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sense and simplicity

Test Automation in an FDA-regulated environment

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Philips Healthcare, GTC - Flat Detectors
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Agenda

- Introduction
  - Philips healthcare / FXD
  - Regulations – FDA
  - Our Test Process
- Test Environment
  - Test framework (Bellerophon)
  - Automated Testing
  - Logging / Tracing
  - Test Reports
  - Round-up
- Questions

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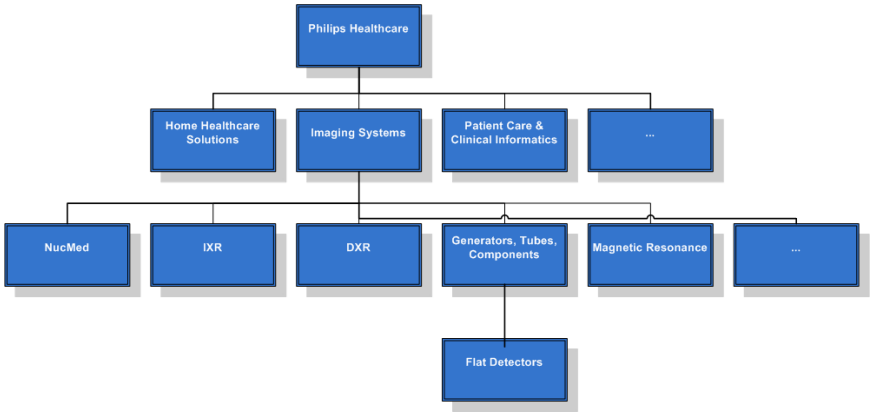

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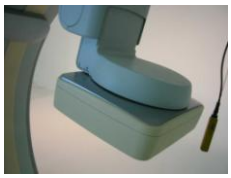

Dynamic Flat Detectors:
- various suppliers
- various sizes

FD-Controllers:
- 3 distinct Types

Grids:
- Detector dependant

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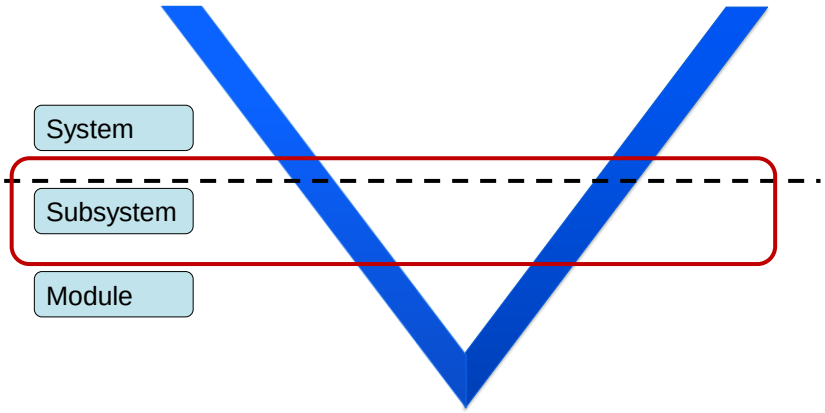
Context regarding V-Model

Hardware, Firmware and Software within the same group, Verification-Team responsible for release of subsystem to system group



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Regulations
FDA / EMEA / SFDA / ISO

- Reviews!
- Signed-off documentation, designs (and even implementation)
- Adhere to standards e.g.
  - ISO 13485
  - CFR 820
- Specify what you (will) do and prove that it is done in this way.
- Just PASS / FAIL is not enough!

