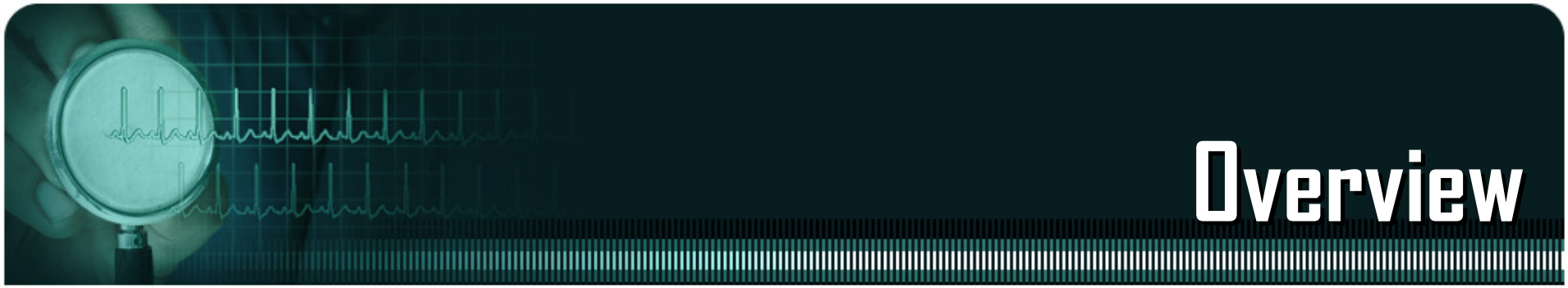
Introduction to ISO 13485

Topics Covered

- **Overview**
- **The 13485 Standard**
- **Importance of 13485**
- **Benefits**
- **Requirements**
- **Process Approach**
- **Details of the Standard:** Sections 4 through 8
- **Summary**
- **Tools for Implementation**



Overview

The ISO 13485 title page says:

INTERNATIONAL STANDARD

Medical devices – Quality management systems – Requirements for regulatory Purposes

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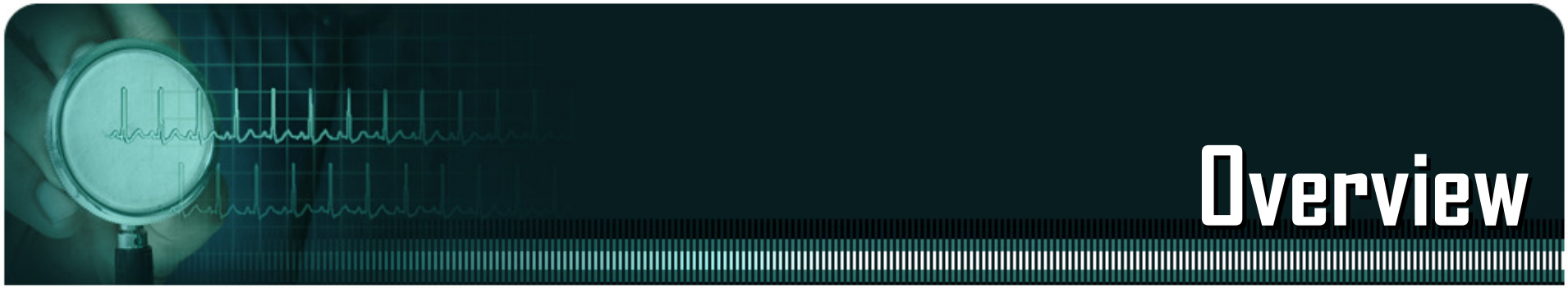
It was released in year 2003 to address the specific needs for quality management systems for organizations in the medical devices industry.

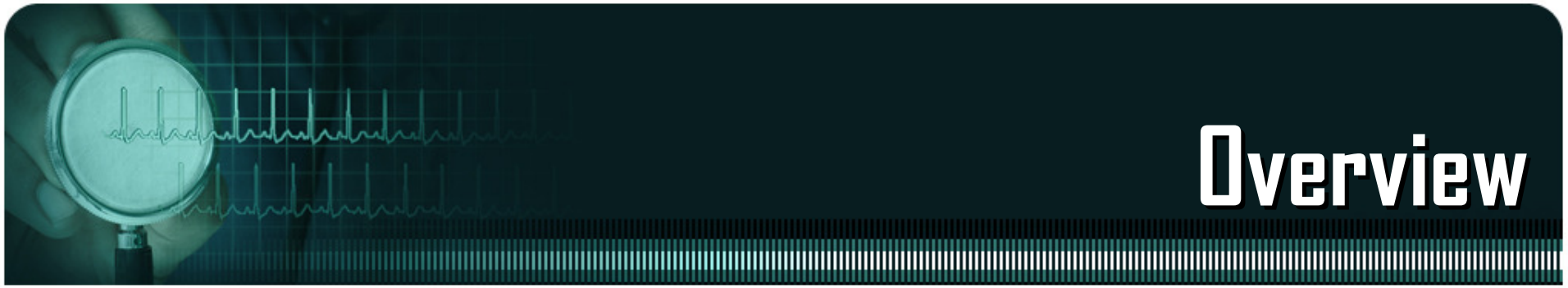


ISO 13485 is a Quality Management System

Medical devices – Quality management systems – Requirements for regulatory purposes

ISO 13485 provides the requirements for a comprehensive management system for the design and manufacture of medical devices.

