

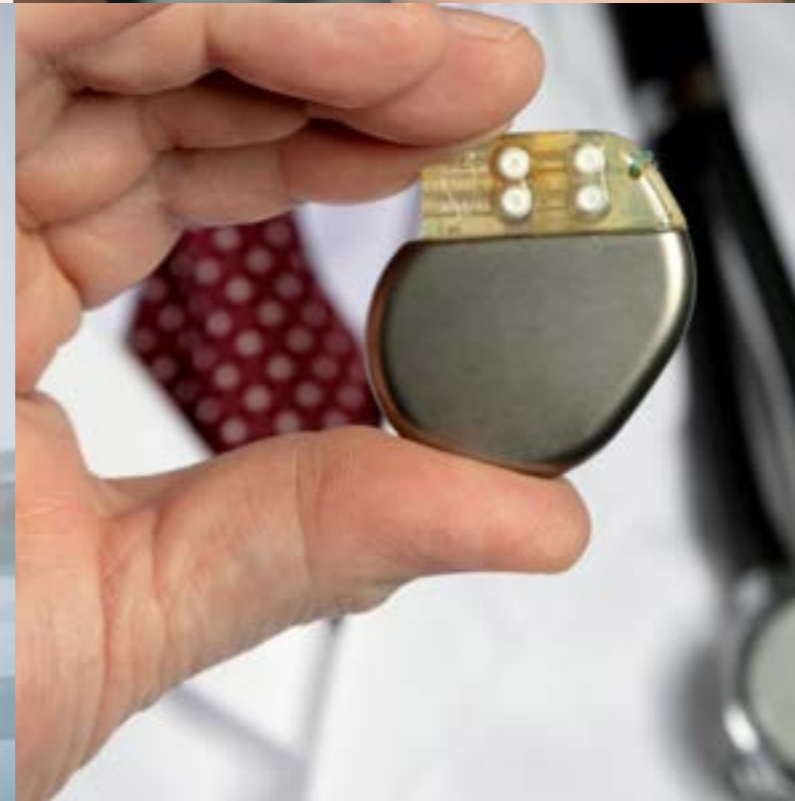


ASYS
GROUP

LIFE SCIENCE

Automation Solutions for the Life Science Industries

High-end engineering for your automation task



Life Science

Automation Solutions for the Life Science Industries

Increasing life expectancy combined with new possibilities of diagnostics and therapeutics offers new opportunities to help patients worldwide. Automation in the Life Science Industries is the key lever to reduce costs while increasing quality. We offer comprehensive and GxP-compliant machines and process solutions from one source.

ASYS Applications for the Life Science Industries

Medical Electronics



We have delivered various solutions for the manufacturing of medical electronics such as sensor technology for blood gas analysis at the point of care (POC), sensors for blood pressure monitoring or systems enabling continuous monitoring of blood glucose levels. We have also realized test systems for medical devices or the production of control units for hospital equipment.

Diagnostics



Fast and reliable test cartridges are required for the comprehensive diagnosis of microorganisms. We supply efficient and reliable production systems for manufacturers of diagnostic tests (IVD, POC, PCR, ...), who are required to manufacture these in accordance with ISO 13485 or FDA 21 CFR Part 820. On our ASYS systems, sophisticated consumables can be produced in a matter of seconds.

Wound Care



In the production of wound care material, there are challenging tasks. The printing of silicone strips on variable wound pads is one of them. Due to our competences in handling and thick-film printing on flexible wound pads, companies in this market segment trust us. We automate your processes around the production of high-end wound pads.

Pharmaceuticals



We also realize the automation of pharmaceutical production with our ASYS systems. This ranges from handling tasks when loading and unloading containers and trays, continues with stacking of glass vials for pasteurization processes and ends with the production, labeling and palletizing of combination packs.

