Testing in regulated frameworks for medical devices

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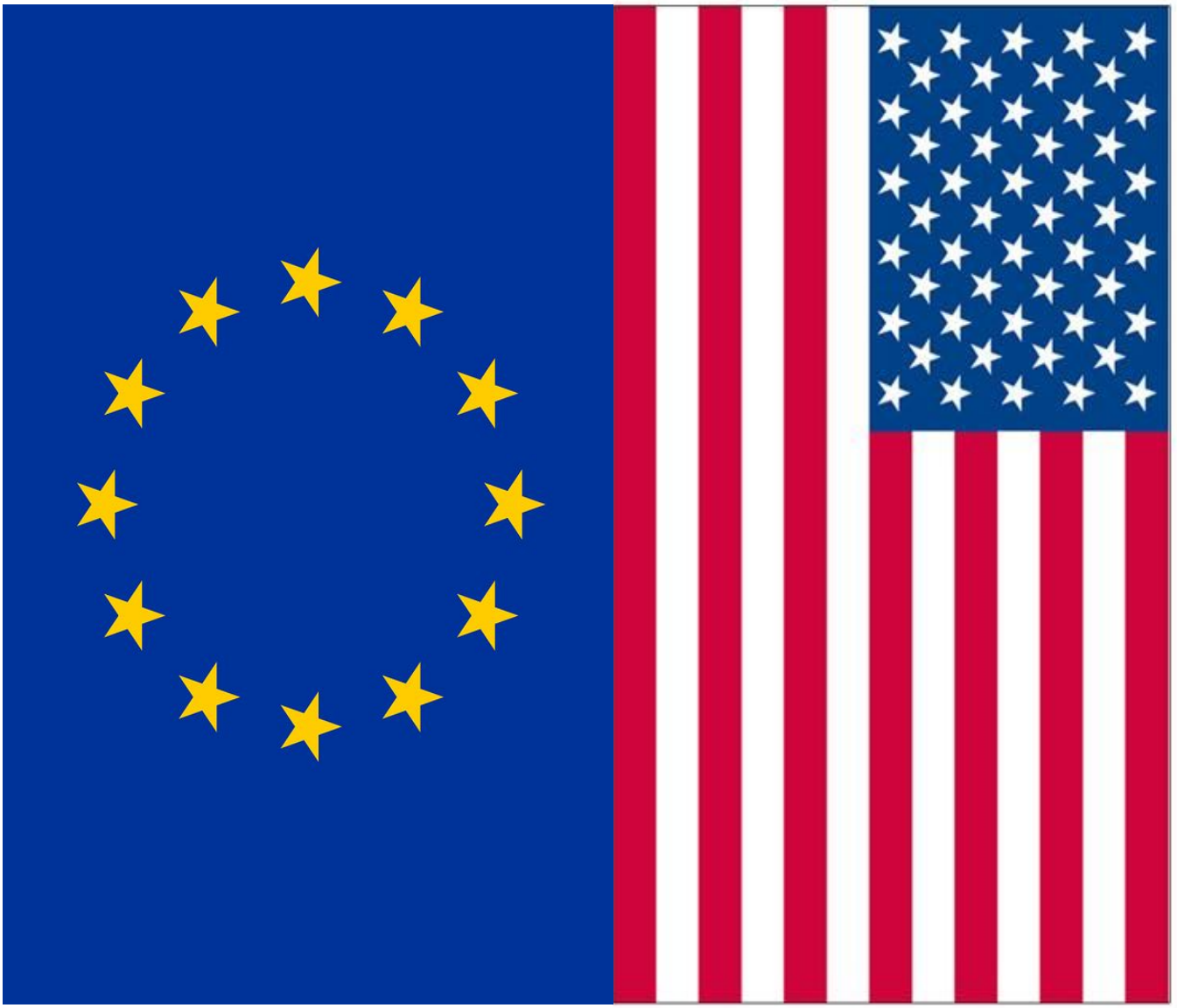
TOPICS: 3 main blocks

