



**BME 590: FUNDAMENTALS OF
ENGINEERING DESIGN**

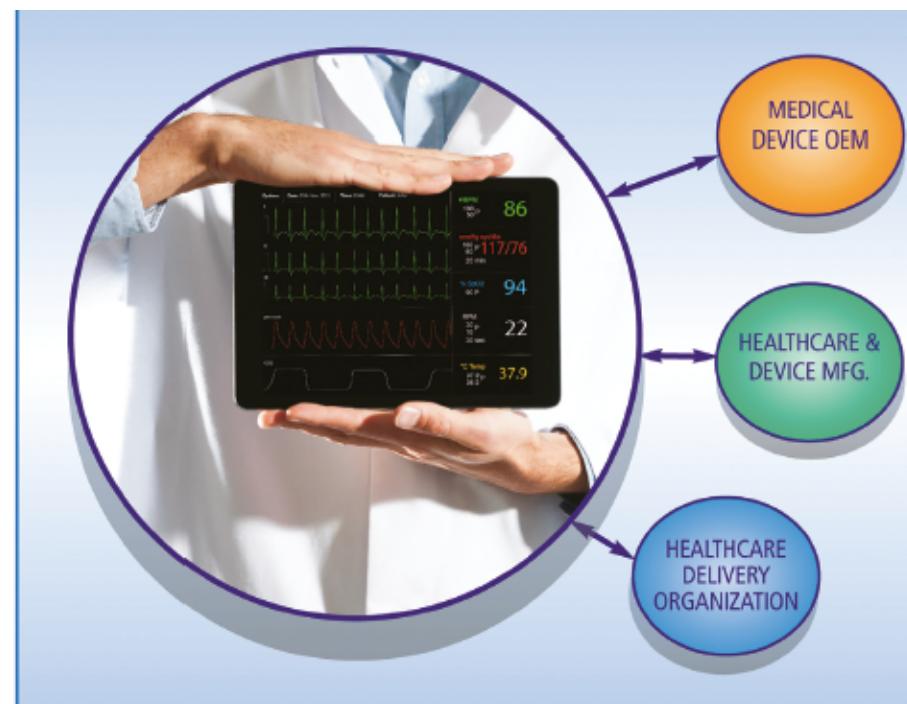
STANDARDS

Salinas

WHAT ARE ENGINEERING STANDARDS?

Standard: a written document that defines the characteristics of a device, process or service.

Code: a law or regulation stating minimum standards to ensure public safety





HOW ARE STANDARDS USED?



"COMMUNICATION" TOOL



PROVIDE 'LEGAL' MEANS FOR EVALUATION



TAUGHT AND APPLIED GLOBALLY



PROTECT PUBLIC FROM QUESTIONABLE DESIGNS

WHO ARE STANDARD ORGANIZATIONS?

International Standards
Organization (ISO)

ISO 13485:1996 Quality systems --
Medical devices -- Particular requirements
for the application of ISO 9001

International
Electrotechnical
Commission (IEC)

ISO 13485:2003 Medical devices --
Quality management systems --
Requirements for regulatory purposes

ISO 13485:2003/Cor1:2009

American National
Standards Institute
(ANSI)

ISO/DIS 13485 Medical devices -- Quality
management systems -- Requirements for
regulatory purposes

US STANDARDS ORGANIZATIONS

HOW ARE STANDARDS ADOPTED IN THE US?

ANSI: US REPRESENTATIVE FOR ISO

AAMI

- ASSOCIATION FOR ADVANCEMENT OF MEDICAL INSTRUMENTATION

ASQ

- AMERICAN SOCIETY FOR QUALITY



FDA

- ISO 14971:2007
- ANSI/AAMI/ISO 14971:2007 (R2010)

TYPES OF STANDARDS



QUALITY



ENVIRONMENTAL



HEALTH AND SAFETY



ETHICS

WHAT TO CONSIDER?

Standards documents are thorough and can provide unlimited aspects of consideration

1. Medical Device Standards:
ISO 14971
2. Standards for People with Disabilities: BS EN 12182: 1999

