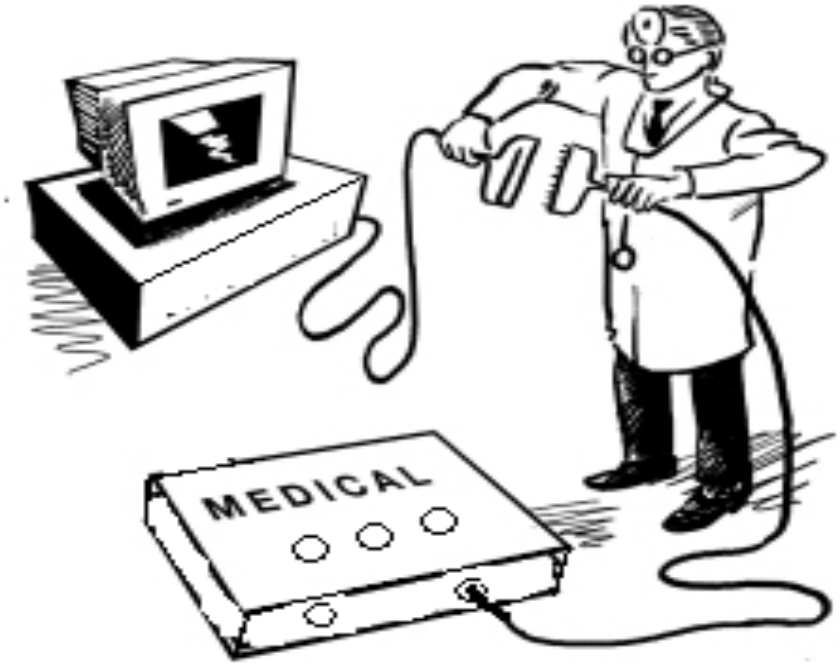
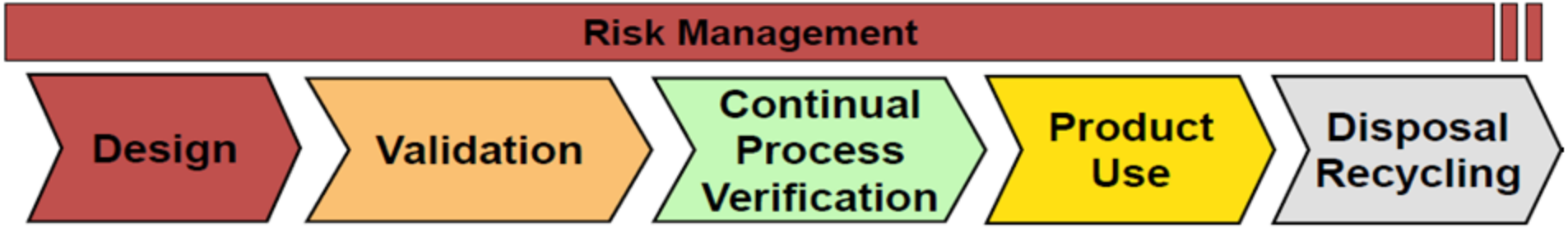
ANECTO

Trusted Test Experts

Test, Validation and Regulatory Requirements for Medical Electronics



Life Cycle Approach



- ☑ Design input
- ☑ Select & Evaluate materials
- ☑ Design
- ☑ Evaluation and Verification
- ☑ Develop validation plan

- ☑ Performance
- ☑ Stability
- ☑ DQ, IQ, OQ, PQ
- ☑ process is capable and in statistical control

- ☑ Detect shifts in process or unnoticed changes

- ☑ Post Market Surveillance

A science-based systematic approach

Why Risk

- Risks and associated measures are called in the following regulations / standards:
  - 43 sections in the MDD
  - 14 sections in the AIMDD
  - 34 sections in the IVD
  - 4 sections in the ISO 13485
  - 35 sections in the CMDR
  - 3 sections in the J-GMP

  - 153 sections in 60601-1 3rd Edition

Establish Initial Risk

- What are you testing
  - Is it a electronic / electro mechanical?
  - Does it have embedded or external software?
  - Is it externally controlled?
  - What is the power source?
  - What are the environmental limitations?
  - What are inputs / outputs?
  - What market are you supplying?
  - What standards / regulations do you need to meet?

Results of Risk Management

- Influence the supplier evaluation activities
- Deliver important inputs for the design process
- Serve as criteria for the evaluation of design output
- Show the necessity for design modifications
- Serve the process controls and the assigned acceptance criteria

- Verification and Validation, what do we have to do?

Verification

- **Verification**: “Are we building the thing right?”
  - Verification activities include:
    - Worst case analysis,
    - Fault Tree Analysis,
    - Failure Mode and Effects Analysis,
    - Inspection,
    - Testing.

Validation

- **Validation**: “Are we building the right thing?”
  - Validation: encompasses all activities that demonstrate that the product meets user needs.
  - It answers the question, “Are we building the right thing?”

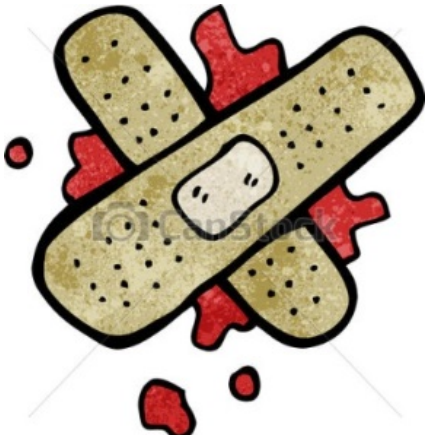
Verification and Validation

- **Hardware**
  - **Verification** and **Validation**, in hardware, confirms that a product or service meets the needs of its users.

