

# ISO 13485 Quality System

**The quality system helps us to achieve higher customer satisfaction**

**Quality policy and quality objectives define our goals**

**Your “customer” is the next person who uses the output of your process**

**How processes are controlled**

**How the quality system works**

**Our quality system is defined in three levels of controlled documents**

**You should use, maintain and improve the quality system**

# ISO 13485 Requirements

- 4.1 General Requirements
- 4.2 Documentation Requirements
- 5.1 Management Commitment
- 5.2 Customer Focus
- 5.3 Quality Policy
- 5.4 Planning
- 5.5 Responsibility and Authority
- 5.6 Management Review
- 6.1 Provision of Resources
- 6.2 Human Resources
- 6.3 Infrastructure
- 6.4 Work Environment
- 7.1 Planning of Product Realization
- 7.2 Customer-related Processes
- 7.3 Design and Development
- 7.4 Purchasing
- 7.5 Production and Service Provision
- 7.6 Monitoring and Measuring Devices
- 8.1 Planning and Statistical Techniques
- 8.2 Monitoring and measurement
- 8.3 Control of Nonconforming Product
- 8.4 Analysis of Data
- 8.5 Improvement

**ISO 13485 audits**

**What happens during the registration audit**

**Where auditors look**

**How auditors examine documents and records**

**What can you do to prepare for the audit**