

# QUALITY STANDARDS

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Software Qualitätsmanagement

# ISO 9000

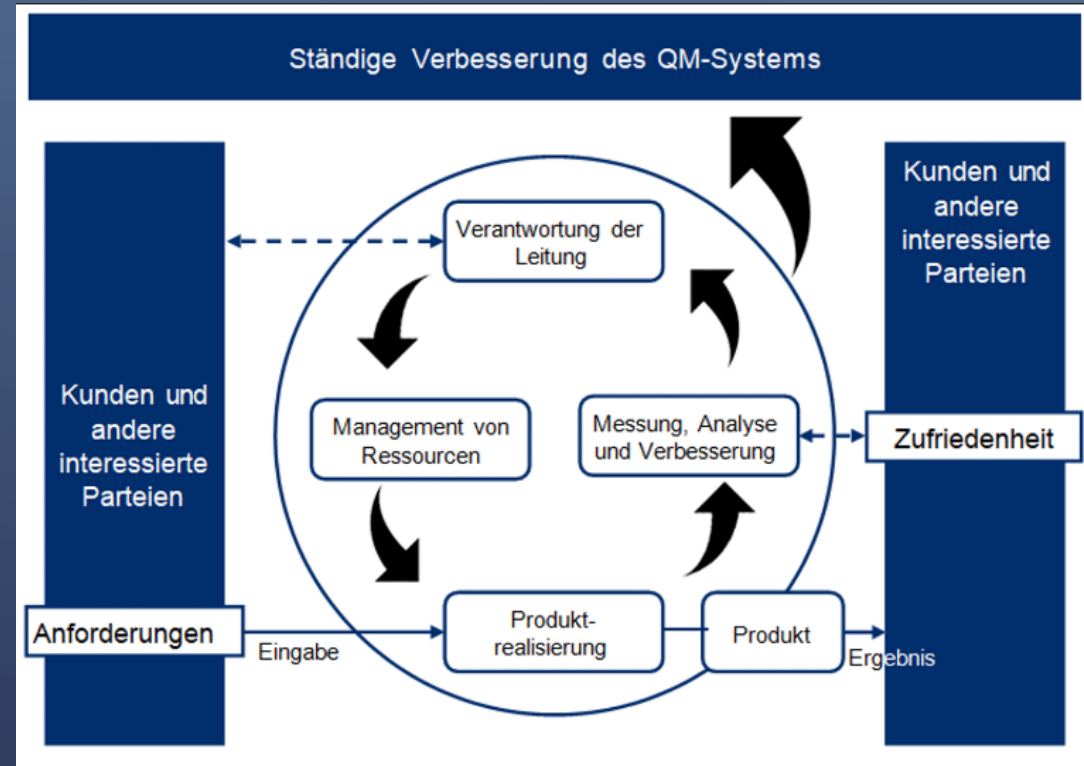
Family of standards focused on quality management systems, ensuring organizations meet customer and regulatory requirements

**Origin** International Organization for Standardization - ISO

**Focus** Quality management principles

**Replaced by** ISO/IEC 330xx standards

**Usage** Used widely across various industries



# SPICE

ISO/IEC 15504

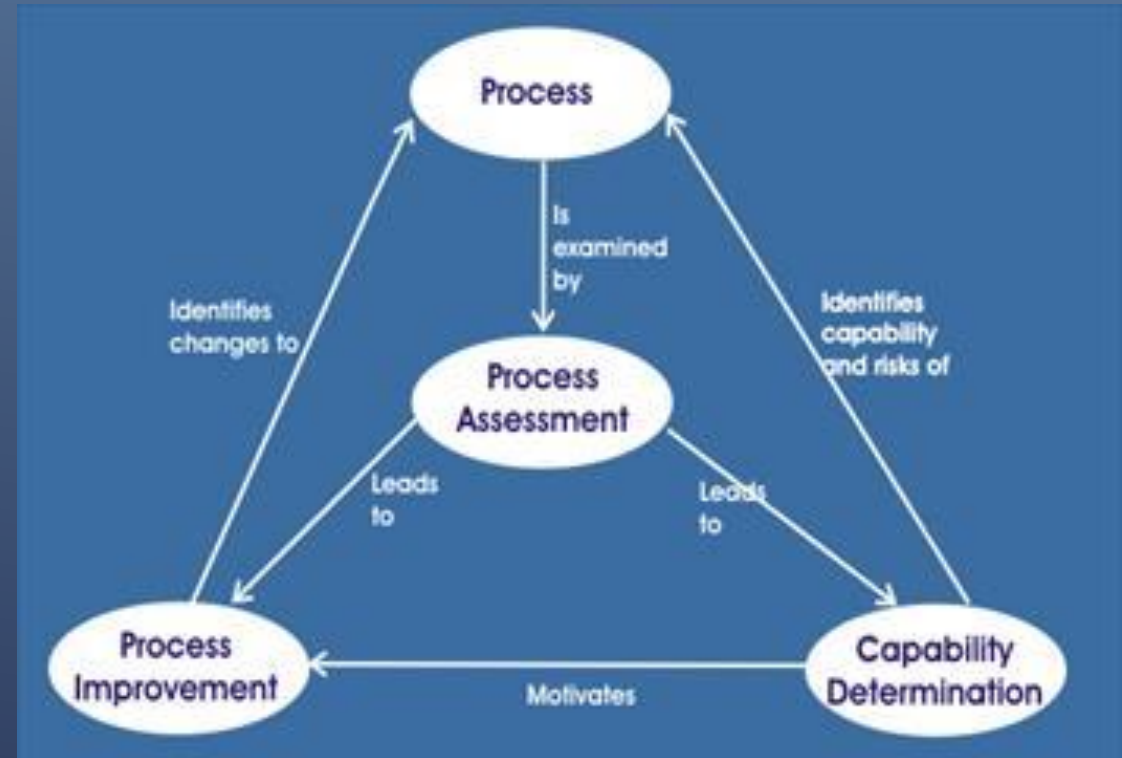
SPICE is a framework for software process assessment and improvement, measuring process capability and maturity in software development

