

# Design Controls: Case Study

## FDA Small Business Regulatory Education for Industry (REdI)

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# Impact of Medical Device Technology



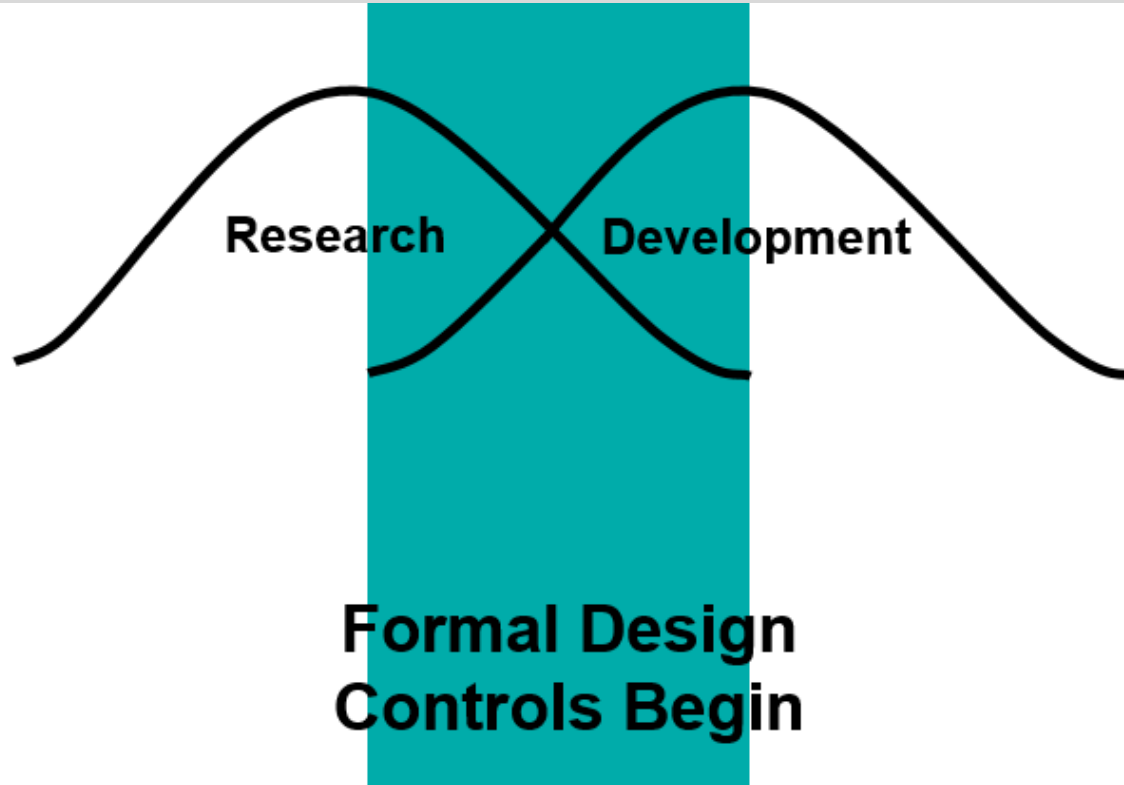
# Learning Objectives

1. Explain when and where to begin design controls
2. Determine intended use, human factors and benefit/risk
3. Recognize who should be doing what and when
4. Discuss the design water fall diagram with an example

# Our Case Study's Back Story

- Research team developed new rapid technology
  - to detect microscopic organisms
- Identified virulent Andromeda strain
- Strain diagnosis time - important
- Executive management:
  - Proof of concept is sufficient
  - Time is right to go to market

# When to Start?



# Where to Start?

- Review Regulatory Requirements
  - including [21 CFR 820](#) (820.30); [21 CFR 812](#)
- Review available [guidance documents](#), [standards](#) and [educational materials](#)
- Implement your approved design control procedures

# **Intended Use, Human Factors and Benefit/Risk**

# Intended Use and Human Factors

Device is a rapid diagnostic assay to test for Andromeda infections in human clinical samples

- What sample type?
- Who will be using it?
- What are the performance characteristics?
  - How long does the test take – Test Run Time?

# Benefit / Risk

Start determining the test's benefit/risk profile by using risk management and risk analysis tools.

