
© Michael Novotny | Fotolia

The structuring and management of a qualification process and the automatic documentation can be significantly improved by using an optimized software solution.
A complex software solution for the cleanroom qualification is interesting for companies offering services for testing of cleanroom quality.

Cleanroom Qualification 2.0

Software-supported Cleanroom Qualification

International Standards (ISO 14644, EU GMP, VDI 2083) describe qualification and validation measurements in cleanrooms in different areas of the pharmaceutical and micro-electronic industry but also in hospitals, pharmacies and at cytostatic work benches.

The growing number of cleanrooms requires an increasing amount of work for the companies which examine the acceptance of cleanrooms and cleanroom facilities.

Time-consuming measurements and high data volume with subsequent evaluation and documentation characterize the cleanroom acceptance. The effort increases with the size and complexity of the cleanroom system. The manufacturers in these areas are therefore obliged to meet the cleanliness of product and personal safety.

The qualification process arranges itself primarily in terms of quality management into the following areas:

- Installation Qualification (IQ)
  (testing of all installations after completion of the cleanroom – as built)
- Operational Qualification (OQ)
  (in absence of staff with no production (at rest), it is checked if all requirements are met)
- Performance Qualification (PQ)
  (With staff in ongoing production (in operation) compliance with the requirements is checked.
  Only tests can be carried out which do not endanger the production process.

The benefits of software support by CRQWin are mainly:

- Structuring of the test subjects and tests
- Automatic data acquisition
- Online visualization of results
- Automatic report

Requirements

The requirements for the qualification should be analyzed at the planning stage of the cleanroom by a risk analysis of the production process. The individual tests (e.g. required cleanliness class) shall be agreed in accordance with risk analyses and standard between the auditor and the manufacturer. In the configuration phase CRQWin supports the acquisition and structuring of the test object (rooms, workbenches, filters), the schedule tests, all necessary measuring points as well as all system and test-specific parameters.

The effort for the test configuration of the project acceptance for initial acceptance of the system (IQ) is omitted for periodic requalification (OQ,PQ) according to ISO 14644-2 if the auditor is repeatedly instructed. However, the expenditure of time increases greatly if the measurement data must be transferred in protocols by hand. An automatic data acquisition (as at CRQWin) prevents input errors and allows a direct calculation of the test results to assess whether the measurements were carried out correctly. Further advantages of automatic data acquisition of the software CRQWin:

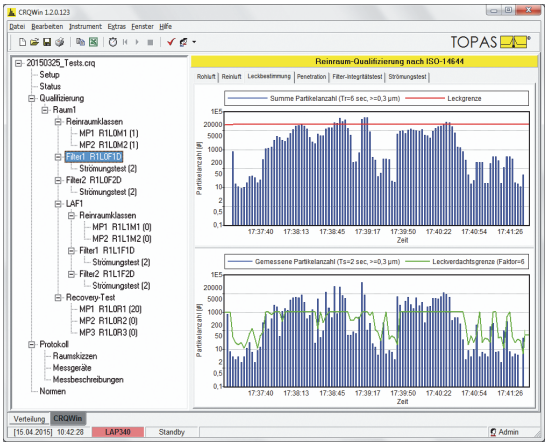
- The comfortable implementation of sequential sampling method
- The temporal assignment of upstream and downstream concentrations at the filter integrity test
- Simultaneous measurement at the determination of the cleanliness class

Master of the data

The large number of data is based on the large number of tests and especially the test objects. These test verdicts should most widely automatically be determined by the software and neatly arranged.

Test	Object	Mixing Air Flow	Displace-ment Flow	Phases of Qualification	Measurement Devices
Differential Pressure	Adjacent rooms	Yes	Yes	Operational & Performance Qualification (OQ, PQ)	Differential pressure gauge
Airflow Test	Room, filter, work bench	Yes: air change	Yes: homogeneity	Operation & Performance Qualification (OQ, PQ	Anemometer (air velocity)
Filter Integrity Test, Leakage Test	Filter	Yes	Yes	Operational Qualification (OQ)	Particle counter, dilution system, aerosol generator
Class Detection	Room, work bench	Yes	Yes	Operational & Performance Qualification (OQ, PQ)	Particle counter, dilution system, aerosol generator
Recovery-Test	Room	Yes	Yes	Operation & Performance Qualification (OQ, PQ	Thermometer, moisture meter
Temperature, Humidity	Room, work bench	Yes	Yes	Operational & Performance Qualification (OQ, PQ)	Particle counter, dilution system
Cleanup-Test	Room	Yes	Yes	Performance Qualification, Operational Qualification (OQ, PQ) (GMP)	Particle counter, dilution system

Table 1: Selection of qualification tests (ISO & GMP) supported by CRQWin



For the report additional documents (e. g. certificates of the used measuring devices, specific descriptions) need to be assigned to the qualification project. This allows the transfer of the project from one to another instance. The automatic creation of the report significantly reduces the total time for the auditors.

Figure 1: CRQWin, Left: Structure of the test objects and test, Right: measured value

Contact

Topas GmbH
Technologie-orientierte Partikel-; Analysen- und Sensortechnik, Dresden
Tel.: +49 351 2166 430
office@topas-gmbh.de
www.topas-gmbh.de