MODULAR CLEANROOM HVAC SYSTEM- PHARMA FACILITIES

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NICOMAC CLEANROOMS

PRESENTATION PURPOSE

Focus on Improvements at various stages of Clean HVAC system- Design , Implementation and Operations- this presentation is to briefly delve on critical aspects of pharma HVAC applications where improvements are being sought after on a continual and ongoing basis

CONDUCIVE ENVIRONMENT-HVAC SYSTEM

- Conducive Environment commences from the site layout and onwards to the finished goods leaving the facility.
- Confine this to the HVAC system itself and it's a major topic
- The HVAC system should facilitate and provide for
  - Man movement-entry to exit
  - Material Movement right from raw material to Finished Goods
  - Product stage-wise manufacturing and intermediate storage
  - Equipment and consumables handling in the manufacturing process
  - Packing the product , storage and dispatch
  - Handling the rejected/disposable material

EXPECTATIONS OF HVAC SYSTEM

- Critical Role in Operations of Pharma Manufacturing
- HVAC system to ensure the Facility environment parameters are validated and subject to successful periodical validation
- HVAC system should be maintainable towards a declared SOP and monitored during the course of operations of the pharma facility
- Records of operation, performance and maintenance of the HVAC system are as important as that of the process of medicine manufacture itself and to the stated objectives of the pharma facility.

URS-USER REQUIREMENT SPECIFICATION

- Understanding URS of the HVAC system and Avoiding Overkill
  - States the area wise-zone wise important requirements of the HVAC
    - Area detail such as dimensions, activity /process in the room/equipment load data
    - Dry Bulb temperature & RH requirements
    - Pressure Gradient requirements
    - Clean Classification requirements
    - Process dust extraction, exhaust details from the process activity
    - Containment requirements
    - Specific Monitoring and Control requirements

HVAC SYSTEM- AVOID OVERKILL

One of the Primary Objectives is to ensure minimal Operating Costs and in-turn make the manufacturing cost economical- not just a system provider or manufacturing target but a societal responsibility

Avoid overkill in Design & Implementation- no energy guzzlers

Integrate BMS System

Integrate EMS System

HVAC SYSTEM-EMS-TRENDS

- Understanding Intent of EMS system

  Design & Implementation of EMS Accordingly
- EMS to help in quality of product manufactured- a very key aspect – key management intent to ground level action
- Providing BMS for HVAC System & in-turn helping EMS System
- Reliance on manual recording is waning and in due course expensive

HVAC SYSTEM- BMS(BAS)

- BMS immensely aids in efficient operation and maintenance of large HVAC systems in a Pharma facility
- Integrates the operations of various components of the HVAC system including high side and low side
- Connects various interfaces that help in obtaining efficient and effective EMS results Normal mode, safe mode, failure mode of operations coordinated and established thru BMS
- To ensure maximum uptime of clean HVAC system and thereby efficient clean room operations and maximise profitability of the facility

FOCUS ON ESSENTIAL COMPONENTS- INTERFACES

- Air handling units- selection of efficient components
- Air distribution systems - Integrity
- Filtration- focus on minimal required ACPH and low operating costs
- Effective Modular panel constructions -Ease of maintenance and Integrity- avoids overkill on pressurisation needs. Fresh air needs to IAQ, pressurisation and save on operating costs- avoid overkill on AC loads
- Terminal extraction with panel, - transparency and thereby efficient work place

FOCUS ON ESSENTIAL COMPONENTS-INTERFACES

- Chillers, DX, Hot water/Heaters as per requirements , process exhaust system design and components interface
- Pumping and Piping- Primary & secondary as applicable, continuous service- variable speed drives
- Operation working & standby-Upkeep time
- Controls & Control Parameters & operational logic - Consistent with target URS Parameters

THE TEAM
ENGINEERS AND ENGINEERING- COMPONENTS

In achieving the above processes the HVAC System Provider has to be an integral part of the team that is putting up and eventually maintaining the pharma facility

Detailed Design, Execution, QA,QC, Pre-commissioning, commissioning and finally validation of the Clean HVAC System- A TEAM EFFORT – Every activity and its components have vital definitive role- And every stage-wise improvements are an ongoing process

THANK YOU

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PRESENTATION PURPOSE

Focus on Improvements in Modular and scalable cleanrooms- this presentation is to briefly delve on critical aspects of modular cleanrooms and improvements being developed

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- Integrity of Modular cleanrooms -Critical Role in Pharma Manufacturing
- Proper Layout Understanding and site parameters critical for manufacturing of Modular cleanrooms
- The cleanroom panel system has to be scalable and flexible to integrate various components –Process equipment and related Utilities
- Should be expandable to give flexibility in layouts

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- Manufacturing of cleanroom panels on high precision machinery with pre-integration of various interfaces leads to proper/perfect cleanroom installation
- Various test procedures are being put in place at manufacturing facility to ensure high quality cleanrooms
- Based on the facility requirement, various insulation materials like- PUF, PIR, Rockwool & Honey Comb panels are manufactured with proper procedures and each panel is tested as a regular manufacturing routine to ensure high quality
- Integrity of utilities at manufacturing level itself ,for instance, machine made cutouts for various interfaces such as Electrical, HVAC and other mechanical utilities to avoid/minimise site cutouts

