

A customized quality management system for every business

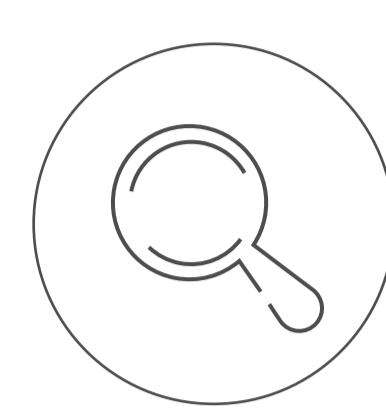
Case Study Neofonie gmbh

The Company

Neofonie GmbH is a digital agency that primarily advises and supports medium-sized and large companies on their digital projects in the areas of e-commerce, content management, AI, and mobile technology.

Another key area of focus is providing support for the development of digital health applications, as well as medical software and apps.

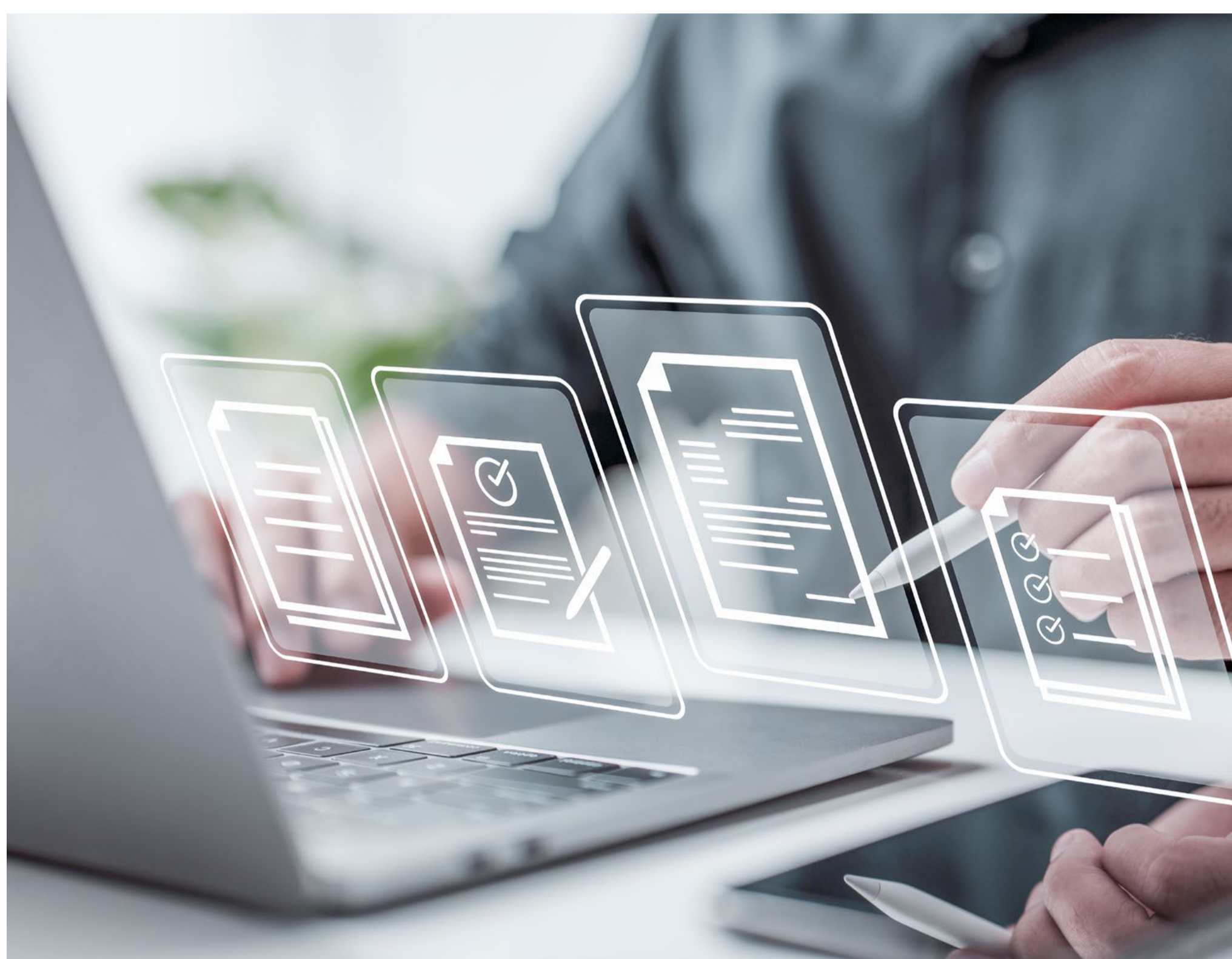
- ✓ Passed the audit with no nonconformities
- ✓ Received ISO 13485 certification
- ✓ A practical and beneficial QMS



