RASCHKA

NEWSLETTER

May 2015

Qualification & Validation

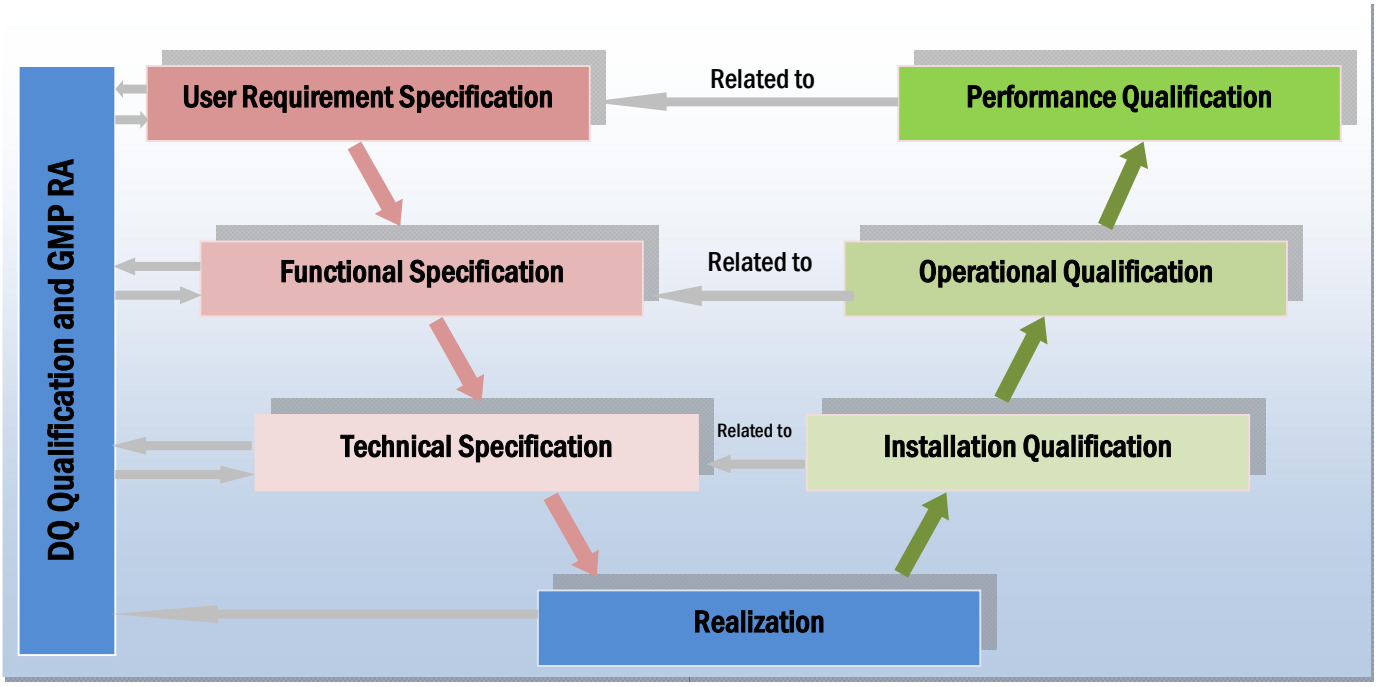
The main purpose of qualification is to establish documented evidence that equipment and ancillary systems are capable of consistently operating within certain limits and tolerances, prove and document proper design, installation and functionality and to ensure that systems and the entire production plant will meet pre defined requirements and ensures correct functionality with the guarantee to deliver the expected product quality.

It is the basis for cGMP practice and a precondition to meet regulatory and customer requirement. Raschka Engineering's design and qualification experience combined with several successful audit participations will make us a valuable service provider.

