

# Software Validation and Testing

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Quality Manager MIPS (Clinisys)

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Belgian Medical Informatics Association

# Agenda

MIPS

Company

Products

MIPS product development process

Defect prevention

Defect correction

Q&A

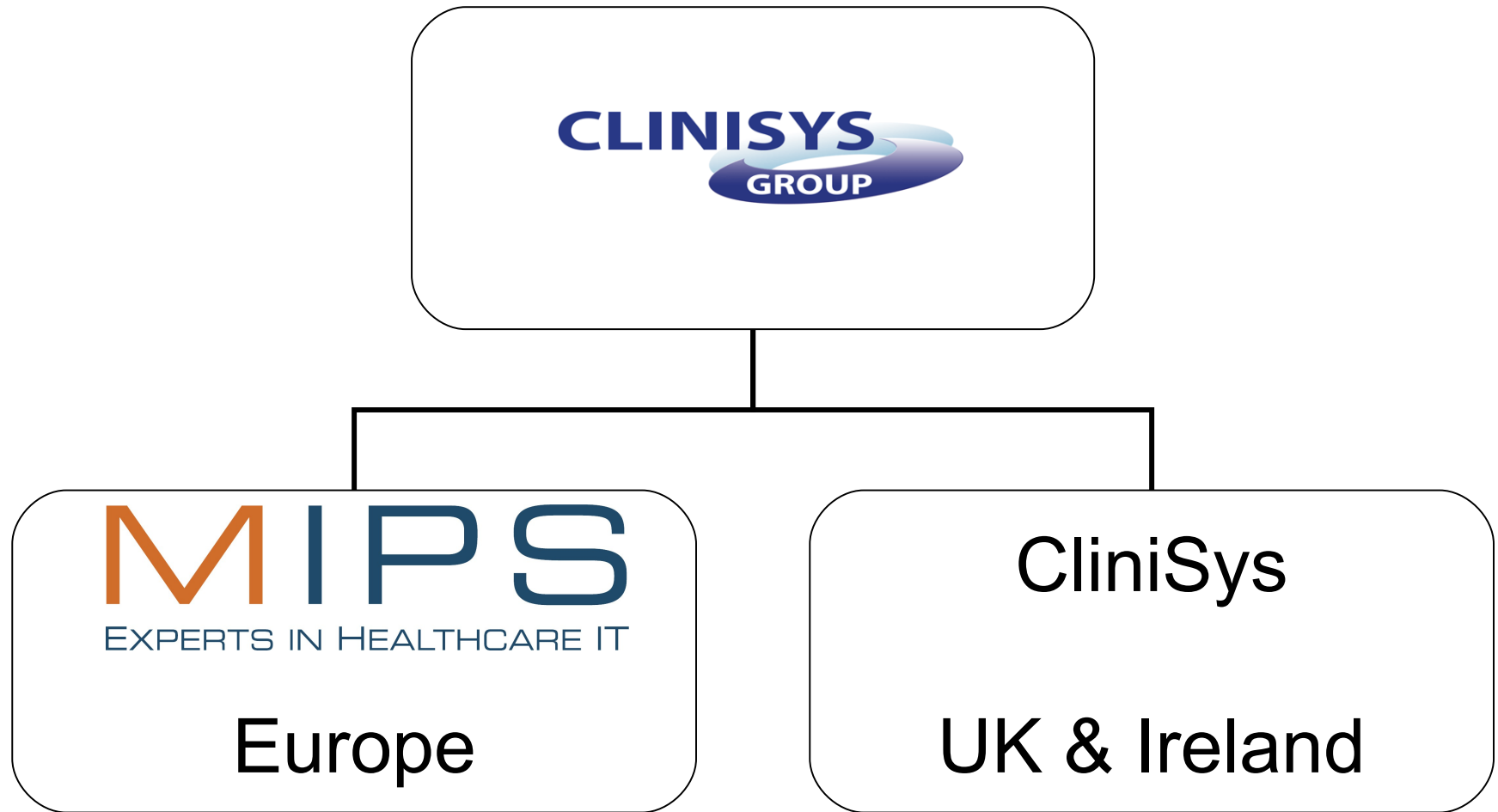
We offer **Solutions** to improve the efficiency of clinical laboratories