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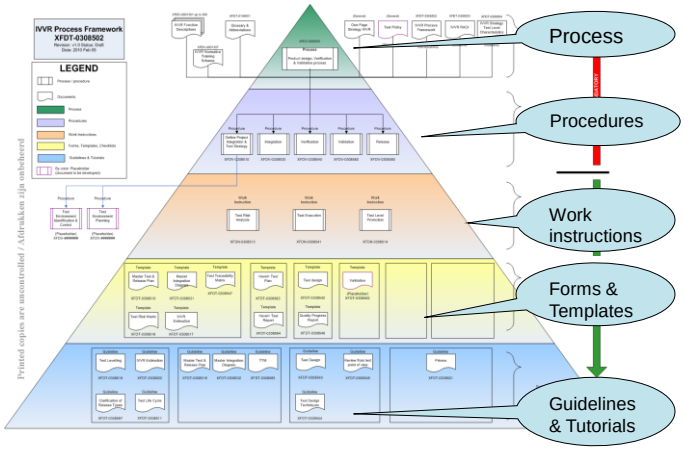
Strict Test Process - Heavy Quality management measures



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Test - Process dictates:

- Required documents per product / phase
- Required people to review documents
- Who is responsible
- How are things done
- Clear, unambiguous traceability from requirements to Test Designs, Test cases and Test results.

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Overall Strategy

- Risk Based Approach

- Main Phases:
  1. Integration Test: integration of functionalities, sub modules
  2. Product Test: focus on performance, reliability and serviceability….
  3. Release Test: Prepare for Production, focus on manufacturability and transfer to production.

- Integration approach: Top Down – Bottom Up
  - Early and continuous integration on (sub) system level (with stubbed interfaces)
  - Low level integration steps replacing stubs

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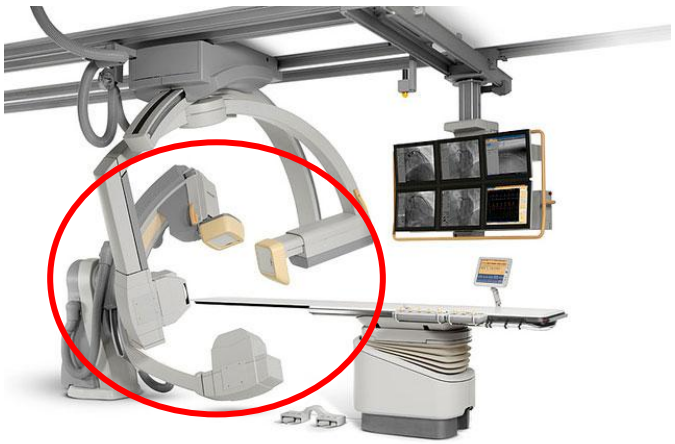
How?



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Every difficult situation requires a hero

Bellerophon

labview application supporting:

- Timing
- Interface
- Simulation of Peripherals
- Power supply control
- Image processing and output
- Libraries required for Tests
- Biplane simulator

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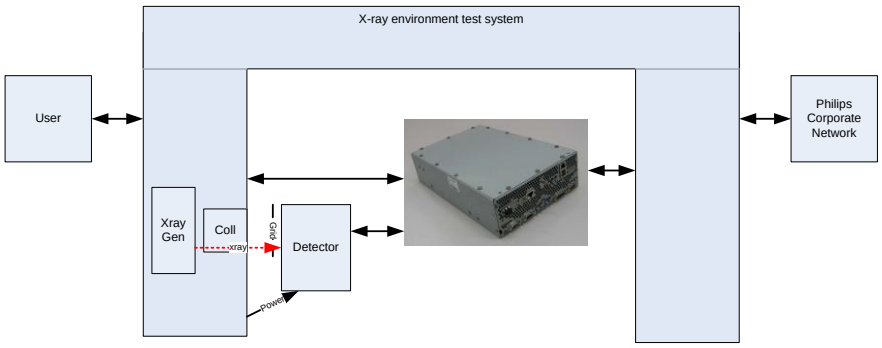
Bello

contains everything (HW/SW) that is needed for our Device Under Test



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Lets start testing allready

- Various configurations, various products
- Only subsystem available
- Clear tracability of testcases to requirements
- Logging and tracing importance
- Re-use test-ware as much as possible

Problem

- Automate!!!
- Test Cases translated into C#-code
- Use unit-test framework to run tests
- Test Cases configuration independant

Solution

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C# isn't that a programming language?

