

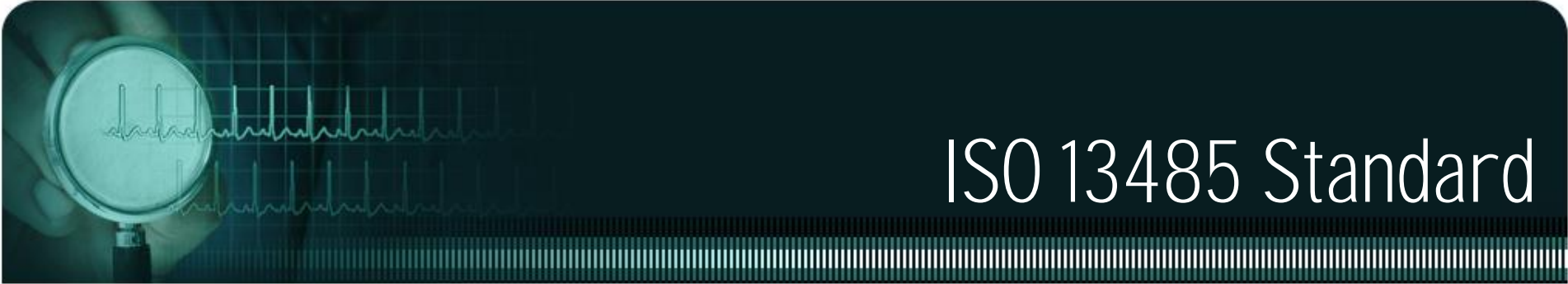
Introduction to ISO 13485

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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**



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



ISO 13485 Requirements

You must use a "Process Management Approach":

- A process management approach is managing your organization as a system of interrelated processes.
- The output of one process is the input for the next process.
- The ISO 13485 Standard is designed to follow a process management approach.



Risk Management in ISO 13485

.. in other words ..

Risk management is part of product realization par 7.1 and is mentioned once again in the design and development inputs at par 7.3.2.

The failure mode and effects analysis (FMEA) methodology can become a useful tool to document the requirement for risk management.