Overview

Neofonie needed a certified quality management system in order to be authorized to develop healthcare software.

As a development service provider, the company faced a unique situation: it did not have to meet all the requirements imposed on, for example, medical device manufacturers. A customized solution was developed in collaboration with the Johner Institute. The quality management system that was established passed the certification audit without any non-conformities and is actively and enthusiastically implemented within the company.



“As a development service provider, we operate in a unique capacity, and over the course of the project, we have gradually adapted to the specific requirements.”

– CHRISTIAN SOBOTTA & SHAKED SPIER
Neofonie GmbH



Challenge

Neofonie has made the strategic decision to establish the healthcare sector as a new pillar of its business and to support clients in the development of healthcare software in the future.

General regulatory knowledge was already in place. The specific challenge now was to establish a quality management system that not only enables ISO 13485 certification but is also practical for the role of a development service provider and can be optimally integrated into the company.



Solution

Neofonie initially attended our “Certified Professional for Medical Software” seminar and later signed up for an Auditgarant membership in order to first build up its own expertise in the regulatory field.

A team of consultants from the Johner Institute then provided step-by-step support to the company as it established its quality management system. Where necessary, relevant subject matter experts were brought in, for example, on topics such as usability, computer system validation, and document management in Confluence.

AN OVERVIEW OF THE SOLUTION

- ✓ Attending a Seminar at the Johner Institute
- ✓ Signing Up for Auditgarant Membership
- ✓ Direct Consultant Support in Setting Up a Quality Management System



Result

“In the end, we passed our certification audit without any nonconformities.”

– CHRISTIAN SOBOTTA & SHAKED SPIER
Neofonie GmbH

Neofonie has an ISO 13485-certified quality management system that is perfectly tailored to the company. The following aspects were particularly appreciated during our collaboration:

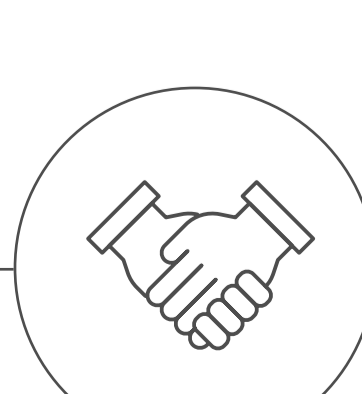
- Competence and excellent technical expertise, even on specialized topics
- A pleasant working relationship that was enjoyable
- Reliable and prompt responses to spontaneous questions
- Flexibility and a commitment to finding customized solutions

Conclusion



SHAKED SPIER (Projektmanager Ehealth)
Neofonie GmbH

“As a development service provider, we operate in a unique environment, and over the course of the project, we gradually adapted to the specific requirements. In the end, we had a quality management system that truly fits our organization and is tailored to our needs. As a result, we passed our certification audit without any nonconformities. We would wholeheartedly recommend this approach to other companies that face their own challenges and have their own unique circumstances.”



Would you like to work with us?

CONTACT