- Developers eager to help
- Code Template to "fill-in" test case
- Many library funcitons available to help with tests
- Very flexible
- A lot of tools available that can be used with ease

But also

- We're not developers so keep it 'easy to use'
- Code reviews; version control
- Many new things to learn

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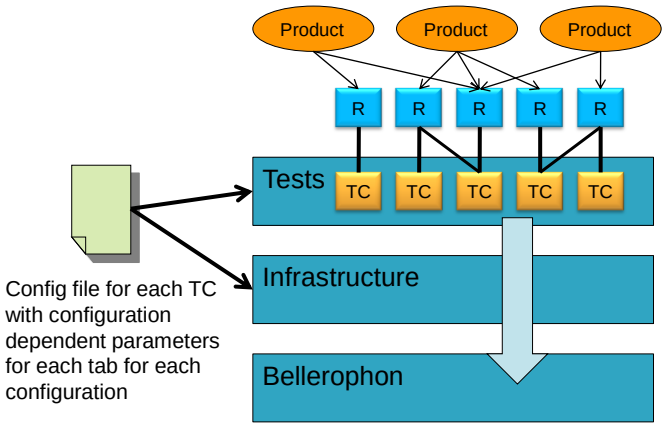
No configuration dependencies in Test Cases



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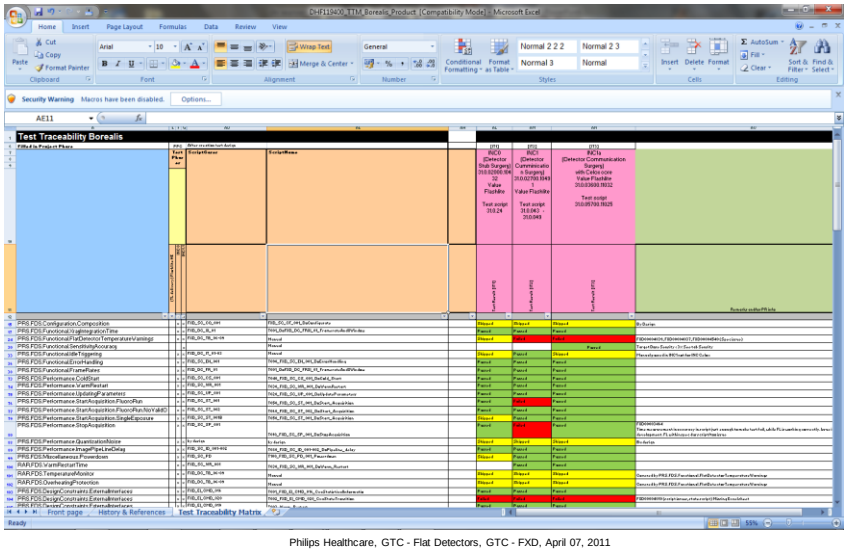
Revisiting our Process Tracability Matrix



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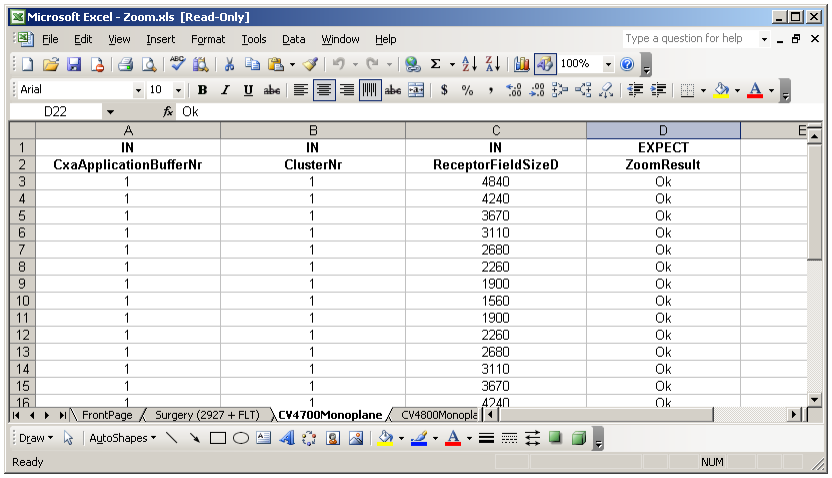
Example of config file



