REFERENCE

QUALIFICATION AND VALIDATION

THE TASK

A hospital operates a system for the central compressed air supply for medical compressed air. As part of the quality assurance and monitoring of the manufacturing process of the "air for medical use", EXCO validates the manufacturing process and qualifies systems and equipment according to current GMP, customer and normative requirements.

EXCO SERVICES

- Requirements specification
- Functional detailed specification
- GMP validation/qualification plan
- GMP risk analysis
- Qualification (DQ, IQ, OQ, PQ)
- Process validation (PV)
- Validation and qualification report
- Traceability matrix
- Supplier qualification
- Accompaniment of FAT and SAT acceptance phases

CLIENT BENEFITS

Achieving quality objectives
Measurements with electrochemical sensors and recordings and archiving of the measurement data mean the customer receives valid statements about their system's conformity.

Controlling suppliers
Supplier qualification ensures that the system and the equipment used are suitable in accordance with GMP guidelines.

Estimating risks
The systems and equipment are qualified and validated prospectively using a risk-based approach. This qualification and validation are integral parts of the product life cycle.

Training employees
EXCO provides employee training and external company training to ensure skills are transferred.

CLIENT:
Healthcare facility/Manufacturer of medical compressed air