HVAC and GMP Environmental Control - for Pharmaceutical Cleanrooms - Recorded Webinar

Description: This webinar details and explains the various US and international regulatory requirements for various cleanroom classifications. Environmental control of pharmaceutical cleanroom is essential to the manufacture of a quality product. Control of such conditions as airborne particulate, microorganisms, temperature, humidity, differential pressure, airflow, air velocity and personnel is crucial to protect the product from contamination.

Therefore, the design, validation and ongoing monitoring of a cleanroom HVAC system is necessary to assure the quality and safety of the pharmaceutical product. Also, a proper understanding and testing of the cleanroom environment according to international regulatory standards is important from a compliance perspective.

Objectives of the Presentation
- GMP Compliance of Cleanroom Environment
- Regulatory Cleanroom Classification and Requirements
- HVAC System Components
- Cleanroom Design and Layout
- HEPA Filtration
- Differential Pressure and Air Pressure Balancing Considerations
- Temperature and Humidity Controls
- Cleaning and Disinfection
- Non-Viable Particulate Monitoring Systems
- Microbial Monitoring Systems
- Personnel Gowning and Aseptic Practices in Cleanroom
- HVAC System Validation

Why Should you Attend:

It is important that a Cleanroom's HVAC system is fully understood, properly designed and properly validated. If this is accomplished, it will provide the environmental control necessary to meet the regulatory particulate and microorganism levels necessary to manufacture quality pharmaceutical product.

The webinar provides a comprehensive overview of the mechanics of cleanroom HVAC. This includes engineering diagrams and schematics. HVAC equipment components are detailed as well as the automated control systems that are available. Cleanroom design considerations are included. Proper building construction and layout is necessary to achieve both optimum efficiency of the system and optimum cleaning and sanitization of the Cleanroom.

The principles of HEPA filtration are described along with desired Cleanroom airflow patterns and how to achieve them. Proper procedures for HEPA filter leak testing is included. The webinar then provides valuable information on differential pressure, air velocity, flow rates, and air pressure balancing. Temperature and relative humidity controls and specifications are also detailed.

All current air monitoring systems for non-viable particulate and microorganism measurement are fully reviewed. Comprehensive procedures for cleaning and sanitization of the Cleanroom environment are presented along with a review of the best disinfectants currently available along with their respective advantages and disadvantages.

The subject of Cleanroom contamination due to personnel is discussed. This includes both gowning technique and aseptic practices. Finally, a full set of requirements for HVAC system validation is detailed. Ongoing monitoring of the Cleanroom environment is discussed with respect to schedule, specifications and OOS (out-of-spec) actions that may be required.

Who can Benefit:
This webinar will provide valuable assistance to all personnel in:

- Quality Assurance
- Environmental Monitoring
- Microbiology
- Manufacturing
- Validation
- Engineering
- Maintenance

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