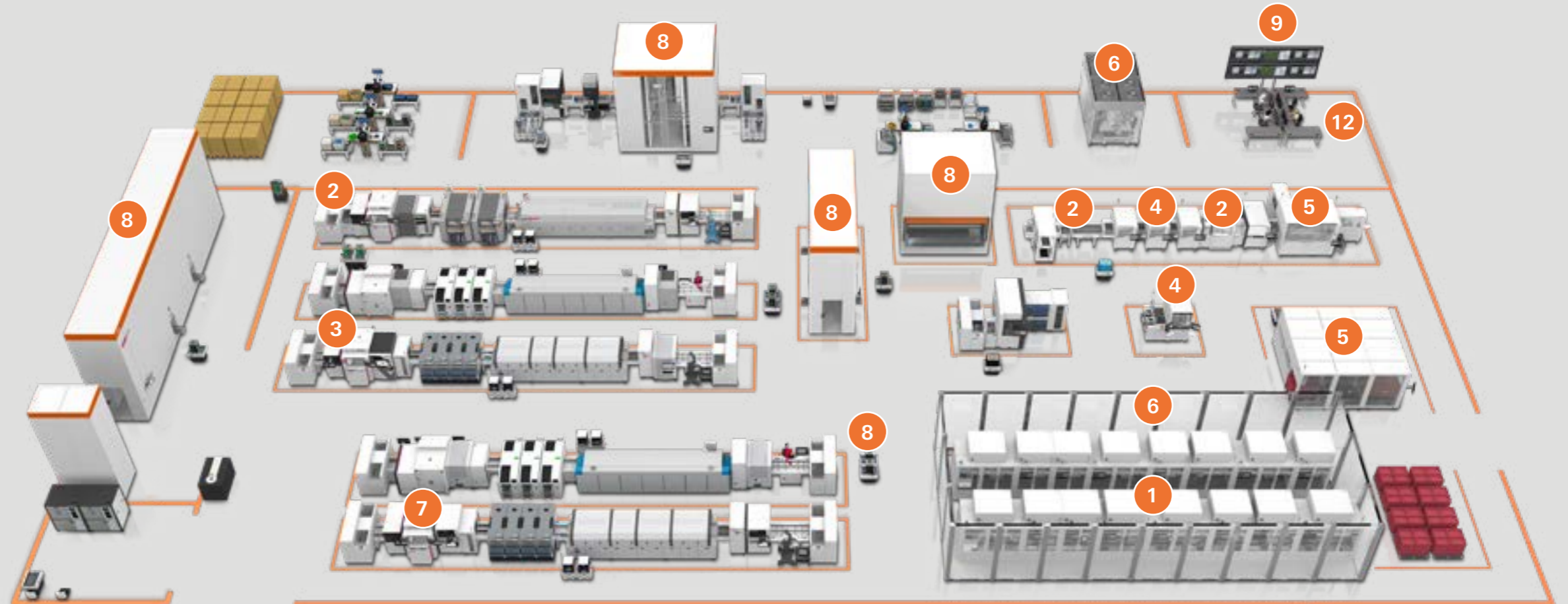
Implants



Implants, mostly class III medical devices, require special care in their manufacturing. Components for pacemakers or hearing implants, for example, are produced and tested on our ASYS systems. Our systems are also used to package class IIIb medical products, such as knee joints or ceramic hip joints, or to mark them with a Unique Device Identification (UDI).

Automation Solutions for the Life Science Industries

On our way to the Smart Factory, we offer solutions for all branches. This also includes the automation of products for the Life Science Industries. Whether individual standard machines, customized solutions or turnkey lines for assembly, handling and packaging processes – we are your competent partner: from the initial idea up to the finished production line for the manufacture of medical technology products.



Validated Assembly Solutions for Medical Devices

For many years, ASYS has been solving assembly tasks for customers in a wide range of industries such as automotive, consumer goods or industrial products.

In the INVENTUS product division, we have combined multiple automation processes and technologies to create customer-specific solutions. We have developed an assembly

platform especially for the Life Science Industries and tailored it specifically to the requirements of the regulated industry. In doing so, we use modules from all business areas. This helps us to provide a process-safe and GxP-compliant solution in a short time. We realize complete assembly lines and plants from one source.

✓ **More than 30 Years of Experience in Automation**
Since 1992, customers worldwide have trusted our solutions.

