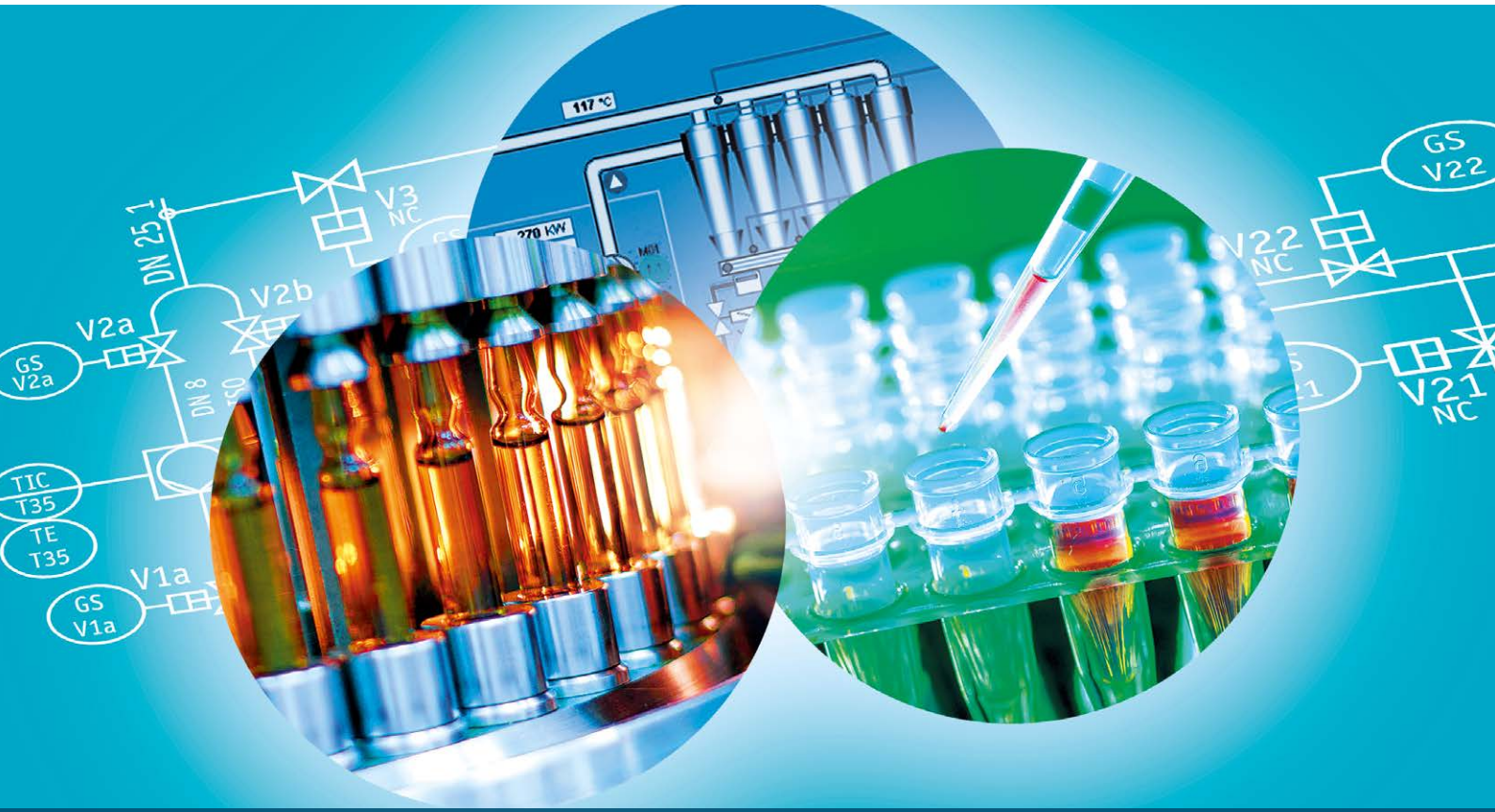
EXCO

EXCO. The Quality Company
Solutions for Industry and R&D

SOLUTIONS FOR PRODUCTION | LABORATORY | PROCESS



LIFE SCIENCE TECHNOLOGY

WE ENSURE COMPLIANCE IN PROCESSES AND DEVELOPMENT

Innovation shapes research and development in the life science and pharmaceutical industries. It is most important for manufacturing processes, methods, procedures and IT infrastructure to meet the special requirements.

