- Design considers the required documentation.

Example 2: Structured Design Review checklist

The generation of system-specific design review (structured) checklists may be necessary and will benefit both the design review and further risk assessments, below is example for a critical HVAC system.

- Will the dedicated User Areas be served by dedicated HVAC systems?
- Will the air handling system adequately cope with external and internal environmental loads?
- Will the system recirculate air?
- Will the system operate 24 hours a day, 365 days a year?
- Will the supply air supply be located in the ceiling?
- Will the exhaust air extract be located at low level?
- Will the HVAC system be interconnected with other HVAC systems?
- Will the HVAC system be adversely affected by other HVAC systems being turned off?
- Will the method of fumigation/sanitation be appropriate?
- Will the system components be constructed of suitable materials?
- Will pressure test certificates be provided for AHU's and ductwork?
- Have the design of dampers been specified in accordance with operating requirements?
- Will there be access for test instruments? (e.g. Thermocouples)
- Have the secondary services to the HVAC been clearly specified?
- Will there be any potential hazard from discharge air?
- Will air supply HEPA filters be terminally located?
- Will air exhaust HEPA filters be located in a safe-change unit in plant room?
- Will the final filters be of the correct classification to ensure that the quality of the air entering the user areas meets specifications?
- Will the final filters be protected by lower grade filters within the systems?
- Will there be means of monitoring the performance of the filters?
- Is there a list of all the filters specifying number and type?
- Will filter housings be cleanable?
- Will filters be integrity testable?
- Will the air be temperature or humidity controlled?
- Do the specifications for temperature meet cGMP?
- Will the air temperature be monitored?
- Will the air be humidity controlled?
- Do the specifications for humidity meet cGMP?
- Will the humidity be monitored?
- Do the specifications for the number of air changes per hour meet cGMP?
- Do the specifications for the air velocities in critical areas meet the requirements of cGMP?
- Will air flow patterns/ distribution in rooms be suitable for process requirements?
- Will terminal devices produce the required air flow patterns/distribution within the rooms?
- Do the specifications for room pressure regimes meet cGMP?
- Will air pressure differentials be adequately controlled?
- Will air pressure differentials be adequately monitored?