EXCO

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

SOLUTIONS FOR DEVELOPMENT | APPROVAL | PRODUCTION

MEDICAL ENGINEERING

WE MAKE

MEDICAL DEVICES

SAFE AND RELIABLE

The medical technology industry is developing rapidly. We provide our customers with support to develop and manufacture medical devices, contributing to faster and safer market launches.

Are you looking for a reliable partner to accompany you from the product idea to approval and product maintenance? We offer tailored support in the development and marketing of medical devices. We ensure quality and safety during the manufacturing and testing processes.

We are proud to be able to ensure product and production quality in the healthcare sector.

Thomas Wolf
Partner, EXCO GmbH

CONTENTS

DEVELOPMENT

We will develop your product and project concepts using agile development methods.

PRODUCTION

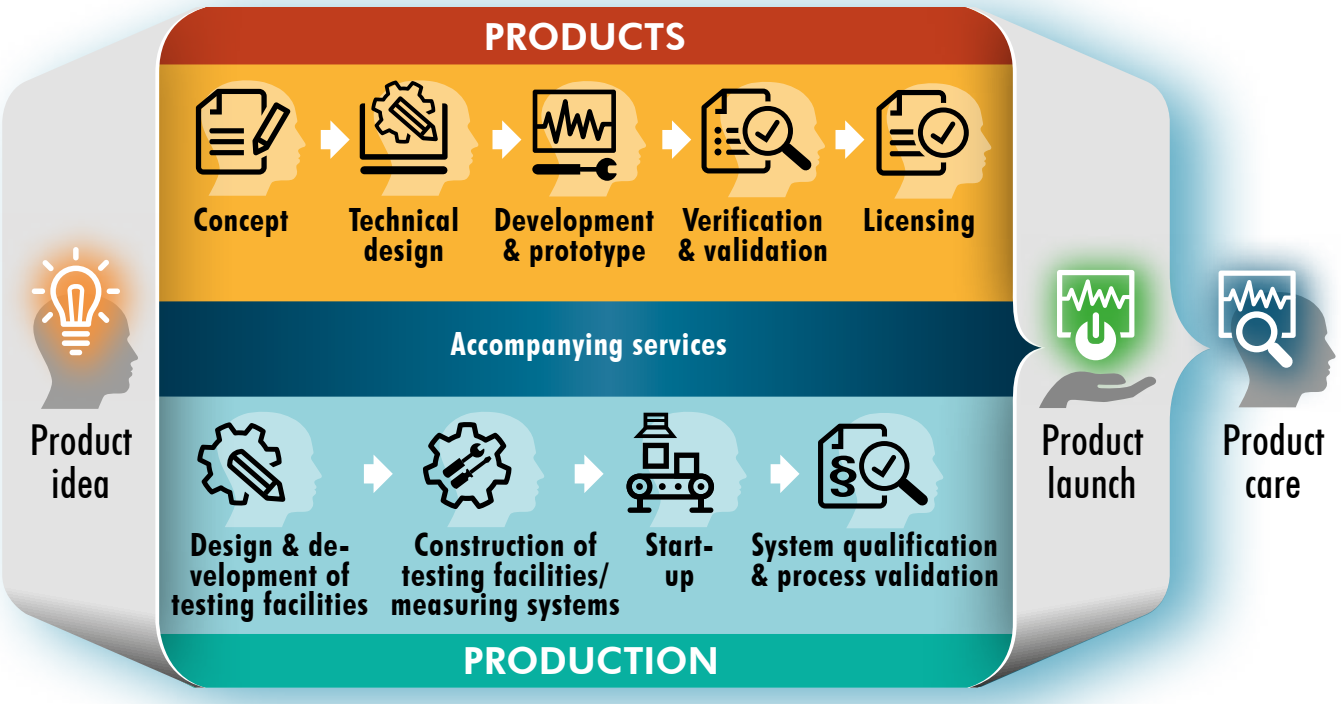
From prototype to test stations in fully automated production lines, we ensure that your manufacturing processes are optimized.

QUALITY

Standards-compliant quality assurance enables market placement of your medical device.

TECHNICAL 1| SOLUTIONS FOR OUR CUSTOMERS

Are you looking for a development partner for complex medical devices? EXCO offers the full range of support in design, development and verification for medical technology. We are ISO 13485-certified and manufacture test facilities and production equipment for medical devices and in-vitro diagnostics.



EXCO is a solution provider for sophisticated development services in the medical technology industry. From the feasibility study to product maintenance, we support you with innovative solutions during the product development process and creation of your modules and components. As a service provider, we offer support throughout the entire life cycle and product maintenance of a product.