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- Increased Visibility with extended view glass partitions leading to transparent layouts
- Easy to supervise operation of the cleanroom area—visitor corridors
- Inspecting authorities welcome glass walls as it allows inspections of the manufacturing process areas without entering and risking contamination
- Glass can be easily assembled and disassembled for equipment integration without the need to remove ceiling and flooring profiles—extremely flexible

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- Efficient and high integrity in modular clean rooms leads to high productivity by saving on energy costs with leakage arrestance
- High quality Cleanroom with less maintenance—Cost efficient
- High efficiency door gaskets lead to auto arrestance of avoidable and undesirable gaps between panel and uneven floor levels

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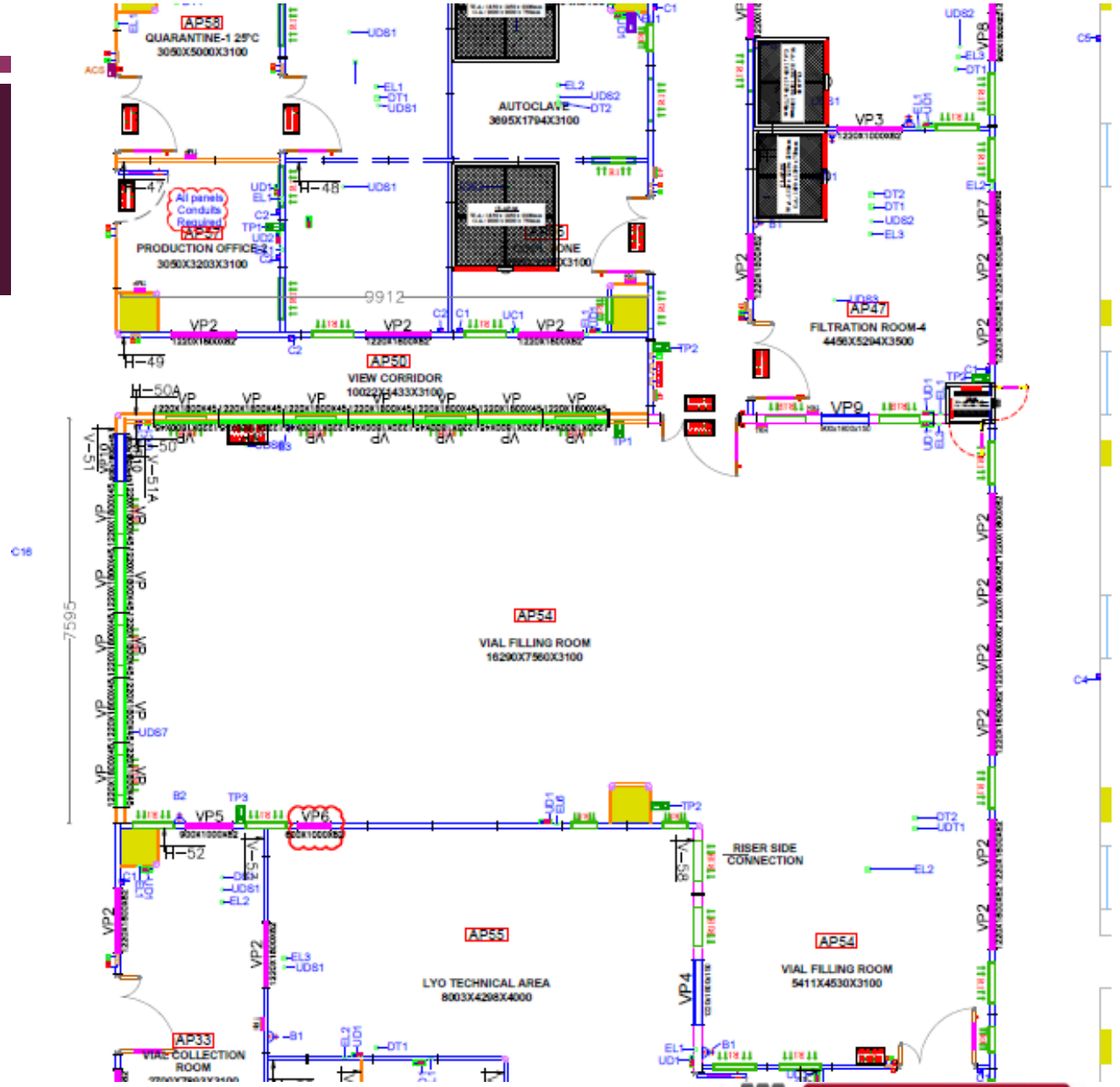
- Detailed engineering documentation in every step of execution
- Easily removable wall panels to ease transfer of large equipment with specialized springs
- View Corridor is being introduced for sterile areas for easy monitoring



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- Secondary packing halls with full visibilities
- Sliding doors at Secondary packing halls for easy material movements

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- Optimization of energy by using various types of doors
- Sliding doors- Manual and Automation for easy material movement

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- Hi-Speed doors in ware houses and dispensing areas
- PLC controlled interlocking systems for GMP compliance

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- Various options such as High Pressure Laminate Partition panels , Powder Coated, Stainless steel partition panels in place
- Conveyor systems in raw material entry areas

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- **CERTIFICATIONS :**

•UNI EN ISO 9001:2008
•UNI EN ISO 14001:2015
•FIRE CERTIFICATION ACCORDING TO ASTM

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