Regulated Frameworks USA/EU

Roche specific Product Life Cycle

Testing at Roche

Regulated Frameworks



Medical Devices

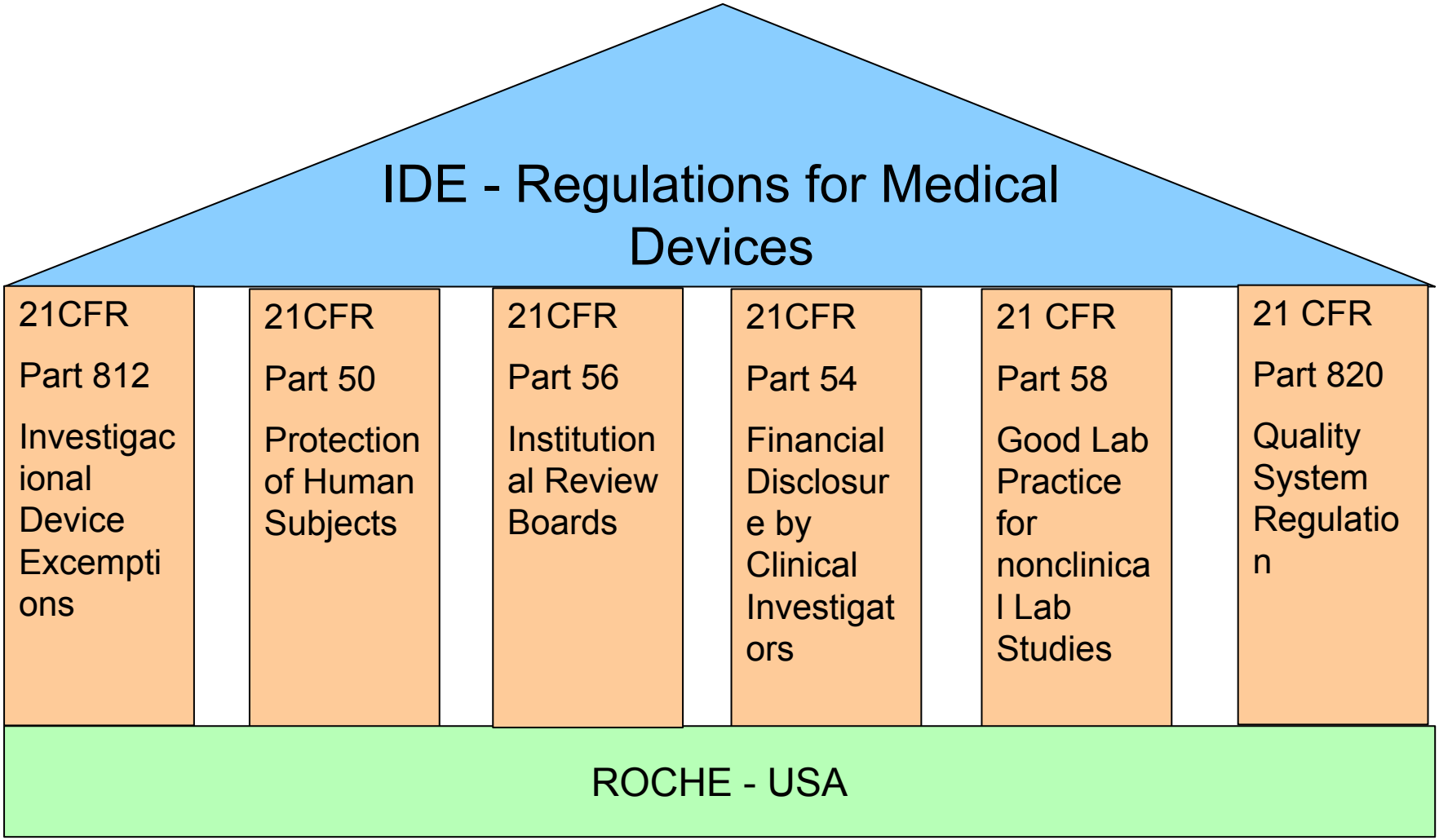
FDA (food and drugs administration)

FDA is an agency responsible for…:

- Assuring that products distributed in USA are **safe** and **effective.**

- FDA regulations are also **federal laws**: title 21 of the Code of Federal Regulations (CFR).

