A web-based "client portal" allows clients 24/7 access to testing status and timelines. On-line ordering – ideal for routine lot release tests – is also available.
- Scheduling flexibility and the option of expedited testing programs can offer a true reduction in turnaround times.
- Over 60 human and animal viruses available as positive controls, adapting easily to thousands of different *in vitro* tests.
- Over 50 cell lines of human and animal origin can create thousands of combinations for detection of viruses.
- Over 40 viral PCR probes and over 100 PCR assays have been developed and implemented to assess potential virus contamination.
- Unique cell-based and infectivity assays have been developed and validated per client or regulatory-driven requests.

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Contact WuXi AppTec for your lot release testing:

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