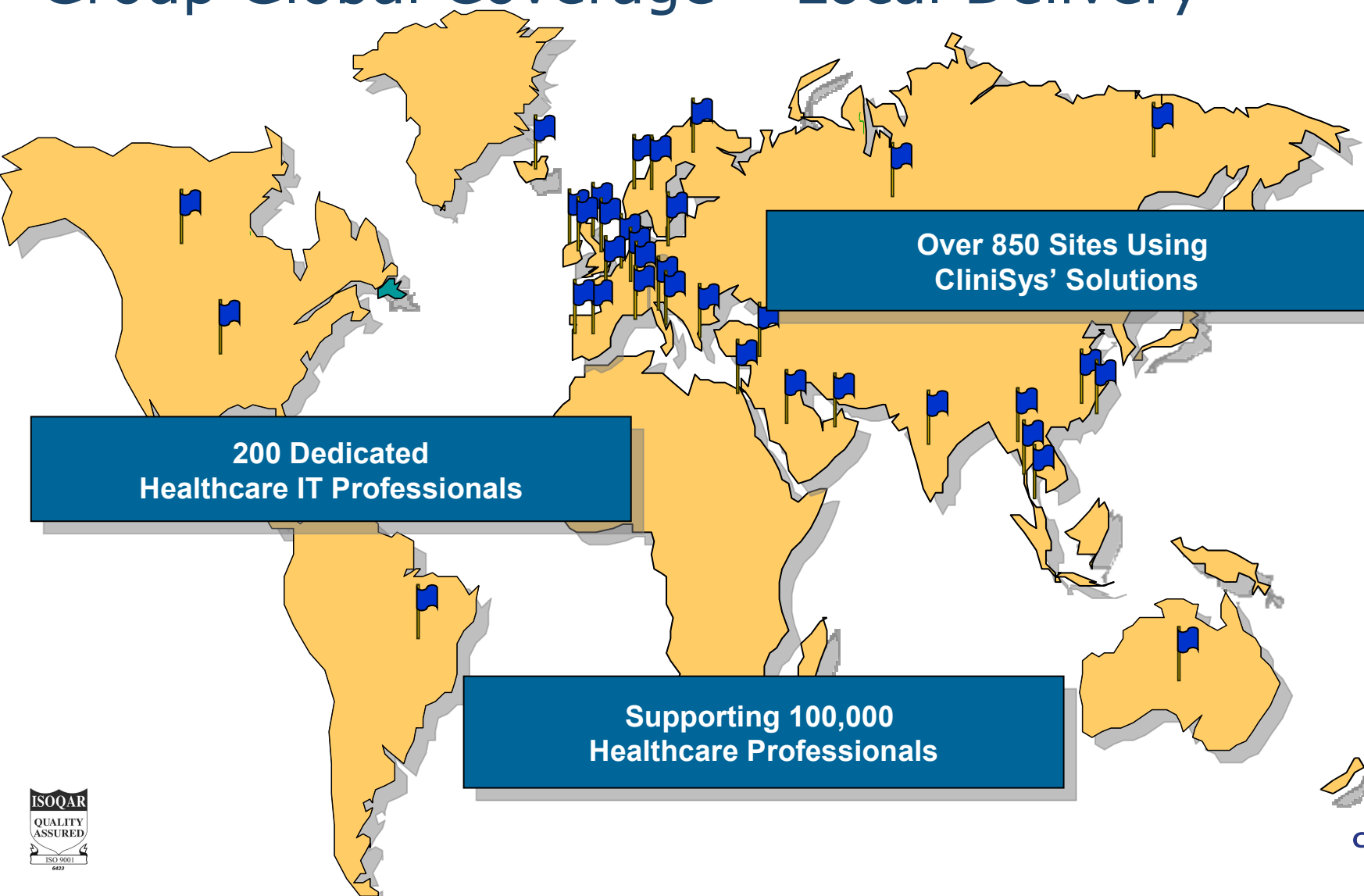
Based on

**Standardized** Software and  
**Customized** Services and Support to  
meet specific customer requirements

## Group Operating structure



## Group Global Coverage – Local Delivery



# Clinisys : Pan-European Group

- Development Centre:
  - Chertsey(Clinisys)
  - Glasgow(Clinisys)
  - Gent (MIPS)
- Sales and Support Offices:
  - Clinisys
    - Glasgow (Scotland)
    - Chertsey (England)
  - MIPS
    - Gent (Belgium)
    - Hamburg (Germany)
    - Paris (France)
    - Madrid (Spain)



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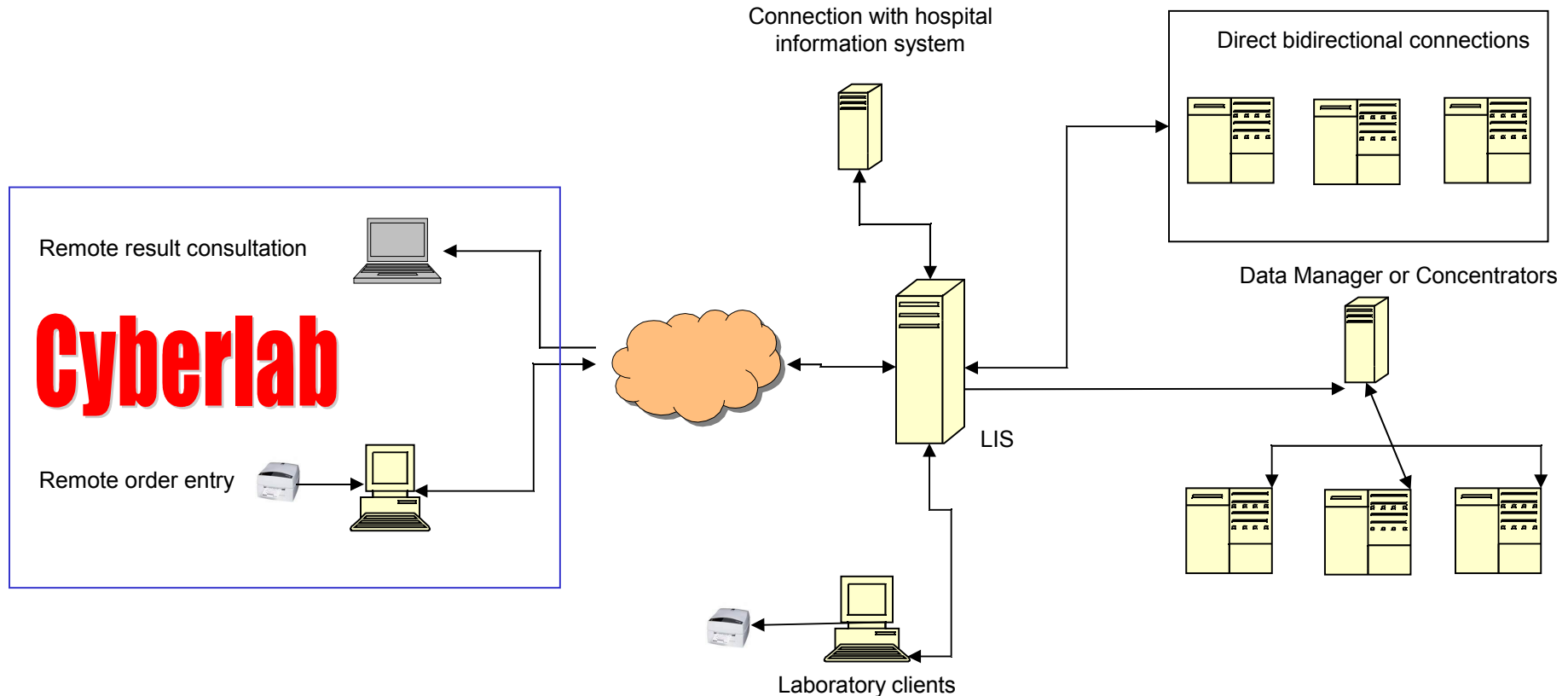
Q&A

## MIPS products

- **Glims** Laboratory information system (LIS)
- **Samplenet** Data manager
- **Cyberlab** Result consultation via Intranet / Internet and electronic order entry
- **Drivers** Interface with IVD MD and HIS
- **Archie** XML Archiving