Regulated Frameworks- Context USA



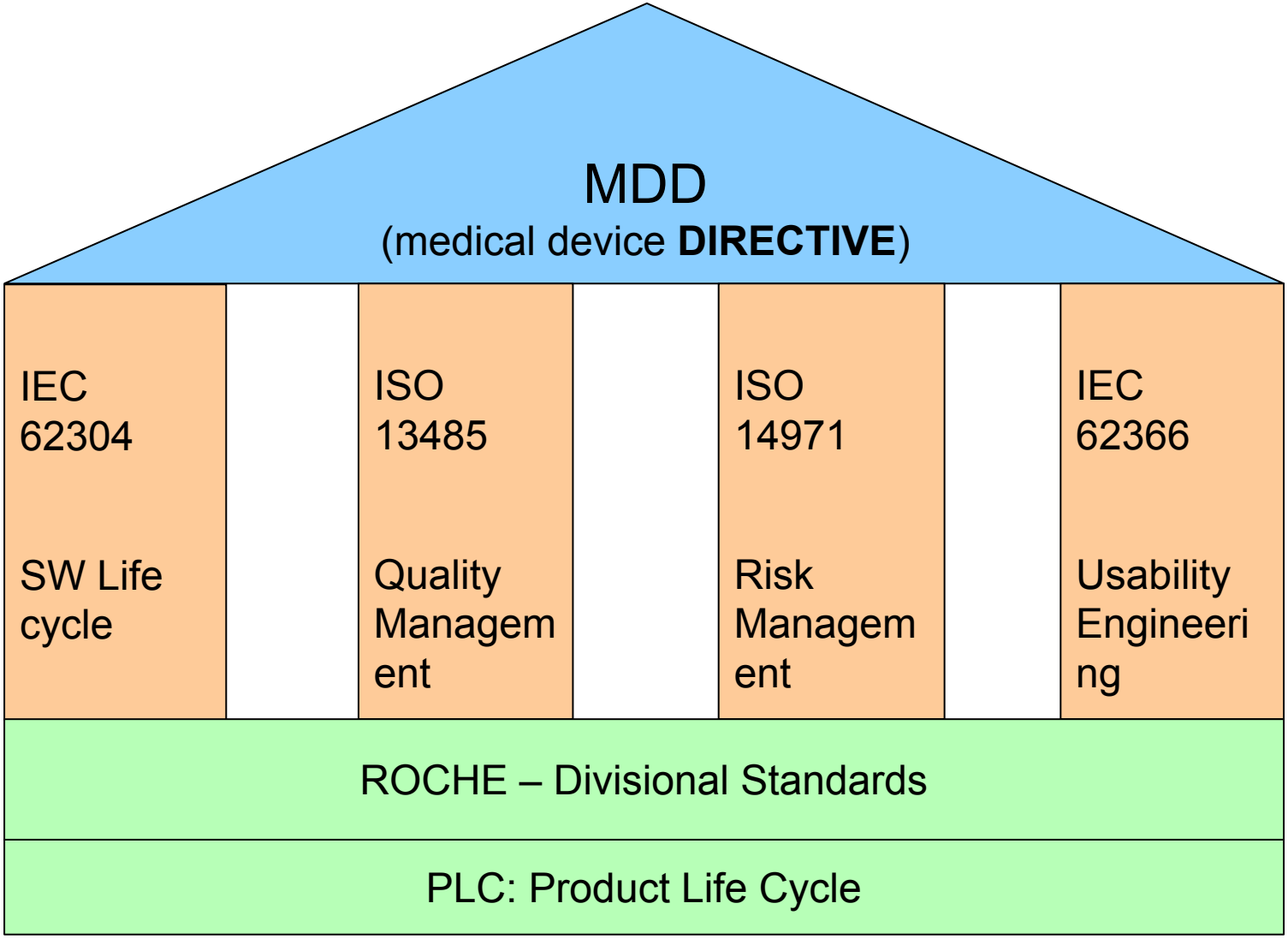
European Union Treaties

The goals of the treaties are achieved by several types of legal acts (some bindings, others no).

Regulations: **binding** legislative acts. They must be applied in all EU.

Directives: legislative acts that set out a goal that EU must achieve. But every country devises its own way to reach this goal.

Regulated Frameworks - Context EU



IEC 62304 - Software Classification

A software is classified in three Safety Classes (A, B, C) according its possibility to health damage.

Class A	Class B	Class C
No injury or damage to health is possible	Non-serious injury is possible	Death or serious injury is possible

ISO 13485 - Medical devices - Quality management system (QMS)

Based on ISO 9001 *(quality management addressed for any organization)*

Focused on **Medical Devices** and related service

MAIN GOAL: meet customer and regulatory requirements:

QUALITY!

ISO 14971 - Medical devices – Application of risk management to medical devices

Establish a process to manage and control the risk related to the medical device

A risk policy must be created to establish a risk acceptability criteria

Risk management file is required to document the intended use and identify the items that could affect safety

IEC 62366 - Medical devices - Application of usability engineering to medical devices

Usability standard for medical devices

User interface to establish effectiveness, efficiency, ease of user learning and satisfaction

Try to avoid errors caused by an inadequate use of the medical device

IEC 62366

Not safe

Not usable

SAFE, OK,
BUT...
USABLE ?

SAFE?

Divisional Standard - Design Control (Company specific)

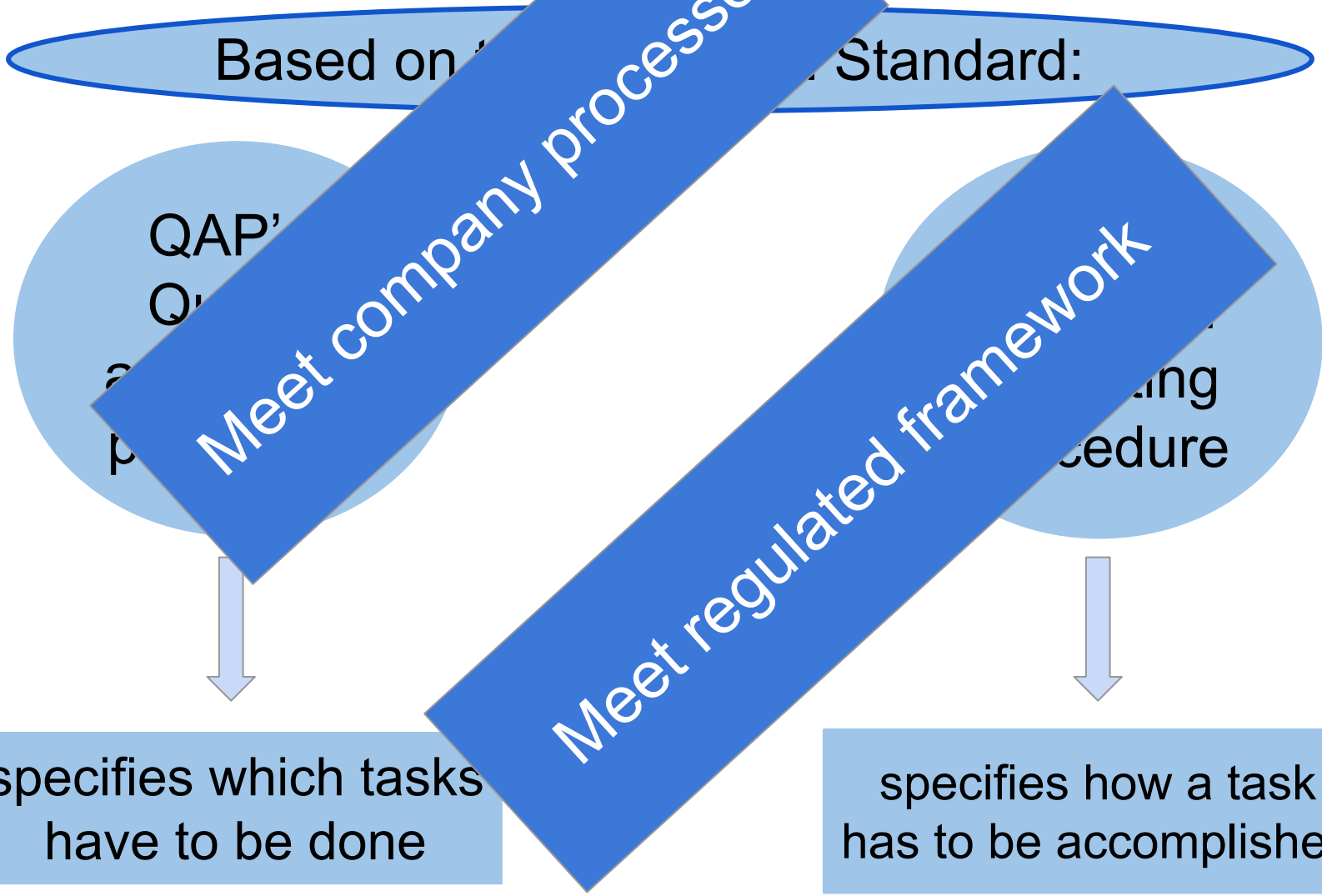
Describe an end-to-end process for the development of regulated Standalone Software