We ensure safety, product purity, data integrity and conformity in process technology. We support our customers in engineering, validation, qualification and infrastructure. We secure GxP-compliance in manufacturing processes in the laboratory and clean room in order to meet international requirements.

EXCO solutions and services are based on the principles of good manufacturing practice. They elevate products and processes in the life science industries to the highest level.

Thomas Wolf
Partner, EXCO GmbH

CONTENTS

1| OVERVIEW OF SERVICES 4

2| FACTORS FOR SUCCESS 6

3| PROJECT REFERENCES 8

4| THE EXCO GROUP 18

MANUFACTURE

The qualification of equipment and systems as well as validation of processes and methods ensure good manufacturing practices.

SUPPLIERS

By evaluating and developing our suppliers, we are able to maintain conformity throughout the value-added chain.

LABORATORY

Our comprehensive scientific services for laboratory and analysis allow us to support quality assurance in lab and clean room.

INNOVATIVE

1| PROCESS SOLUTIONS

FOR OUR CUSTOMERS

EXCO ensures that manufacturing companies can concentrate on their core tasks. We offer our services specific to each individual sector – but often in the medical technology, pharmaceutical and life science industries. We validate your processes, design, automate and qualify your plant equipment and provide you with advice in accordance with guidelines and specifications – in all areas where quality and safety are of great importance.

PROCESSES AND PROCEDURES
Process validation
System qualification
Technical documentation
CAPA, change and risk management
Clean room qualification
GAP analysis und audits

LABORATORY AND ANALYSIS
Development of analysis methods
Method validation
Laboratory analysis
Chemical quality checks
Lab relocations

VALIDATION OF IT SYSTEMS
Validation-as-a-service
Interne Audits & GAP analysis
Requirements engineering

SOFTWARE DEVELOPMENT
Web, mobile & desktop applications
Client/server, database, cloud solutions
Modernization of software solutions
Software for safety-critical industries
Full stack development
Devops, agile development

INFRASTRUCTURE
Supplier development
QM systems - construction and maintenance
Selection and qualification of equipment

2| FACTORS FOR SUCCESS

FOR QUALITY-ASSURED PRODUCTS

Are you looking for a service partner who will continuously support your products on the market in a regulated environment (FDA, GxP, pharmaceutical legislation)? EXCO is at your side throughout your product's entire life cycle providing comprehensive services and ensuring that your process capability is maintained. This means that you receive ongoing support for any product, process and manufacturing changes.

Technology COMPETENCE

Proven through certificates and continuous training and the use of state-of-the-art technologies and methods.

We live QUALITY

This ensures your projects fulfilling the highest standards according to FDA, MDR / IVDR, ISO and GxP.

Your PARTNER

We provide remote support for the quality and punctuality of your projects with innovative solutions: reliable and worldwide.

On your SIDE

We are always close to our customers. Our employees work at eight sites in Germany and Switzerland.

3| PIONEERING PROJECTS

FOR OUR B2B CUSTOMERS

IMPLEMENTED COMPETENTLY AND FLEXIBLY

We have been supporting our customers from the pharmaceutical industry in the development and manufacturing of products for more than 25 years.

A selection of completed projects shows how successfully we work. We explain our approach using specific project examples. We are success and result-oriented in all services and solutions we offer.

