



Klaus **KÖNIG**

Auditor at Notified Body

**Age:** 47

**Education:** Study of Biochemistry



COMPUTER LITERACY



MEDICAL LITERACY

skill scale from 0 (Fundamental Awareness) to 10 (Expert)



## SKILLS & KNOWLEDGE

sense for norms and regulations

assertiveness

quality management

precision

objectivity

conscientiousness



## MOTIVATIONS

multifaceted tasks

each case brings about new challenges

contribute to high quality of medicine



## FRUSTRATIONS

lack of understanding from manufacturers

time pressure and high workload

incomplete documentations



## VALUES & ASPIRATIONS

committed to high quality

demanding a great deal of himself and of others



## PERSONALITY AND BEHAVIOUR

Klaus lives with his wife and their two teenage daughters at the outskirts of the city. They often invite friends for dinner, and Klaus is famous for preparing excellent steaks. He always uses high-quality ingredients and follows the recipe precisely in order to serve friends and family a perfect meal.



## OCCUPATION

After finishing his university studies, Klaus has been working in the research department of a large pharmaceutical company for more than four years. Striving for further qualification, he took training courses in quality management and got a job in the quality management department of the company. Almost ten years ago, Klaus became an auditor at a notified body in the medical sector, and he still likes this job as it is so multifaceted. Klaus works in teams with other colleagues, where each colleague brings in a specific field of expertise such that the team is able to thoroughly assess the regulatory conformance of a medical device before giving a market admittance certificate to that device. Klaus knows that he must work precisely when checking the documents provided by the manufacturer, so that only high-quality medical devices are admitted to the market. However, he sometimes finds it hard to convince manufacturers that strict adherence to the regulations is essential for patients' safety and high-quality medicine.



## OBJECTIVES AND GOALS

By doing his job responsibly, Klaus aims to contribute to patients' safety and high-quality medical treatment. He constantly tries to convince also manufacturers that strict adherence to the regulations is essential for patients' safety.



## ATTITUDES TOWARDS AI

Klaus believes that AI-solutions do have a great potential in medicine. However, he thinks that many of these products are still in their infancy and not yet mature for practical application in medicine. Klaus is convinced, that applications, which do not reach the high quality standards prescribed by the CE IVDR, must not be approved for diagnostics.