RANGE OF SERVICES

PRODUCT SOLUTIONS

- Product and component development
- Prototype development and construction
- Design verification for soft- and hardware
- Hardware development
- Licensing documentation
- Consulting (software life cycle)
- QM system service (development, optimization, rollout)

VALIDATION OF IT SYSTEMS

- Development of test strategies
- Manual & automated software tests
- Test and specification management
- Requirements engineering
- Internal audits & gap analyses
- Validation as a service

SOFTWARE DEVELOPMENT

- Web, mobile & desktop applications
- Full stack web development
- Modernization of software solutions
- Technology evaluation
- SW for safety-critical industries
- SW for medical devices
- IT project management
- Long-term support

PRODUCTION SOLUTIONS

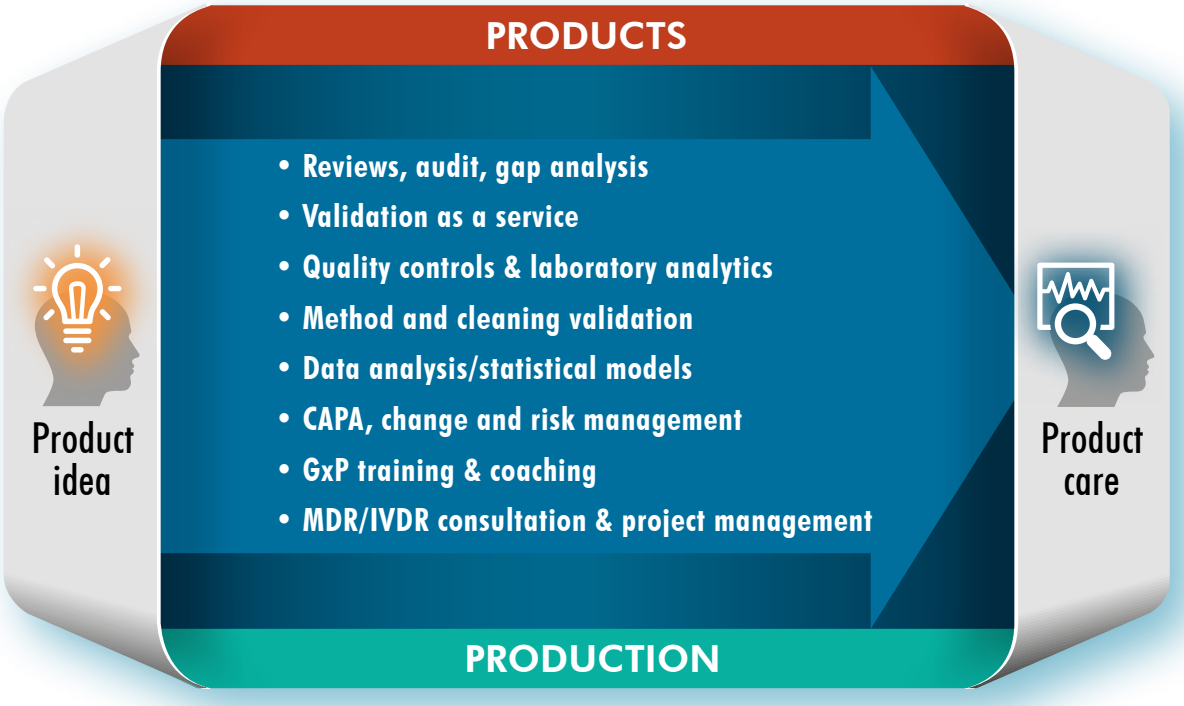
- Development of testing systems
- Design and production of testing facilities
- System qualification
- Process validation
- Technical documentation
- Machinery safety evaluation

SCIENTIFIC SERVICES

- Laboratory analytics
- Development of analytical methods
- Validation and qualification
- Immunassay development
- Clinical studies
- Chemical quality checks

OUR SERVICES FOR YOUR PRODUCT

Are you looking for a service partner who will continuously support your products on the market? EXCO is at your side throughout the entire life cycle of your product providing comprehensive services and ensuring that your product file is well-kept and your process capability is maintained. This means that you receive ongoing support for any product changes, process changes and manufacturing changes.



2| SUCCESS FACTORS
FOR QUALITY-ASSURED PRODUCTS

You can always rely on our employees. Our interdisciplinary teams ensure a flawless interplay between mechanics, pneumatics, electronics and software. They guarantee fulfillment of all regulatory requirements due to their high degree of testing competence.

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.

