Designing Facilities of the Future for Efficient and Compliant Pharmaceutical Production

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We can't predict the future, but we can pre-position a facility for future technologies.

Identify the Business Case Drivers

Number of products and modalities

Understand the facility's capacity requirements based on the number and types of pharmaceutical products and production modalities.

Speed to market

Assess the importance of fast product development and market introduction, which may require design considerations for rapid facility expansion and flexibility.

Cost

Evaluate the facility's initial and ongoing operational costs, balancing the need for efficiency, compliance, and future-readiness.

By carefully considering these key business case drivers, organizations can make informed decisions about the design and investment required for a pharmaceutical production facility that is well-positioned for the future.

Integrated Team

Cross-functional Collaboration

Bring together stakeholders from various departments, including production, quality, engineering, and facilities, to ensure alignment on project goals and requirements.

Early Involvement

Engage the design and construction team as early as possible, even before the site is selected and the business case is finalized, to optimize the planning and design process.

Continuous Communication

Facilitate regular meetings and updates to keep all decision-makers informed and ensure timely resolution of any issues or challenges.

Empowered Decision-making

Ensure that the right stakeholders with the authority to make decisions are present at every step, allowing for efficient and effective project progression.

By involving a diverse, cross-functional team and maintaining open communication throughout the planning and design process, organizations can ensure that the facility is designed to meet the unique needs of their pharmaceutical production operations, both now and in the future.

In Parallel Design - Process Definition and Site Analysis

Define products, modalities, and preliminary equipment arrangements

Identify the specific pharmaceutical products, production modalities, and initial equipment layout to inform the facility design.

Site planning (greenfield + brownfield) or facility assessment (renovations)

Conduct a thorough analysis of the proposed site to understand the site constraints and opportunities.

An efficient and safe facility begins with a well-planned site identifying car, truck, and pedestrian paths

Optimizing the site layout for efficient and safe material, personnel, and vehicle flow is crucial for the overall facility design.

By defining the production processes and conducting a comprehensive site analysis in parallel, we can ensure that the facility layout is efficient, safe, and future-ready

Project Visioning

Visualize the Future Facility

Project visioning helps the team envision the facility of the future, considering factors like flexible equipment layouts, modular design, and infrastructure to support growth and adaptation.

Plan for Adaptability

Designing for future flexibility is essential, allowing the facility to accommodate changes in technologies, equipment, and regulatory requirements over time.

Facility Drivers

- Height limitations
- Equipment placement
- Personnel, raw materials, WIP, waste, finished goods
- Hazardous materials
- Preliminary regulatory requirements

What Came Out of the Planning?

First cost investment in large span structural frame and high bay space

The planning process identified the need for a large span structural frame and high bay space to accommodate future flexibility and potential equipment changes.

What can be modularized?

The planning process explored opportunities to modularize certain facility components to enable easier future reconfiguration and expansion.

How do we optimize the facility floor plans and infrastructure for expansion while minimizing downtimes in future construction projects

The planning process focused on optimizing the facility layout and infrastructure to support future expansion and growth while minimizing disruptions to ongoing operations.

The planning process identified key investments in the facility structure and layout to support future flexibility, modularization, and expansion, while prioritizing operational efficiency and minimizing downtime for future construction projects.

Advancing Sustainable Pharmaceutical Practices

Next-generation design principles for efficient, compliant, and sustainable pharmaceutical manufacturing

Integrated Strategies for Sustainable Facility Design

Sustainability goals and industry commitments

- Reducing carbon footprints
- Aligning with global sustainability frameworks

Innovative practices for energy and water reduction

- Energy-efficient HVAC and cleanroom design
- Waste heat recovery, renewable integration, and intelligent controls
- Water conservation in cleaning and utility systems

Environmental impact mitigation

- Material selection, lifecycle design, and circular economy principles
- Case study example of measurable impact from a recent sustainable project

Sustainable Laboratory Services

Comprehensive Building Assessments

- Perform ASHRAE Level I, II, and III audits to identify energy efficiency opportunities
- Design Charettes, Design for Resilience
- Commission and retro-commission existing systems
- Design for resilience in the building envelope.