Some of the applicable qualification regulation and guidelines include:

- ICH Q7 GMP Guide for Active Pharmaceutical Ingredients
- US Code of Federal Regulation: 21CFR11/210/211
- EU GMP Guide
- Chinese "Good Manufacturing Practice for Pharmaceuticals" (edited version)
- ICH Q9 Quality Risk Management
- PIC/S PI 006-3
  Validation Master Plan Installation and Operational Qualification non-sterile process validation, cleaning validation
- International standards, e.g.
  clean rooms and associated controlled environments
- GAMP 5 published by ISPE (2008)
- ISPE Technical Guides

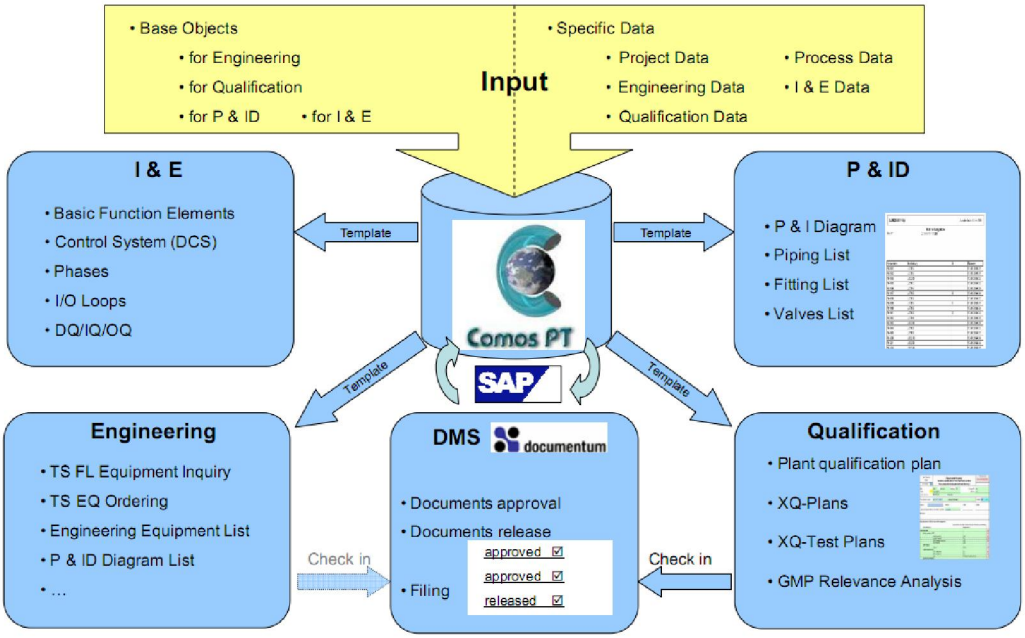
Qualification Strategy –– V Model



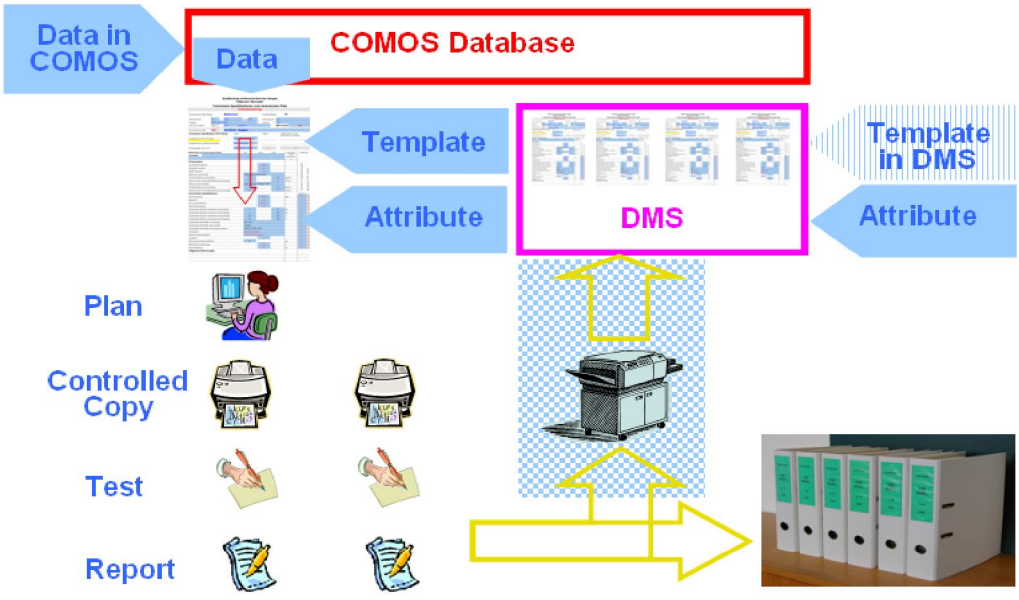
Computer Aided Qualification System: COMOS PT