We are 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

For more than 25 years, EXCO has been supporting developing and manufacturing customers in medical technology.

Here, you will find a selection of completed projects to highlight how successfully we work. We will explain our procedures to you using specific project examples. We focus on success and results in all that we do.

More reference projects and details on our website at:

www.exco-solutions.com

REFERENCE

GLOBAL PRODUCT INFORMATION SYSTEM AS WEB APPLICATION

THE TASK

A self-developed desktop application for managing product information on maintenance and operation with heterogeneous data sources needs 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. It must be documented according to the customer's specifications.

EXCO SERVICES

- Development of the application
- Test and documentation of the application
- Requirements engineering
- Project management
- .NET web development
- Software validation

CLIENT BENEFITS

Homogeneity
The new application is developed in compliance with regulatory requirements and according to our customer's own specifications.

Data integrity
Efficient data integrity is made possible by central data management and authorization concepts.

Compliance
The application complies with the requirements of FDA CFR 21 Part 11.

Rapid releases:
EXCO can provide development, testing and documentation of the application from a single source for its customers. This enables short release cycles.

CLIENT:
Globally active Swiss group with a focus on diagnostics, medical technology, laboratory diagnostics and pharmaceuticals

REFERENCE

SOFTWARE FOR MEDICAL TEST SERIES

THE TASK

In the laboratory environment, a tailored PC software suite is required to carry out measurement series and studies as part of the medical device development. The software is intended to control several identical device prototypes in parallel, the measurement results of which are automatically read out, summarized in study series, documented and exported to third-party programs.

EXCO SERVICES

- Project management and system design
- Software development
- Tests and commissioning
- Creation of documentation and training documents

Microsoft Partner
Microsoft

Gold Application Development
Gold Windows and Devices

CLIENT BENEFITS

Rapid iterations
New software versions of the highest quality with regression and integration tests every two weeks. The software is developed alongside the device. Short-term adjustments are possible immediately, new releases and hotfixes are available without delay.

Modern tool landscape
The agile software development according to Scrum is fully supported by a modern tool landscape, adapted to the project requirements and is flexible and efficient due to a high degree of automation.

Technically demanding solution
The modern, expandable and testable architecture processes large amounts of data quickly. An automated build and deploy pipeline is the basis for successful solutions.

Experienced partner
EXCO is a Certified Gold Partner of Microsoft.

CLIENT:
Global medical device manufacturer

REFERENCE

DESIGN VERIFICATION FOR A POINT-OF-CARE DEVICE

THE TASK

A medical device manufacturer is developing a new diagnostic glucose measuring device for point-of-care testing for professional applications. EXCO provides the customer with support during the development by verifying the new device's hardware and software.

EXCO SERVICES

- HW verification tests: Planning, specification and execution
- Hardware design of the analog front end in PSpice, worst-case simulations and tolerance analyzes
- Coordination and support of the device tests in external laboratories
- Software for verification tests: definition, specification
- Creation of the test framework for manual and automated software tests
- Source code and document reviews

CLIENT BENEFITS

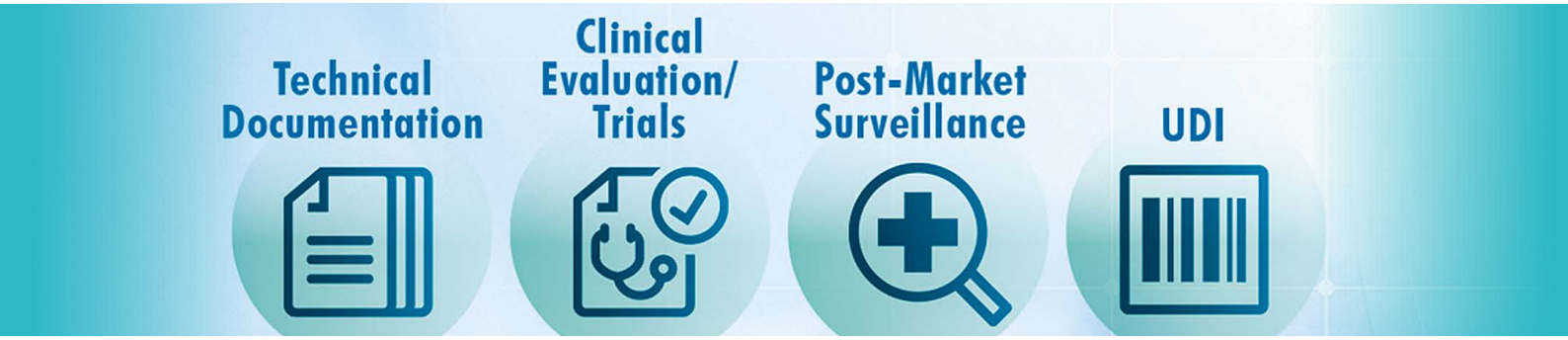
Reliable execution
On-site hardware verification includes the coordination or execution of tests in the customer's own or accredited test laboratories (EMC, climate simulations, mechanical tests, etc.).