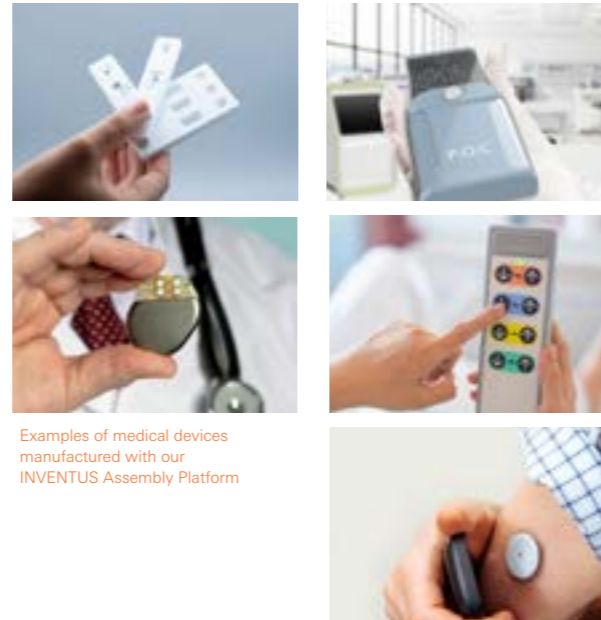
✓ **Turnkey Solutions**
We develop and realize your manufacturing solution.

✓ **Everything from One Hand**
We provide complete assembly lines and plants from a single source.

Assembly Platform

The assembly platform was developed in close cooperation with customers from the medical technology sector and meets the GxP regulations for production in the environment of both 21 CFR Part 820 and ISO 13485. Through the deliberate modular design, the highly flexible platform allows customized automation solutions in short project durations.

The frames are pre-configured and can function as individual cells or as part of complete assembly lines. The process components (robotics, testers, laser applications, handling, etc.) are mounted on the base plates and aligned with the highest precision: accuracies of $< 10 \mu\text{m}$ @ 6 sigma and greater can be achieved.



Examples of medical devices manufactured with our INVENTUS Assembly Platform



Customized Solutions for a Wide Range of Processes



Laser Marking



Labeling



Testing



Depaneling



Tray Load/Unload



Press-Fit



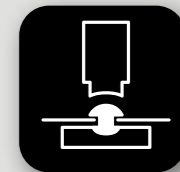
Feeder Solutions



Screwing



Tray Handling



Riveting



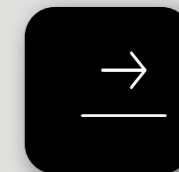
Plasma Cleaning



Dispensing / Potting



Resistance Welding



Transport



Laser Welding



Laser Cleaning



Laser Depaneling



Laser Cutting



Laser Reflow Soldering

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Handling



We handle components as well as assembled parts or packaged products. We transport or stack them in controlled or clean rooms. In this way, we reduce distances and personnel costs as well as increase quality and production volume.

3

Laser Marking



Laser processes enable the highest precision and reduce mechanical stress to a minimum. With our POLYPHOS series, we can process almost all conceivable materials using a wide range of laser processes. For example, our customers use our solutions for marking polymers like IVD casset-

tes, hand controllers for hospital beds and test cartridges. Our solution not only enables high-resolution, high-contrast and precise marking, but also ensures patient safety, as no toxic particles are deposited on the product during the marking process.

Besides the direct marking of cardiac pacemakers and defibrillators, we also face the requirements for the production of implants with machines from the POLYPHOS MK series, for example. Two 6-axis robots unload the ceramic hip implants from a tray loader and place them in the laser marking area. The marked data verification is done by two integrated cameras.



Broad Variety of Testing Solutions

We develop and integrate a wide variety of tests for the manufacturing processes as well as vision checks, leakage tests or functional tests. If required, machines can be delivered in compliance with FDA 21 CFR Part 11.

For example, we have implemented advanced test systems for cardio management devices (e.g. pacemakers, defibrillators, ...) After carriers with the device are fed into the system, different tests are performed: For example, we test for resistance

against vibrations, temperature resistance at body temperature or functionality. After the tests, the devices are sorted into good and bad containers or magazines depending on the test results.





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Fully Automated Palletizing & Trayloading Solutions

We use our expertise in handling components, trays and pallets on a daily basis to perfect the automation process. For this purpose, we rely on our standard product PARIO, although we can adapt it to your process.

For example, we have realized automated depalletizing machines for the separation of different vial sizes and subsequent connection to a packaging machine. The automated unloading

from trays and boxes massively relieves the employees in their daily work. At the inlet and outlet, there is space for two euro pallets each, which corresponds to an autonomy of up to 1,600 vials per pallet. The machines are designed according to GxP. The equipment is also suitable to meet audit trail, user access and management requirements in accordance with FDA 21 CFR Part 11.

