Sakraida & Associates, LLC

How to Commission a Cleanroom

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Seminar Outline

- Introduction
- Design Phase
- Installation Verification
- Operational Verification
- Functional Verification
- Post Occupancy.

Introduction

Vincent Sakraida, PE, LEED AP

- **Bachelor of Mechanical Engineering from Georgia Institute of Technology.**
- **Licensed Professional Engineer in Colorado and Montana.**
- **27 Years Experience in Cleanroom Design, Construction, and Operations.**
- **Written Articles for Engineered Systems and HPAC Magazines. Cleanroom Articles on Cleanroom Design include *Cleanroom Design in Ten Easy Steps and Cleanroom Variable Airflow Design*.**

Commissioning

"Commissioning is a systematic process of assuring that a building performs in accordance with the design intent and the owner's operational needs."

1993 National Conference on Building Commissioning

Cleanroom Commissioning Plan

The Cleanroom Commissioning Plan will have the Five Commissioning Steps:

- **Design Phase**
- **Installation Verification**
- **Operational Verification**
- **Functional Verification**
- **Post Occupancy.**

Cleanroom Commissioning Plan

Design Phase

- **Establish Vision for Facility**
  (How Does Cleanroom Meet Owner's Needs and Mission?)
- **Develop Owner's Project Requirements (OPR)**
  - **Project Goals**
    (Build Sterile Fill Facility Dedicated to New Drug and Having 10,000 Vials Capacity per Day)
  - **Design Goals**
    (Design Sterile Fill Facility that Meets Industry Standard of Care, Regulatory Requires, Flexibility, Energy Efficiency, and Client SOPs)
  - **Measurable Performance Criteria**
    (Vials Filled Per Day, Space Particulate Level, Cleaning Changeover Time Frame)
  - **Budgets**
  - **Schedules**

Cleanroom Commissioning Plan

Design Phase

- **Develop Basis of Design**
  - **Weather Data**
  - **Space Performance Requirements**
    (Cleanliness Classification, Unidirectional/Non-Unidirectional Airflow, Air Change Rate, Modular Flow, Temperature, Humidity)
  - **Applicable Codes**
    (International Building Code, Uniform Building Code, EU)
  - **Applicable Standards**
    (IEST, ASHRAE, ASTM)
  - **Applicable Regulations**
    (FDA, EPA)
  - **Applicable Guidelines**
    (ISPE Sterile Fill Guidelines)

Cleanroom Commissioning Plan

Design Phase

- **Develop Commissioning Plan**
- **Establish a Project Budget**
- **Review Design at Meeting Owner's Project Requirement, Maintainability, Constructability, and Commissionability.**

Cleanroom Commissioning Plan

Installation Verification

- **Verify Equipment and Material Meet Design Intent.**
- **Verify and/or Attend Factory Acceptance Testing.**
- **Verify Equipment and Material Installation Meet Industry Standard of Care.**
- **Verify Equipment Pre-Start Functions That Meet Manufacturer's Requirements are Completed.**

Cleanroom Commissioning Plan

Installation Verification

- **Verify Equipment and System Start-up Meet Established Protocols.**
- **Verify Test and Balance Report.**
- **Assemble Operation and Maintenance Manuals.**

Commissioning Process

Operational Verification

- **Verify Equipment and System Operate Per Design Intent Sequence of Operation.**
- **Manage Maintenance Staff Training.**

Cleanroom Commissioning Plan

Operational Verification

The Operational Verification is Performed During Three Different Installation Phases, which are:

- **As-Built**
- **At-Rest**
- **Operational**

Why????

Cleanroom Commissioning Plan

Operational Verification

As-Built: The Cleanroom Enclosure, Electrical, and Mechanical Systems are Complete but the Cleanroom is Empty. Process Equipment and Workbenches are not Installed.

Cleanroom Commissioning Plan

Operational Verification

At-Rest: The Cleanroom Enclosure, Electrical, Mechanical, and Process Systems are Installed and Operating with NO Operators.

Cleanroom Commissioning Plan

Operational Verification

Operational: The Cleanroom Enclosure, Electrical, Mechanical, and Process Systems are Installed and Operating with Operators.

Cleanroom Commissioning Plan

Operational Verification

The Cleanroom Operational Verification should be separated into its major components, which are:

- **Cleanroom Enclosure**
- **Lighting/Electrical**
- **Noise**
- **Process Equipment and Systems**
- **HEPA Filters**
- **HVAC Systems**
- **Vibration**

Commissioning Process

Operational Verification

Cleanroom Enclosure

Enclosure Leak Testing to:

- **Verify there are No Contamination Entering Cleanroom**
- **Verify Cleanroom Air Leakage is Not Excessive.**

Commissioning Process

Operational Verification

Light/Electrical

- **Lighting Foot Candle Levels**
- **Lighting Level Uniformity**
- **Lighting Wave Length**

Commissioning Process

Operational Verification

Noise

- **Cleanroom Noise Level**
- **Material: Sound Meter**

Commissioning Process

Operational Verification

Process Eqpt

- **Exhaust Air Flow**
- **Cooling Water Flow**
- **Electrical**

Commissioning Process

Operational Verification

HEPA Filters

- **HEPA Filter Air Leakage**
- **Material: Aerosol Generator and Particle Counter**

Commissioning Process

Operational Verification

HEPA Filters

- **HEPA Filter Air Flow**
- **Material: Airflow Hood or Anemometer**

Commissioning Process

Operational Verification

HEPA Filters

- **Air Velocity Testing**
- **Anemometer**

Commissioning Process

Operational Verification

HEPA Filters

- **Airflow Parallelism**

Commissioning Process

Operational Verification

HVAC System

- **Total Supply Air Flow**
- **Total Return Air Flow**
- **Space Pressurization and Stability**

Commissioning Process

Operational Verification

HVAC System

- **Space Temperature**
- **Space Humidity**

Commissioning Process

Operational Verification

HVAC System

- **Space Particulate Level**
- **Room Recovery**

Commissioning Process

Operational Verification

Vibration Testing

Commissioning Process

Functional Verification

- **Verify Equipment and Systems Operate Per Design Intent Sequence of Operation When Integrated With All Associated Equipment and Systems.**
- **Verify Equipment and Systems Fail Per Prescribed Failure Cascade.**

Commissioning Process

Post Occupancy

- **Alternate Season Testing.**
- **End of Warranty Inspection.**
- **End of Warranty Occupant Interviews.**
- **Develop Recommissioning Plan.**

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Thank you

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