Sustainable System Design

- Implement MEP infrastructure upgrades
- Renewable energy systems (RECs)
- Electrical and thermal storage, combined heat and power
- Electrification
- Energy recovery to improve energy efficiency and reduce emissions.

Sustainable Material Sourcing

Prioritize the use of sustainable materials

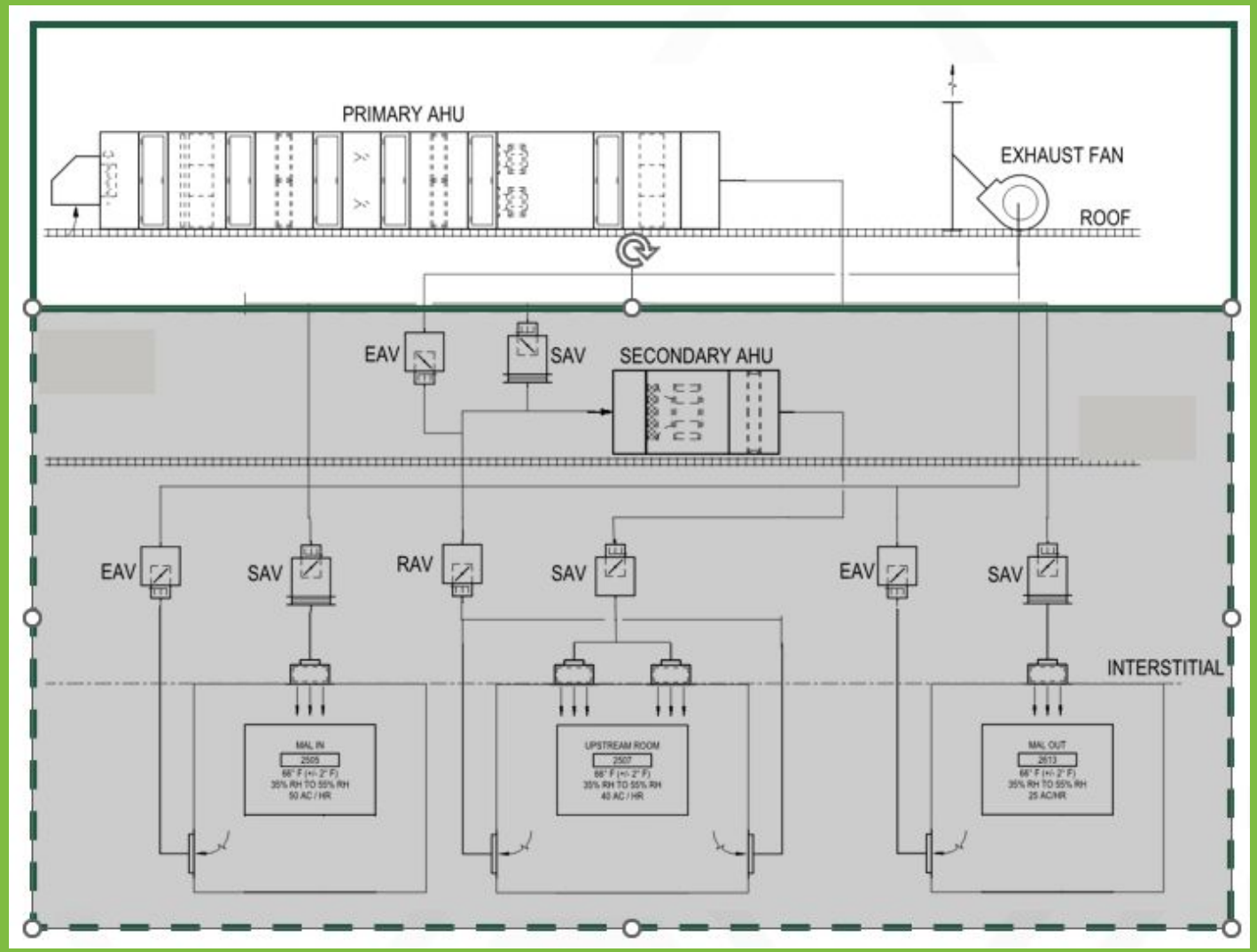
Considering both direct and indirect emissions, to minimize the environmental impact across Scope 1, 2, and 3 emissions.