Provides a basic framework how to apply principles to Standalone Software development

Takes into account up to date guidance documents and standards

The mandatory, minimum requirements for software development are described

Product Life Cycle - Depa nt specific

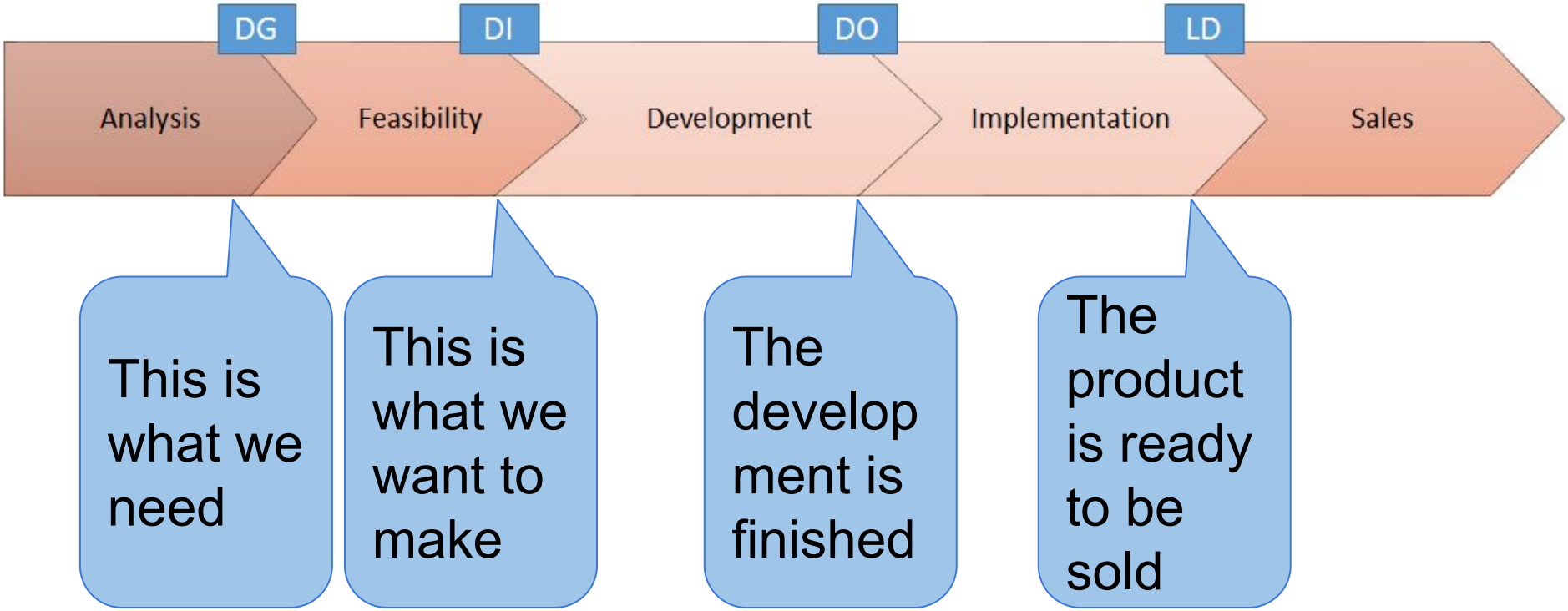


HEALTHCARE

ROCHE SPECIFIC PLC:

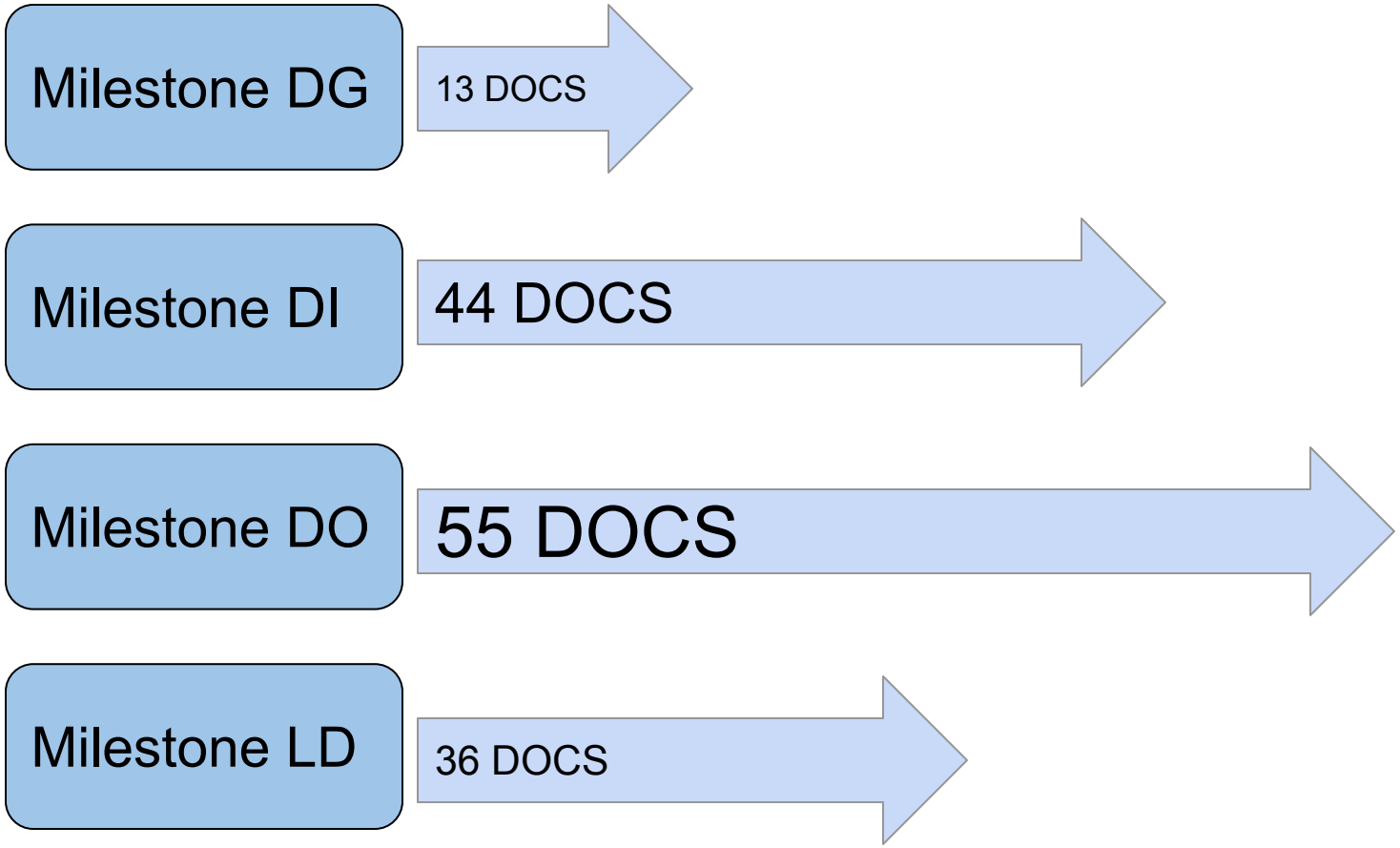
Project x:

4 key Milestones:



\+ List of Deliverables (LoD) for every milestone

Real example of deliverables:



How to manage the documents:

In addition, all documents have their own **thor, reviewer/s and approver/s**

A complete tool to mana ocumentation is needed:

- version has to l liable
- documen
- to pre e
- documents with date and signature

