



Risk analysis of complex medical devices:

Comparison of the use of ISO 31000, ISO 14971 and STAMP/STPA for microprocessor-controlled prosthetic knees

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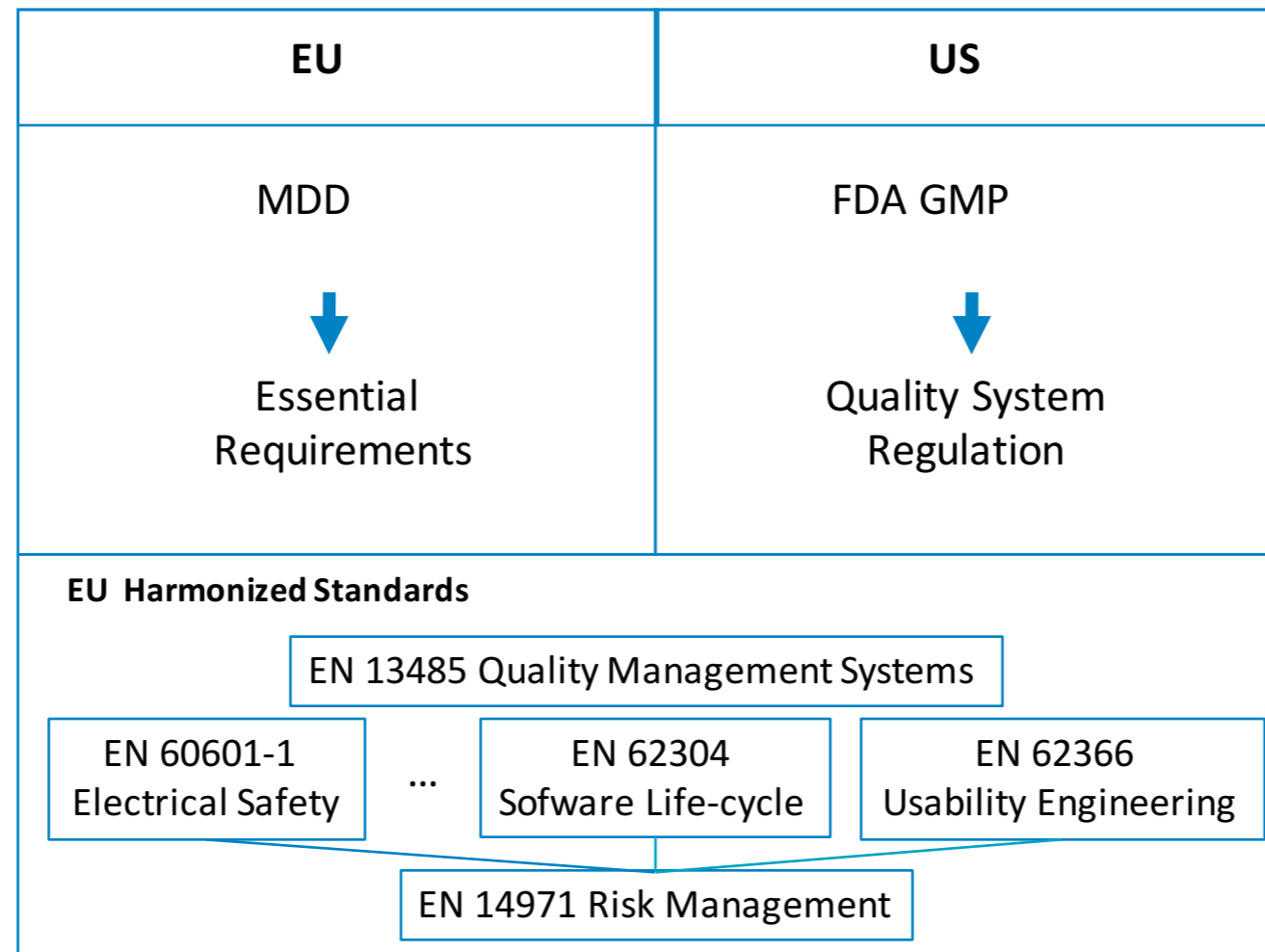
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Background



The challenge



For complex medical devices ISO/EN 14971 does not cover EU regulators' essential requirements and is complemented by other standards and a periodic audit process.

Objective

- Compare the risk analysis process of ISO 14971, ISO 31000 and STAMP/STPA
- How are the differences relevant to risk management of complex medical devices?

General

ISO 31000

ISO 14971

STAMP

Guidelines

Guidelines
(harmonized standard)

Method

Core concepts

	ISO 31000	ISO 14971	STAMP
Accident	“Occurrence or change of a particular set of circumstances”	Undefined	“An undesired and unplanned event that results in a loss (including loss of human life or injury, property damage, environmental pollution and so on)”
Harm	Undefined	“Physical injury or damage to the health of people, or damage to property or the environment”	Undefined

Differences in nomenclature

Risk Analysis

ISO 31000

ISO 14971

STAMP/STPA

Generic and abstract
model

Manufacturer selects
appropriate methods

Systematic approach
(STPA)

Manufacturer defines acceptable risks
Importance of communication and documentation

Conclusions

How are the differences relevant to risk management of complex medical devices?

- STAMP/STPA provides a more systematic approach to analyse risks originating from interaction between the components of a complex system.
- STAMP/STPA designed to address risks through design.
- Is STAMP/STPA more cost effective for regulatory compliance?