- **Software**
  - **Verification** and **Validation** in software, checks that a software system meets specifications and fulfils its intended purpose.

Common Validation Questions

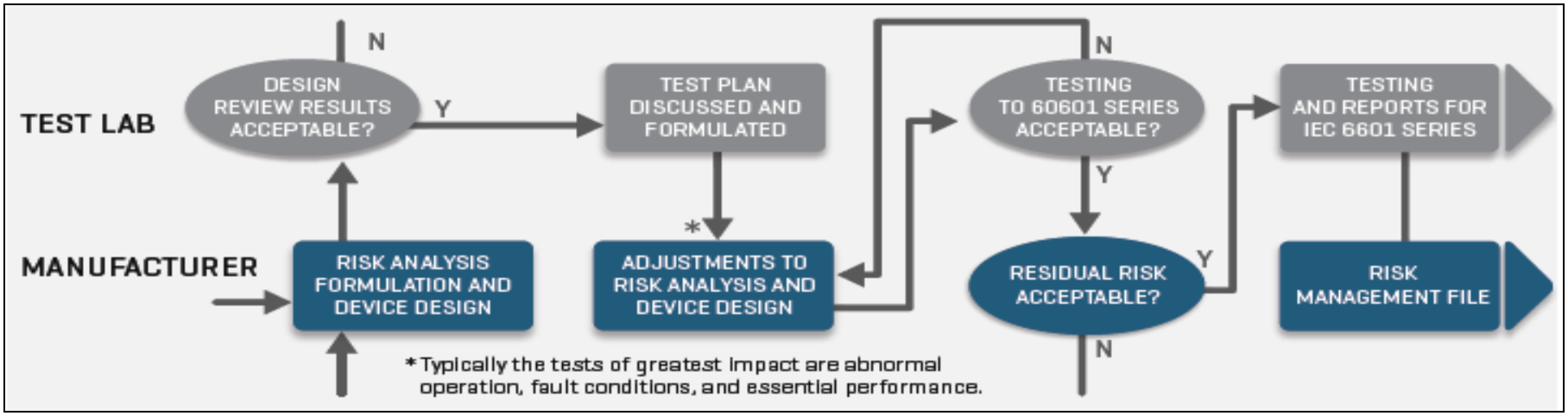
- How much?
- How soon?
- How often?
- How fast?
- How long?
- How many?
- How accurate?
- How will it be documented?
- How easy?
- How hard?



ISO60601-1

- is a series of technical standards for the safety and effectiveness of medical electrical equipment.

- This is a risk based approach



- You have to define the risks and test to show you have either negated or eliminated the risk

Case Study Unexpected Outcome

- The medical device customer changed some screws in the unit assembly and wanted to perform some vibration retesting to determine that this would not cause a problem.
  - During the operational vibration test, the system stopped working.
- Root Cause
  - The cause of the failure was traced to the power supply module.
  - The power supply manufacturer had changed the mounting method for a transformer core from glue mounting to double sided adhesive tape.
  - The core and coil separated from the PCB during the vibration test resulting in the failure.
- This had nothing to do with the original purpose of the test but highlights the benefit of ongoing periodic monitoring.

ISO and ASTM

6 standards required 29 different tests over 4 weeks

- Environmental Storage Conditions
- Environmental Operating Conditions
- Environmental Thermal Shock
- Laboratory Accuracy
- Leakage Currents
- Dielectric Strength
- Ingress of Water and Particulate Matter
- Cleaning and Disinfection
- Excessive Temperature
- Battery Interruption
- Resistance to Heat
- Mechanical Strength - Push
- Mechanical Strength - Drop
- Mechanical Strength – Mould Stress Relief
- Mechanical Strength – Mechanical Shock
- Mechanical Strength – Random Vibration
- Label Test

- Storage Conditions Test
- Ambient Conditions Test
- Shock Test
- Low Power Operation Test
- Labelling & Marking Tests
- Cleaning & Disinfection Documentation Checks
- Vibration
- Manual Handling
- Compression
- Altitude
- Concentrated Impact
- World Wide Environmental Conditions

This could have been a multiple of this depending on risk and product

Product Ownership

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We are all Owners
of the success and failures

Who is responsible if product fails and creates a problem?

- Typical Answer:
  - Who ever is responsible for causing the failure.
    - Material manufacturer
    - Shipping Agent
    - Storage Conditions
    - Mishandling
    - Any number of options

- Real Answer:
  - The product manufacturer.
  - Your Company name on the product = your problem

Product Ownership

The most expensive product is the one that is rejected by the customer or stops working after a short period of time

- Recall / retrofit often leads to loss of reputation
- Scraping of damaged Product / Packaging
- Customer satisfaction
- Loss to competition

You must remember the name on the product is your company name

Certification & Accreditations

ISO17025:2005 Test Laboratory Accreditation

ISO9001:2008 Quality Management System

ISTA (International Safe Transit Association)

ASTM International Organisation Member

What Can Anecto Offer You

Accredited test facilities coupled with regulatory knowledge

Expertise in a an array of disciplines

Dedicated Technical Project team

Experienced engineering staff

Large range of test equipment

Continuously adding new equipment and processes

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