Johner Institute

Getting your medical device approved in Europe and the US

The Johner Institute will help you navigate the medical device approval process in Europe (CE-mark) and in the US (FDA) getting your device to market as quickly, easily, and safely as possible

The Mission

The Johner Institute's mission is to help manufacturers market active medical devices quickly and successfully in the European and US markets by fulfilling regulatory requirements, passing audits and inspections, and preparing successful submissions.

The Johner Institute's ambition is to make sure that the innovative potential of medical device manufacturers is not limited by quality management bureaucracy nor mis-understood regulations.

The Team

The Johner Institute employs auditors (at notified bodies), computer scientists, physicists, physicians, engineers, members of standard committees, quality management and regulatory affairs experts.

Its founder is professor Christian Johner, PhD. The Institute has a strategic alliance with UserWorks, Inc., a US firm specializing in user experience design and human factors/usability engineering.

The Specialization

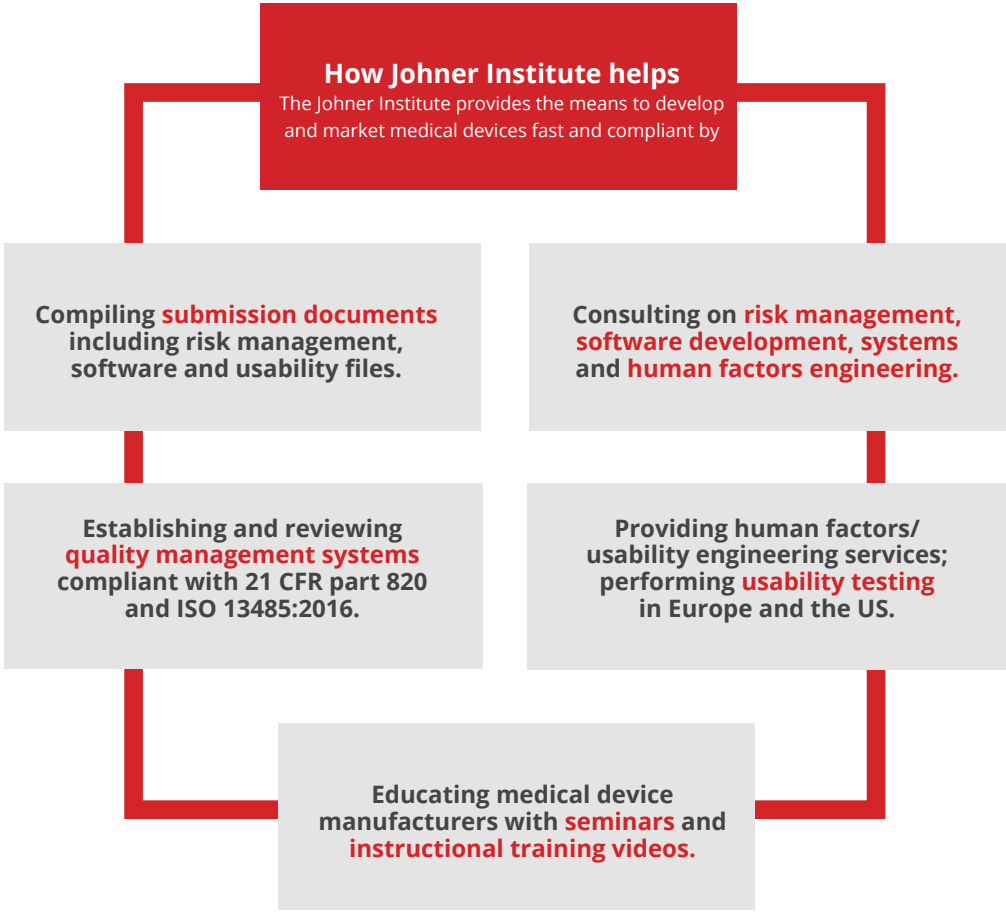
The Johner Institute supports manufacturers of medical devices, in particular of devices with embedded and of stand-alone software.

In this domain Johner Institute is the leading consultancy firm in the largest European market -- the German speaking countries.

With no exception, all of Johner Institute's customers (several hundred) passed audits, inspections and submissions successfully.

The Customers

When it comes to regulatory affairs, medical device software, risk management and human factors engineering, the Johner Institute is **the** consultancy and training provider for medical device manufacturers, engineering service providers, and most of the German notified bodies.



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