Customer-focused design verification
Our experienced teams carry out hardware and software verification for embedded systems, complete medical devices or PC-based medical devices flexibly and in proximity to our customer.

Compliant documentation
The test specifications are created in accordance with the currently applicable regulatory requirements.

Safe product launch
Due to EXCO's extensive product knowledge, your product is launched safely in a much shorter time scale.

CLIENT:
Manufacturer of in-vitro diagnostic equipment



REFERENCE

MDR PRODUCT LICENSING

THE TASK

The new European Medical Devices Regulation (MDR) introduced considerable changes to approvel requirements for medical devices in Europe. EXCO is advising a medical device manufacturer on fundamental changes and requirements of the new regulation (EU) 2017/745 on medical devices and provides services for the legally compliant implementation of the new requirements for development, production and marketing processes.

EXCO SERVICES

- Consultation for MDR/IVDR requirements
- GAP analysis QM system
- Development and optimization of QM systems according to currently valid specifications
- Risk management 14971
- Employee training
- Compilation of product-specific standards and guidelines
- Creation of technical documentation
- Audit support

CLIENT BENEFITS

Harmonized QM system
The customer receives a QM system that is harmonized on the basis of DIN EN ISO 13485:2016 and the European Medical Devices Regulation (MDR).

MDR readiness
Our EXCO-MDR specialists are available at short notice, which provides our customer with a knowledge advantage so that their product meets all regulatory requirements.

Optimized risk management
As an experienced service provider for risk management according to ISO 14971:2019, EXCO provides its customers with support for risk management during the development and life cycle of a product.

Safe market launch
EXCO's knowledge guarantees the safe, efficient and timely marketing of the customer's product.

CLIENT:
Manufacturer of medical devices

REFERENCE

MANUAL TEST STATIONS FOR MEDICAL PNEUMATIC VALVES

THE TASK

A manufacturer of medical pneumatic valves that are used in ventilators is replacing the test stations used in production with modern test systems. EXCO is providing support with a complete solution including development, implementation and qualification of the entire test station.

EXCO SERVICES

- Test station concept
- System architecture
- Electronics development
- Pneumatics development
- Mechanical design *
- Complete construction *
- Test station framework
- Qualification (DQ, IQ and OQ)

* in cooperation with external partners

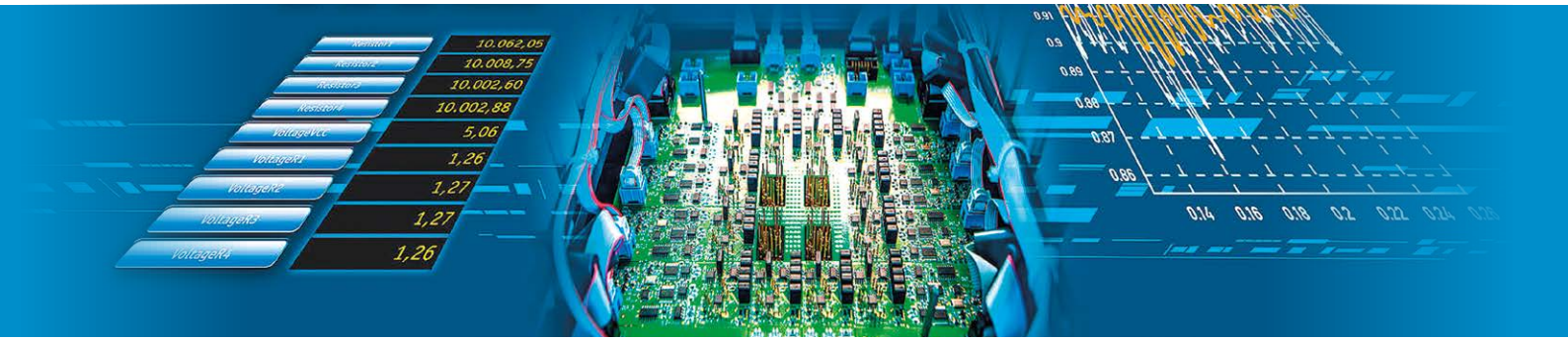
CLIENT BENEFITS

Integrated systems
As a system integrator, EXCO ensures the perfect interaction of measurement technology, software, electronics and mechanics in embedded systems and devices in medical technology.

