

pharma

PHARMACEUTICAL QUALITY ASSURANCE EDITION



TECH OUTLOOK

EUROPE SPECIAL

Mrs. Dana Graupner, Managing Director ▶



QUALITÄTS
wandel
PHARMA CONSULTING · GMP · ISO

**QUALITY MANAGEMENT
EXCELLENCE DELIVERED**



pharma

ISSN 2644-2787

TECH OUTLOOK

EUROPE SPECIAL

WWW.PHARMATECHOUTLOOK.COM

PHARMACEUTICAL
QUALITY ASSURANCE
EDITION



QUALITÄTSWANDEL



*The annual listing of 10 companies in Europe that are at the forefront of providing
Pharmaceutical Quality Assurance services and impacting the marketplace*

pharma
TECH OUTLOOK TOP 10
PHARMACEUTICAL
QUALITY ASSURANCE
SERVICES PROVIDERS IN EUROPE - 2023

QUALITÄTS *wandel* PHARMA CONSULTING · GMP · ISO

QUALITY MANAGEMENT EXCELLENCE DELIVERED



We deliver the best in quality management and help clients fulfill product attributes and process standards by handholding them from start to finish, and beyond

← Mrs. Dana Graupner,
Managing Director



By Stacey Smith

The success and growth of pharmaceutical companies rely on their commitment to upholding stringent GMP and ISO standards.

A robust regulatory posture is also crucial in streamlining their operations and meeting product quality standards. It allows pharma to deliver safe and efficacious medications and avoid losses associated with drug recalls.

Understanding the nitty-gritty of GMP and ISO audits, and resolving compliance issues demands proven experience in the pharmaceutical industry and ingrained knowledge of regulatory frameworks.

Qualitätswandel leads the charge in strengthening regulatory compliance posture and optimizing processes for pharma companies.

A German quality management consulting company with deep-rooted GMP and ISO expertise, it helps clients navigate the highly complex quality assurance landscape and achieve their goals. Its wide-ranging services include developing a GMP quality management system (GMP), ISO 9001 and ISO 13485, process analysis, training and audits.

“We deliver the best in quality management and help clients fulfill product attributes and process standards by handholding them from start to finish, and beyond,” says Mrs. Dana Graupner, managing director of Qualitätswandel.

Where Expertise Meets Excellence

The company’s roots trace back to when Mrs. Graupner, a seasoned pharmaceutical quality expert, was solicited by a pharmaceutical startup struggling to build a robust quality



assurance system. Recognizing the gap in the market for a consultancy, she began her entrepreneurial journey to help clients achieve quality management excellence.

A parent, Mrs. Graupner established a company with a difference, rewriting the stigma associated with the career progress of women with young children. The company allows them to strike a balance between personal and professional commitments with an employee-friendly, remote work culture.

Backed by a passionate team with profound expertise in the pharma industry, Qualitätswandel shines as a beacon of empowerment for working parents, creating a legacy that extends the boundaries of quality management and consulting.

As a trusted ally for clients, it caters to their quality management system (QMS) needs in various fields, including sterile production, pharmacy, biotechnology and advanced therapy medicinal products. The team comprises quality assurance and quality control specialists with over 20 years of experience and lab managers for ISO-regulated medicinal products. It has established a strong reputation with mastery in interpreting regulations, which is an essential ingredient of regulatory compliance for clients.

“Our ingrained knowledge helps us think out of the box, tap into the nuances of quality management, and tailor a QMS per specific requirements,” says Mrs. Graupner.

The commitment to offering customized services has positioned it as a go-to service provider for pharmas seeking assistance to build their quality assurance system from the ground up, and train and support staff to effectively run the programs.

Qualitätswandel tailors a robust client-specific GMP QMS and improves the existing ones to make processes more transparent and efficient. With extensive experience in quality assurance and control, troubleshooting, validation, qualification and auditing, the team ensures that the regulatory statements are implemented in a practice-oriented manner.

For companies that already have a GMP QMS but struggle to cope with complex regulations and staff shortages, the team optimizes processes, improves training and provides expert guidance. Working in tandem with clients, Qualitätswandel helps resolve backlogs, deviations and complex changes while conducting certification audits, including batch record review and site and cleanroom inspections.

Qualitätswandel has an outstanding track record for helping clients receive certifications for ISO 9001 and ISO 13485 vital for quality management and upgrade to a new certification standard.

Its expertise also factors in when assisting clients in navigating overwhelming FDA approval procedures. This distinctive aspect of Qualitätswandel ensures clients are motivated and determined even during the most challenging moments.

The value of its services came to the fore when it helped a European pharmaceutical manufacturer get FDA approval. The client sought the assistance of freelance consultants, who failed to deliver results. Qualitätswandel assisted the client with audits and continues to help manage their workload and prepare for future inspections.

On another occasion, it helped a Germany-based pharmacy looking to expand its production space, including the clean room area. They were facing a staffing crunch and delays in getting site approval. Directly coordinating with the regulatory authorities, Qualitätswandel was successful in getting the client’s site approved.

It also helped a client that needed to transfer their production unit from Germany to Poland. Support was provided to client for two years to guarantee a seamless transition. The team also helped the client overcome the staff shortage by taking over quality management responsibilities, helping them



Our ingrained knowledge helps us think out of the box, tap into the nuances of quality management, and tailor a QMS per specific requirements

accelerate the move and continue production during the transfer.

Quality Ingrained in its DNA

Sharpening Qualitätswandel’s competitive edge is its remote approach to holistic quality management. For instance, the non-availability of a regulations officer can cause an audit to stall, leading to delays and uncertainties in production. Events like war or pandemic can also bring production to a halt. With remote audit capabilities, the team allows clients to focus on their core business operations without interruption.

From analyzing the process and managing deviations to performing supplier qualifications and inspection readiness for clients, the team always excels.

Heading into the future, Qualitätswandel is poised to make a significant transition from a standalone company to a limited liability GmbH company, contributing to its continued growth. It also intends to harness the power of digital transformation by developing proprietary tools to simplify quality management and make the process more efficient for clients.

Establishing a dominant presence in the German market, Qualitätswandel envisions expanding across Europe to remain a partner of choice for businesses looking to transform their quality management systems and drive a positive business impact. 