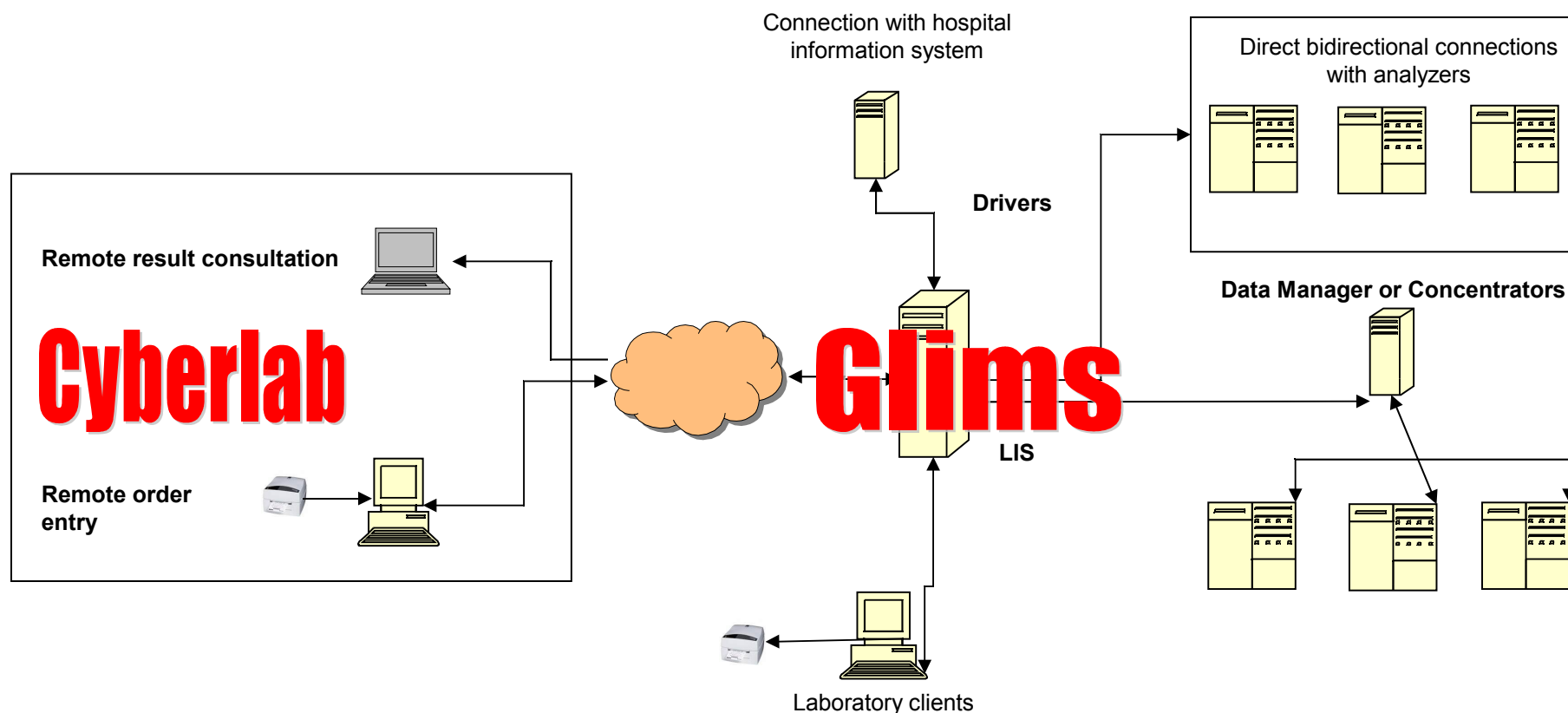
# Specialised in large complex IT-solutions for clinical laboratories



## Cyberlab

- Web based Result consulting and Order entry system
- Real-time result consultation for wards /outpatient clinics/GP
- Electronic order entry for wards / outpatient clinics / GP
- Reporting management
- Can be interfaced with any LIS
- Can be integrated in an EPR
- Better interaction between the lab and its end users
- Better service for hospital

# Specialised in large complex IT-solutions for clinical laboratories



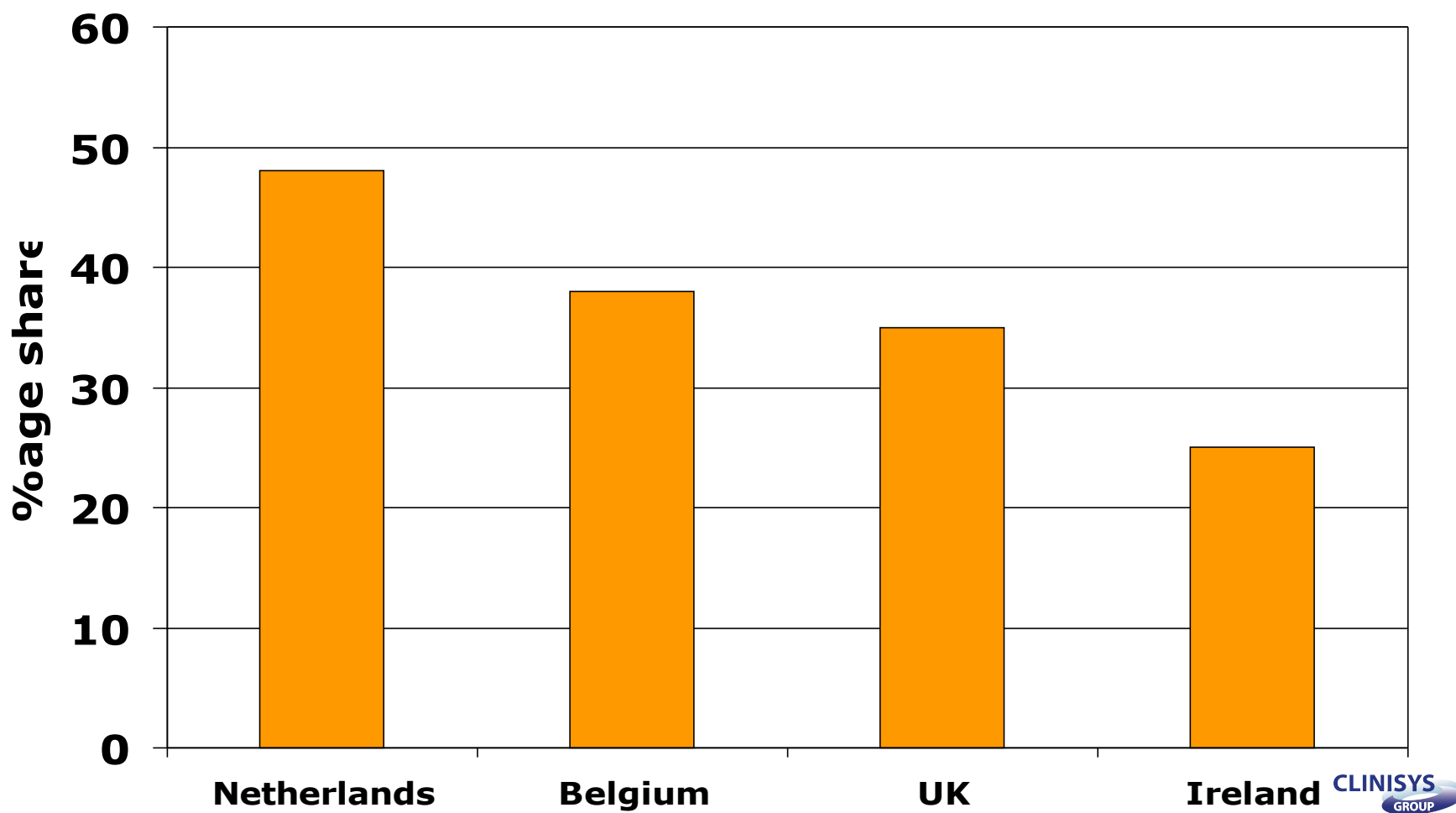
## GLIMS covers following labs:

