QUALITY CANON

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Abstract

Example

Contents

Processes MUST be documented within a quality management system. The QMS governs the organizations ability to consistently provide products/services that meet requirements.

Example: ISO 9001:2015 process approach, risk-based thinking, PDCA (Plan-Do-Check-Act) cycle. Seven quality management principles: customer focus, leadership, engagement of people, process approach, improvement, evidence-based decision making, relationship management. Management review (Clause 9.3) top management must review QMS at planned intervals. Documented information (Clause 7.5) replaces the old documents and records terminology. Context of the organization (Clause 4) understanding internal/external issues and interested parties. QMS scope must be documented and available.

0.1 2. Medical Device Quality

Medical device quality systems MUST satisfy regulatory requirements specific to the device classification.

Example: ISO 13485:2016 QMS requirements for medical devices, harmonized globally. FDA 21 CFR 820 (Quality System Regulation) being transitioned to QMSR (Quality Management System Regulation) aligned with ISO 13485. Design controls (820.30 / ISO 13485 Clause 7.3): design input, output, review, verification, validation, transfer, changes. Design History File (DHF), Device Master Record (DMR), Device History Record (DHR) the three critical record sets. EU MDR (2017/745) replaced MDD, requires UDI (Unique Device Identification), clinical evaluation, post-market surveillance. Risk management: ISO 14971 risk analysis, evaluation, control, and residual risk assessment throughout device lifecycle.

0.2 3. Pharmaceutical Quality

Pharmaceutical manufacturing MUST comply with current Good Manufacturing Practice (cGMP) and ICH guidelines.

Example: cGMP 21 CFR 210 (general), 211 (finished pharmaceuticals), 212 (PET drugs), 600 (biologics). ICH Q10 pharmaceutical quality system model integrating GMP with ICH Q8 (pharmaceutical development) and Q9 (quality risk management). Process validation (FDA Guidance 2011): Stage 1 (process design), Stage 2 (process qualification), Stage 3 (continued process verification). CAPA (Corrective and Preventive Action) investigate root cause, implement corrective action, verify effectiveness, prevent recurrence. Annual Product Quality Review (APQR) trending of quality data. Data integrity: ALCOA+ principles (Attributable, Legible, Contemporaneous, Original, Accurate + Complete, Consistent, Enduring, Available).

0.3 4. Measurement & Calibration

Measurement systems MUST be calibrated, traceable, and within acceptable uncertainty limits.

Example: ISO/IEC 17025:2017 competence requirements for testing and calibration laboratories. Metrological traceability to SI units through unbroken chain of calibrations with stated uncertainties. Measurement uncertainty: GUM (Guide to the Expression of Uncertainty in Measurement) Type A (statistical) and Type B (other) evaluations. Gauge R&R (Repeatability and Reproducibility) measures variation attributable to the measurement system vs. the parts. MSA (Measurement Systems Analysis) AIAG reference manual. Calibration intervals determined by historical performance data, not arbitrary schedules.

0.4 5. Audit & Assessment

Quality systems MUST be audited to verify conformance and identify improvement opportunities.

Example: Internal audit (ISO 19011:2018) guidelines for auditing management systems. Audit program management, audit planning, conducting audits, competence of auditors. Third-party certification audits: Stage 1 (documentation review), Stage 2 (implementation assessment). Surveillance audits annually, recertification every 3 years. FDA inspections: 483 observations (documented deviations), Warning Letters (regulatory action), consent decrees (court-ordered compliance). Notified body audits under EU MDR unannounced audits, technical documentation review, QMS assessment. Supplier audits: second-party assessments per ISO 9001 Clause 8.4 (control of externally provided processes).

0.5 6. Continuous Improvement

Quality systems MUST drive continuous improvement through data-driven methods.

Example: Six Sigma DMAIC (Define, Measure, Analyze, Improve, Control) statistical methodology for process improvement. Lean manufacturing eliminate waste (muda): overproduction, waiting, transport, overprocessing, inventory, motion, defects, unused talent. SPC (Statistical Process Control) control charts (Xbar-R, p-chart, c-chart) distinguish special cause from common cause variation. Root cause analysis methods: 5 Why, Ishikawa/fishbone diagram, fault tree analysis (FTA), Pareto analysis. Kaizen continuous small improvements. Cost of quality: prevention costs + appraisal costs + internal failure costs + external failure costs (Jurans model).

1. Constraints

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MUST:     Cite specific ISO clause or CFR section for quality claims
MUST:     Distinguish between voluntary standards and regulatory requirements
MUST NOT: Present ISO certification as regulatory approval
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