Cleanroom



Cleanroom solutions according to VDI, ISO, GxP and controlled rooms according to VDA 19

As an independent company within the ASYS Group, ASYS Prozess- & Reinraumtechnik has been providing innovative solutions in the areas of cleanroom technology, laminar flow systems, dry storage systems, storage lift systems and special solutions for 25 years.

These high-quality solutions protect your products in production according to GxP, ISO and VDI. As a customer-oriented solution supplier, ASYS Prozess- & Reinraum-

technik works with companies and research institutes in the fields of microelectronics, semiconductor manufacturing, precision mechanics, optics, biotechnology, pharmaceuticals and medical technology.

From commissioning to maintenance and after sales service to qualification – we offer you everything from a single source.

Climate Control Modules



Laminar or turbulent air flow for cleanroom classes up to ISO 5

VERDICO climate control modules for process machines make it possible to carry out demanding manufacturing or assembly processes under precisely measurable and controllable ambient conditions – independently of the surrounding production area. We generate a controlled atmosphere directly at the process and do so completely autonomously and flexibly. Whether dry, air-conditioned, clean or a combination of these – VERDICO adapts to every requirement.



Controllable microenvironments in the process cabinet



Printing Solutions – From the Idea to the Production Solution

Our subsidiary EKRA offers standard printing systems and customized solutions for thick film applications. Further applications are the printing of fine structures, three-dimensional bodies (3D printing) or functional layers on different materials like glass, ceramics, LTCC/HTCC, foils, metallic tubes or wafers.

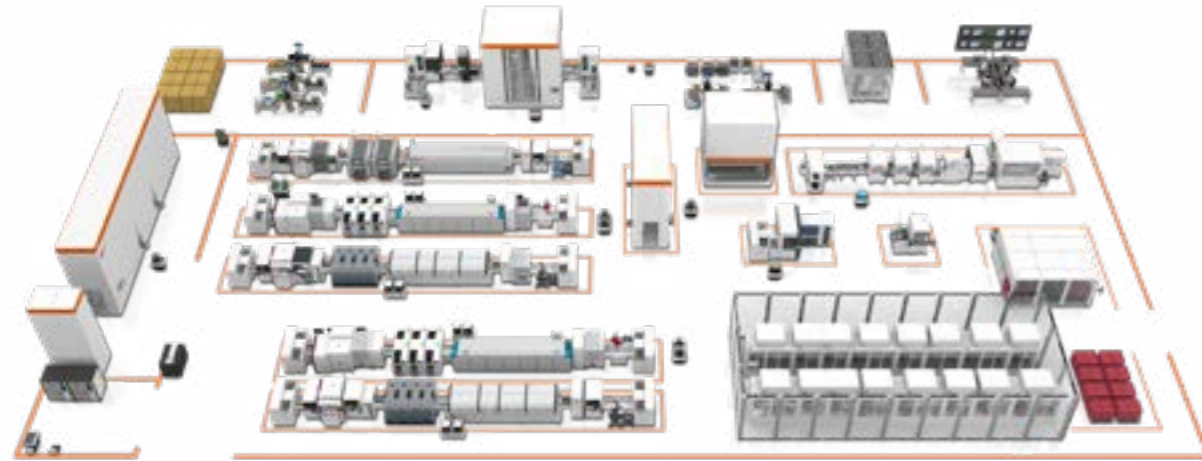
For example, we realize the automated, reproducible production of multi-layer sandwich structures on flexible wound pads with our EKRA printer X5 Professional. It prints medical silicone

strips on the wound pad with an output of up to 100 pieces per minute. Our solution achieves a long production time between the automatic cleaning cycles and reliably handles the flexible material.



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Material Logistics



We offer the largest product portfolio and the most experience on the market when it comes to the automation of material logistics in production. Thanks to a modular approach, we are able to implement material logistics solutions in various degrees of automation. In this way, existing factories with their prevailing conditions are adapted step by step to the specific requirements of our customers from the Life Science Industries.