- Biochemistry
- Toxicology
- Immunology
- Blood transfusion
- Epidemiology
- HLA / Histocompatibility
- Microbiology
  - Bacteriology – Parasitology – Serology - Virology
- Hematology and coagulation
- Anticoagulants treatments
- Immuno-hematology
- Statistics :
  - Microbiology - Activity - Financial -Blood transfusion - Histology

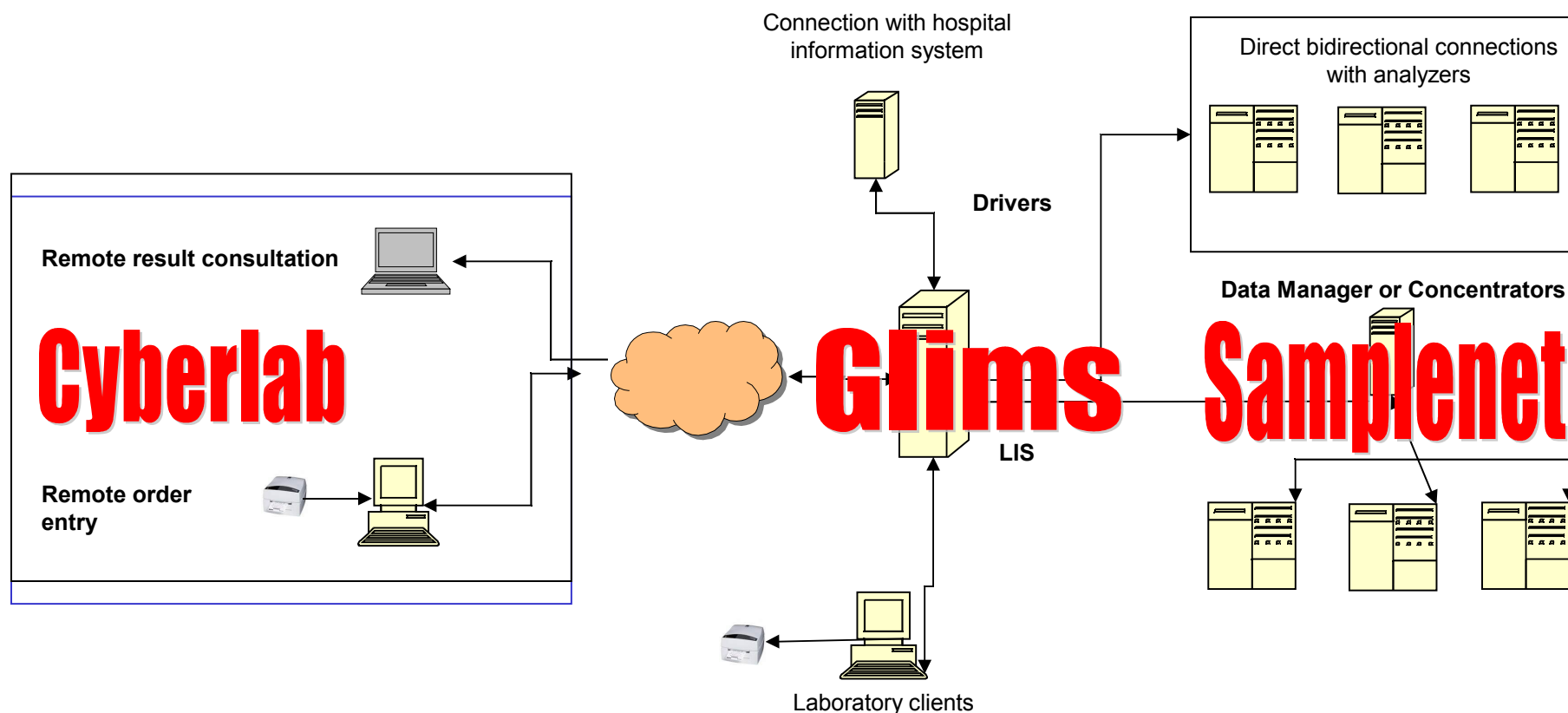
# Leading European LIS Supplier

- Market leader in Netherlands (50+) and Belgium (90+)
  - Pre-configured solution for Partezis, 22 hospitals in Belgium
- Rapid growth in France (50+) and Spain
  - France: Deploying standard solution to 15 hospitals in AP-HP group in Paris – centrally hosted
  - Spain : bioMérieux distribute pre-configured microbiology solution
- 20 years history of successful deployment
- 200 pathology specialists
- 400+ LIMS installations in 10 countries
- Scaleable solutions ranging from small private lab through to large, complex, multi-site pathology network
- Multi-lingual solutions

