cleaning validations

Planning a comprehensive strategy for the lifecycle of your sterile product, including cleaning validations, is crucial to avoiding regulatory issues. Because cleaning and sanitization processes may have direct impact on product purity, potency, stability, safety and efficacy, global regulatory agencies are requiring a thorough risk assessment and validation of all of your cleaning processes – for everything from clean rooms to production equipment to cleaning agents.

KEY CONSIDERATIONS

Cleaning agents | Techniques | Time points | Surface materials | Potential microbial/viral contaminants

REGULATIONS

The FDA has provided positions on sterilization programs in various guidance documents and warning letters. **21 CFR 211.67**, Equipment Cleaning and Maintenance, states "equipment and utensils shall be cleaned, maintained and sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product."

The following **FDA Guidance Documents** are suggested resources for additional information:

- Guidance for Reprocessing (Draft)
- Amendments to Sterility Test Requirements for Biological Products

Recently, FDA auditors have shown heightened awareness and increased expectations of sterility assurance programs, focusing especially on:

- Use of ISO 11607 Physical Testing of Packaging
- Sanitizer Efficacy Validations
- Environmental Monitoring
- Reprocessing Validations

Talk to us and find out how our cleaning validation programs can work for you.

Contact a WuXi AppTec Account Manager at 651-675-2000 or email: info@wuxiapptec.com

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WuXi AppTec

features of our cleaning validations program

EXPERIENCE

WuXi AppTec is the clear leader in this field with more than 20 years' experience and has developed standard cleaning procedures for bacterial and viral contamination. Our experienced Ph.D.-level virologists and microbiologists have the investigational expertise to identify novel contaminants and develop customized assays for you. For example, simulating the exact spraying and cleaning processes at small scale is critical to ensure that larger-scale cleaning procedures will provide the same results as the validation program.

AVAILABLE CONTAMINANTS

Choosing the right organisms is important to the overall success of the cleaning validation. Microbial panels are chosen based on baseline environmental sampling and potential contaminants from the product process. Numerous bacterial banks are available and we can work with relevant new isolates. Additionally, we have over 40 high-titer human and animal viral stocks, including:

- HIV • BVD • MVM • Ad5
- HSV • PPV • Reo • MuLV

Plus we have the capability to develop custom virus titer or qPCR for a wide variety of adventitious agents.

STERILIZATION SOLUTIONS: Antibacterial & Virucidal Agents

Typical cleaning agents include:

Inorganic Compounds

- Peroxides • Hypochlorites (Bleach)
- Cupric and Ferric Ions • Hydroxides

Organic Compounds

- Ethanol • Lipids • Peroxyacetic Acid
- Glutaraldehyde • Quaternary Ammonium Salts

Custom methods and/or agents can also be evaluated.

AVAILABLE SERVICES

- Sanitizer/Virucidal Efficacy
- Virucidal Kinetics
- Clean in Place (CIP)
- Sterilize in Place (SIP)
- Reusable Instruments Used in Manufacturing
- Components / Materials Cleaning and/or Disinfection
- Chromatography Column Cleaning
- Virus and Microbial Risk Assessment/Consultation

AVAILABLE MATERIALS / COUPONS

- Stainless Steel
- Vinyl
- Epoxy
- Glass
- Enamel
- Acrylic
- Plastic
- Resin
- PEEK

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Learn more about our wide range of services at wuxiapptec.com