



EN 15224

Services in healthcare – Quality management systems Requirements based on ISO 9001



MOTIVATION AND BENEFITS

In March 2017 the update of the European norm EN 15224 was completed and has thereby used the opportunity to translate or update the general ISO 9001 specifically for the healthcare sector. This standard is a sector specific quality management standard for healthcare organizations, that includes the complete ISO 9001.

This standard created the foundation to open the access to services in the healthcare sector in comparable quality in all EU countries and enables exchange beyond national borders. Moreover, the “translation” of ISO 9001 requirements, which was sometimes difficult for healthcare institutions, is omitted.

For the promotion of high-quality healthcare the focus is set on clinical processes and their risk management. The requirements of EN 15224 include those of ISO 9001 as well as some additional interpretations and specifications for the healthcare sector. The requirements have been incorporated and clarified in accordance with the specific healthcare context. Additional requirements have been included when considered important. This standard also includes aspects regarding the management of clinical risks in the planning, execution and steering processes (excerpt Introduction EN 15224 Chapter 0.1).

OBJECTIVES

In the centre of interest are clinical risk management, compliance with additional legal / regulatory burdens and the eleven quality features:

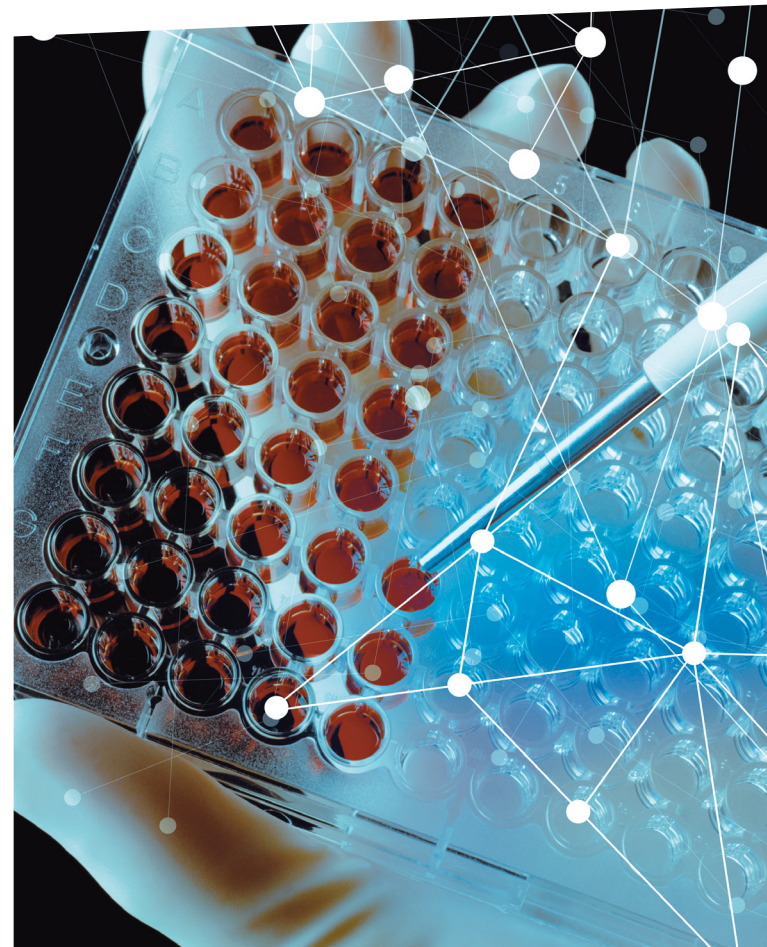
- adequate and correct healthcare
- availability
- continuity of healthcare
- effectiveness
- efficiency
- equality
- healthcare based on evidence / knowledge
- healthcare focusing on the patient, including the physical, psychological and social integrity
- involvement of the patient
- patient safety and security
- timeliness / accessibility

TARGET GROUP

In principle, the standard is applicable for all service providers active in this sector as well as for doctors' offices, hospitals, nursing homes, hospices, healthcare institutions, psychiatric nursing institutions, dentists' offices, physiotherapeutic institutions, institutions providing labour protection services and pharmacies.

OTHER RELEVANT STANDARDS

ISO 9001, ISO 13485, ISO 14001, ISO 27799, ISO 31000





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