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LPC Snapshot:
Accelerated Commissioning of Cleanrooms

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INTRODUCTION

The commissioning of cleanrooms can be a lengthy process, dependant on the size of the facility. Performed upon build or following major renovation, the cost and resources required to successfully commission a cleanroom in a timely manner can be challenging. The following is a summary of a proposed path forward to expedite the commissioning process, without compromising on quality, safety and regulatory requirements.

Commissioning of a facility should be managed through a change control or change management process, which is dependent upon the structure of the Facility's Quality Management System. Commissioning activities are based on ISO 14644 Cleanrooms and associated controlled environments requirements, and based on risk assessment processes undertaken. Consideration must be given to the risks associated with the room designation and products intended to be manufactured within the area. Defining the parameters of the cleanroom is critical to ensure the correct limits are applied during commissioning. Refer to the PIC/s Guide to the Manufacture of Medicinal Products Annex 1 and ISO 14644 for guidance.

Determination of air flow patterns using smoke tests are important to identify air flow patterns within the rooms and to enable environmental monitoring sampling plans to be developed. It is recommended that a video taping of the smoke pattern activity be performed, to enable clear visualisation of the air flow patterns for future reference.

There are three phases of commissioning:

- As-Built – A condition where the cleanroom is complete with all services connected and functioning, but with no equipment, furniture, materials or personnel present.
- At-Rest – A condition where the cleanroom is complete with equipment installed and operating in a manner agreed upon, but with no personnel present.
- In-Use – A condition where the cleanroom is fully functional, with personnel present.

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COMMISSIONING

As- Built

During this phase of commissioning, there are no materials, personnel or equipment in place. Clean the room and ensure the cleaning dates and disinfectant used are recorded on relevant documentation. Particle counting during commissioning activities requires a defined number of sampling locations. This is dependent upon the size of the cleanroom. If the room size is in between the number of locations as described within ISO 14644-1, then the higher number of locations should be tested. For As-Built activities, particle counting should be performed over 3 consecutive runs; however, air flow exchange rates, air pressure differences, HEPA filter installation and integrity and temperature humidity can be performed in a single day.

At-Rest

Once As-Built commissioning has successfully met specifications, move all equipment into the room. This includes benches and chairs. Commissioning activities are completed in the same manner as the As-Built; however, for accelerated commissioning, At-Rest testing can be performed in a single day. Settle plates can be placed down for 4 consecutive hours, with three consecutive runs performed for particle counts, swabs and HVAS (High Volume Air Sample) during that time. It is important that allowance for the room to settle after the first testing run is given – this is dependent upon on the amount of air changes in the room.

In-Use

In-Use commissioning should be completed within two weeks of successful completion of At-Rest Commissioning; however, this timeframe is not critical. Ensure a clean of the room is performed before and after each In-Use testing, allowing time for the room to settle before commencing the next In-Use testing. In-Use testing should be completed while mimicking the normal operations within the cleanroom. As such, cleanroom operator capacity validation can be performed at the same time. Following successful In-Use testing, additional environmental monitoring should be performed every two weeks for a month to ensure that the rooms are functioning as required.

CONCLUSION

With careful planning, risk analysis and communication, a streamlined approach can be adopted to commission a facility without compromising on quality.