ISO 13485:2016
CERTIFICATION PROCESS

Quality Management System for Medical Devices

Presented by: [**PRIYA CONSULTANCY (I) PVT. LTD.**]

What is ISO 13485:2016?

- International standard for QMS in the medical device industry
- Aligns with regulatory requirements
- Emphasizes risk management, process validation, and product safety

Benefits of ISO 13485 Certification

- Ensures product safety & effectiveness
- Increases market access and customer confidence
- Facilitates regulatory compliance
- Improves internal process control

Certification Process Overview

- Gap Analysis
- Documentation Development
- Implementation
- Internal Audit
- Management Review
- Pre-assessment (Optional)
- Certification Audit (Stage 1 & Stage 2)
- Certification Issuance
- Surveillance Audits

Step 1 - Gap Analysis

- Assess current practices vs ISO 13485 requirements
- Identify missing elements in QMS
- Define action plan

STEP 2 - DOCUMENTATION

Develop/Update:

- Quality Manual
- SOPs
- Risk Management Files
- Records & Forms

Step 3 - Implementation

- Train staff
- Apply QMS across processes
- Maintain records of activities
- Monitor compliance

Step 4 - Internal Audit

- Conduct internal audits
- Identify non-conformities
- Implement corrective actions

Step 5 - Management Review

- Review audit results, complaints, improvement actions
- Set objectives
- Allocate resources

Step 6 & 7 - Certification Audit

- Stage 1 Audit: Document review
- Stage 2 Audit: On-site audit of QMS implementation
- Address non-conformities (if any)

Step 8 - Certification

- Certification issued after successful audit
- Valid for 3 years (with annual surveillance)

Step 9 - Surveillance Audits

- Annual audits by the certification body
- Ensure continued compliance and improvement

SUMMARY

- ISO 13485 ensures QMS excellence for medical device companies
- Helps meet global regulatory requirements
- Drives quality, safety, and trust

CONTACT INFORMATION

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