SAP

Main Key Point to be compliant

DI ⟺ DO

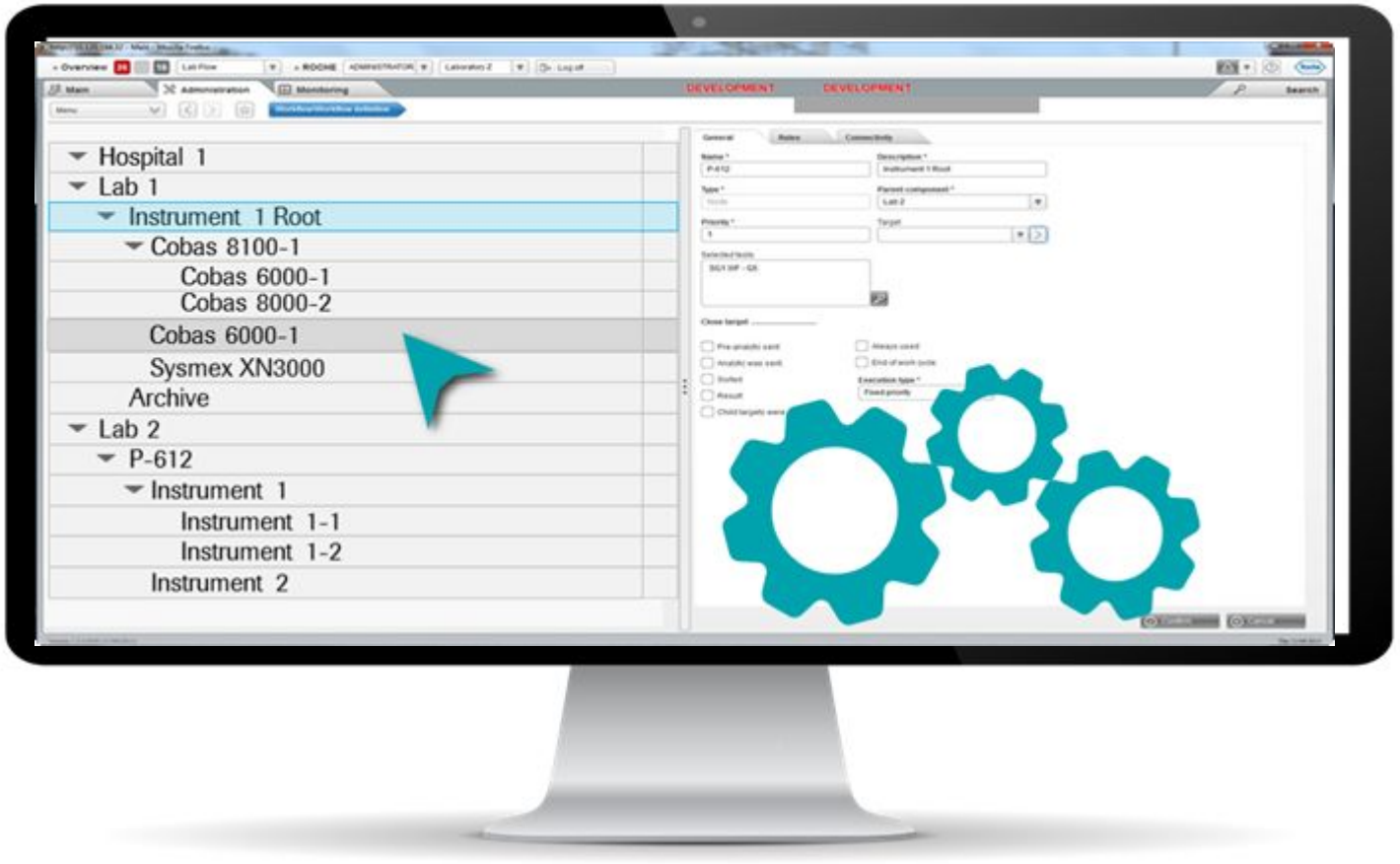
What we wanted to make

is

What we have made

The requirements are met

TESTING AT ROCHE



Key test document (for DI)

VERIFICATION & VALIDATION PLAN:

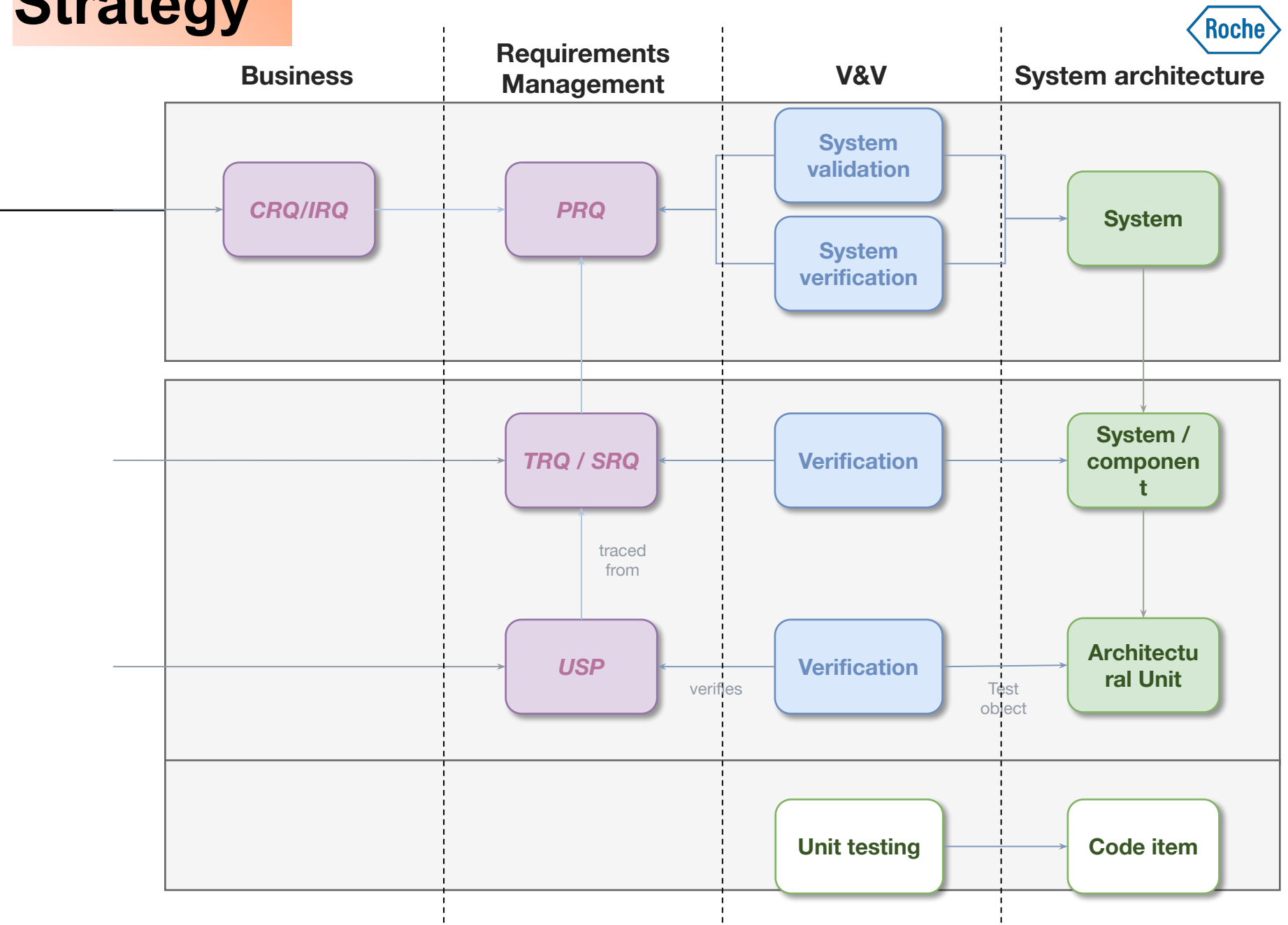
- Scope to test
- Verification and validation objectives
- Assignment of activities and responsibilities
- Deviations for the standards (if any)
- Plan, timeline, resources and phases
- Verification and validation strategy