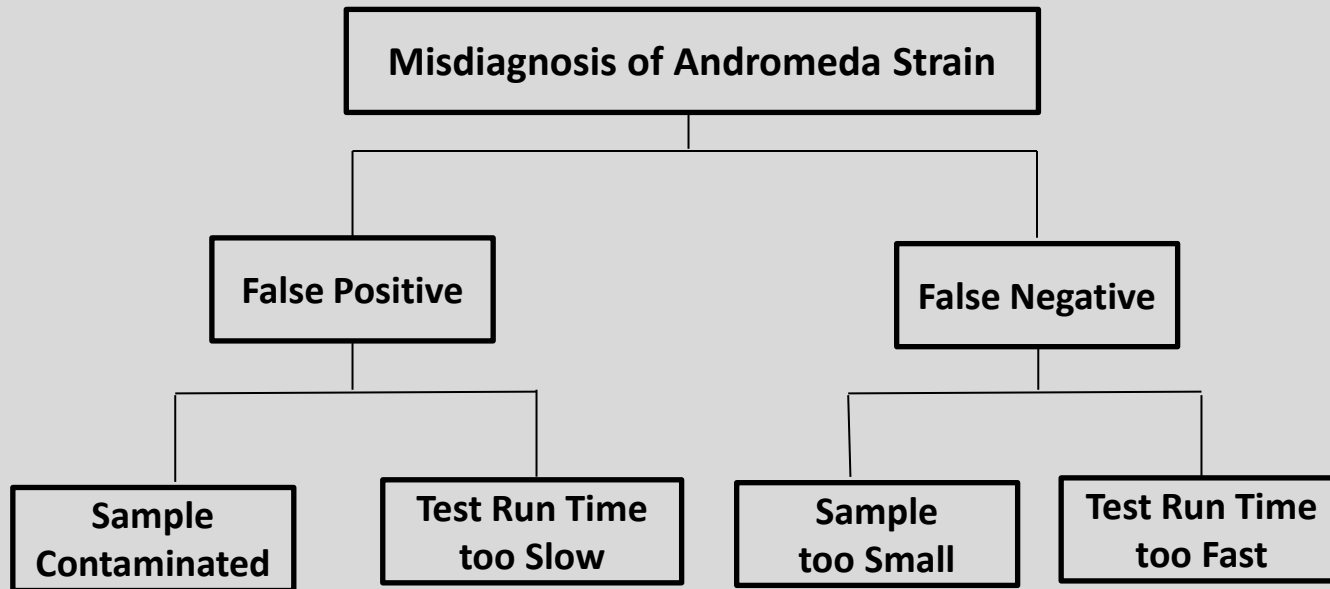
- Benefit – positive impact or desirable outcome of the use of medical device on the health of an individual, or a positive impact on patient management or public health.
- Risk – combination of the probability of occurrence of harm and severity of that harm.

# Potential Test Hazards

- Hazard – potential source of harm
  - Incorrect test results, leading to misdiagnosis
  - Data Integrity
  - Biological Agents
  - Chemical Agents

# Example of a Risk Analysis Tool

## Fault Tree Analysis (FTA): Test



# Knowledge Check

The intended use of the test can be determined once it is in distribution.

1. True
2. False

# Who, What, When

# Who Should Be Doing What

## Establish a Cross-Functional Design Team

- Besides us, design team includes:
  - Research Scientist, Dr. Bruce Banner
  - Independent Clinical Investigator, Peter Parker
  - Senior Manufacturing Engineer, Tony Stark
  - Executive Marketing Lead, Steve Rogers

