



## DESIGN REVIEW AND EQUIPMENT STARTUP CHECKLIST FOR cGMP CLEAN ROOM APPLICATION

— With 100% Outside Air And Exhaust With Energy Recovery System

**Equipment type:** Air-handling unit  
**Equipment designation:** AHU-1  
**Bar code designation:** 111111  
**Area served:** cGMP (current good manufacturing practice) clean room  
**Equipment location:** building roof

ELECTRICAL INSPECTION	YES	NO
• Electrical completed and disconnect installed per code compliance.	<input type="checkbox"/>	<input type="checkbox"/>
• Heat tracing completed.	<input type="checkbox"/>	<input type="checkbox"/>
• Starter and wire sized per contract documents.	<input type="checkbox"/>	<input type="checkbox"/>
• Outdoor disconnect furnished and installed.	<input type="checkbox"/>	<input type="checkbox"/>
• Motor "bumped" to verify rotation.	<input type="checkbox"/>	<input type="checkbox"/>
• Terminations and panel circuit labeled.	<input type="checkbox"/>	<input type="checkbox"/>
• Voltage and motor amps (per phase) documented.	<input type="checkbox"/>	<input type="checkbox"/>

ELECTRICAL INSTALLATION (PER CONTRACT DRAWINGS AND SPECIFICATION)	YES	NO
• Piping complete at unit.	<input type="checkbox"/>	<input type="checkbox"/>
• Vibration isolation complete.	<input type="checkbox"/>	<input type="checkbox"/>
• Seismic restraints complete.	<input type="checkbox"/>	<input type="checkbox"/>
• Interior of AHU washed down and cleaned.	<input type="checkbox"/>	<input type="checkbox"/>
• Manufacturers' O&M available.	<input type="checkbox"/>	<input type="checkbox"/>
• Manufacturers' startup sheets attached with this checklist.	<input type="checkbox"/>	<input type="checkbox"/>
• Warranty certificate available.	<input type="checkbox"/>	<input type="checkbox"/>

DISTRIBUTION (TO AND FROM EQUIPMENT)	YES	NO
• Piping pressure tested per contract documents.	<input type="checkbox"/>	<input type="checkbox"/>
• Insulation completed.	<input type="checkbox"/>	<input type="checkbox"/>
• Non-toxic glycol solution at correct percentage.	<input type="checkbox"/>	<input type="checkbox"/>
• Installation per contract documents (specification and details).	<input type="checkbox"/>	<input type="checkbox"/>
• TAB report (and field notes) attached with this checklist.	<input type="checkbox"/>	<input type="checkbox"/>
• Identification per contract documents.	<input type="checkbox"/>	<input type="checkbox"/>

AUTOMATIC CONTROLS	YES	NO
• Temperature controls complete.	<input type="checkbox"/>	<input type="checkbox"/>
• Control "points" confirmed.	<input type="checkbox"/>	<input type="checkbox"/>
• Electrical system interlocks complete.	<input type="checkbox"/>	<input type="checkbox"/>
• Unit furnished controls interfaced with owner's BAS computer.	<input type="checkbox"/>	<input type="checkbox"/>

### REFERENCE

• 2004 ASHRAE Handbook — Systems & Equipment, Chapter 1 and 2003 ASHRAE Handbook — Applications, Chapter 16 for additional information relative to clean room design. Also reference other technical books including *Pharmaceutical Engineering Guides for New and Renovated Facilities*.

### DESIGN REVIEW / TRICKS OF THE TRADE

• Create an airflow diagram indicating cfm, air changes, and space pressure.

- Confirm safe access to equipment.
- Confirm there is manufacturer's recommended clearance around equipment.
- Consider routine maintenance can be achieved without shutting down the AHU and/or having to get access via the cGMP clean room.
- Spot-check air changes based on Class 100,000; 10,000; and/or 100 categories.
- Spot-check even distribution of air from ceiling-mounted HEPA filter/supply air outlets to low exhaust inlets.
- Attach equipment schedule and design criteria to checklist.
- Attach sequence of operation to checklist.
- Attach associated contract detail drawing to checklist.

### NOTE

- Refer to equipment manufacturers' literature for additional data and requirements.
- Refer to pharmaceutical manufacturer (building owner) standards and guidelines for additional criteria. **ES**



If you have any comments, suggestions, or questions regarding this designer checklist, contact Amanda McKew at [amckew@rdkengineers.com](mailto:amckew@rdkengineers.com). This column is meant to provide some basic guidelines for good design. Always consult all necessary codes and resources relevant to each particular project.