Innovative Energy Conservation Measures

- Optimize utility metering
- Lab ventilation
- HVAC controls to reduce energy consumption
- Including implementing measures like variable geometry exhaust
- CAV to VAV Conversion
- Static pressure reset
- Fume hood occupancy sensors & Sash Closers
- Reduce ACH
- Reduce Fume Hood Face Velocity
- Smart Stack & Aircuity
- Broaden Temp & RH Setpoints

District Utilities and Cogeneration

- Leverage district utilities, such as steam and chilled water
- Cogeneration and trigeneration systems to maximize energy efficiency and minimize environmental impact.



Primary/Secondary Everywhere: Target #1

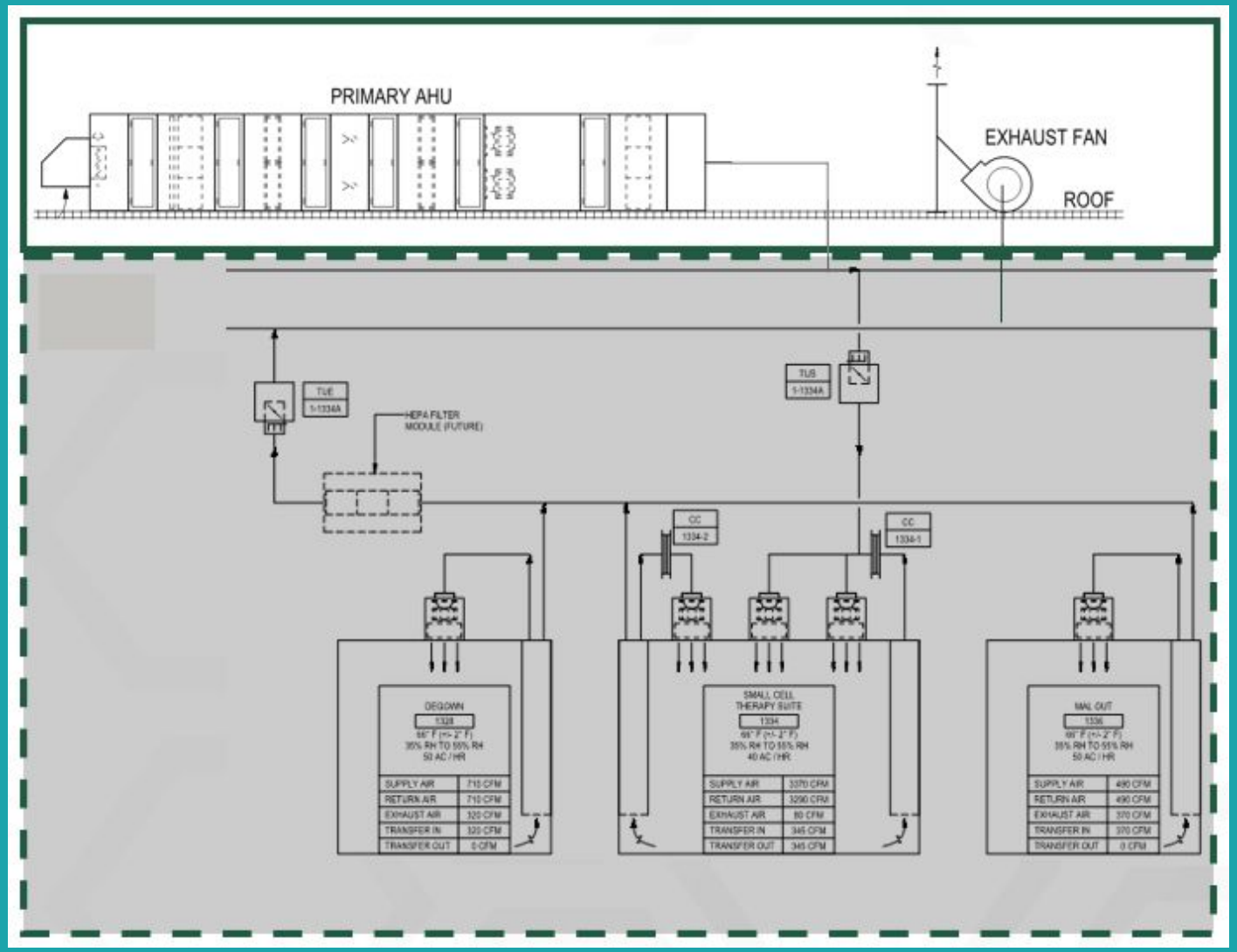
Manufacturing Area Configuration

Filtered air changes and conditioning of pressurization air are managed by two decoupled systems. Very commonly used configuration and is the most energy efficient.

Recirculation is localized within a single room or suite. No crossing / blending of return airstreams between rooms.

Recirculate whenever you can.

It saves 50%-70% in energy costs!



Primary/Secondary Everywhere

Alternative Configuration