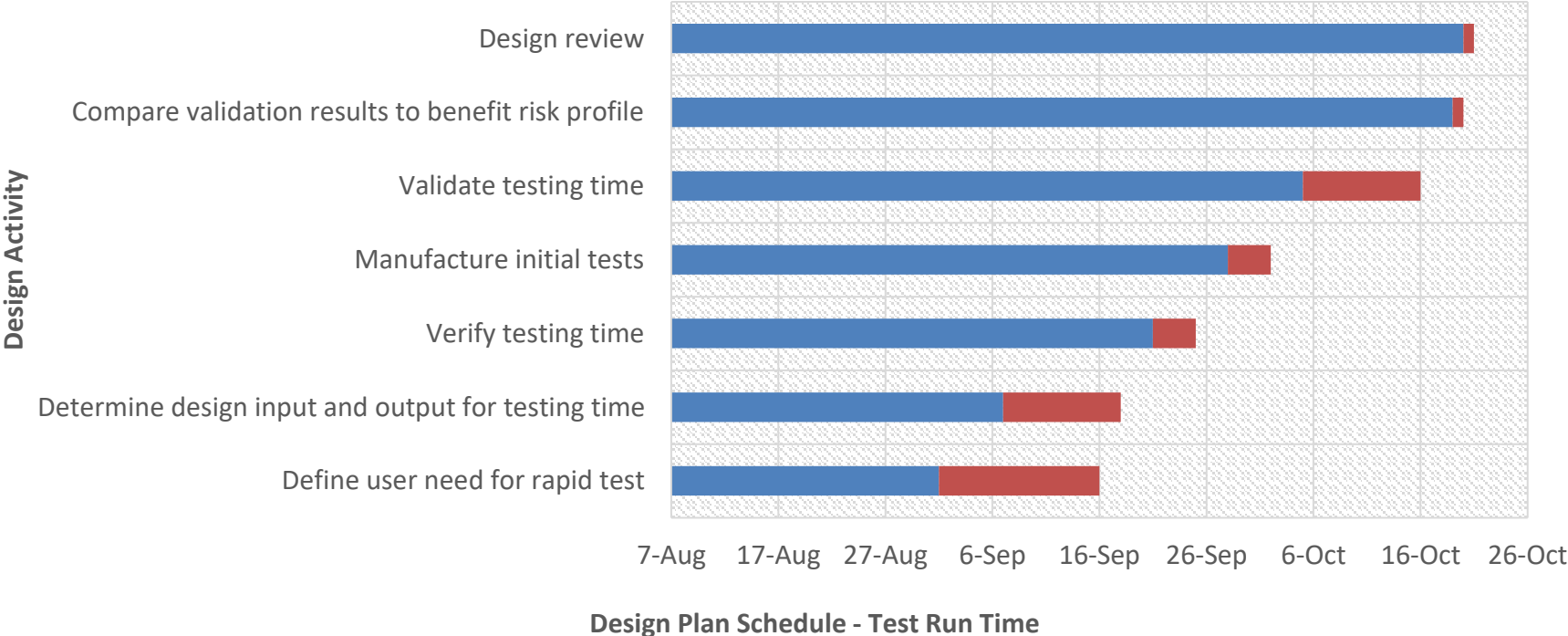
# What to Do Next

- Determine the device (test) classification and requirements
- Have a pre-submission meeting with CDRH
  - in this case, OHT7 (OIR)
- Establish a design plan
- Continue to define the test benefit/risk profile

# When to Do It

- More information gathered upfront the better
  - especially to understand benefit/risk profile  
(Example: side effects of gamma radiation use)
- Follow the design plan
  - Examples: Gantt, PERT or Flow Charts, Spreadsheets and Tables
  - Update them as needed