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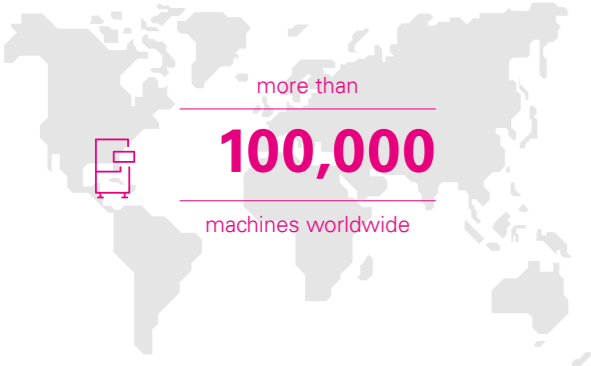
Smart Factory Manager



The PULSE PRO Smart Factory Manager offers software modules that will help you to control automated material flows in the shopfloor, to achieve a dynamic just-in-time supply for each production step and to track all data flows. The operator has the production in sight and can achieve an optimum of productivity. In this way, the faster growing complexity becomes manageable.

ASYS Group – Facts & Figures

The ASYS Group is a global technology company and leading supplier of machines for the electronic, life science and energy industry. The ASYS brand guarantees the same high quality and processing standards all over the world. The corporate headquarters in Dornstadt (near Ulm) coordinate activities across five continents and guarantees highest standards in quality and service.



The success of the ASYS Group is based on the qualification and personal commitment of more than 1,500 employees. Inspired and dedicated people are the key to developing and providing first-class products.

Business Areas

Business Unit
Electronics



Business Unit
Life Science



Business Unit
Energy



Strong and Fast Growing for over 30 Years

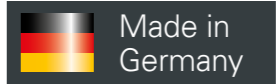
The launch of market leading innovations has significantly contributed to the success and growth of the company. Over the past two decades ASYS Group has expanded steadily and has attained a leading position with new products and processes.

Our Success Factor: Dedicated People

ASYS Group has installed more than 100,000 systems worldwide and invests continuously in state-of-the-art production processes at its worldwide sites. The production space at the headquarters in Dornstadt is constantly increasing and currently amounts to more than 27,000 sqm.

“German Engineering” and Manufacturing

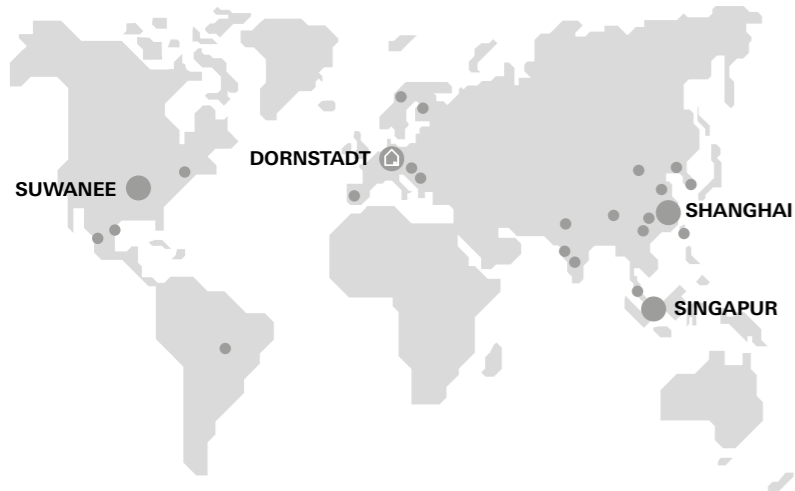
ASYS products exemplify the prestigious “Made in Germany” trademark: precise, high quality systems and machines that are intuitive to use and offer best functionality.



German Quality Across Five Continents

Worldwide Sales and Service Centers

The Group's business activities in more than 40 countries are controlled from the company's headquarters in Dornstadt near Ulm, Germany. A broad global network with local service centers in Asia and the Americas ensures a customer-focused service support. Worldwide service teams guarantee best response and spare parts availability.