Similar design however, Fan Filter Units (FFUs) are used to re-circulate room air.

FFUs may be purchased in bulk, allowing flexible fit-out, on-demand.

100% OA Annual Total Energy Cost				15,000 CFM	
	Fan Electric Power (kWh)	Chiller Electric Power (kWh)	Natural Gas (Therm)	Carbon Dioxide (Lb)	Cost ($)
100% OA w/ Energy Recovery					
Occupied Hours	114,938	64,442	10,260	247,938	$56,459
Unoccupied Hours	223,601	125,060	22,655	513,659	$114,175
Total	**338,540**	**189,502**	**32,915**	**761,597**	**$170,634**

Pr-Sec Total Annual Energy Cost	6,700 CFM		38% OA		
	Fan Electric Power (kWh)	Chiller Electric Power (kWh)	Natural Gas (Therm)	Carbon Dioxide (Lb)	Cost ($)
Primary-Secondary Unit (w/primary energy recovery)					
Occupied Hours	24,027	10,938	2,038	48,772	$11,067
Unoccupied Hours	51,935	21,227	5,314	114,333	$24,798
Total	**75,962**	**32,165**	**7,351**	**163,105**	**$35,864**
Assuming 8 weeks per year at 100% OA:					
Total	**116,358**	**56,370**	**11,284**	**255,181**	**$56,598**

Savings:	**222,181**	**133,131**	**21,631**	**506,416**	**$114,036**

Case Study: 100% Outside Air vs. Recirculation

Massachusetts-Based Project

Project Conditions:

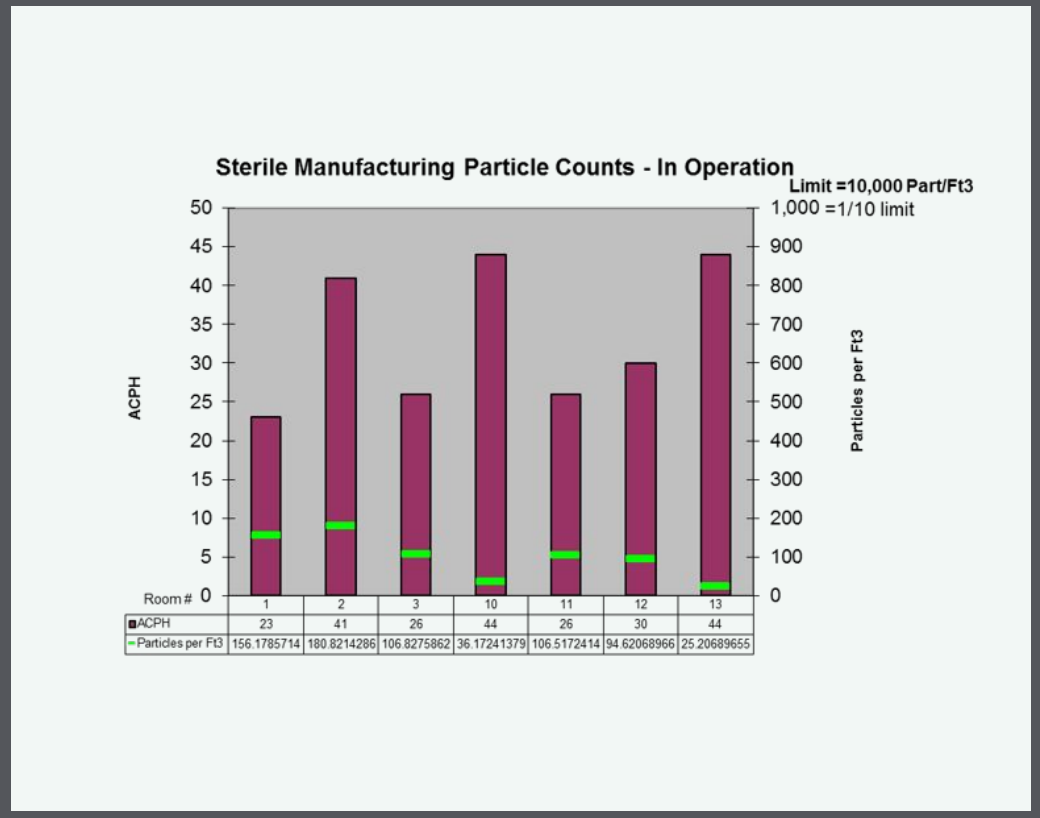
- Grade C Space
- 22ACH
- Includes Heating & Cooling Costs
- Includes Sensible-Only Energy Recovery
- Utilizes Unoccupied Setbacks

Minimize/Challenge Space Classifications

Process Closure/Microenvironments ● Lower Classification Requires Less Airflow

GMP AREA DESIGN MINIMUM AIR CHANGE RATES			
Area	Room Classification (EU/FDA)	Recirculation (Air Changes per Hour)	Outside Air (Air Changes per Hour)
Grade A Spaces	Grade A/ISO 5	200+	6
Grade B Spaces	Grade B/ISO 7	40	6
Grade C Airlocks	Grade C/ISO 8	30	6
Grade C Spaces	Grade C/ISO 8	25	6
Grade D Airlocks	Grade D/CNC+LM	25	6
Grade D Spaces	Grade D/CNC+LM	20	6
Controlled Not Classified Spaces	CNC	4	0.8
Controlled Not Classified Airlocks	CNC	6	0.8
Unclassified	UNC	0	Per Code

Air Change Rates: Target #2



Significant energy is expended each year maintaining pharmaceutical cleanrooms at high air exchange rates.

Investigation shows that air change rates have limited value as a primary cleanroom design criterion.

- Use dilution models rather than ACH
- CFD Modeling
- Utilize enough air to reliably produce the desired results.
- Don’t focus solely on air change rates.

