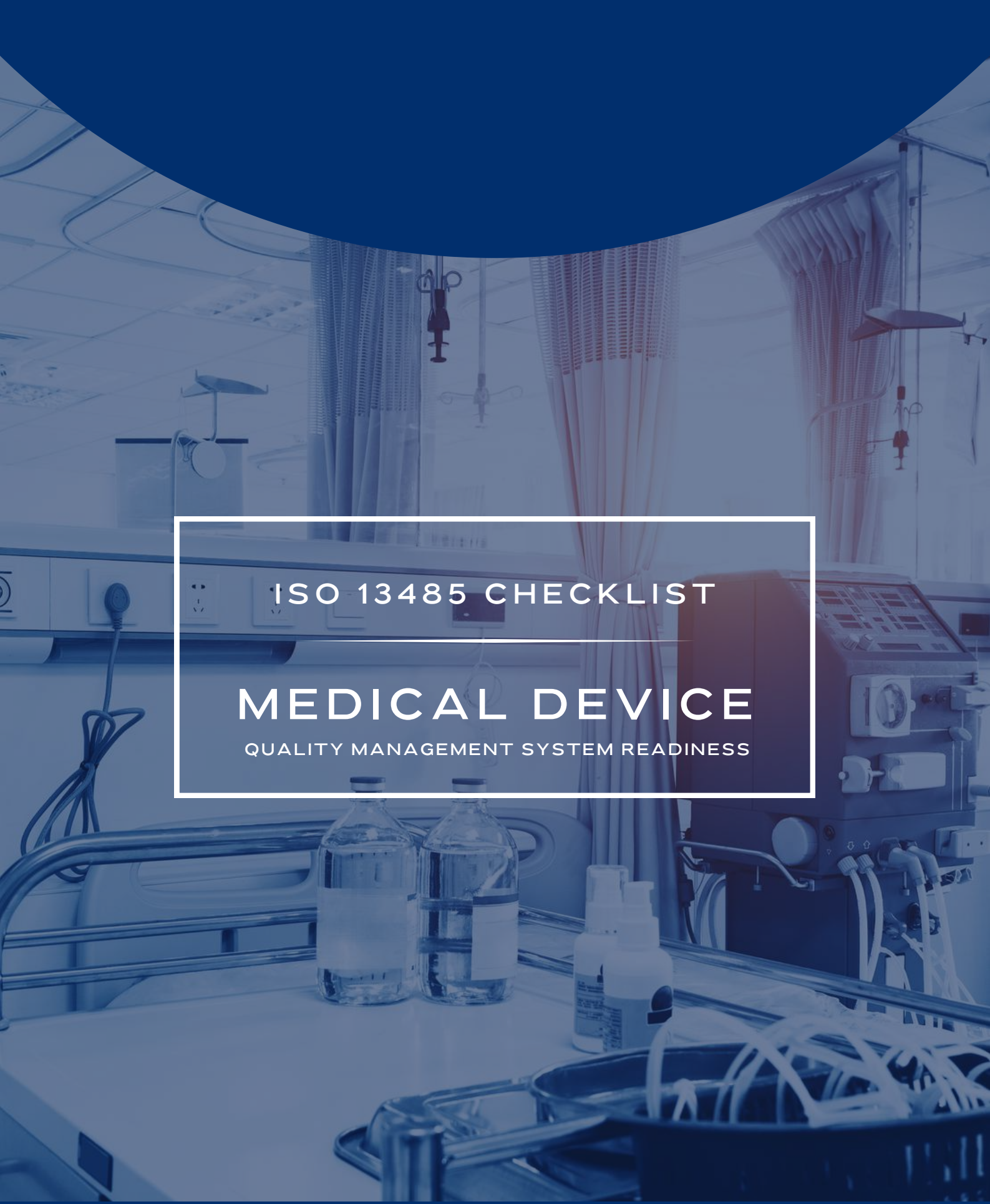


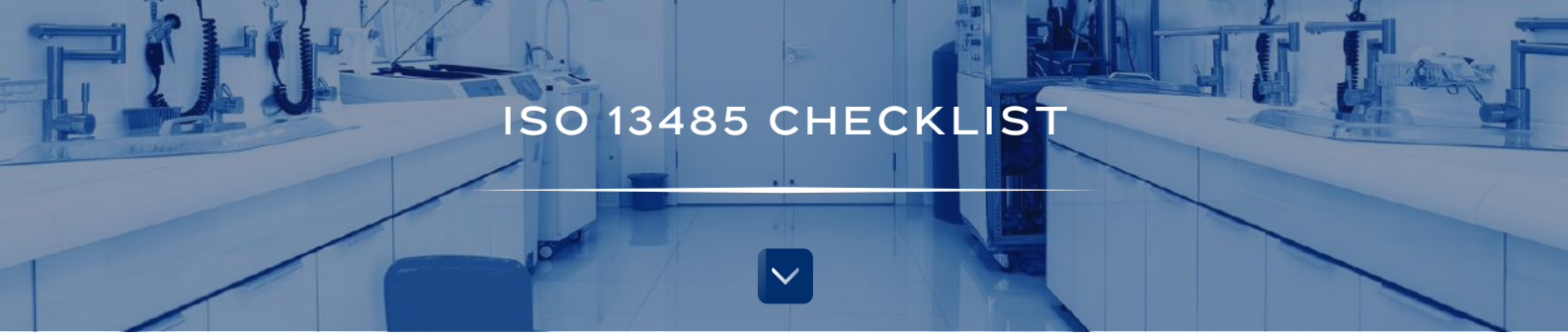
ISO 13485 CHECKLIST

MEDICAL DEVICE

QUALITY MANAGEMENT SYSTEM READINESS

JC AUDITORS

TRIED AND TRUSTED ™



ISO 13485 CHECKLIST

Key Points Checklist

General Requirements

- [ ] Documentation
- [ ] Regulatory requirements and risk-based approach
- [ ] Management of change
- [ ] Control of outsourced processes
- [ ] Software validation

Documentation Requirements

- [ ] Documented procedures and records
- [ ] Quality Manual
- [ ] Medical device file
- [ ] Control and maintenance of documents and records

Management Responsibility

- [ ] Focus on customer and regulatory requirements
- [ ] Establish quality policy and quality objectives
- [ ] Defined, documented and communicated roles and responsibilities
- [ ] Documented procedures for management review at planned intervals

Human Resources

- [ ] Documented processes for competence, training and awareness of personnel
- [ ] Effectiveness of risk-based training

Infrastructure

- [ ] Processes for product requirements, handling & preventing mix-up
- [ ] Process equipment & supporting services infrastructure
- [ ] Documented requirements for maintenance activities

Work Environment & Contamination Control

- Documented requirements for work environment
- Contamination controls & cleanliness

Planning of Product Realisation

- Processes for risk management
- Requirements for handling, storage, distribution, traceability & product acceptance

Customer-Related Processes

- Determine and review product requirements
- Documentation for communication with stakeholders, including regulatory authorities

Design & Development

- Documented processes for design & development
- Traceability of inputs to outputs, including review and specialist personnel invoved
- Documentation for verification, validation and associated activities