# Design Gantt Chart Using Excel



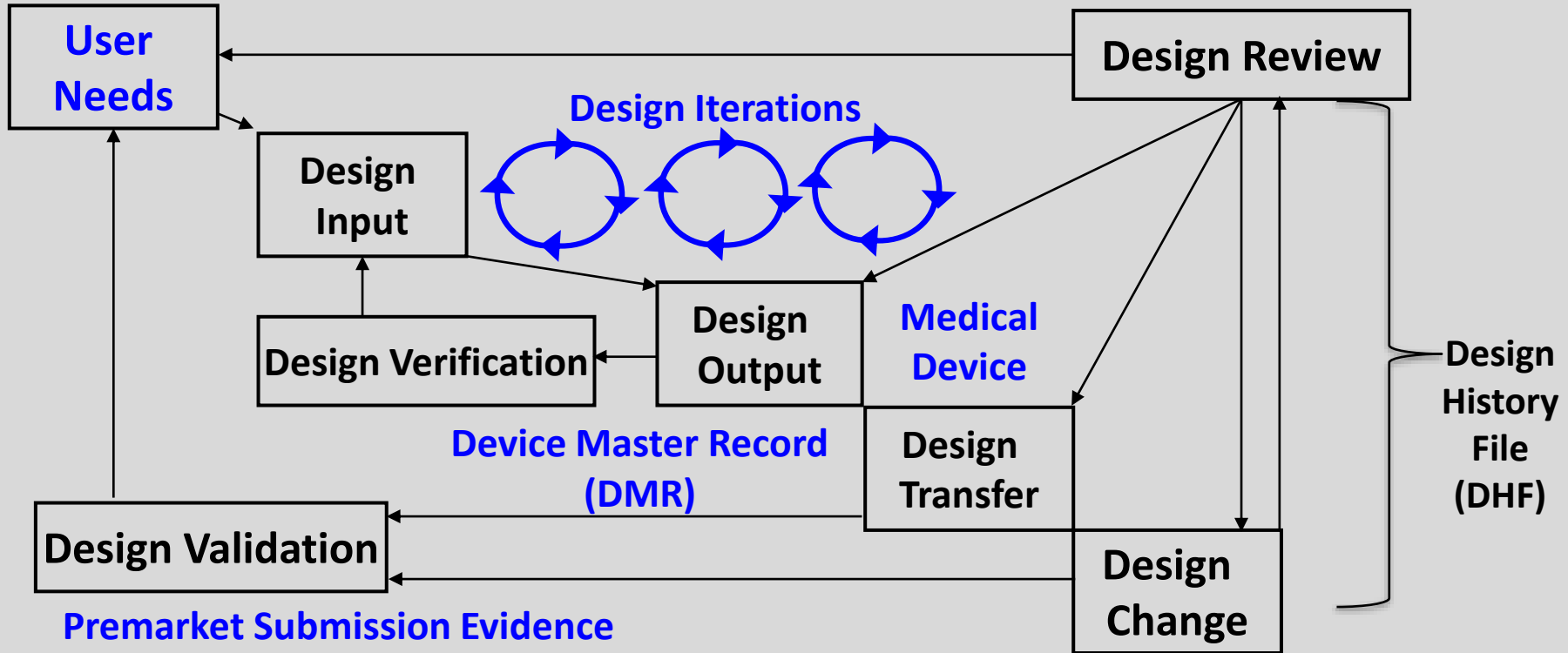
# Knowledge Check

Who is needed to approve the design review?

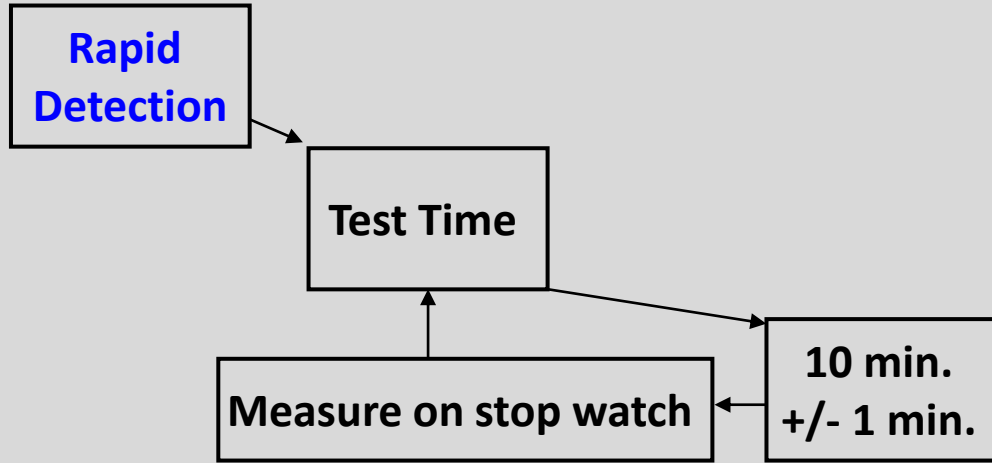
1. Only the Executive Marketing Lead
2. Only the Lead Research Scientist. It is his project
3. Design Team
4. Just Research and Marketing. Manufacturing can find out later