	A	B	C	D	E
1	IN	IN	IN	EXPECT	
2	CxaApplicationBufferNr	ClusterNr	ReceptorFieldSizeD	ZoomResult	
3	1	1	4840	Ok	
4	1	1	4240	Ok	
5	1	1	3670	Ok	
6	1	1	3110	Ok	
7	1	1	2680	Ok	
8	1	1	2260	Ok	
9	1	1	1900	Ok	
10	1	1	1560	Ok	
11	1	1	1900	Ok	
12	1	1	2260	Ok	
13	1	1	2680	Ok	
14	1	1	3110	Ok	
15	1	1	3670	Ok	
16	1	1	4240	Ok	

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Automating the execution

- VS Solution contains 2 parts,
  - configuration dependant containing a reference to all test cases needed to run
  - Configuration independant with all automated test cases
- An abstraction layer is used to read configuration files while running test cases
- Besides the configuration and actual testcases test data such as images are also part of the solution

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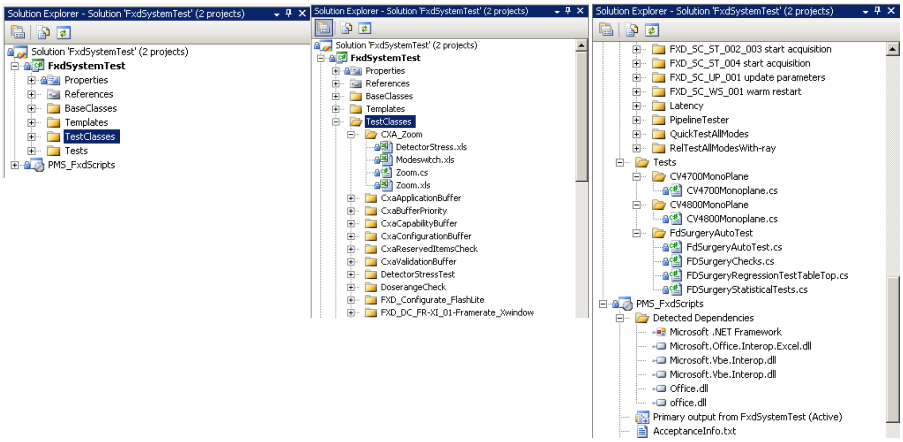
MS Visual Studio Solution



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Integrating nUnit

- nUnit supports categories which can be defined in code
- Resulting DLL can be by nUnit to build a tree of tests for each configuration
- Based on test result UI is updated to give a quick one-look glance about the status of current test run

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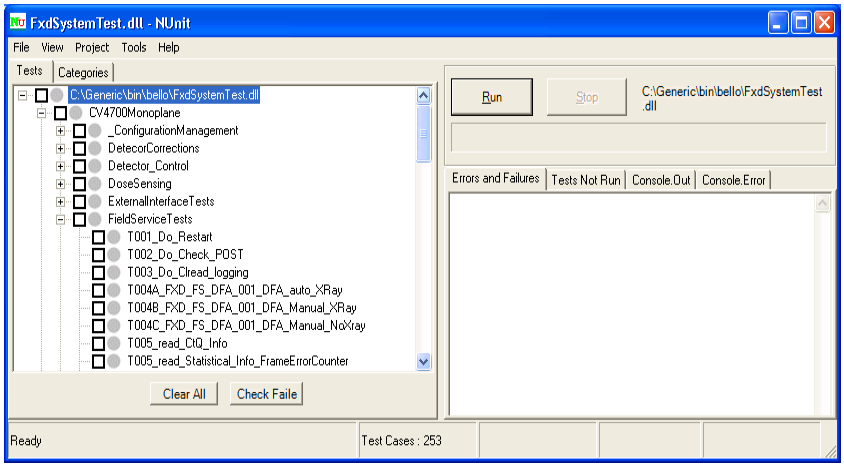
nUnit as a framework to execute tests



