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Guidances

Supply Chain Risk Management Standard to Address Pharmaceutical Compliance Concerns

A planned new U.S. standard on supply chain risk management to assess the impact that compliance lapses have on supply chain security

FDA Offers Q&A Guidance on Quality Design Requirements

This Q&A Guidance on development of quality systems outlines how a product is designed in the quality target product profile (QTPP), which forms the basis for developing critical quality attributes (CQAs) and critical process parameters (CPPs) that ensure the product's quality over time.

Warning Letters

FDA issues warning letters for two vaccine plants in Canada and France. Major violations related to microbiology can be summarized as:

- Sterility Test Method-Failed bacteriostatis/Fungistatis test
- Multiple counts of non-conformances within the aseptic processing area. Mold contamination not addressed using appropriate disinfectants
- Inadequate environmental monitoring and personnel monitoring program
- Inadequate disinfectant qualification studies
- Aseptic techniques and clean-room behavior not followed-
- Facility non-conformances due to pressure differentials and pest control
- Process related non-conformances due to "Seed Lot" control
- Personnel flows and personnel access not adequate
- Inadequate and untimely investigations for contamination issues

Recalls

Microbial Contamination

Ear lubricant that may be used for hearing devices, was recalled due to possible bacterial and mold contamination. Per clinical references the most common types of bacteria causing ear infections are *Pseudomonas, Streptococcus pneumoniae* (also called pneumococcus), *Haemophilus influenzae*, *Moraxella catarrhalis* and *Staphylococcus aureus*. *Aspergillus* species has been cited related to fungal ear infections. Testing for objectionable organisms cannot be emphasized enough to ensure that the patient is safe.

Particulate Contamination

More than one recall related to visible particles embedded in glass vials. The risk of having foreign matter is that the particles can be dislodged in the solutions and injected in patients' body.

Herbal Supplements

Probiotics for children was recalled due to a possible *Salmonella* contamination. Probiotics consist of beneficial bacteria belonging to genera *Lactobacillus* and *Bifidobacterium*. Salmonellosis is a type of food poisoning caused by the *Salmonella* bacterium. There are many species of *Salmonella*, however serotypes *typhimurium* and *enteritidis* are the most common types related with food poisoning.

Pharmacy

Human and veterinary sterile preparations were recalled by a pharmacy after environmental sampling of clean room revealed the presence of microorganisms and fungal growth. USP <797> discusses all measures to be taken by pharmacies to dispense sterile preparations under aseptic conditions.

Medical Device

Ventilator recall was initiated due to potential risks associated with leak in patient breathing circuit or the system, however; the device was device was set to activate both audible and visual alarms to notify the health care professional that ventilation delivery to the patient may be compromised.

Wipes

This recall is being initiated due to concerns about potential microbial contamination with *Burkholderia cepacia* of Benzalkonium chloride antiseptic wipes. Benzalkonium chloride is a QUAT; use of these wipes in healthcare facilities may lead to nosocomial infections, especially in immunocompromised patients.

White papers coming soon

Recent 483 Observations

Facility Related

*1.*IQ, OQ, and PQ for the biological safety cabinets, incubators, and centrifuges was not performed.

*2.*No requirements were set for pressure differential between the clean rooms and the exterior rooms to assure that non-controlled air does not flow into the cleanrooms.

*3.*Temperature or humidity of the processing rooms was not monitored.

Procedures

*1.*Procedures designed to prevent microbiological contamination of drug products purporting to be sterile were not established and written.

Testing

*1.*Each batch of product required to be free of **objectionable microorganisms** was not tested through appropriate laboratory testing, specifically, product manufactured was injected to the patients intravenously as well as into other locations on the body. Sterility test was not performed.

*2.*Drug product container and closure systems were not tested for conformance according to written procedures.

*3.*Incoming vials had no testing plan; inspection was based on experience of personnel.

*4.*Inadequate sample identifications pulled for testing during fill.

Contamination

*1.*Thermophillic bacterium was reported from sub-culturing vials with particulates; as part of media fill investigation. Formulation contained the same organism.

*2.*Feathery dark gray matter appearing like fungal growth inside filled vials.

*3.*Filled glass vials were cracked with mold growing on contents.

Training

*1.*Vial inspection performed at a different rate than the personnel were qualified for.

Recent 483 Observations (Continued)

Pest Control

*1.*What appeared to be an insect was found inside a vial.

*2.*Dark particles were floating inside a vial.

*3.*Human hair lodged between the flip cap and stopper of the vial.

*4.*Insects were reported in aseptic manufacturing areas.

*5.*Spider was found intact in a filled vial during inspection process.

*6.*Live spider was found in the aseptic corridor.

*7.*Insect was found in wash fill airlock.

*8.*Vials were found with body parts of weevil.

Process related

*1.*Stopper hopper of fill line was located at waist height inside ISO 5 fill area, resulting in operators reaching over the stopper bowl as well as empty vials to perform necessary adjustments for jams.

*2.*Vent filters were not integrity tested during validation studies, protocols were missing in order to provide reason for not testing.

*3.*Media fill protocol did not address actions to be taken when particulate matter is found in filled vials.

*4.*Sampling plan for final product testing was inadequate and not scientifically sound.

*5.*Contamination of filled and lyophilized product contain metal particles in the lyophilized cake probably from equipment.

*6.*Media fill simulation for parenteral sterile drug product filling operation inadequately performed. Documentation was inadequate , and integral filled vials after capping were segregated to be destroyed, when previous media fill runs had vials with particulate matter.

*7.*Inconclusive or no investigations for media fill failures.

Laboratory systems

*1.*Method validation was not performed by the transfer site analyst, instead was performed by the transfer originating scientist.

*2.*QC laboratory management software not validated.

Upcoming Webinars, Seminars & Workshops

Upcoming Webinars

Auditing Cleanroom Gown Suppliers

August 23rd, 2012

1:30 to 3:30 EST

GMP's in Microbiology

August 28th, 2012

1:30 to 3:30 EST

Disinfection & Cleaning Validation for Reusable Medical Devices

September 6th, 2012

1:30 to 3:30 EST

Upcoming Seminars

Microbial Contamination Control

Chicago, IL

September 27th & 28th, 2012

Upcoming Workshops

Disinfectant Qualification-A Step by Step Workshop

Dedham, MA

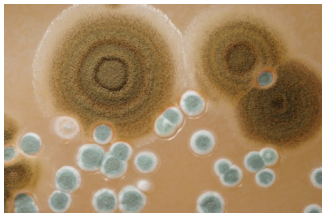
September 13th & 14th, 2012

Cleaning Validation Swab Recovery Studies and Analysis

St. Joseph, MO

October 18th & 19th, 2012

Featured Course



Advanced Course
In Fungal Identification
Hands-On Training

St. Joseph, MO

November 7th, 8th & 9th, 2012