An introduction to Design Verification and Validation

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- **Design programs have many variations, ranging from small to large, simple to complex, short-term to long-term, etc.**
- **Regardless of the size, complexity, or duration, each program must be clearly defined and follow pre-determined development phases/stages.**

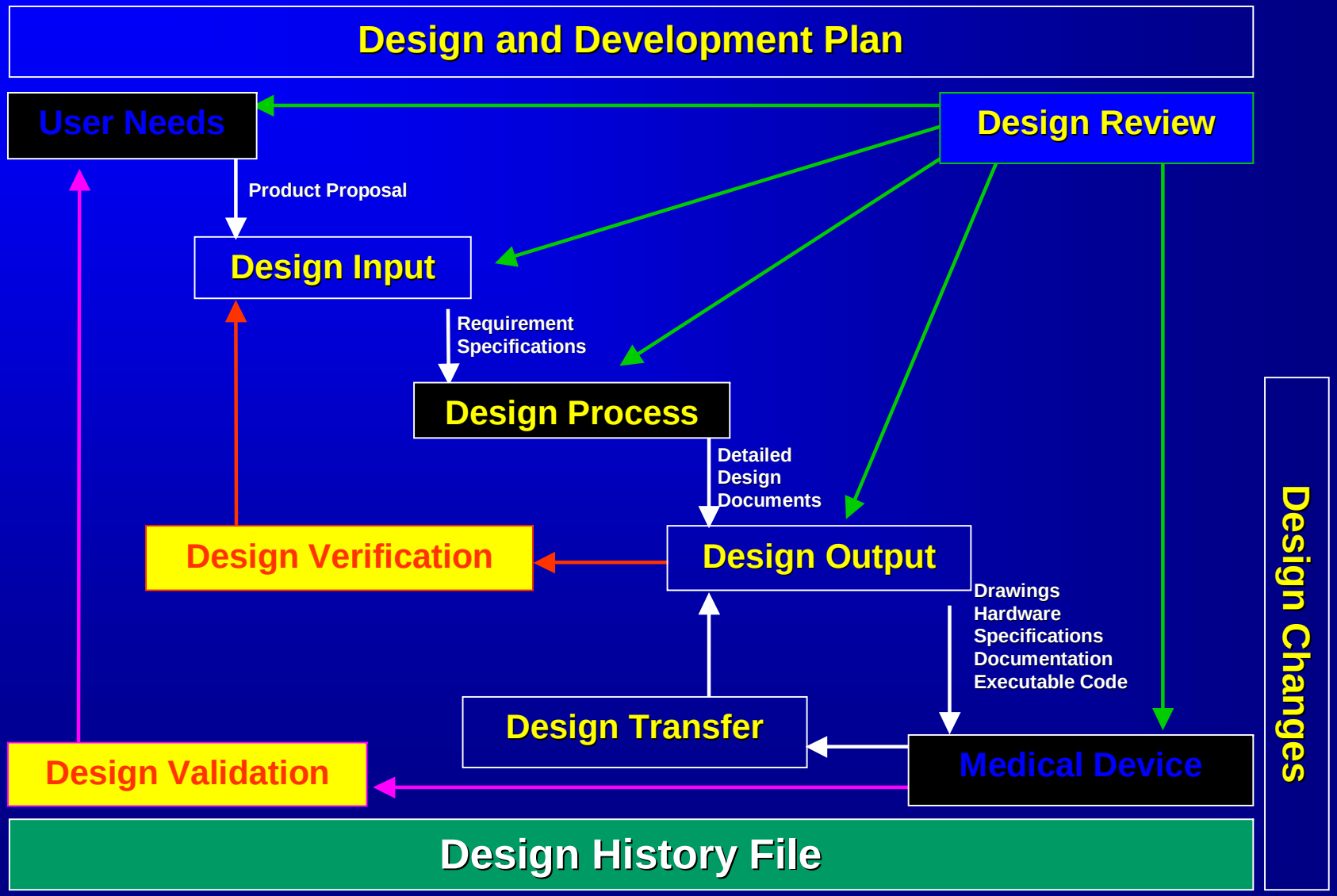
- **The composition of Design teams depends on the type of program:**
  - **cross-functional team**
  - **individuals with diverse skills in the areas of**

- **program management**
- **software design**
- **service design**
- **marketing**
- **regulatory affairs**
- **system design**
- **hardware design**
- **manufacturing**
- **sourcing**
- **quality**

