



Siemens Healthineers - INSIDE: HEALTH

From technical documentation to dossier preparation and approval

Siemens Healthineers is a leading medical technology company that enables healthcare providers worldwide to increase value by empowering them on their journey towards expanding precision medicine, transforming care delivery and improving patient experience, all enabled by digitalizing healthcare.

Every day, an estimated five million patients worldwide benefit from Siemens Healthineers' innovative technologies and services in the areas of diagnostic and therapeutic imaging, laboratory diagnostics and molecular medicine. For an efficient approval process, the global player in the healthcare sector trusts in the expertise of **4PEP Regulatory Affairs Management**.

*“Within the framework of the cooperation with ILC GmbH, we appreciate the high level of professionalism, the practice-oriented way of working and the pleasant personal and also reliable cooperation. By using **4PEP Regulatory Affairs Management**, we were able to improve our approval process efficiently.”*

Elmar Seeberger
Project Manager

Company

- name: Siemens Healthcare GmbH
- headquarters: Erlangen and in 75 countries worldwide
- industry: Medical Technology
- products: diagnostic and therapeutic imaging, laboratory diagnostics, information technology
- revenue: 14.46 bn EUR (2020)
- employees: 54,000
- www.siemens-healthineers.com

Initial Situation and Challenges

- sale of over 4,300 products in around 100 countries
- certificate of approval for every product for each country, where it is supposed to be sold
- taking different and changing regulations for each country or product category into account
- control of approval processes distributed among various business areas

Solution

- web-based, globally accessible approval management
- organization management and authorization control depending on region and business area
- integrated document management and secure document storage
- personalized work environment

Customer Benefit

- mapping of the global approval process during the different stages
- transparency concerning all approval activities
- direct access to the approval status of a product

