DUONING
多宁生物

Testing and Validation Service Series

Product Booklet

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Single-use product validation service

Introduction to Validation Services

Compared with the traditional stainless steel system, the single-use system has many advantages in application, such as rapid design and construction of the factory building, no need for cleaning validation, small footprint (less supporting clean facilities), low cost, fully enclosed process, disposable, high mobility and flexibility.

Since the single-use system is in direct contact with the feed liquid, the key components involved include disposable bags, pipelines, connectors, filters, etc., which have high risks and require risk assessment and corresponding research and validation work to confirm the impact of single-use systems on quality, efficacy, and safety of the drug.

Senior teams of Shanghai Doning Biotechnology Co., Ltd. and Centre Testing International Group Co., Ltd. work together to establish a single-use system testing and validation platform, which will focus on quality testing and product validation in the fields of extractables/leachables research, microbial testing, filter integrity and virus removal validation of the single-use system.

Validation service scope

◎ Extractables/Leachables

- Extractables: Chemical substances that can be extracted from the contact surfaces of process media of single-use system component materials under the worst conditions (e.g. organic solvents, extreme heat, ionic strength, pH, contact time, etc.). Extractables represent
  the greatest amount of chemical substances that migrate into the product.
- Leachables: Chemical substances that migrate from materials in contact or non-contact products into pharmaceutical products or process fluids under storage or conventional process conditions. Leachables are usually a subset of extractables and may also include reaction products or degradation products of extractables.
- Customized validation services are carried out according to the results of risk assessment conducted based on the customer-specific process. After obtaining the extractables/leachables data, experts strictly judge whether the extractables/leachables affect the quality of drugs and patient safety according to the actual production process of drugs and relevant administration information.

◎ Chemical compatibility test

- Confirm the integrity of the single-use system (disposable bags, pipelines, filters, etc.) after contact with the process liquid under specific conditions.
- The specific test indicators are related to the type of the single-use system, usually selected from test indicators such as integrity, pressure resistance, weight, surface analysis, thickness, tensile strength, etc.

◎ Bacterial retention test

- Simulate the worst-case conditions in the actual production filtration process, filter product solutions or product replacement solutions which contain a certain amount of challenging microorganisms, and confirm the microbial retention capacity of the sterilization filter.

◎ Adsorption test

- Confirm that the concentration or quality of the liquid medicine or solution components will not meet the established standards due to the adsorption of the single-use system.
- Disposable bags, pipeline assembly, and filters may all have adsorption risks, and the adsorption mechanism may be ionic bonds, van der waals forces, and hydrophobicity. In addition, factors such as solution composition, product concentration, contact time, and temperature may also affect the degree of adsorption.

Compliance testing validation

Introduction to Validation Services

Shanghai Duoning Biotechnology Co., Ltd. acquired Ximai (Shanghai) Testing Technology Service Co., Ltd. (hereinafter referred to as "Shanghai Ximai") in 2021 to provide GMP compliance testing and validation services for biopharmaceutical customers.

Shanghai Ximai focuses on professional content such as biosafety testing, instrument and equipment validation, on-site service, and other testing validation, and provides services to enterprises and institutions such as new drug research and development, biotechnology development, and medical treatment. Shanghai Ximai has the NSF testing qualification (certificate number: C0259046-01) authorized by the National Health Foundation of the United States and the CMA testing qualification (certificate number: 160921341132) issued by the State Bureau of Quality and Technical Supervision. So far, it has served more than 500 well-known pharmaceutical companies, medical apparatus, and other companies.

Validation service scope

·Testing and validation of wind speed/cleanliness;

Safety cabinet, super clean table, fume hood, clean room, biosafety laboratory, animal room;

·Instrument and equipment validation

IQ, OQ, PQ services for temperature and humidity;

Liquid nitrogen tank, cooling instrument, ultra-low temperature freezer, refrigerator, oven, muffle furnace, sterilizer, centrifuge, warehouse, cold storage;

·Utility Validation

Air conditioning system validation, water system validation, steam and other gas system validation

·CSV validation

·On-site service

Equipment classification, logbook preparation, information entry perfection;

Coordination of internal routine maintenance, external measurement calibration and maintenance;

Due reminder, review assistance, year-end report.

·Featured Services

Safety cabinet formaldehyde fumigation and disinfection, filter screen removal and replacement, laboratory hydrogen peroxide disinfection (in compliance with EHS requirements);

Laboratory instrument relocation services;

MD microplate reader PQ validation, PCR instrument validation, vial washing machine validation, BIOTEK microplate reader/plate washing machine validation, HPLC/GC PQ validation;

assistance in EHS filing, system establishment, risk assessment, security training, pre-marketing compliance audit;

Interpretation of GMP regulations/guidelines, guidance consultants, registration application, rational suggestions.

SHANGHAI DUONING BIOTECHNOLOGY CO.,LTD.

Tel: 021-64340155

E-mail: marketing@duoningbio.com

Website: www.duoningbio.net

Address: Building 30, Shentian New Office Space, No. 1525, Minqiang Road, Songjiang District, Shanghai