State-of-the-art technology
The test systems developed by EXCO represent the latest software-controlled measurement and testing technology, optimally adapted to the task.

Shorter time-to-market times
are achieved through the flawless interaction of regulated development processes and the qualification of equipment in the production environment.

CLIENT:
Manufacturer of ventilators



REFERENCE

FULLY AUTOMATED FUNCTION TESTER FOR PCBs

THE TASK

A customer needs function testers for the circuit boards used in blood glucose meters for his production line. EXCO is commissioned with the iterative development of the function tester and creates a test setup for manual testing for development and debugging, a semi-automatic tester for functional models, prototypes and the first batches as well as a fully automatic tester that is integrated into a production line with a unit capacity of 20 million units/year.

EXCO SERVICES

- Development of test strategy, test concept and system architecture
- Development of test adapter incl. signal adjustments, interfaces
- Switch cabinet design and construction
- CE declaration of conformity
- SW architecture, SW design, implementation and test
- On-site start-up (FAT and SAT), product care and maintenance
- Complete qualification (DQ, IQ and OQ)

CLIENT BENEFITS

Use synergies
The coordination effort for the customer is reduced by the provision of development, implementation and qualification from one single source, creating synergies.

Dynamic development process
As part of the V-Model, development periods are divided into phases, thereby enabling the iterative approach with agile approaches.

Short development times
The iterative approach and the use of a framework developed by EXCO for manual, semi-automatic and fully automatic testing enabled the development time to be shortened.

Cost reduction
With modular test frameworks in test bench construction, the development effort could be significantly reduced and costs were thereby lowered.

CLIENT:
Manufacturer of blood sugar meters

REFERENCE

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, the products and types of delivery, malfunction and failure in productive operation must be prevented.

EXCO SERVICES

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

CLIENT 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 his system.

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

REFERENCE

CLEANING VALIDATION OF PRODUCTION FACILITIES

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

CLIENT BENEFITS

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

Compliant processes
As a specialist for regulated industries, EXCO accompanies its customers as they work toward 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 responsible for the project is the point of contact from the draft concept to the validation activities and validation report.

CLIENT:
Global life science company

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

REFERENCE

METHOD DEVELOPMENT FOR LABORATORY DIAGNOSTICS

THE TASK

A customer wants to develop new diagnostic methods on the basis of biological markers. In point-of-care devices, biomarkers should be proven with a specific method through standardized reaction procedures. The customer entrusts EXCO with project tasks in the context of test strip development and the development of biochemical measurement methods.

EXCO SERVICES

- Development of biochemical measuring methods in connection with the minimization of interferences
- Immunassay development, assay configuration
- Chemical analysis and evaluation of input materials (purity, contamination, enzyme activity)
- Order analytics and documentation
- Construction and composition of a test strip in sample production
- Execution of function tests with the constructed test strips

CLIENT BENEFITS

Advanced expert knowledge
Qualified EXCO specialists work on the cutting edge of technology and GMP-relevant regulations.

Compliant methods
The existing customer methods are now validated in accordance with the current guidelines of the life science industries.

One contact person
One person responsible for the project, from the concept draft to laboratory activities and the final report.

Shorter development times
EXCO employees are responsible for carrying out the laboratory analysis and the customer receives reliable information about the suitability of newly developed measurement methods and can significantly shorten their product's development time.

CLIENT:
Manufacturer of medical devices and diagnostic equipment


// Handle all requests in queue.
iterRequestQueue = m_queueRequest.begin();
while (m_queueRequest.end() != iterRequestQueue
Step7
S1 N MW2
MW2
T3
Trans3

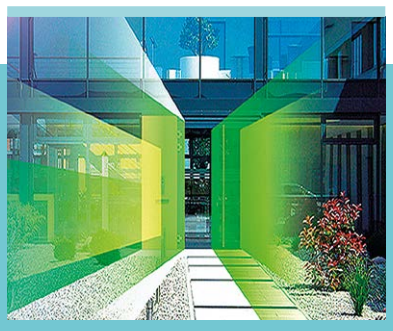
OUR 4| COMPANY

For more than 25 years, market-leading companies, system suppliers and hidden champions have trusted excellent and interdisciplinary teams for support in

- Technical design
- Development and verification
- Production
- Lab work
- Qualification and validation
- through to product launch and beyond.

Whether you need consultancy, project work, service or turnkey solutions for your company: as a service provider with industry experience, EXCO delivers tailored service packages in medical technology 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
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