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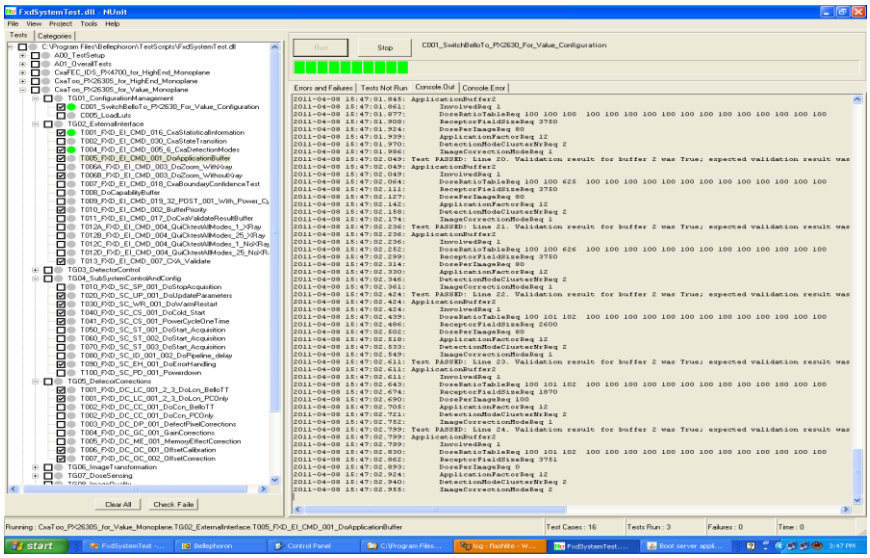
nUnit continued



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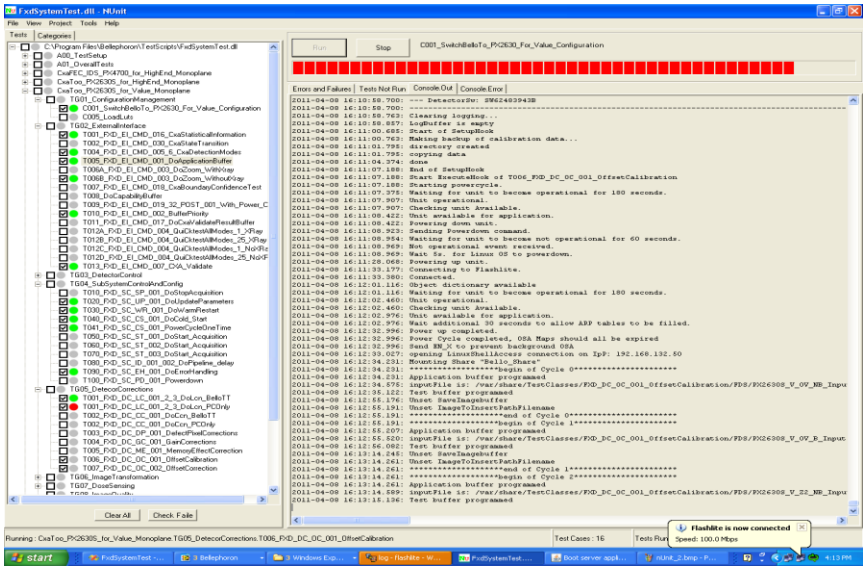
nUnit continued



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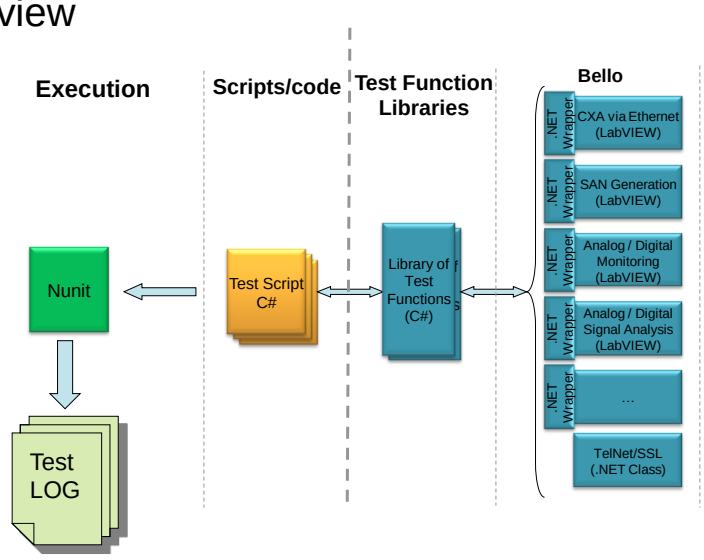
Overview