## LIS Market Share in Mature Markets



# Specialised in large complex IT-solutions for clinical laboratories



## Drivers

- More than 250 different analyzers are currently in use with Glims.
  - Over the years, in total 600 analyzers have been interfaced with Glims.
- GLIMS is able to communicate with several hospital information systems simultaneously to support laboratories servicing several hospitals.
- The standards supported include HL7, HL7-XML, HPRIM, LDT, ASTM, XML, CPAGE and Edifact



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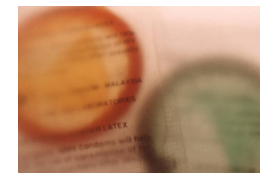
Defect prevention

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Q&A

## MIPS product development process

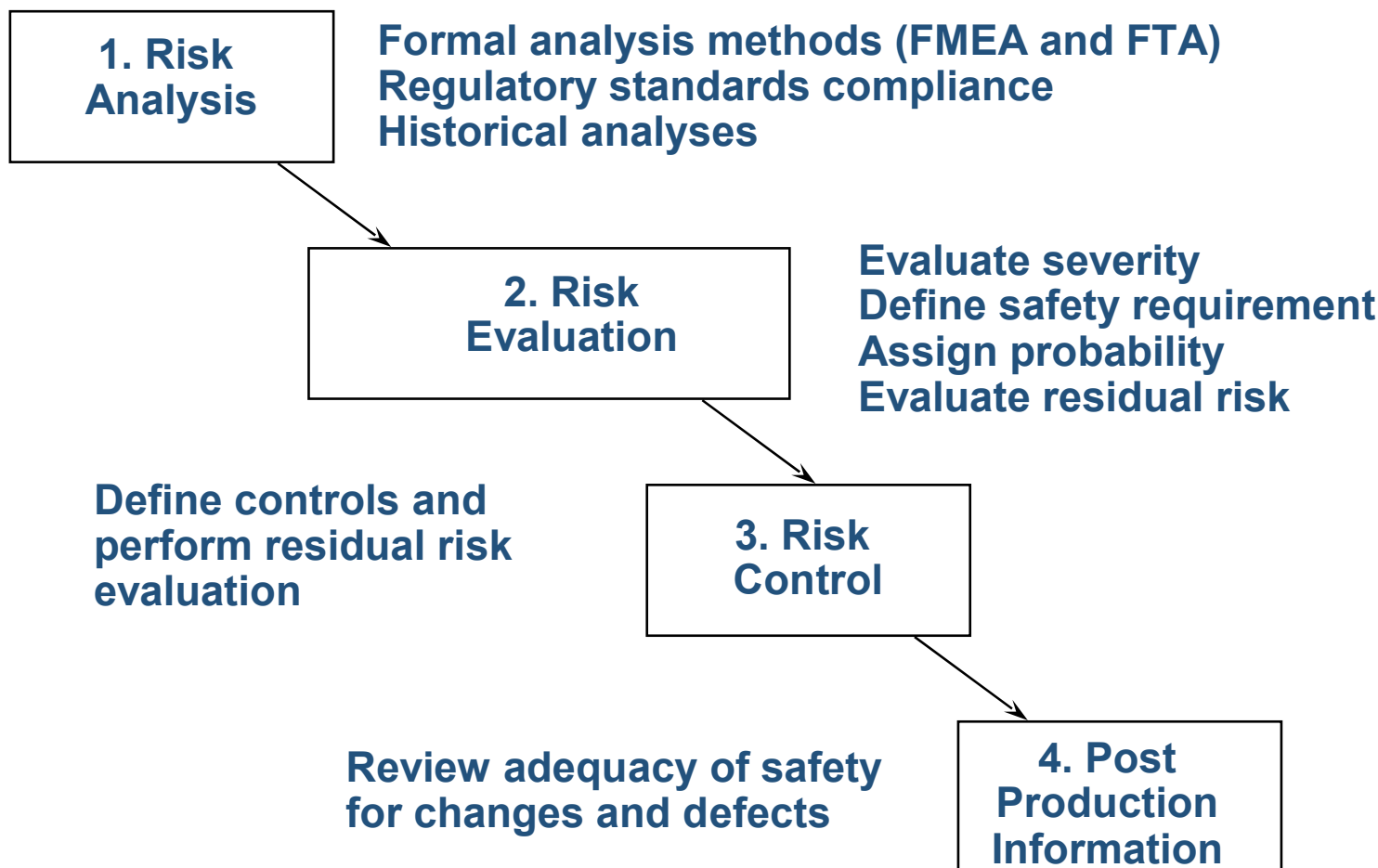
- Pro-active : **Defect prevention**
  - Development process includes
    - Safety risk management process
      - Guided by IVD MD FDA and ISO regulations
    - Multiple reviews
- Re-active : **Defect correction**
  - Verification : Did we make it right ?
  - Validation : Did we make the right thing ?



## DP: Safety risk management process

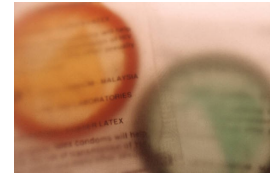
- An effective risk management program encourages a defect prevention **mindset**
- Safety risk management can **prevent** safety related **problems**
- Safety risk management provides a basis for defining different **levels of test and review**
- Safety risk management encourages **defensive design** practices
- Safety risk management reduces **civil liability** as well as satisfies **regulatory requirements**

