



BioPharma
Product Testing

A Journey of Facility Validation in Switzerland

Key learnings from real-world qualification projects

Shahbaz Arif

Head of Sales

Eurofins BioPharma Product Testing Switzerland AG

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Facility Validation: More than just testing

- Environmental Monitoring
- Utility & Water System Qualification
- Gas Testing: The often forgotten media
- Cleaning Validation

Facility validation looks simple on paper:
reality during qualification is very different.



Environmental Monitoring Qualification Phases

At Rest

- Equipment installed and ready
- No personnel present
- HVAC fully operational
- Focus on non-viable particles

In Operation

- Equipment running
- Defined number of operators
- Simulated or real activities
- Viable air, settle plates & surfaces



Key Challenges During Cleanroom Qualification

- Achieving ISO 14644 limits in In Operation conditions
- Impact of personnel behaviour and gowning
- Definition of meaningful sampling locations
- Alignment between QA, QC and Manufacturing
- High workload during OQ/PQ compared to routine monitoring



Compendial requirements (USP, EP and JP) of water grades used in the pharmaceutical industry

Pharmacopeia Requirements for Purified Water

	USP <1231>	Ph. Eur. 0008	JP
Conductivity (µS/cm)	< 1.3*	< 5.1*	< 2.1 ***
TOC (ppb)	< 500	< 500	< 500
Bacteria (CFU/mL)	****	< 100	< 100
Endotoxin (EU/mL)	NR	< 0.25**	NR
Nitrates (ppm)	NR	≤ 0.2*****	ND
Heavy Metals (ppm)	NR	NR	NR
Aluminium (ppb)	NR	< 10 **	NR

Pharmacopeia Requirements for Water for Injection

	USP <1231>	Ph. Eur. 0169	JP
Conductivity (µS/cm)	< 1.3*	< 2.1*	< 2.1 ***
TOC (ppb)	< 500	< 500	< 500
Bacteria (CFU/100 mL)	****	< 10	NR
Endotoxin (EU/mL)	< 0.25	< 0.25	< 0.25
Nitrates (ppm)	NR	NR	NR
Aluminium (ppb)	NR	< 10 **	NR

Same specifications apply for clean steam (CS) as per GMP-Annex 1 (microbial testing is not mandatory)

Legend

* Limit is for 25±1°C for stage 1 which is temperature dependent.

** if intended for use of dialysis solutions

*** preferred continues measurement of conductivity

**** in-house limits shall be established

***** Only if Conductivity failed

NR = not required

ND = not detectable

COMPENDIAL DIFFERENCES EXIST: RISK ASSESSMENT IS KEY

Water System Qualification: Typical Challenges

- Sampling strategy and route optimisation during PQ
- Risk of biofilm formation and system design limitations
- Training of sampling personnel
- Seasonal fluctuations of incoming water quality
- Fast turnaround times for trend evaluation



Gases in pharmaceutical industries

- **Process gases:** Air, N₂, CO₂, O₂
- **Utility gases:** Compressed air, nitrogen for blanketing
- **Mechanical / equipment gases:** Pneumatic actuation, instrument pressure, drying ovens (e.g., nitrogen)
- **Contact gases:** Headspace or fill gases (N₂, Ar) that remain with the final drug product (especially oxidation-sensitive biologics e.g mABs)



Compendial standards & guidelines

- **USP:** <1235> (Residual Solvents), <1079> (Microbial Limits)
- **Ph. Eur.:** Chapter 2.2.1 (Gases)
 - Monograph 1238 for Compressed ambient air (*Aer medicinalis*)
 - Monograph 0375 for CO₂ (*Carbonei dioxidum*)
 - Monograph 1247 for N₂ (*Nitrogenium*)
 - Monograph 0417 for O₂ (*Oxygenium*)
- **ISO:** ISO 14644-1 (Cleanrooms), ISO 8573-1 (Compressed Air Quality)
- **EU GMP Annex 1:** 4.23-4.32 (Cleanrooms and particles), 6.18 - 6.19 (Sterile manufacturing, gas purity requirements for aseptic processing)
- **FDA Guidance:** “Sterile Drug Products Produced by Aseptic Processing” (covers gas qualification)



Why Cleaning validation Matters

- Demonstrates that cleaning procedures consistently remove residues of APIs, intermediates, excipients and cleaning agents
- Prevents cross-contamination and protects operators and patient safety
- Satisfies regulatory expectations for product quality and compliance

Effective cleaning validation is essential for ensuring safe and reliable pharmaceutical manufacturing



Main techniques and solutions

- **TOC:** Rapid, broad-scope screening tool for generic residue detection.
- **HPLC:** Specific and quantitative for known compounds
- **Supplementary methods**
 - Surface swab sampling
 - extractable-level testing
 - mass-spectrometry-based analyses
 - Address challenging matrices and ultra-low-level detection needs



How We Support Facility Validation

Environmental & Utility Monitoring

- Cleanroom qualification (at rest / in operation)
- Water systems (PW, WFI, Clean Steam, Feed Water)
- Viable air, surfaces, particles & trending

Gas Qualification (microbiological)

- Sampling & testing of product-contact gases
- GMP-compliant documentation and CoA release

Cleaning Validation Support

- TOC-based screening approaches
- Microbiological residue assessment
- Risk-based support for validation strategies

Fast Turnaround & Project Peaks

- High-throughput capacity during OQ / PQ phases
- Same-day test initiation for critical parameters
- Local project management as single point of contact



365-Day Support & Late Shift Operations

- Laboratory **support 365 days** per year on request
- **Late-shift testing until 11PM** to maximize sampling windows
- Support for **weekend, holiday** and peak-phase activities

On-site Sampling & Swiss-wide Logistics

- Direct sampling or client sampling support
- **Same-day sample transport** within Switzerland
- Evening & weekend logistics available

Take-home Message

01

Facility qualification
causes workload
peaks
Plan resources
early

02

Gases are utilities,
but must be treated
as product-relevant
media

03

TOC is a powerful
tool when its
strengths and limits
are understood



BioPharma
Product Testing

Thank you

Eurofins BioPharma Product Testing Switzerland AG
2nd + 3rd Floor
Parkstrasse 10
5012 Schönenwerd
Switzerland

BioPharma.Switzerland@bpt.eurofinseu.com

Get in touch

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