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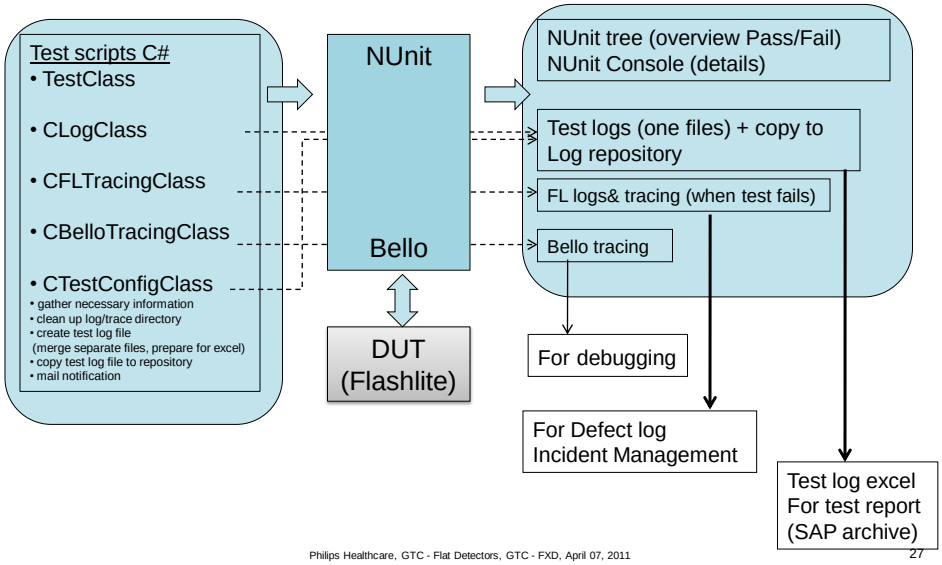
Facilitate/automate test log process



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Test Reporting

- Test Reports highly related to TTM
- Overall result of all test cases included
- Requirements that are covered are also part of it
- Test Logging and Tracing from controller is archived and referred to in Test Report

- At this moment most of the reporting is done manually, however work is being done to automate this last part too

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Some Benefits so far

- Increase of depth of test coverage
- Increase test productivity
- Continuous automated regression testing (out of office hours)
- Happy verification engineers

- Examples:
  - Product Test time decreased from 8 weeks → 1 week
  - Check detection modes 12+hours (not all modes) → 2 hours, all modes
  - Power cycle tests 2000+ cycles not possible → 36 hours
  - Reliability batches only basic functions → advanced functions with automatic image analysis (150k+ images per weekend)

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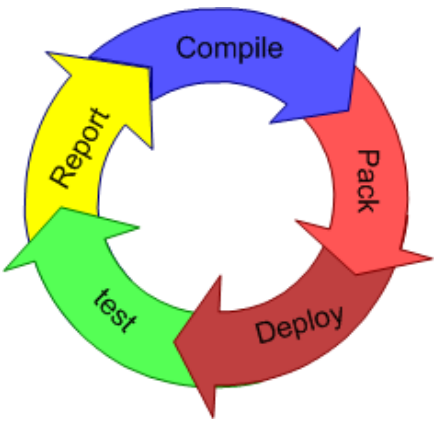
Continuous Testing after build



- Not just the unit-tests
- Fully automated regression tests run when buildserver is done
- Automated reporting is the next step

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Future steps

- Fully automated reporting
- Integration of model based testing for certain types of tests to automated test runs
- Improvements to the infrastructure
- Addition of various levels of abstraction for testing on different levels

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Thank you....
Questions?

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