More reference projects and details on the technologies we used on our website at:
www.exco-solutions.com

REFERENCES

1| CLEANING VALIDATION OF PRODUCTION PLANTS 9
Analytical method development - process validation

2| RE-VALIDATION OF ANALYSIS METHODS 10
Method validation - execution of validation - technical documentation

3| QUALIFICATION AND VALIDATION OF PLANTS 11
Qualification of plant and infrastructure media - process validation - CSV

4| QUALIFICATION AND VALIDATION IN HOSPITALS 12
Plant qualification - process validation - supplier qualification

5| CLEAN ROOM QUALIFICATION PHARMACEUTICALS 13
Requirements management - supplier development - plant qualification - process validation

6| LAB RELOCATIO'N "PRE-CLINICAL RESEARCH" 14
Method validation - execution of validation - technical documentation

7| COMPUTER SYSTEM VALIDATION (CSV) AS A SERVICE 15
Continuous CSV - technical documentation

8| CSV GAP ANALYSIS 16
GAP analysis - CSV - technical documentation - consultation - training

9| SOFTWARE DEVELOPMENT AND VALIDATION 17
Software development - software validation - CSV - technical documentation

REFERENCE 1

CLEANING VALIDATION OF PRODUCTION PLANTS

THE TASK

A manufacturer of diagnostic products wants to provide evidence of the optimal cleaning of its production facilities. EXCO is going to contribute its knowledge to identify potential process residues and develop an analytical method including representative sampling for qualitative cleaning assessment.

EXCO SERVICES

- Analytical method development for the quantitative detection of very low concentrations with limit values in the ppm range
- Creation of a residue profile
- Process FMEA
- Creation of validation protocol and report
- Execution of practical validation tests in the laboratory
- Chemical analysis
- Liquid chromatography with mass spectrometry coupling
- Training for representative sampling in ongoing production

CUSTOMER BENEFITS

Optimized methods
EXCO experts optimize and validate methods so that the customer can continuously monitor his cleaning processes.

Compliant processes
EXCO accompanies its customers on the way to compliant processes that comply with all current guidelines of the life science industry.

High level of personal responsibility
EXCO employees independently develop analysis methods tailored to the customer. One person is the point of contact from draft concept to validation report.

CUSTOMER:
Research-based pharmaceutical company that produces drugs and active pharmaceutical ingredients

REFERENCE 2

RE-VALIDATION OF ANALYSIS METHODS

THE TASK

A manufacturer of pharmaceutical products needs a revalidation of their analysis methods for the approval of raw and input materials, after the raw material supplier was changed. EXCO is to provide formal and documented evidence that the chemical analysis methods of the manufacturer are suitable for their intended purpose and that they fulfill all requirements.

EXCO SERVICES

- Planning of method validation
- Execution of preliminary tests
- Execution of validation in the customer's laboratory
- Technical documentation

KUNDENNUTZEN

Proven standards
By re-validating tried and tested procedures and methods, the customer can keep their technologies up to date.

Continuous validation
The successful synchronization of the validation in the laboratory routine meant our customer could maintain their routine analysis without any delays.

Technology used
- Gas chromatography / flame ionization detector
- LC-MS detector
- HPLC-UV-Vis detector
- Software solution: Empower, ChemStation

CUSTOMER:
Global pharmaceutical company

REFERENCE 3

QUALIFICATION AND VALIDATION OF PLANTS

THE TASK

A production company specializing in the manufacture of technical and pharmaceutical active ingredients intends to increasingly establish itself as a supplier to the pharmaceutical industry in the future. EXCO is to qualify the production plants and infrastructure media of the new production building with different systems according to GMP and validate the manufacturing process and the PCS7 control system.

EXCO SERVICES

- Qualification and validation coordination
- Execution of qualification and validation
- CSV validation
- Technical documentation: GMP qualification and validation documentation
- Supplier coordination

CUSTOMER BENEFITS

Advanced expert knowledge
In addition to planning and execution activities in the creation of documents, the manufacturer benefits from coaching and advice from EXCO. Proven GMP specialists transfer qualification and validation know-how to the customer's production environment.