# Design Waterfall Diagram with Example

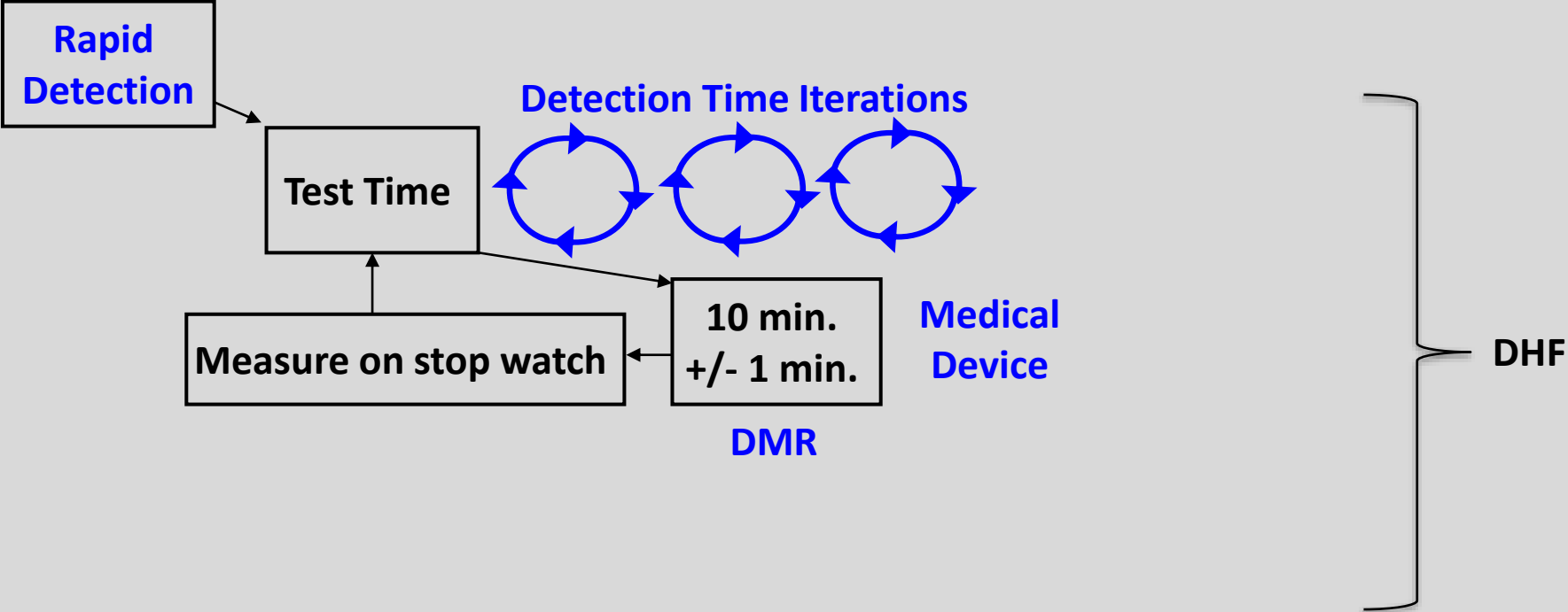
# Design Control Overview



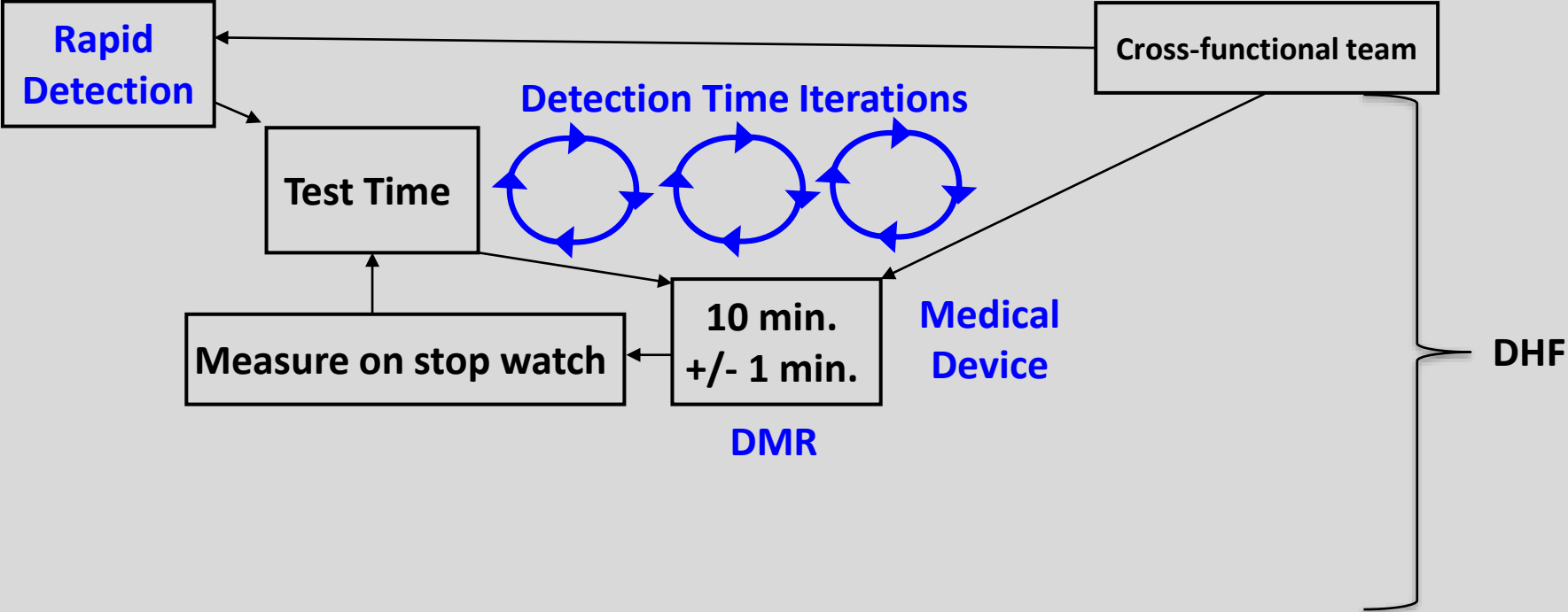
# User Need to Design Input



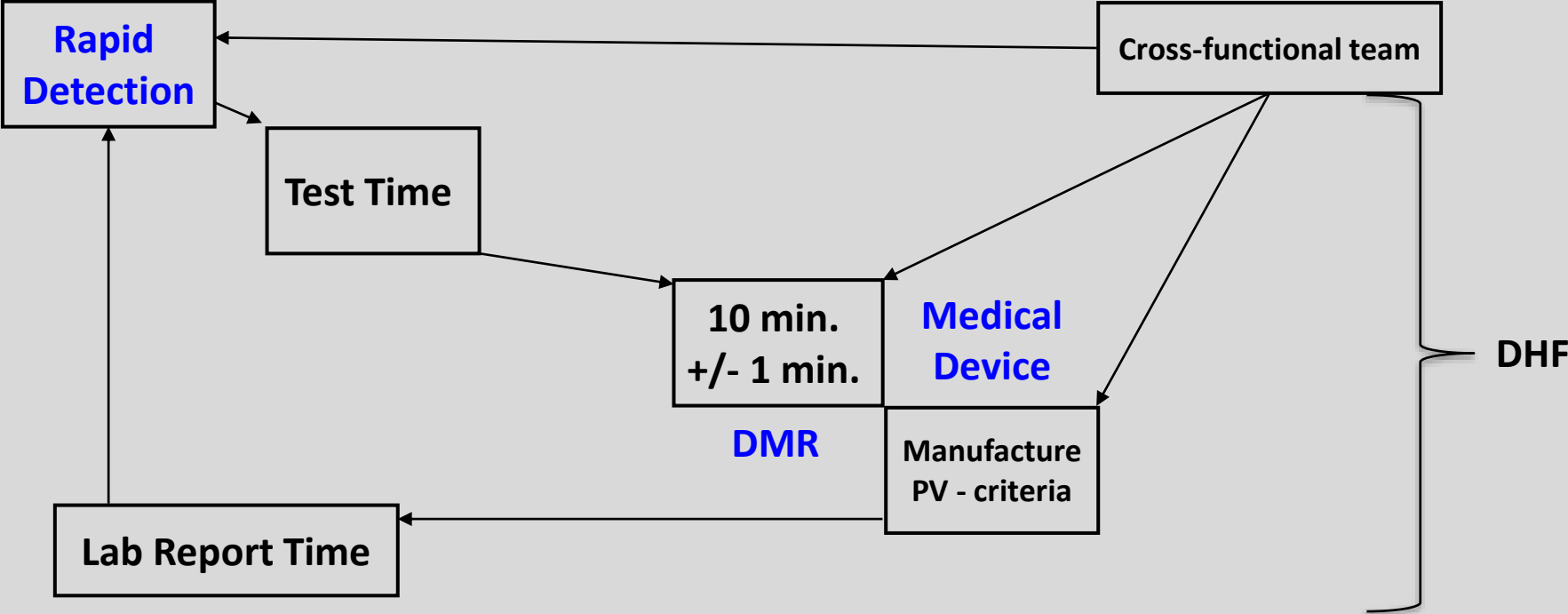
# Design Input, Output and Verification



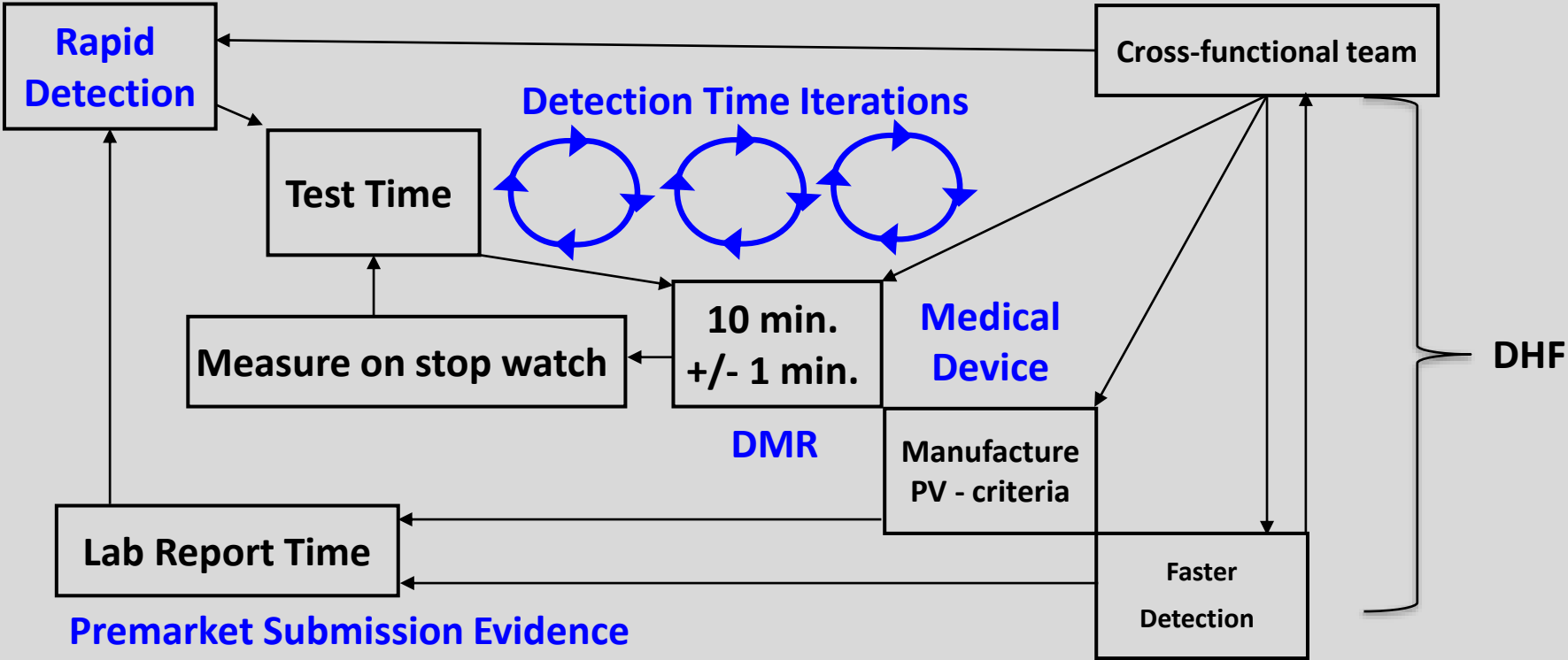
# Design Review and Design History File



# Design Validation and Design Transfer



# Design Control Case Study Overview



# Knowledge Check

What is not part of the design waterfall?

1. Design Validation
2. Design Sales Confirmation
3. Design Review

# Summary

1. Starting design controls at the right time is essential
2. Determining the initial intended use, human factors and the benefit risk profile early is critical
3. It's important to have a design team that represents all functions
4. Knowing the phases of design controls is good

# Resources

Cited Resource	URL
21 CFR 820 Quality System Regulation	<a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820">www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820</a>
Recognized Consensus Standards	<a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm">www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</a>
Design Control Guidance	<a href="http://www.fda.gov/media/116573/download">www.fda.gov/media/116573/download</a>
ISO 14971 Medical devices – Applications of risk management to medical devices	<a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard_identification_no=40369">www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard_identification_no=40369</a> (for purchase from standards organization)
CDRH Learn – Design Controls	<a href="http://fda.yorkcast.com/webcast/Play/a12e1a3b9faa40ae96225b236de6d1a51d">fda.yorkcast.com/webcast/Play/a12e1a3b9faa40ae96225b236de6d1a51d</a>

# Questions