ISO 13485 promotes the awareness of and compliance to regulatory requirements as a Management Responsibility.

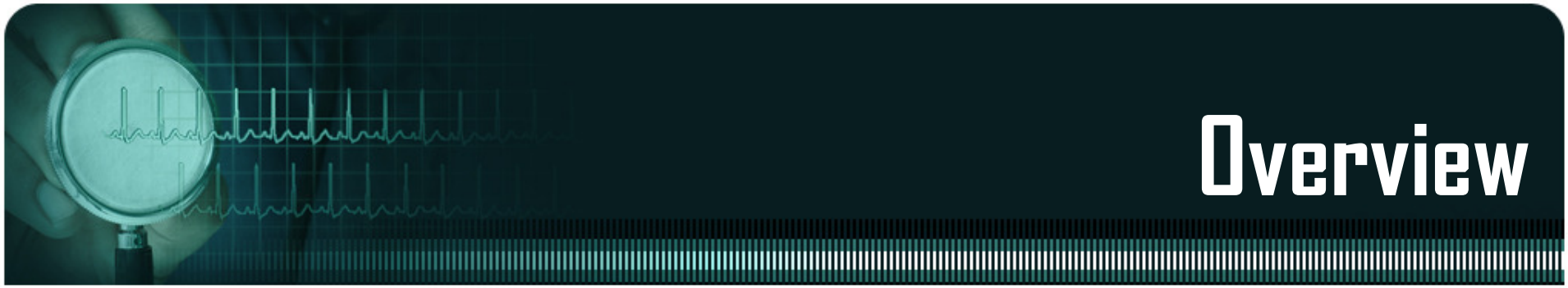


Overview

ISO 13485 provides an outline for a Quality Management System

- When you build a Quality Management System based on ISO 13485, you will be managing your medical device organization as a system of interrelated processes.

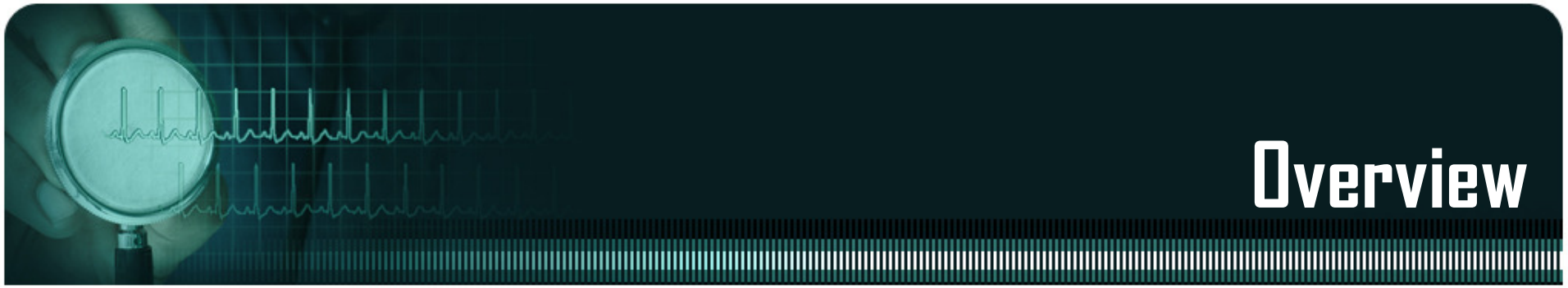
- You will need to plan these processes, identify how they relate to each other, set goals, measure the processes and make improvements.



Overview

The letters I.S.O. mean
International Organization of Standardization

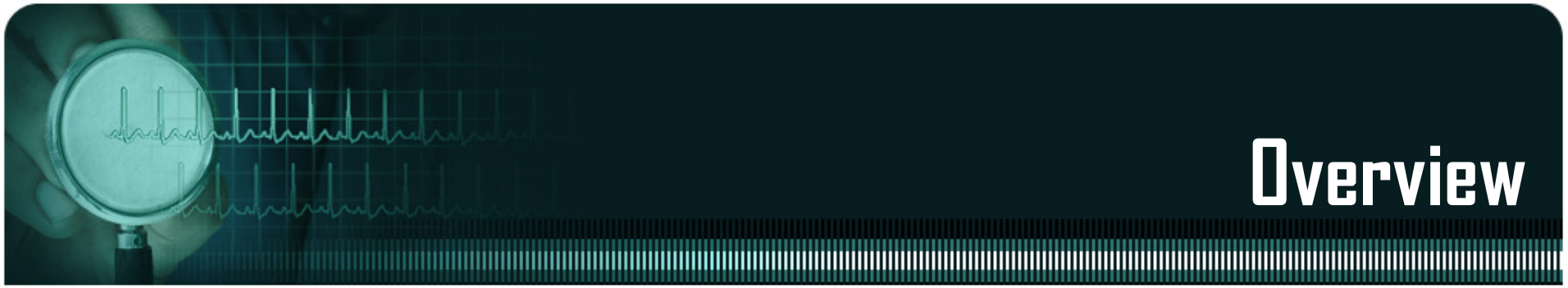
- ISO is an organization that develops Standards for use worldwide.
- ISO 13485 helps companies do their share in protecting consumers and users of medical devices.
- ISO 13485 Outlines criteria for a good Quality Management System (QMS).