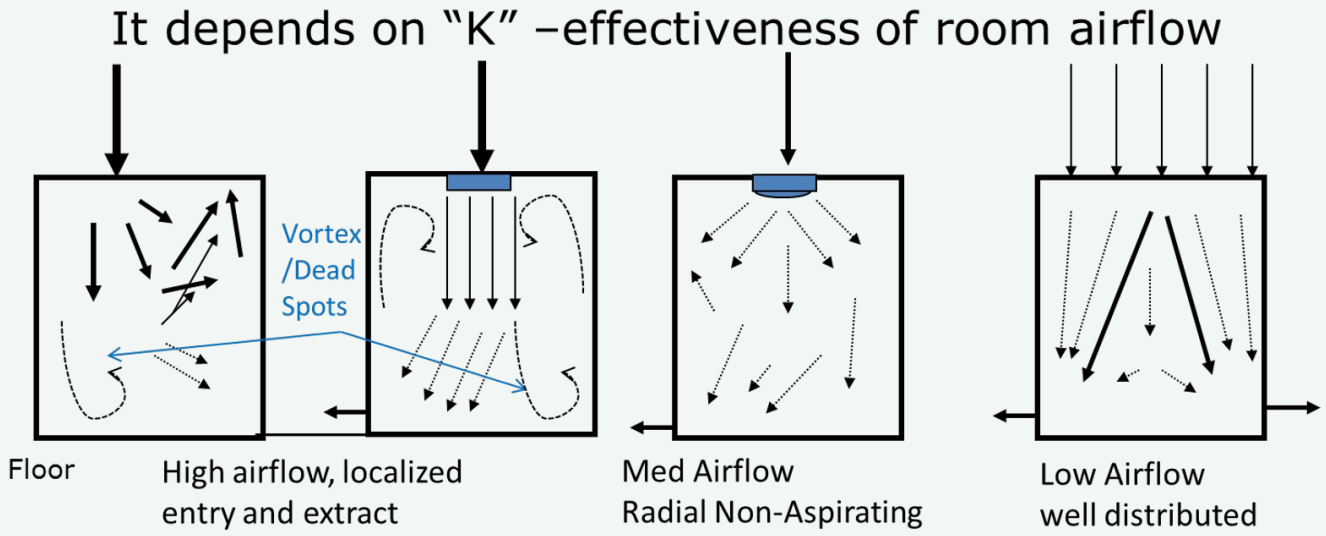
Air Change Rate is No Guarantee

The ventilation (air change) rate does not assure quality.

Ventilation depends on the effectiveness of air distribution in the space

NOTE: MOST REGULATION DOES NOT SPECIFY AIR CHANGE RATES!

You cannot expect prescriptive reliance on air change rate as the primary design criteria and quality acceptance criteria for cleanrooms.



Pragmatic Approach to Establishing Airflow

Evaluate Heat Loads and Broaden Temp. and RH Limits

- Evaluate allowable product and process requirements to maximize temperature and relative humidity limits.

Evaluate Exhaust Requirements

- Assess the necessary exhaust airflow rates to maintain desired pressure differentials and dilute contaminants.

Evaluate Pressurization Impacts

- Analyze the effects of pressurization on infiltration/exfiltration airflows and challenge setpoints.

