



**Quality management for software and app development**  
for pharmaceutical, medical technology and industrial companies

## Establish QM systems and pass QM audits safely

### 1 WHAT?

We can provide you with everything you need to know about quality management for the development of software and apps in accordance with ISO 9001 and ISO 13485 if you are planning to introduce or further develop a QM system. Our QM team specialises in the quality management of software and apps for industrial companies and medical software for pharmaceutical and medical technology companies.

Our aim is to support you in developing software and apps in compliance with laws and standards, in setting up lean QM systems and in safely passing QM audits.



ISO 9001 CONSULTING



INTERNAL AUDITS



PLACING MEDICAL  
SOFTWARE ON THE MARKET



ISO 13485 CONSULTING



EXTERNAL QM CONSULTANTS



APPROVAL OF DIGITAL  
HEALTH APPLICATIONS



QM MANUAL



TECHN. DOCUMENTATION



CE LABELLING  
OF MEDICAL DEVICES



### Services for the implementation of the QM system according to ISO 9001 & ISO 13485

With individual services for QM consulting and implementation of the QM system according to ISO 9001 and ISO 13485, our team supports you sustainably and without causing you unnecessary effort with your QM system. Our QM team is available to you as QM advisors, implementers and representatives.

#### Services related to QM consulting:

- ISO 9001 consulting for quality management systems
- QM consulting according to ISO 13485
- Creating QM manuals according to ISO 9001 or ISO 13485
- Internal audits according to ISO 9001 or ISO 13485
- Quality management representative – External QMR

# How we help you with quality management in a targeted way

## EVERYTHING ABOUT APP & SOFTWARE DEVELOPMENT

There are many aspects of how we can help you with ISO 9001 or ISO 13485 quality management in a targeted way. Some of them are the following.

### Ensure high quality in software development

High quality originates in the mind and then in the company. We help you to ensure high quality in the development of software, apps or medical software by supporting you to develop software in compliance with laws and standards, to pass audits and to successfully market medical software.

The most important goals are to improve product quality and product safety, service quality and to increase customer satisfaction.

### Establish a lean QM system that is lived by employees

We support you in setting up a lean QM system without superfluous content. Because only such QM systems are used with pleasure, because they do not complicate the work of your employees but relieve them in the process.

## HOW?

# 2



### Services for product approval:

- Technical documentation for medical devices
- Advice for CE marking for medical devices
- Advice for the placing on the market of medical devices

## Increasing efficiency & quality awareness

### HOW?

#### Increasing the efficiency of corporate processes as an opportunity

We ensure that increasing the efficiency of corporate processes can be used as an opportunity.

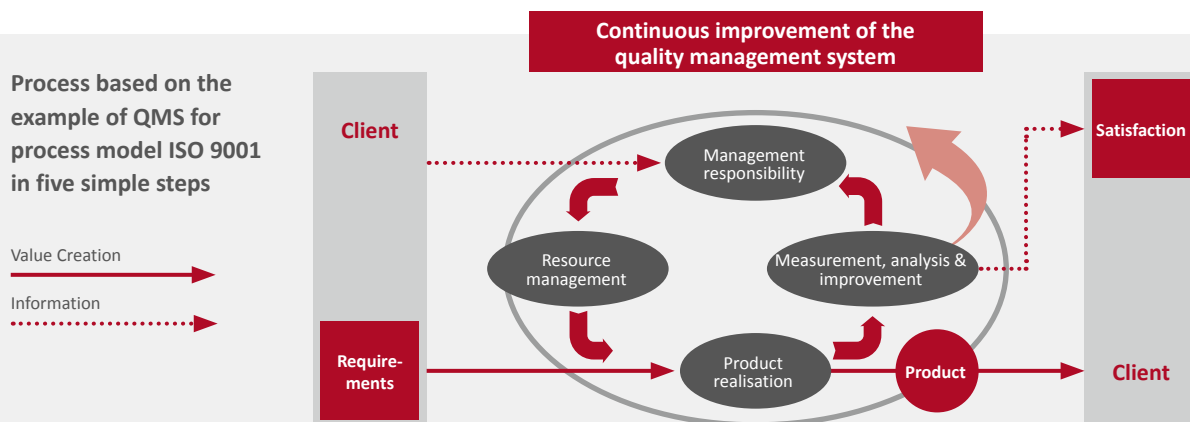
The structure of all quality management systems always follows the process-oriented approach. Accordingly, the core processes and support processes are documented in a comprehensible way and interfaces are considered. Together with you, we develop ideas for process optimisation:

