ANNEX 1

Supporting your sterile manufacturing

Annex 1 builds upon existing guidance for the manufacture of sterile products and calls for a holistic approach to contamination control. From personnel training to environmental monitoring and disinfection validation, find out how Reading Scientific Services Limited (RSSL) can support you with Annex 1 regulations.

Raw materials

Testing the identity, purity and quality of your raw materials is a vital regulatory requirement. We can test a wide variety of raw materials in accordance with pharmacopeial monographs, including materials destined for sterile manufacture.

Vials and stoppers

To ensure the sterility of the product is maintained, guidance around container and closure integrity is included in the updated Annex 1. We offer routine vial and stopper analysis to pharmacopeial standards, including hydrolytic resistance testing, dye ingress testing and elemental impurity testing.

Water testing

Annex 1 outlines extensive guidance for water generation and distribution systems to minimise the risk of microbial contamination. This covers purified water and water for injection (WFI) systems, which should include continuous monitoring systems. At RSSL, we have the capability to perform both chemical and microbial water testing, including post-disinfection.

Environmental testing

Annex 1 covers cleanroom classification and outlines requirements for environmental cleanliness for each manufacturing operation. We offer a full environmental monitoring service, including a team that can conduct on-site visits, to produce a risk assessment and Environmental Monitoring Performance Qualification (EMPQ). Our team can assist with your routine testing or can perform analysis on your plates shipped to our site.

Extractables and leachables

With increasing use of single use systems (SUS) in aseptic processing, Annex 1 provides guidance to ensure that extractables and leachables from SUS do not alter product quality. We enable accurate testing, with screening methods to profile extractables, identification of impurities above safety thresholds and toxicological support for the evaluation of leachables.

Microbial identification

Annex 1 outlines new requirements for the identification and evaluation of risk from detected microorganisms. We can support your microbial identification strategy with the use of MALDI-ToF mass spectrometry, as well as extensive expertise, to provide rapid, reliable and accurate results.

Cleaning and disinfectant validation

With increasing use of single use systems (SUS) in aseptic processing, Annex 1 provides guidance to ensure that extractables and leachables from SUS do not alter product quality. We enable accurate testing, with screening methods to profile extractables, identification of impurities above safety thresholds and toxicological support for the evaluation of leachables.

STERILITY

Sterility testing is a vital regulatory requirement for manufacturers of any terminally sterilised or aseptic products. We offer both Steritest membrane filtration and direct inoculation methods to the harmonised European, US and Japanese pharmacopeial standards, supporting a variety of different options.

MYCOPLASMA TESTING

We currently outsource our mycoplasma testing to a fully qualified, GMP facility.

BACTERIAL ENDOTOXINS

All pharmaceutical products that will enter the body must be tested for the presence of endotoxins before release, and the tests must comply with regulatory requirements. We can support this testing with method validation and routine testing, including turbidimetric and chromogenic endotoxin testing, and have experience with new sustainable recombinant endotoxin testing kits.

FOREIGN PARTICLES

Regulations require visible and sub-visible particle counts and Annex 1 places further emphasis on visual inspection of finished products, with facilities required to have a list of critical deficiencies. We can perform a range of analyses for visible and sub-visible particles to European and US pharmacopeial standards and can help create a database of potential particulates from your production line.

Training and Consultancy

Annex 1 updates the guidance around appropriate skills and training of all personnel, with a specific focus on sterile manufacturing, packaging and distribution processes. We offer a variety of accessible courses to upskill your team, as well as a consultancy service to provide you with the expert support you need.

Contact us for more information

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