- ✓ 24 / 7 / 365 support worldwide
- ✓ Teams of experienced specialists
- ✓ Experts for each product segment
- ✓ Preventive maintenance
- ✓ Service agreements
- ✓ Installation of new systems
- ✓ Maintenance seminars
- ✓ On-site training upon installation

24 Hour Availability for Service and Support

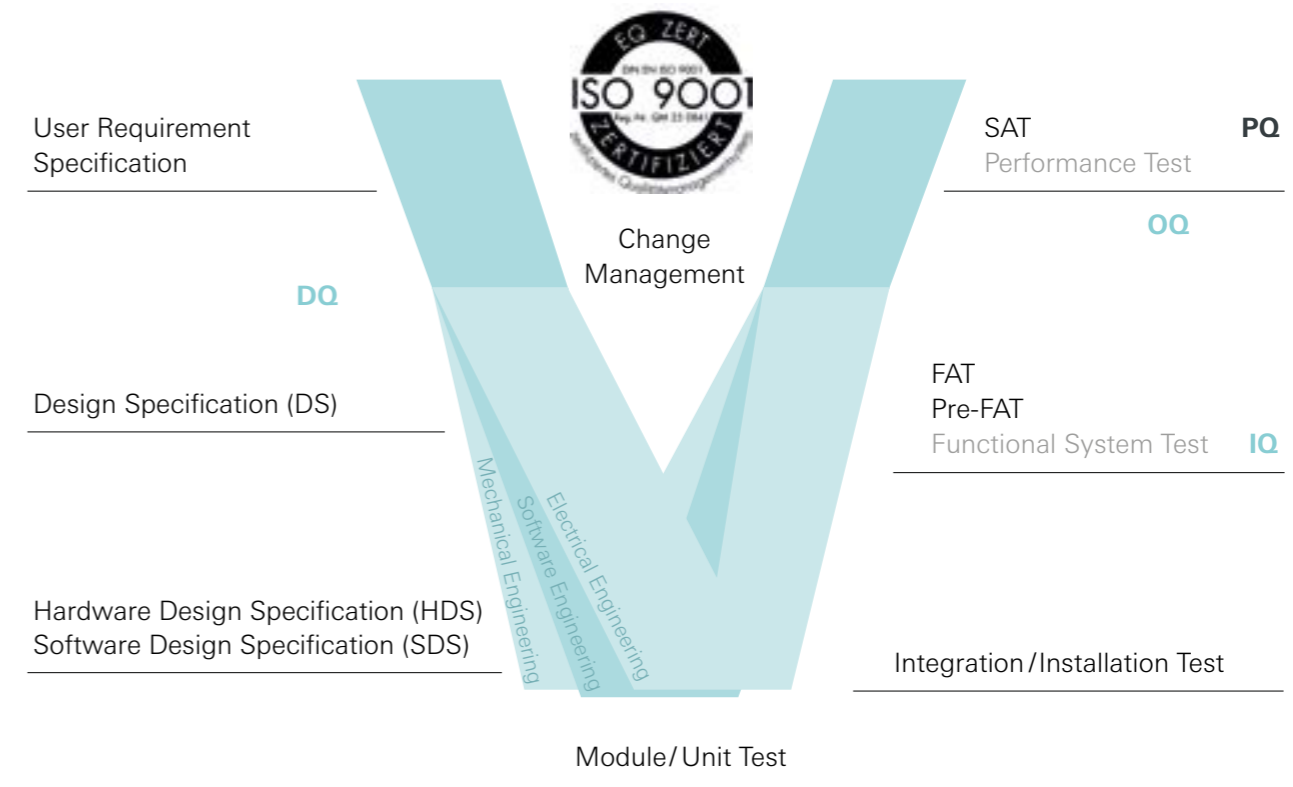
ASYS Group services are comprehensive and tailored to your individual needs. From installation and maintenance to training and a 24-hour service hotline. Our service takes you further in the long term and creates the best conditions for optimal use of your ASYS systems.



Qualification Services

- ✓ Design Documents (DS, HDS, SDS)
- ✓ IQ, OQ-Documents
- ✓ Traceability Matrix, Qualification Plan
- ✓ GMP Risk Analysis workshops and documents
- ✓ Qualification support on site

GxP-compliant Project Management at ASYS Life Science



**ASYS
GROUP**

TRANSFORMING IDEAS
Automate, Digitalize & Connect

ELECTRONICS

AUTOMATE, DIGITALIZE & CONNECT

LIFE SCIENCE

ENERGY



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www.asys-group.com

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