**Origin** International Organization for Standardization – ISO

**Focus** Process assessment and capability levels

**Certification** ISO 9001, which is a norm for quality management systems

**Usage** Mainly in Software and IT service industry



# CMMI

## Capability Maturity Model Integration

A model for improving process maturity in development, service, and acquisition, aiming for process optimization.

**Origin** Developed by the Software Engineering Institute (SEI)

**Focus** Process improvement

**Also** Unofficial certificate for maturity of processes

**Usage** For Development, Services, and Acquisition



# GAMP

Good Automated Manufacturing Practice

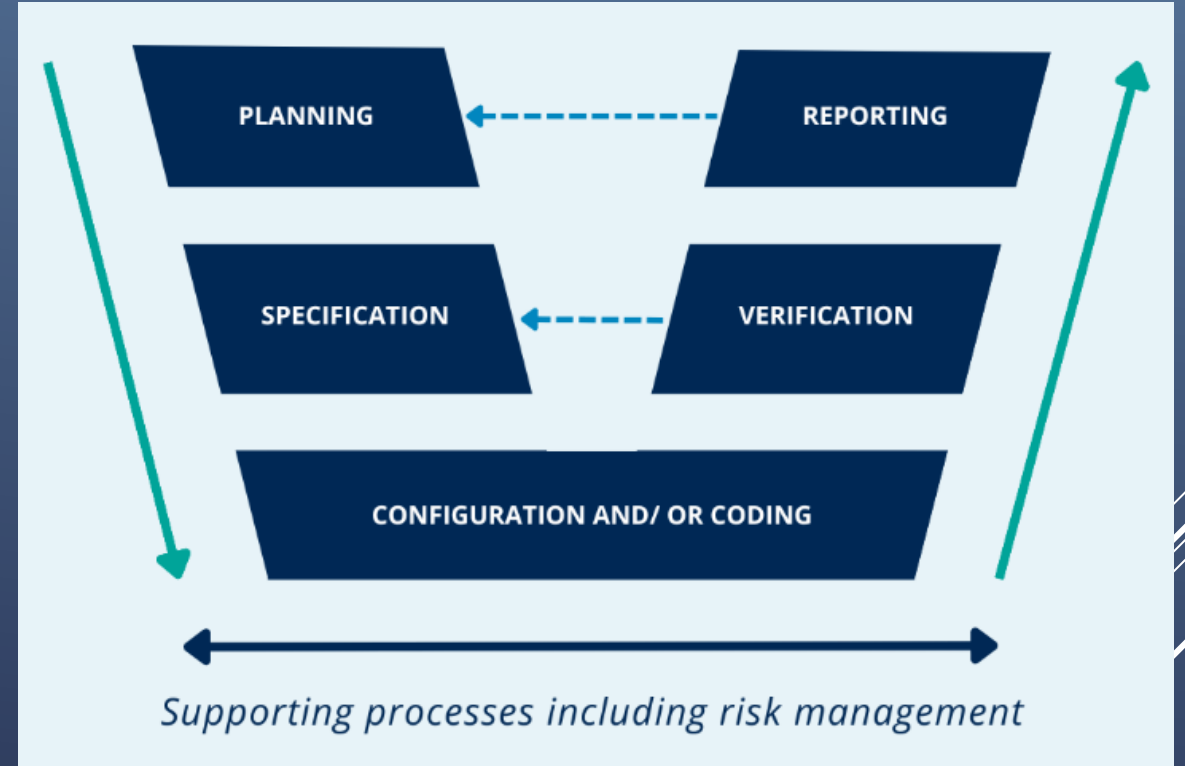
A set of guidelines for ensuring quality in automated systems within the pharmaceutical industry

**Origin** International Society for Pharmaceutical Engineering (ISPE)

**Focus** Pharmaceutical manufacturing and compliance

**Promotes** Risk management and validation of computerized systems

**Standard** GAMP 5 (current version)



DANKE