QMS criteria are good business practices ...

for example:

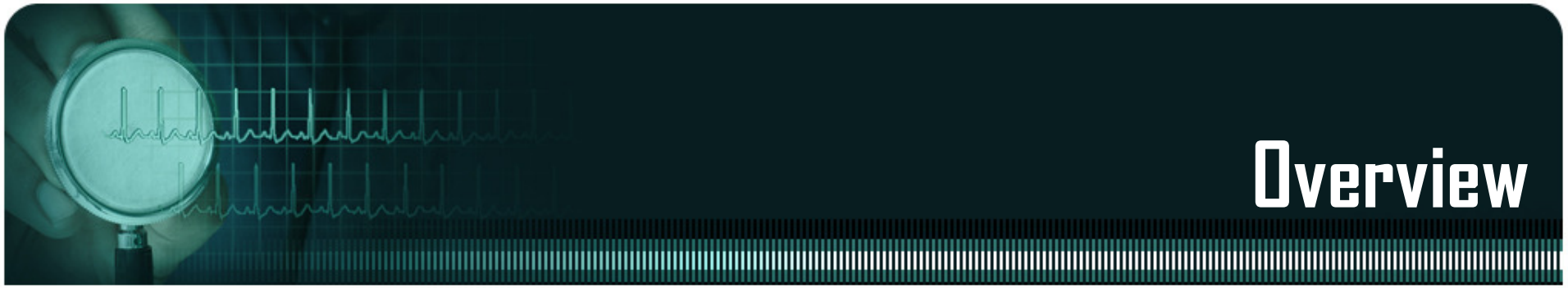
- Set Quality goals
- Ensure that regulations and other requirements are understood and met
- Train employees
- Control your production processes
- Purchase from suppliers that can provide products that meet your requirements
- Correct problems and make sure they do not happen again



Overview

Once the QMS is in place a Registrar is contracted to work with you and conduct an audit.

- When all the criteria are being followed, the company will be ISO 13485 Registered.
- Registered companies can market and advertise their registration certificate.
- Existing and potential customers will know that you have a good Quality Management System in place for your medical devices.

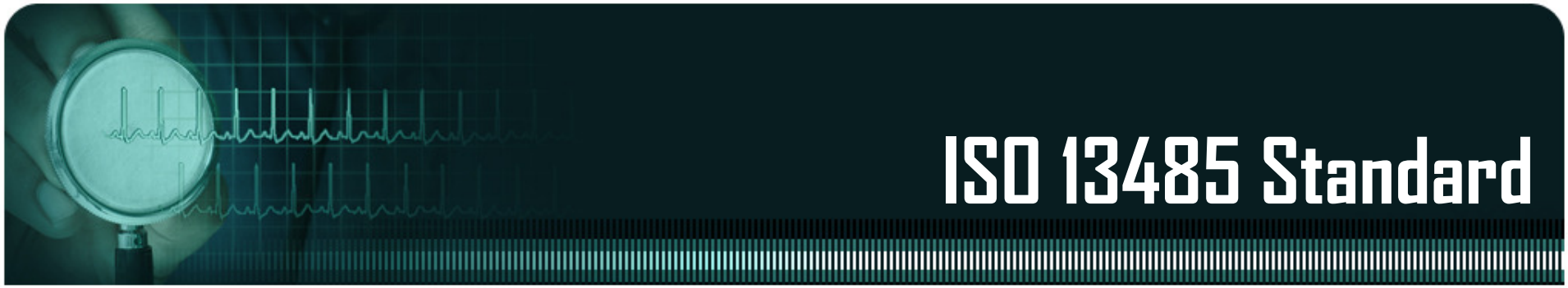


Overview

It is an international standard that describes **Quality Management System requirements for Medical Devices.**

ISO 13485 contains 5 clauses that are numbered 4, 5, 6, 7, 8

4 .. Quality management system
5 .. Management responsibility
6 .. Resource management
7 .. Product /service realization
8 .. Measurement, analysis and improvement



ISO 13485 Standard

- **Section 1: Scope**
  Talks about the standard and how it applies to organizations
- **Section 2: Normative Reference**
  References another document that should be used along with the standard
- **Section 3: Terms and Definitions**
  Gives definitions related to medical devices