- Documented procedures for design & development transfer and changes
- Design and development files

Purchasing

- Documented procedures on purchased product conformity
- Supplier performance and associated risk
- Written agreements and traceability
- Verification and risk-based evaluation

Production & Service Provision

- Production controls
- Documentation for cleanliness of product & contamination control
- Documentation for installation & servicing activities
- Sterilization records
- Documented procedures for validation of processes and software according to associated risk
- Validation of sterile barrier systems
- Documented procedures for product identification: unique device identification if applicable
- Documented processes for traceability
- Preservation of product

Monitoring & Measurement

- Customer feedback input into risk management
- Documented processes for determining if customer requirements have been met
- Documented procedures for complaint handling
- Reporting to regulatory authorities
- Planned internal audits at defined intervals
- Documented arrangements for product release & service delivery

Control of Non-Conforming Product

- Documented procedures for the controls of non-conforming product
- Advisory notices in accordance with regulatory requirements
- Documented procedures for rework

Analysis of Data

- Sources of data for analysis to determine effectiveness of QMS
- Data analysis input into improvement processes

Improvement

- Corrective actions to eliminate non-conformances without undue delay
- Evaluation of corrective actions
- Preventative actions proportionate to the effects of the potentials problems

Our team of medical device experts will gladly assist with any further information or guidance required

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