Evaluate Airflow Required to Dilute Contaminants

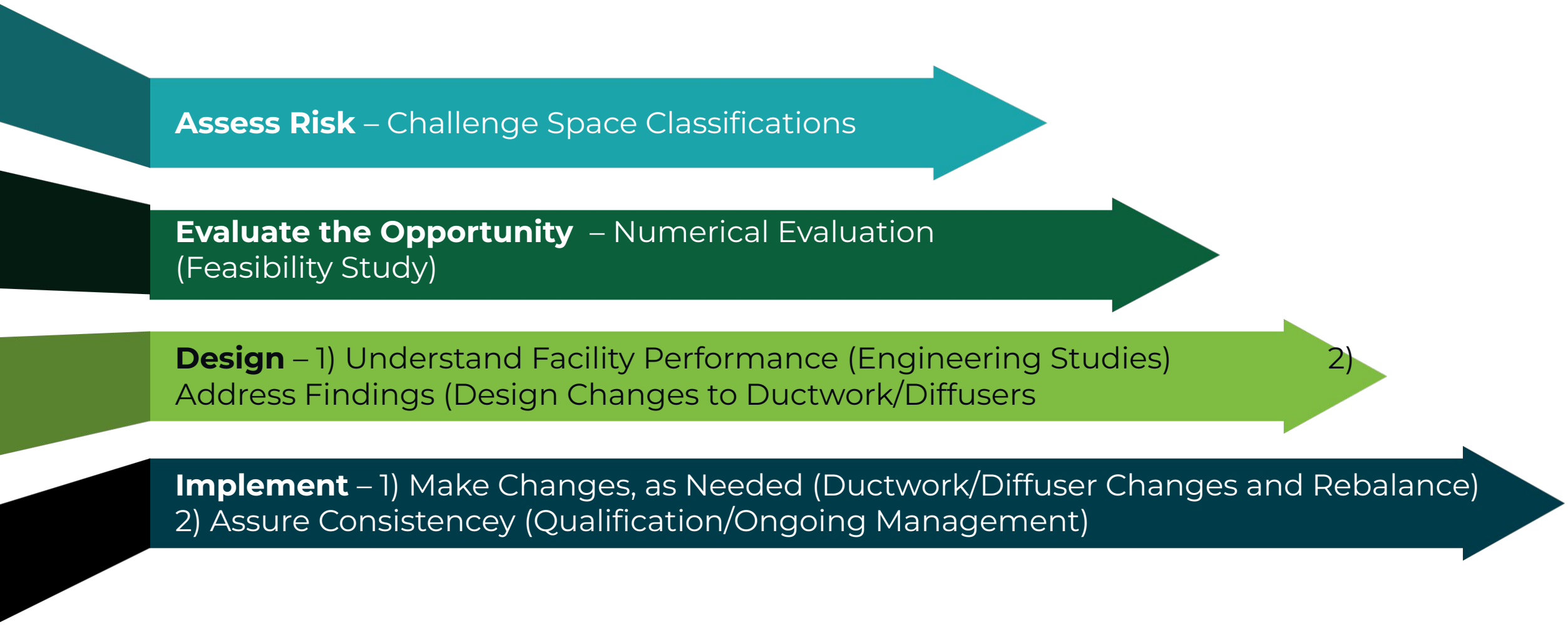
- Determine the minimum airflow needed to effectively dilute and remove contaminants in the space.
- Establish Occupied/Unoccupied Controls
- Utilize Particle Counters
- Risk Assessment

Establish Occupied/Unoccupied Controls

- Utilize Particle Counters to reset ACH
- Conduct risk assessment as it's the key to reducing air change rates
- Test and optimize cleanrooms
- Manage particle generation: design equipment for low contaminant contribution noting that operators may be top source.
- ISO 14644 (Part 16: Energy efficiency in cleanrooms and separative devices)

Taking Action

Challenge the link between criterion and product quality ● Invest only as much energy as required to assure reliable quality ● Adopt a 4-Step Process Methodology noted below



Advancing Pharmaceutical Manufacturing:

Commissioning, Qualification, and Validation (CQV)

Verifying that all building systems and components are installed and perform according to the design specifications and the owner's operational requirements.

Demonstrating that equipment and ancillary systems are properly installed, work correctly, and can consistently deliver the expected output. This includes Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ).

Demonstrating that a procedure, process, or activity consistently leads to the expected results. Validation confirms that the equipment, utilities, and processes meet all predetermined requirements and specifications and are suitable for their intended use.

Ensuring Readiness through Commissioning, Qualification, and Validation (CQV)

- Integrate CQV early in the design process
  - Design with compliance and operational readiness in mind
  - Use digital CQV strategies for efficiency and traceability

- Tap best practices for seamless production start-up
  - Utilize risk-based qualification
  - Leverage automation in documentation
  - Collaborate between design, engineering, and quality teams

OUTCOME: Accelerated time to market, reduced deviations, and optimized lifecycle performance.