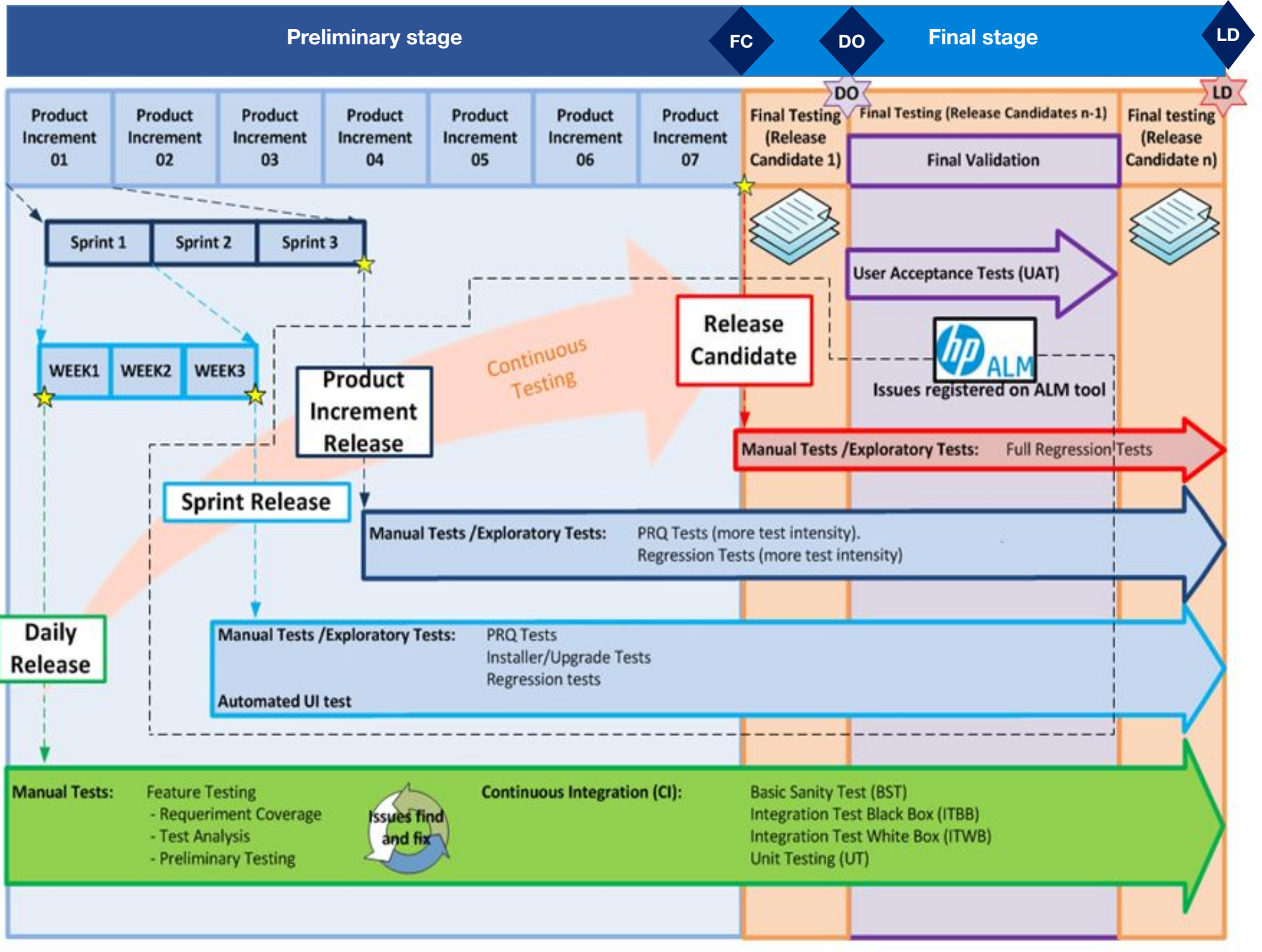
Other test documentation

Once the plan is approved, every specific round of test should include its own documents, such as:

- Specific test plan
- Test cases (TC) to be executed
- Test Results + **OBJECTIVE EVIDENCE** for every TC
- Specific test report

Strategy


Business
Requirements Management
V&V
System architecture
CRQ/IRQ
PRQ
System validation
System verification
System
TRQ / SRQ
Verification
System / componen t
traced from
USP
verifies
Verification
Test object
Architectu ral Unit
Unit testing
Code item


Preliminary stage
FC
DO
Final stage
LD
Product Increment 01
Product Increment 02
Product Increment 03
Product Increment 04
Product Increment 05
Product Increment 06
Product Increment 07
Final Testing (Release Candidate 1)
Final Testing (Release Candidates n-1)
Final Validation
Final testing (Release Candidate n)
Sprint 1
Sprint 2
Sprint 3
WEEK1
WEEK2
WEEK3
Continuous Testing
Release Candidate
Product Increment Release
Sprint Release
Daily Release
User Acceptance Tests (UAT)
ALM
Issues registered on ALM tool
Manual Tests /Exploratory Tests: Full Regression Tests
Manual Tests /Exploratory Tests: PRQ Tests (more test intensity).
Regression Tests (more test intensity)
Manual Tests /Exploratory Tests: PRQ Tests
Installer/Upgrade Tests
Regression tests
Automated UI test
Manual Tests: Feature Testing
- Requeriment Coverage
- Test Analysis
- Preliminary Testing
Issues find and fix
Continuous Integration (CI): Basic Sanity Test (BST)
Integration Test Black Box (ITBB)
Integration Test White Box (ITWB)
Unit Testing (UT)

Once final verification arrives...

