

## Checklist Performance Qualification

An Excerpt from the GMP Series PDF Download [The Ultimate Checklist for Premises and HVAC Qualification](#)



by Hans H. Schicht, PhD

### Performance Qualification (PQ)

Performance qualification (PQ) is the documented proof that premises and utilities, in harmony with the production equipment, are suitable for manufacturing the product reproducibly in the specified quality. Performance qualification is the responsibility of the user of the facility and is initiated immediately after the transfer of facility ownership from the contractor to the user.

Regarding premises and the infrastructure systems installed therein, not many surprises are to be expected at that point in time. During operational qualification, air cleanliness measurements have been performed in the at rest occupancy state. During performance qualification, they are repeated in the in operation occupancy state, i.e. with the numbers of persons present as foreseen for normal production.

During PQ, the infrastructure systems and the process equipment operate, for the first time, as an integrated entity. For the first time, all machinery and other elements contributing to the heat load are now active in parallel. Therefore, only now it is possible to assess whether the HVAC system is capable of meeting its performance requirements at the extreme thermal load conditions regarding air temperature and air relative humidity specified for summer and winter as calculation base for dimensioning.

In addition, during performance qualification the human being is present for the first time in the facility in his condition as dissemination source for micro-organisms. Now, for the first time, it is possible to assess – where this is relevant – whether the limits established for microbiological monitoring are met. For sterile manufacturing, they are stipulated in Annex 1 to the EU GMP Guide (see Chapter C.6.1 and Chapter 3.C.2 GMP Requirements for Cleanrooms: Air Cleanliness Grades). In all other cases where microbiological risks have to be taken into consideration, they have to be specified case-specifically upon risk assessment considerations.

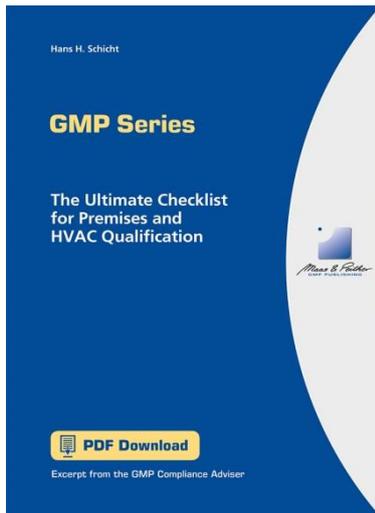
A selection of suggested PQ checks and tests is compiled in Figure 3.I-5. As now the manufacturing process and everything related to it is considered as an entity and as all interferences between the different elements of the premises, equipment, the HVAC system, process media and the human being are now fully effective, no longer a distinction is made in this table between the different infrastructure systems now acting together.

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Figure 1: Checklist for performance qualification (HVAC related topics only)

Document identification	Document no., revision, date	o.k. yes/no	Date	Signature
PQ plan, production system including utilities (HVAC related topics only)				
Room air temperature and relative humidity at full heat load (including full operation of process equipment) as specified for the pre-determined outside air conditions per room, for the: <ul style="list-style-type: none"> <li>• Summer</li> <li>• Winter</li> </ul> standardized limit values				
Room-specific air cleanliness classification in the occupancy state <i>in operation</i> <ul style="list-style-type: none"> <li>• in agreement with specified limits</li> <li>• performed with calibrated instruments (with calibration certificates attached to test report)</li> </ul>				
Microbiological tests (if required) regarding <ul style="list-style-type: none"> <li>• Airborne microorganisms</li> <li>• Microbial sedimentation</li> <li>• Surface cleanliness</li> <li>• Glove test (5 fingers)</li> </ul> successfully passed				
Air flow pattern visualization documented with video/DVD (where required), e.g. <ul style="list-style-type: none"> <li>• Unloading areas of autoclaves into room areas with unidirectional airflow</li> <li>• Transfer belts penetrating walls</li> </ul>				
Worst case situations regarding the interactions between infrastructure and production systems simulated completely and successfully				
Media fill, where required, successfully performed				
Production operators successfully trained and qualified, e.g. regarding <ul style="list-style-type: none"> <li>• Garmenting procedures</li> <li>• Operation of equipment (contamination control aspects)</li> <li>• Emergency actions</li> <li>• Performing the media fill</li> </ul>				



**The Ultimate Checklist for Premises and HVAC Qualification** provides you with all you need to know about:

- Objectives of qualification
- Regulative and normative fundamentals of qualification
- Qualification master plan
- Qualification plans and qualification reports
- Requirements for measurement and test reports
- Requalification

**What's more, you will get detailed checklists for all qualification stages!**

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