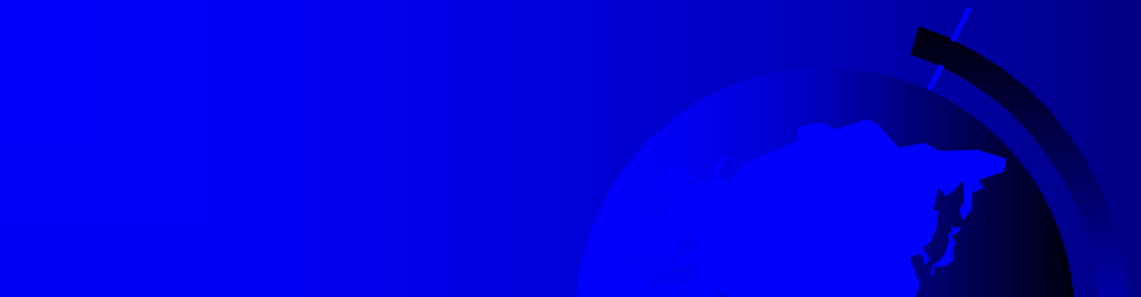
Design Cycle Activities and Corresponding clauses of ISO13485:2003

	ISO 13485: 2003
Design and Development Plan	§7.3.1
Design Input	§7.3.2
Design Output	§7.3.3
Design Review	§7.3.4
Design Verification	§7.3.5
Design Validation	§7.3.6
Design Transfer	§7.3.1
Design Changes	§7.3.7