Support for all suppliers
At EXCO, the customer has a contact person for the support and coordination of all suppliers involved up to complete GMP-compliant documentation of all systems. Each system is tested in its environment.

CUSTOMER:
Swiss production site of an international chemical company that produces active pharmaceutical ingredients

REFERENCE 4

QUALIFICATION AND VALIDATION IN HOSPITALS

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/qualification report
- Traceability matrix
- Supplier qualification
- Accompaniment of FAT and SAT acceptance phases

CUSTOMER 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 is an integral part of the product life cycle.

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

CUSTOMER:
Manufacturer of medical compressed air in a Swiss hospital

REFERENCE 5

CLEAN ROOM QUALIFICATION PHARMACEUTICALS

THE TASK

A manufacturer of industrially manufactured, patient-specific pharmaceutical infusion solutions is adapting its production environment to new requirements. As part of the project management, EXCO reduces the workload for the customer when procuring new cytostatic drug workbenches. The workrooms, the clean room and the cytostatic drug workbenches/ isolators are qualified by EXCO.

EXCO SERVICES

- Supplier development
- Requirements management
- Plant qualification: DQ, FAT, IQ, OQ, PQ
- Technical documentation
- Licensing support

CUSTOMER BENEFITS

Compliance
Relieving customers' workload through EXCO's expertise in QS regulations, GMP guidelines and legal specifications.

Supplier evaluations
Because EXCO examines and evaluates quality management, processes and documentation of the suppliers, it's easier for manufacturers to select standard-compliant suppliers.

Consistent documentation
As a proven partner for validating processes and qualifying systems, EXCO ensures traceable and consistent documentation of all sub-processes in the supply chain.

CUSTOMER:
Pharmaceutical manufacturer in Switzerland

REFERENCE 6

LAB RELOCATION "PRE-CLINICAL RESEARCH"

THE TASK

Areas from four existing buildings are to be relocated to a new building with approx. 36,000 m² gross floor area on seven floors within six weeks. Approx. 4,000 items (excluding consumables and documentation) are to be removed from 350 workstations in the in-vitro and in-vivo laboratories (approx. 140 rooms) of the preclinical pharmacology with a focus on cardiovascular research.

EXCO SERVICES

- Drafting a master plan for the relocation
- Creation of a packaging concept
- Safety concept for radiation protection area
- Drawing up a risk-based emergency plan
- Damage management
- Initiation and coordination of the relocation

CUSTOMER BENEFITS

Validated relocation
EXCO applies the principles of a "validated relocation" using tried-and-tested process plans and checklists. The customer is given one contact person to coordinate the large amount of people involved in the process.

Reliable project and time planning
EXCO demonstrates knowledge of equipment and organizational processes in modern biomedical research as well as in-depth process knowledge and experience with "laboratory relocations" in a regulated environment (e.g. pharmaceutical and medical device industry and clinical research institutions).

Risk-based project management
Based on risk assesment all the requirements of the regulated pharmaceutical industry are met - and that largely without any loss of time.

CUSTOMER:
Preclinical research lab of a global pharmaceutical company in Germany

REFERENCE 7

COMPUTER SYSTEM VALIDATION AS A SERVICE

THE TASK

A customer needs a continuous CSV service to keep their computerized systems valid in the long term. A proprietary, highly-complex logistics system, which has to be regularly adapted and expanded due to regulatory requirements and internal optimizations, should maintain its validity within EXCO's "Validation-as-a-Service" model. Due to the criticality of the process and the products and types of delivery to be shipped, there's no room for malfunctions or failures during the productive operation.

EXCO SERVICES

- Conception of a life cycle validation strategy
- Ensuring ongoing valid operation
- Support for all releases
- Documentation as per customer specifications

CUSTOMER BENEFITS

Obtaining valid state
Thanks to constant support from qualified CSV specialists, regulatory requirements are continuously fulfilled.