# DP: Safety risk management process

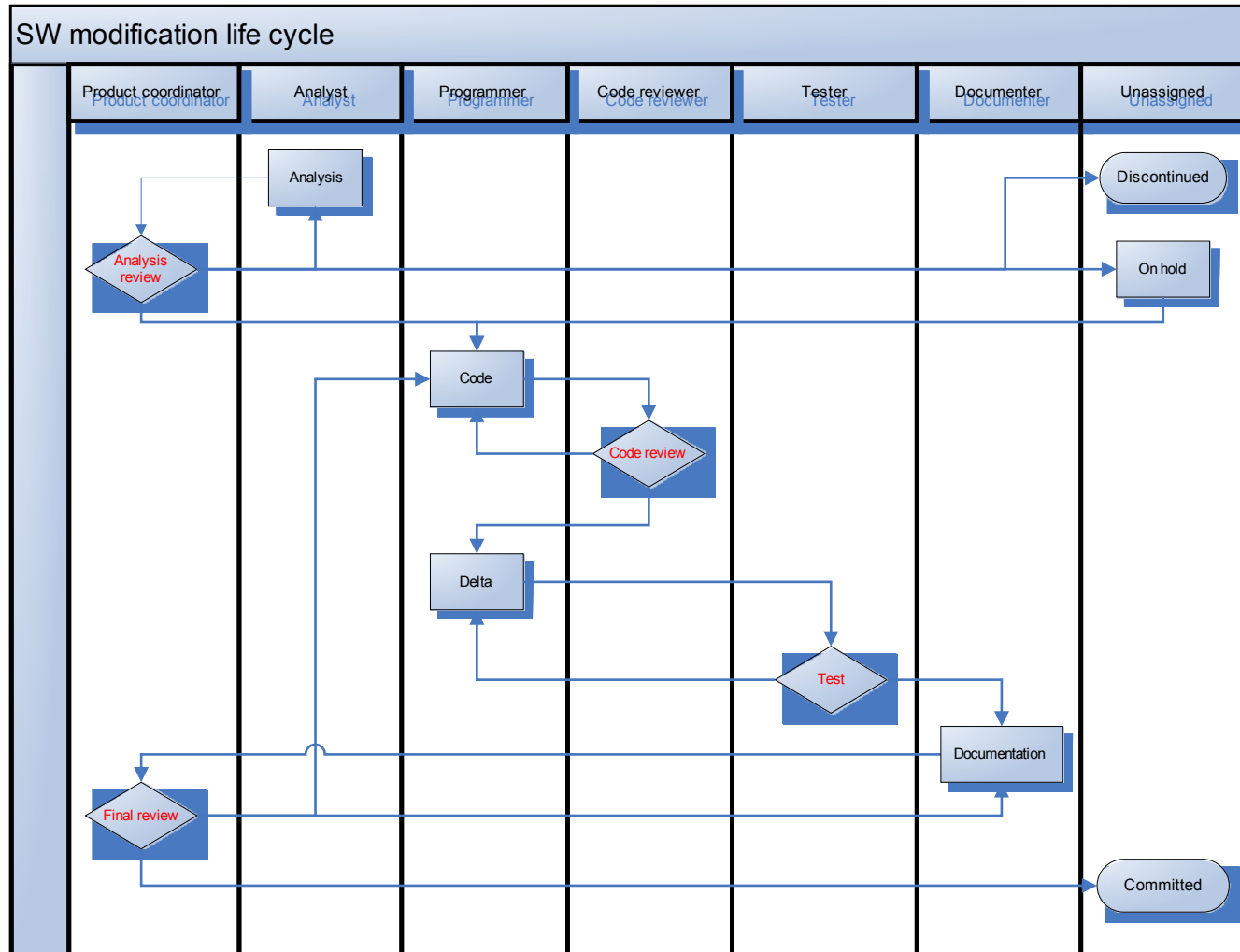


## MIPS product development process

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# Defect prevention: Multiple reviews



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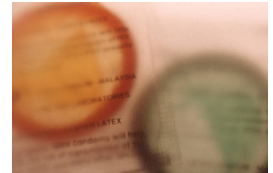
Defect prevention

**Defect correction**

Q&A

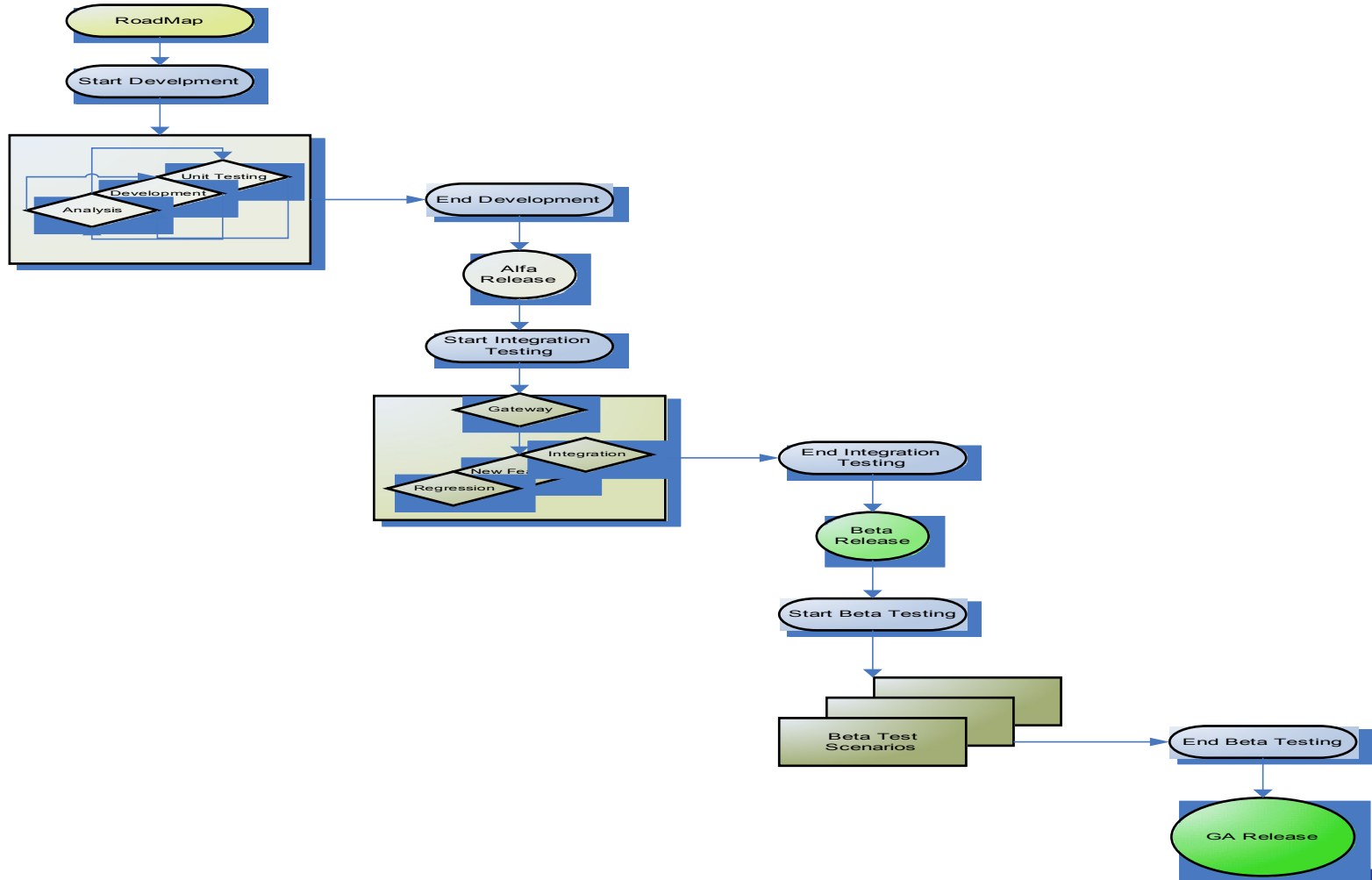
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# DC: Verification and Validation process