Verification and Validation in the Design Cycle



Design Verification and Validation Case Studies



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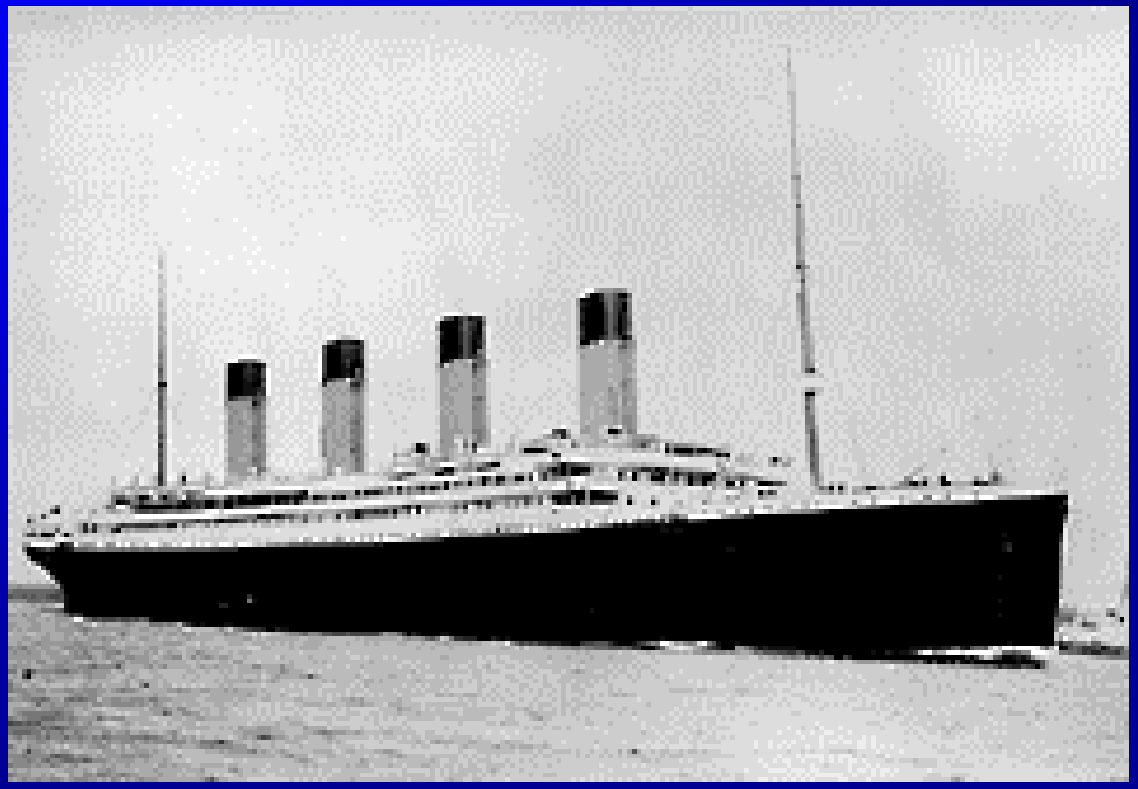
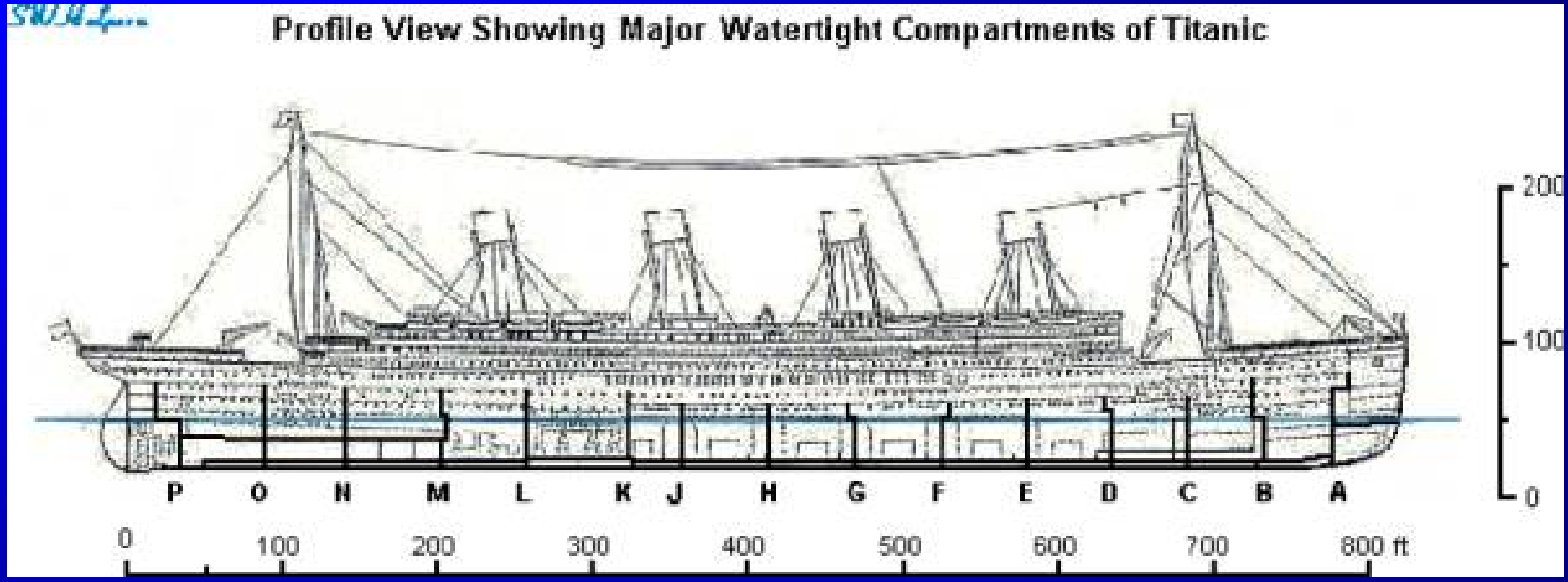
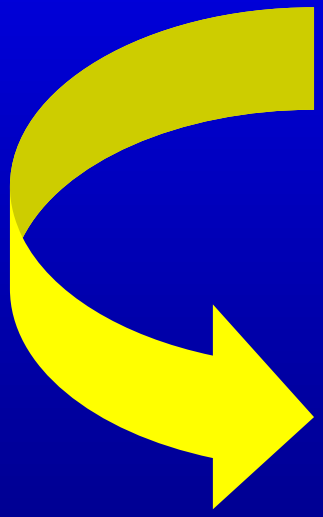
The Titanic





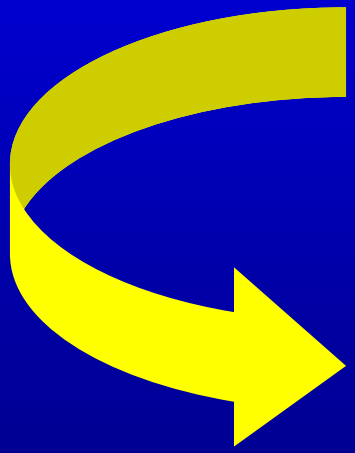
- **Titanic's double bottom and other design features were presumed to ensure it being unsinkable**

