Qualification Services

- Management of qualification services
- Qualification of new machines (Syntegon/non-Syntegon)
- (Re-)qualification of systems and devices for pharmaceutical production and packaging
- Risk-based determination of requalification scope and comparison with the last qualification
- Requalification after replacement of system control
- SCADA, PLC, and HMI updates including data migration
- Requalification after modifications
- Preparation of GMP and risk analyses
- SMEPAC testing
- Development and validation of H_2O_2 biodecontamination processes

Services provided during calibration include the following:

Calibration of:

- Pressure gauges, conductance sensors, temperature sensors, air velocities, humidity sensors, scales, belt speed, rotational speeds, surface speeds, load cells, ultrasonic sensors, filling depth on tablet presses, web height on pre- and main pressure roller on tablet presses, ejection force on tablet presses, pre- and main pressing force on tablet presses, capsule closing force determination, transfer force determination, powder bed height, torque, compressed air volume, spray rate, pH sensors, air volume flow, cycle frequency

Services provided in the context of (re-) qualification include the following:

1. **Installation Qualification (IQ):**
    - Verification of installation location, sequence of components, and connections
    - Review of documents, process-critical components against design documents, and their selection
    - Verification of the restoration of electrical connections, media connections, and piping for dead spaces/slopes
    - Inspection of machine layout, environmental conditions, parameters, and software
    - Conducting a hardware loop check

- Measurement and certification of surface roughness

2. Operational Qualification (OQ):

The following points are checked or verified:

- Calibration status, counting process, alarms, control and special functions, OQ readiness, AFT documentation, behavior in the event of a power failure
- System speed and light intensity in optical inspection
- Software: PC system backup, recovery, software tests (CSV), disaster recovery procedure (CSV)
- Ball drop station, room classification of isolators and UDAF areas, air velocity in isolator/UDAF system
- HEPA filter, isolator leakage test (pressure drop), H_2O_2 bio-decontamination system, airflow test in isolators/UDAF systems
- Ergonomics in barrier systems, differential pressure in the isolator, temperature control of the isolator
- Recovery time under UDAF systems/RABS, rotation test, liquid in ampoule tips, rejection function "Leak Detection"
- HVLD measurement system with reference standards, functional test of the crimping
- Room classification, airflow test, and air velocity in tunnels
- Differential pressure in the tunnel, inspection system at the rejection station, silicone application amount using sliding value determination
- Silicone layer thickness, ultrasonic bath on cleaning machine, water flow per spray needle
- Drainage of piping systems, residual water in glass objects, internal siliconization of glass containers with challenge substance
- Sanitization capability, heating and cooling rate, temperature distribution
- Production counter, machine room and product room thigtness, automatic feedback control in the production process

3. Performance Qualification (PQ):

- „"Headspace" leak test performance run

4. OQ/PQ:

The following points are checked or verified:

- Machine performance and transfer situation
- Data matrix code

- Cleanability of containers/apparatus using riboflavin (qualitative)
- Optical inspection: systems with defined patterns, function of rejection system, further qualification tests
- Leak testing and endotoxin load: headspace, washing processes, stoppers, dry heat
- Automated functions: pouch/tub opening, denesting/renesting, tray loading
- Piston rod insertion, labeling function, filling accuracy (vials, ampoules, cartridges, bottles)
- CIP/SIP functionality and process controls: in-process control scales, sampling, protective gassing
- Quality: crimping, screwing, stopper seating, ampoule height, dose-in/dose-out
- CIP with riboflavin, burning/sealing of ampoules, residual oxygen content
- Fill level in cartridges, mouse-hole protection, glove testing device, HVLD sorting test
- Temperature distribution in the tunnel, sterilizability of the cooling zone, black burner detection
- Cleaning effects (on an external cleaning machine): riboflavin, particles, P3-aquanta Blue, Cochineal Red A
- Drying effect: on the external cleaning machine and using the weighing method, washdown spray pattern with Cochineal Red A
- Stirring speed, emptying process in mixing tanks, filling accuracy for capsules and micro-dosed hard capsules

Statistics

Abbreviations Used:

1. **GMP** – Good Manufacturing Practice
2. **SCADA** – Supervisory Control and Data Acquisition
3. **PLC** – Programmable Logic Controller
4. **HMI** – Human-Machine Interface
5. **SMEPAC** – Standardized Measurement of Equipment Particulate Airborne Concentration
6. **H_2O_2** – Hydrogen Peroxide
7. **CSV** – Computerized System Validation

8. **HEPA** – High Efficiency Particulate Air
9. **UDAF** – Unidirectional Air Flow
10. **HVLD** – High Voltage Leak Detection
11. **RABS** – Restricted Access Barrier System
12. **CIP** – Cleaning in Place
13. **SIP** – Sterilization in Place
14. **P3-AQUANTA** – A cleaning agent used in the pharmaceutical industry.
15. **Riboflavin** – Vitamin B2, commonly used as a marker for cleaning processes
16. **HVLD Sorting Test –** Test for detecting leaks in packaging using high voltage leak detection