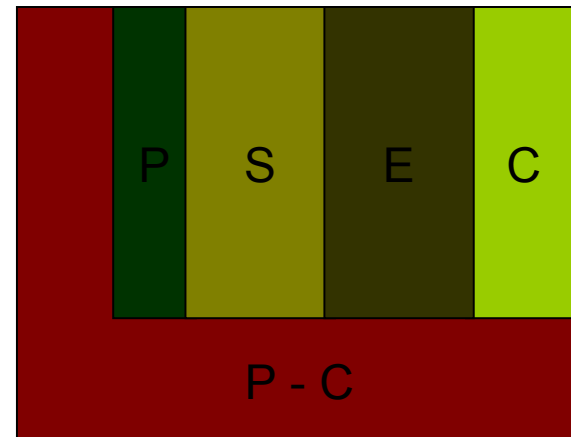


# DC: Verification – unit testing process

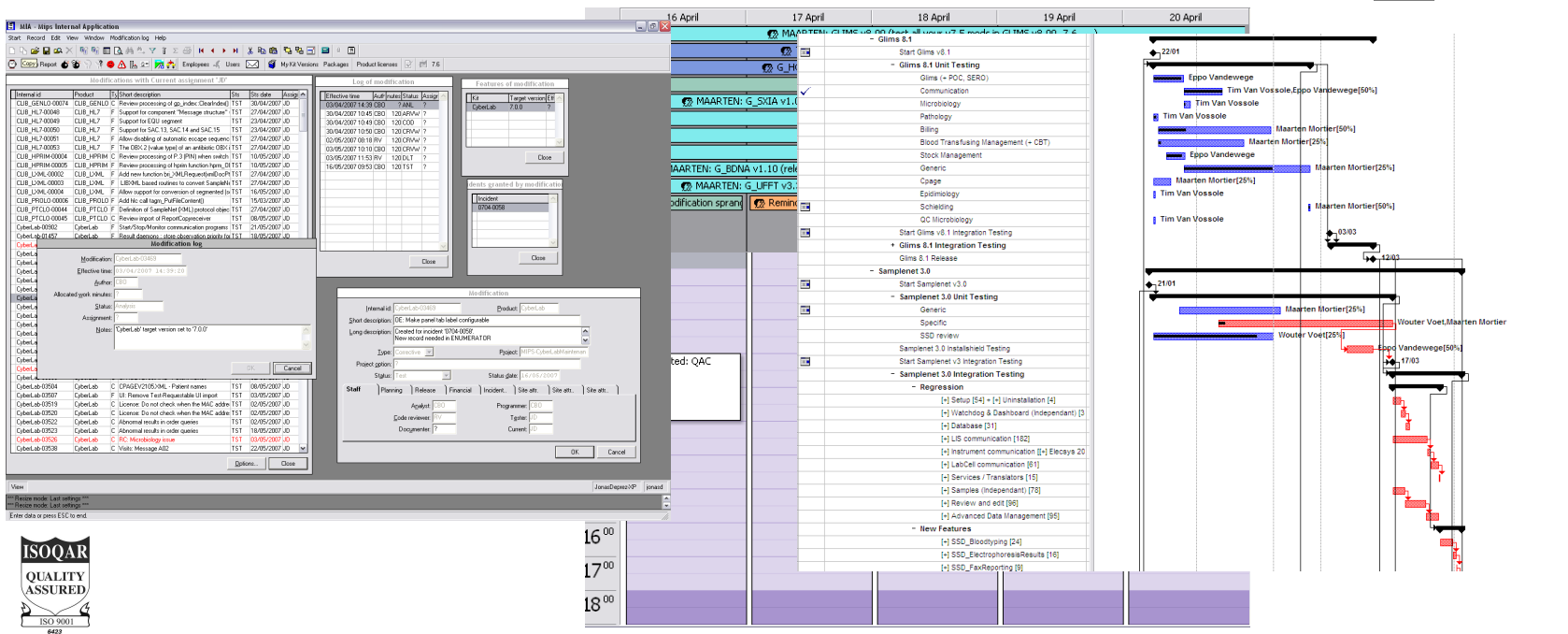
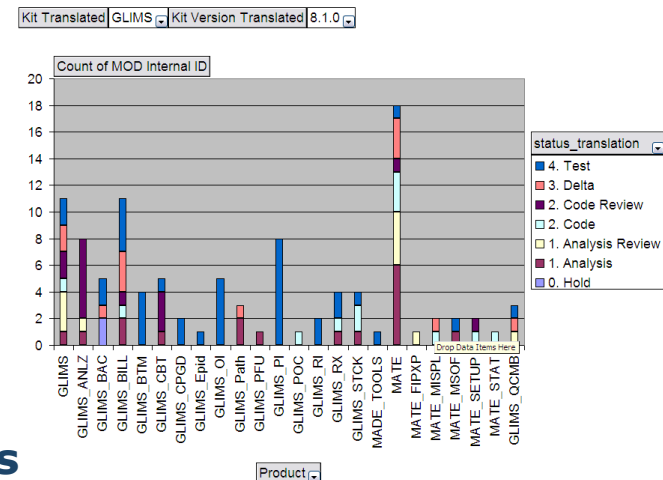
# DC: Verification -integration testing process

## DC: Verification -integration testing process

- Verification and Validation process :
  - How ? **Structured Testing**
- Lifecycle of Structured Testing: LST (Tmap)
  - **P**lanning & **C**ontrol
  - **P**reparation
  - **S**pecification
  - **E**xecution
  - **C**ompletion



- **MIA (MIPS Internal Application)**
- **MS Project**
- **Access (ODBC on MIA) Pivot Tables and Charts**



## Test Preparation

- **MIA: Modification and Incidents Logs**
- **SSD (Software Specification Document)**