- **All "regulatory requirements" (e.g. hull thickness, lifeboats, properly sealing doors, life vests, etc.) were confirmed.**



"Verification" **successful**

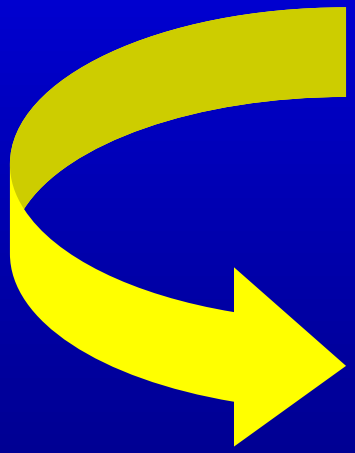
- **Despite meeting all requirements, the ship sank within 3 hours.**



WHAT WENT WRONG?

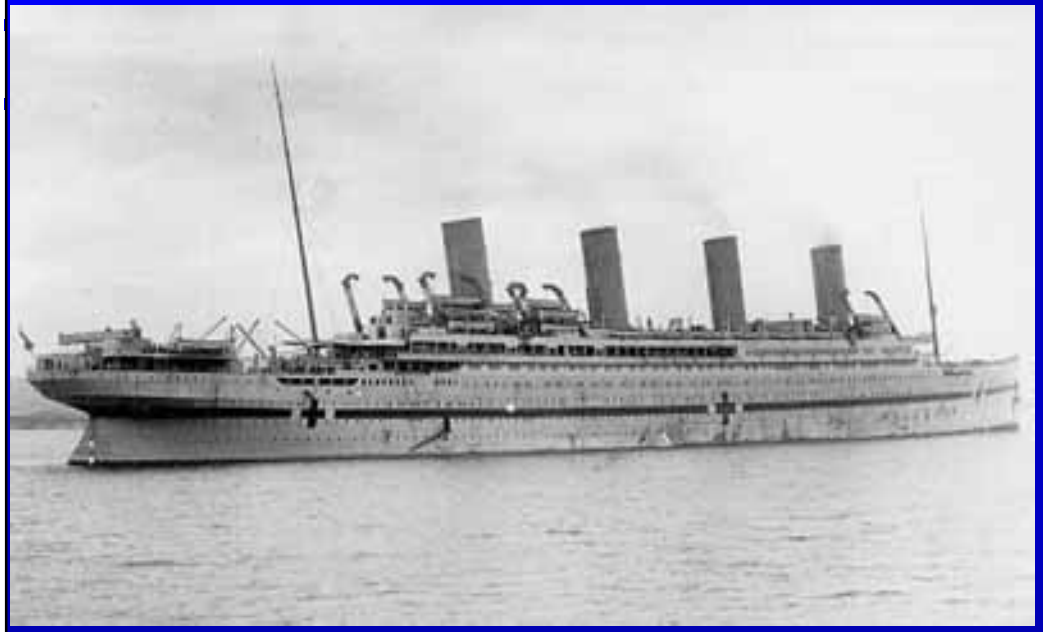
WHY?

- **Despite meeting all requirements, the ship sank within 3 hours. Many people perished due to the assumption the ship was unsinkable and could not reach life boats in time!**



Risk Management **(FMEA, etc.) may have highlighted this and** ***Validation*** **may have confirmed this (e.g. evacuation drill with fully occupied ship, simulated tests, etc.)**

Titanic's Sistership – The Britannic



The Britannic sank after sustaining damage she theoretically should have been able to survive with little difficulty.

More surprisingly she sank 3 times faster than the Titanic, despite the ***many additional safety features*** that were included into her design following the Titanic disaster.

Are assumptions made during design always valid?

Device Labeling

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Consider instructions printed on the enclosure of a medical device and the environment in which the device is used.

What activities would be recommended for the manufacturer?

Most medical devices are subject to cleaning with disinfecting agents.

Operator's manuals should define acceptable cleaning solutions and methods.

Validation needs to confirm that

- the ink withstands the cleaning agent
- the ink withstands repeated rubbing activity
- the enclosure material is not adversely affected by either

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Thank you on behalf of Study Group 3 and the GHTF for your time and attention.

Questions?