A written validation protocol should be established that specifies how validation of a particular process will be conducted. Within Raschka China, COMOS PT is used to support a computer aided qualification system to establish the qualification documents enabling an integrated plant life cycle management and to facilitate qualification activities in general.

- Auxiliary tool providing a database which is accessible by different systems enabling management of changes in a single place
- Large numbers of qualification documents can be generated automatically
- Record and track qualification data and utilize data for maintenance plan
- Exchange data with SAP system



Database transportation of COMOS PT

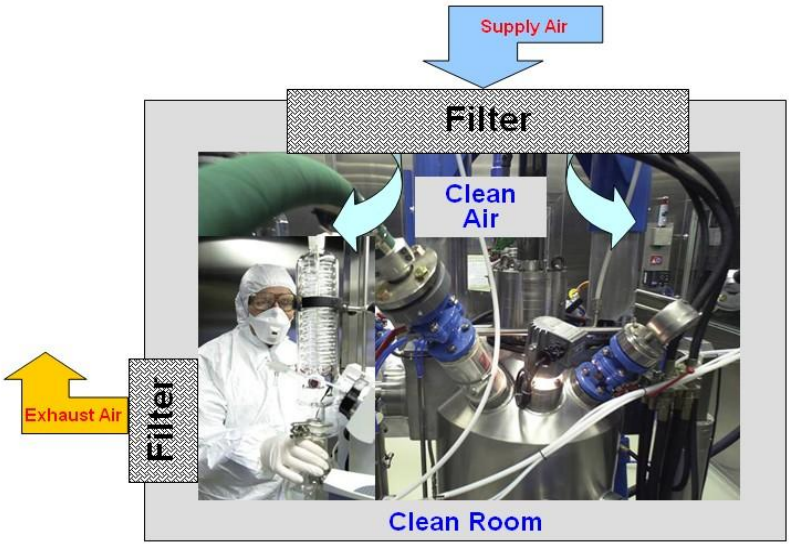


The qualification documents workflow with COMOS PT and DMS

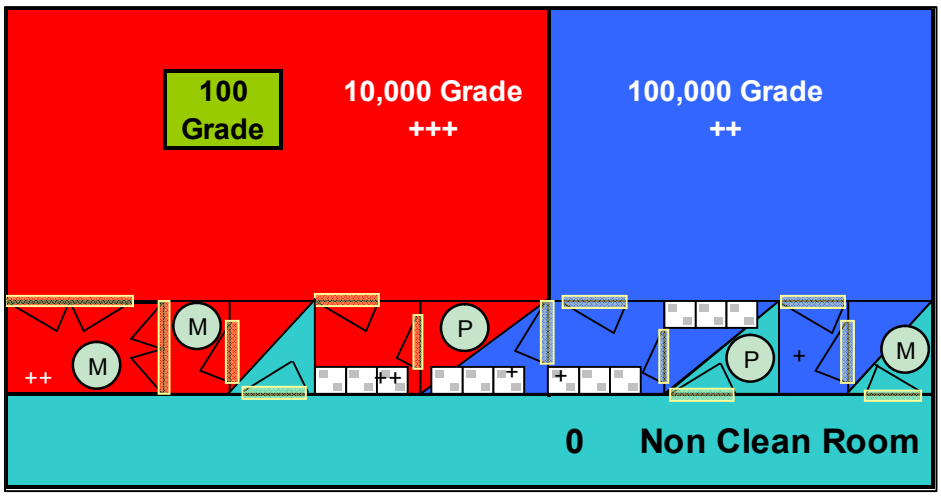
Clean Room Qualification

Key Points of Clean Room Qualification:

- High efficiency filter
- Temperature and relative humidity
- Air cleanliness
- Differential pressure and air exchange rate
- Sterilization

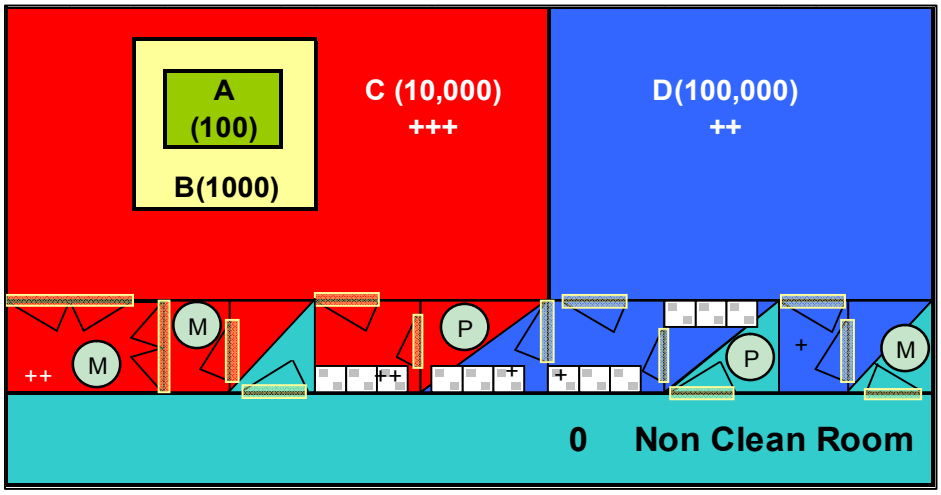


Clean Room Criteria for Chinese GMP



Not classified room
D Area (100, 000)
C Area (10, 000)
B Area (1000)
A Area
(100 unidirectional airflow)

Clean Room Criteria for EU GMP, USA-FS209

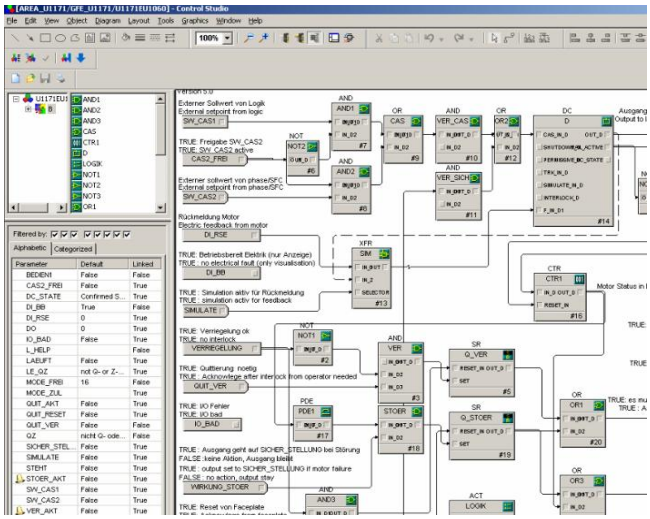


M Material Flow
P Personnel Flow
0 Atmospheres
\+ 5-12.5Pa
++ 10-25.0Pa
+++ 15-37.5Pa