Calculating costs
A service contract with fixed rates means customers can reliably plan their expenses to maintain their valid systems.

Scaling team strengths
By temporarily adjusting the team strength for unplanned projects, optimal capacity is always available.

From a single source
EXCO organizes and covers all topics of validation so that the customer can outsource all tasks and activities to a competent partner to maintain the valid status of its system.

CUSTOMER:
US corporation with a focus on medical engineering, laboratory diagnostics and pharmaceuticals

REFERENCE 8

CSV GAP ANALYSIS

THE TASK

A company in the pharmaceutical sector is starting to develop its own software. There is a lack of clarity as to whether all regulatory requirements have been or will be correctly implemented. EXCO carries out a GAP analysis, identifies points that need to be adjusted and, if required, will support the implementation of these points.

EXCO SERVICES

- Performance of the GAP analysis
- Creation of a review report
- Identification of recommendations
- Consultation on implementing regulatory guidelines
- Implementation of regulatory guidelines
- Execution of CSV and GxP workshops
- Compliant with 21 CFR Part 11 / Annex 11 / GAMP5

CUSTOMER BENEFITS

Uncovering gaps
The GAP analysis provides clarity about both weaknesses and strengths. This means that the current status can be recorded and plans can also be implemented for the future.

Compliance
EXCO highlights potential for improvement so that regulatory requirements can be fulfilled.

Maintaining lasting validity
EXCO actively supports the implementation of any recommendations it identifies and trains the customer's employees in how to sustainably implement the regulatory requirements.

CUSTOMER:
A well-known company for pharmaceutical services

REFERENCE 9

SOFTWARE DEVELOPMENT AND VALIDATION

THE TASK

A self-developed, historically grown desktop application (legacy system) for managing product and batch information for maintenance and operation with heterogeneous data sources is to be replaced by a modern and globally available web platform using .NET technologies. The entire project must be implemented to conform with processes and the law and documented according to the customer's specifications. All production sites, sales and service employees need to have access to this information. Due to the sensitivity of the information stored, high standards for data storage, data access and security must be maintained.

EXCO SERVICES

- Complete package: development, testing, coordination
- Requirements engineering (workshop)
- Project management
- .NET web development
- Software validation

CUSTOMER BENEFITS

From a single source
EXCO offers developing, testing and validation from a single source

Homogeneity
Technical documentation and developing is in line with the customer's guidelines

Data integrity
EXCO is using central data management and authorization concepts and modern security mechanisms

Compliance
Software is compliant to FDA CFR 21 Part 11

CUSTOMER:
Global pharmaceutical company

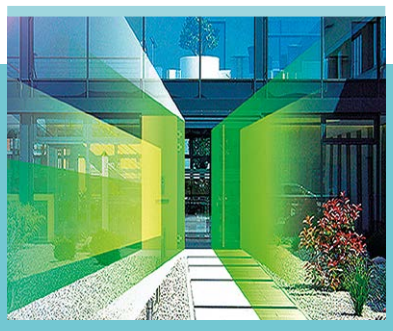
OUR COMPANY

For more than 25 years, market-leading companies, system suppliers and hidden champions have trusted excellent and interdisciplinary teams to handle projects

- in medical engineering,
- in the pharmaceutical industry,
- in bio-technology
- and in the chemical industry.

Whether you need advice, project work, service or turnkey solutions for your company: As a service provider with industry experience, EXCO delivers tailored service packages wherever products and processes need to meet the highest requirements in terms of quality, efficiency and process reliability.

EXCO GMBH



EXCO PCC GMBH

EXCO CONSULTING GMBH

3 companies – 1 goal: Satisfied customers

Talk to us!

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+ 230
COMMITTED EMPLOYEES

+ 30
PARTNERS IN NETWORKS

+ 8
SITES CLOSE TO CUSTOMER

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