Before starting	- All the required testing documentation has to be done, reviewed and approved (V&V plan et.al)
Sequence of events	- It is not possible to approve a doc if it depends on another one that is not approved
Control measures	- They have to be planned to be executed
Objective Evidences	- They have to be collected

Once final verification ends...

Test documents	- Summarizing the activities and results (created, reviewed and approved)
V&V Report	- Closing all the chapters explained in V&V plan
External Evaluation	- Real customers can evaluate the product before it is officially launched (validation process)
Product Launch	- Once the validation process is finished and the findings are addressed.

Validation

Confirmation that the product is created according to the intended use.

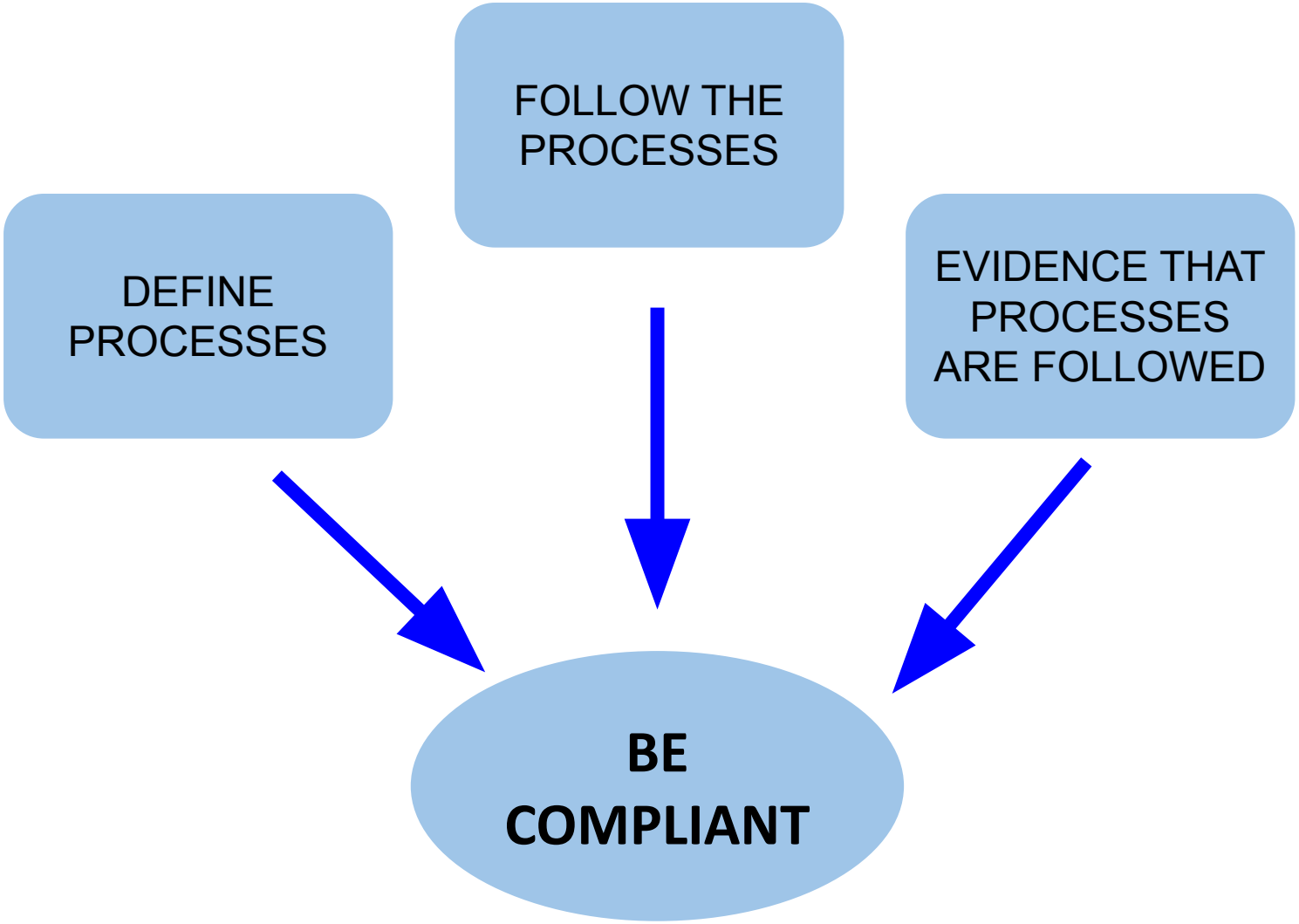
Real customers have to confirm that the product fulfill their needs in a real environment

→ Medical practitioners
→ Patients

→ Experienced and well trained laboratory staff
→ Novices

→ Field Service Engineers

The Main Takeaway



Thank you for your attention!

Q&A