Instrument Validation

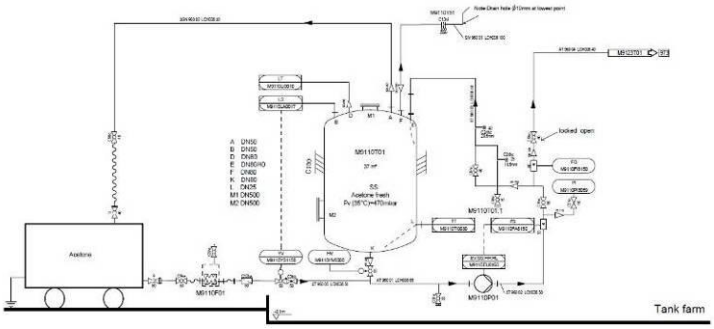
Instrument I/O loop test

Instrument calibration



Configuration structure

Instrument qualification on site



Version controlled P& ID Drawings

Computer/DCS Validation

Main purpose of computer/DCS validation is to produce evidence that a system will meet its specification. This definition does not refer to a computer application or a computer system but to a process. The main implications in this are that validation should cover all aspects of the process including the application, any hardware that the application uses, any interfaces to other systems, the users, training and documentation as well as the management of the system and the validation itself after the system is put into use.

Computer/DCS validation consists but is not limited to the following areas:

- System hard- and software
- Application software
- Alarms/events
- Historical data
- Loop test
- Back up
- Disaster recovery
- Diagnostics
- Logbooks
- User access
- Network / interfaces
-

Specifically for Computer/DCS Validation, the following industry guidance is available:

- 21 CFR Part 11
- Annex 11 of the EU GMP regulations (EMEA 1998)
- GAMP published by ISPE (2008) with category definition as outlined in tables below

Category	Description
GAMP 3	Standard software package. No customization. Examples: MS Word (without VBA scripts). Computer controlled spectrophotometers.
GAMP 4	Standard software package. Customization of configuration. Examples: LIMS, Excel spreadsheet application where formulae and/or input data are linked to specific cells. Networked data systems.
GAMP 5	Custom software package. Either all software or a part or the complete package has been developed for a specific user and application. Examples: Add-ons to GAMP Categories 3 and 4, Excel® with VBA scripts.

System	GAMP3	GAMP4	GAMP5
High risk	Test critical functions. Link tests to requirements.	Test critical standard functions. Test all non standard functions Link tests to requirements	Test critical standard functions. Test all non standard functions Link tests to requirements.
Medium risk	Test critical functions.	Test all critical standard and non standard functions Link tests to requirements.	Test critical standard functions. Test all non standard functions Link tests to requirements.
Low risk	No testing	Test critical non standard functions	Test critical non standard functions

In this context, Raschka Engineering's service could include:

- Integrated validation activities like DQ/IQ/FAT/SAT/OQ/PQ/ computer and DCS validation
- Instrument validation, mechanical qualification, process validation, cleaning validation, QC validation
- Establish change control system
- Establish your validation master plan based on CHP/USP/EUP standards
- Provide GMP relevance analysis
- Provide gap analysis and action list for your existing system
- Provide training for your in-house team
- Establish, evaluate and improve the quality management system in order to meet cGMP requirement

Please feel free to discuss your needs with our expert team, we would be very happy to share our experience in the field of qualification and validation, in order to help your organisation to achieve full cGMP compliance.

An extensive service list is available on our website: http://www.raschka-engineering.com

Raschka Engineering Ltd

Raschka Engineering Ltd. Liestal, Switzerland (previously known as Lonza Engineering) now reflects the superior and well known Raschka FBI technology in its name together with its wholly owned subsidiary Raschka Engineering & Consulting Co., Ltd, China provides customer oriented services with a professional, experienced and highly motivated engineering team. We have 20 years of successful project management experience in China which makes us a perfect partner for the chemical, pharmaceutical and biopharmaceutical industry. A board range of services with a project reference list underlining our capabilities is available upon request.

Raschka Engineering has successful managed multiple complex projects such as continuous operating plants for the production of food and feed additives as well as active pharmaceutical ingredient plants including waste gas and liquid waste treatment facilities.

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