- Avoiding duplication of work by constantly identifying and implementing optimisation potential in the corporate processes
- Promoting cooperation between departments by improving the interface management of company processes

#### Support for the daily work of your employees

Over the years, we have developed numerous QM documents, such as processes, work instructions, forms and checklists for manufacturers of customised software or medical software.

From these QM documents, we have created templates that you can use for your project. Of course, we have to adapt the templates specifically to your company. However, they offer useful assistance and reduce the effort and costs.





## Expertise for your QM system

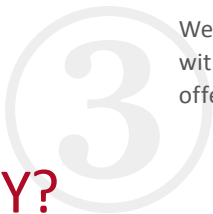
### Trained and experienced QM consultants for your QM project

You will be supported by trained and experienced QM consultants for your QM project. The understanding of our QM consultants is to be there for you, to help you sincerely and to find sustainable solutions for challenges.

Our QM team works precisely, quickly and in a structured manner so that your project costs remain within an economically reasonable framework. Flat hierarchies and team spirit provide the necessary freedom for this.

We always combine our theoretical knowledge with practical experience. This is how we can offer you practice-oriented solutions.

WHY?



## Advantages of setting up & further developing QM systems with SINOVO

- 1 Years of experience** in the establishment & further development of QM systems according to ISO 9001 & ISO 13485
- 2 Analysis of individual integration needs for your quality management system** according to ISO 9001 or ISO 13485
- 3 Establishment of lean QM systems** without superfluous contents, which are put into practice
- 4 Practice-oriented implementation of internal audits** to identify and eliminate weak points in the QM system as an opportunity for the future
- 5 Professional & methodical competence** according to current legislation, current regulations and quality management systems
- 6 Own certified QM systems** according to ISO 9001 & ISO 13485
- 7 Customer confidence:** Quality certificates and compliance with standards such as ISO 9001 contribute to gaining the trust of customers and increase competitiveness



## At a glance: Services, your advantages & contact persons



**COMPANY NAME & LEGAL FORM:**  
SINOVO business solutions GmbH

**COMPANY SEAT:** Bad Vilbel, Germany  
**YEAR OF FOUNDATION:** 1998  
**NUMBER OF EMPLOYEES:** >80

**CUSTOMERS:** SMEs & Corporations

**QM-SERVICES:**

- ISO 9001 consulting for quality management systems
- QM manual according to ISO 9001 or ISO 13485
- Internal audits according to ISO 9001 or ISO 13485
- Quality management representative – External QMR
- Technical documentation for medical devices

**COMPLIANCE WITH LEGAL REQUIREMENTS & RISK MINIMISATION TO STRENGTHEN CUSTOMER CONFIDENCE**

**ISO 9001 QM system**

Customised services for the introduction or further development of an ISO 9001 QM system to support you. We also prepare you for ISO 9001 certification so that your auditing is always guaranteed.

**ISO 13485 QM system**

Our service for implementing the ISO 13485 QM system covers all the necessary steps for medical device manufacturers and takes the burden off you. Together, we identify all relevant processes, create the required documents, and ensure that manufacturers are certified on time.



## WHO?

### WE SUPPORT YOU WITH YOUR QUALITY MANAGEMENT ...

**YOUR CONTACT PERSONS**

**Martin Drabowicz,**  
Unit Manager

**Dilek Imre,**  
Head of Sales

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