Notes

See //hyperion/home/ori/glims/anz/7.6:  
Code is almost same as in 8.0.  
7.6 will also contain 2 new sources: wlst\_chd.p and wlst\_sds.p, based on the versions in v8.0 and called with same arguments from stn\_ing.p, but with different implementation (since station mark in version < 8 was by means of station mnemonic, in version 8.0 it is by station id)  
Assignment changed to 'SDL'

Close

GLIMS\_ Status: Code review  
GLIMS\_ Assignment: ?  
GLIMS\_ Notes: See //hyperion/home/ori/glims/anz/7.6:  
GLIMS\_ 7.6 will also contain 2 new sources: wlst\_chd.p and wlst\_sds.p, based on  
GLIMS\_ Assignment changed to 'SDL'

Incident

Internal id: 0608-0123 Company: DLVGAdam Support Project: DLVGAdam Support  
Announcement date: 07/08/2006 External id: ?  
Contact: Van Leeuwen, Jeroen  
Short description: Ondersteuning downloadgroep op concentrator rivo  
Long description: Klant wil graag met downloadgroep gaan werken op concentrator rivo  
Product: GLIMS Kit: GLIMS Kit version: 7.0.3  
Priority: Average Owner: SW Current assignment: ?  
Cause: ? Status: Development Status date: 28/03/2007  
Preventive

Log of incident

Effective time	Author	Status	Assignme
09/08/2006 10:22	BW	SDL	?
09/08/2006 14:42	OR	SDL	?
09/08/2006 14:43	pe	SDL	?
09/08/2006 16:02			
10/08/2006 15:27			
21/08/2006 10:42			
24/08/2006 09:47			
29/08/2006 11:50			
13/02/2007 16:20			
13/02/2007 19:07			
05/03/2007 11:01			
05/03/2007 12:56			
05/03/2007 15:23			
06/03/2007 15:13			
06/03/2007 17:11			
14/03/2007 11:37			
20/03/2007 14:35			

Incident log

Main page Site att:

Incident: 0608-0123  
Effective time: 04/03/2007 17:11:37  
Author: ID  
External author company: ?  
External author phone: ?  
Status: Solution  
Assignment: ?  
Internal notes: Sowieso via offerte heb ik de indruk  
ik kan het verhaal niet genoeg volgen om een intelligent advies te geven. Misschien moet dit eens met paar mensen grondig worden doorgesproken.  
Assignment changed to 'OR'

Internal notes

Sowieso via offerte heb ik de indruk  
- Ik kan het verhaal niet genoeg volgen om een intelligent advies te geven. Misschien moet dit eens met paar mensen grondig worden doorgesproken.  
Assignment changed to 'OR'

View

ISOQAR  
QUALITY  
ASSURED  
ISO 9001  
4402

# Test Specification

- **Test Case Specification Document**
  - **Test Cases** (if applicable)
    - Pre-condition
    - Test case
    - Expected result
  - **Test Data** (if applicable)
  - **Test System Requirement** (if applicable)

```
#####
HEADER
#####

Modification GLIMS-04307 is tested on:

Test
Glims v 7.5.4 dev environment (windows + oracle / Progress Connection): Dutch version

Verification (reproduction of incident)
Glims v 7.5.3 dev environment (windows + oracle / Progress Connection): Dutch version

#####
TEST REPORT: Delta of this Modification will be PASSED based on following testing.
#####

### DEFECT OR REMARKS

NA
### TEST CASES

The following test cases verify if the correct sequence of Pre-Commit trigger execution
and the EMPTY ORDER CHECK in case of empty orders creation.

#CONFIGURATION

PRE_COMMIT#1: (Pre-Commit Trigger)
Message("Dit is de Pre Commit Trigger");
RETURN BillingMark;

#CASES

IF a empty ORDER is created
AND PRE_COMMIT#1 is specified as pre-commit trigger
THEN PRE_COMMIT#1 is executed
AND after the EMPTY ORDER CHECK is executed

IF ORDER is created with 1 or more requests
AND PRE_COMMIT#1 is specified as pre-commit trigger
THEN PRE_COMMIT#1 is executed
AND after the EMPTY ORDER CHECK is NOT executed
AND that ORDER is correctly created.

### TEST LOG

New data created according test configuration
```

# Test Execution (1)

- Test Case Specification document executed and logged in MIA (incl. attachments) → Traceability

The screenshot displays the MIA - Mips Internal Application interface, which is used for test case execution and logging. The main window shows a list of test cases with columns for Internal ID, Product, Short description, Status, and Date. A 'Log of modification' window is open, showing a table of modifications with columns for Effective time, Author, Rules, Status, and Assign. The table lists various modifications made to test cases, including changes to the 'Short description' and 'Status'.

Below the main window, there are several smaller windows and panels:

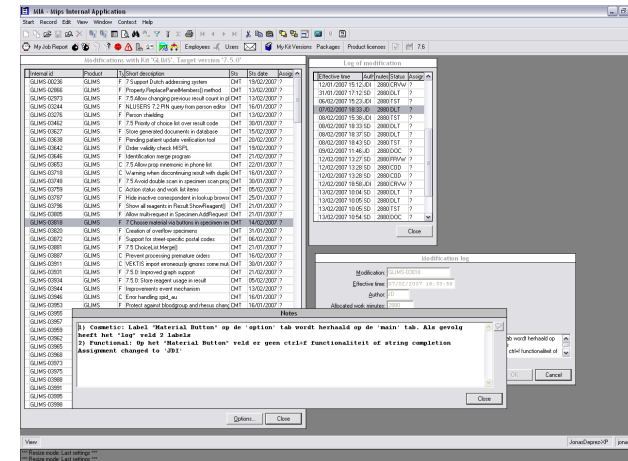
- Modification log attachments:** A window showing a list of attachments for a specific modification, including files like 'remark2\_step1.jpg', 'remark2\_step2.jpg', and 'GLIMS-03872.mt'.
- Microsoft Office Picture Manager:** A window showing a preview of a selected image, 'remark2\_step3.jpg'.
- Modification log:** A window showing a detailed log of modifications, including the author, rules, status, and a description of the change.

The interface also includes a 'Notes' section at the bottom left, which contains a list of test cases and their status. The overall layout is typical of a legacy software application, with multiple overlapping windows and a complex menu structure.

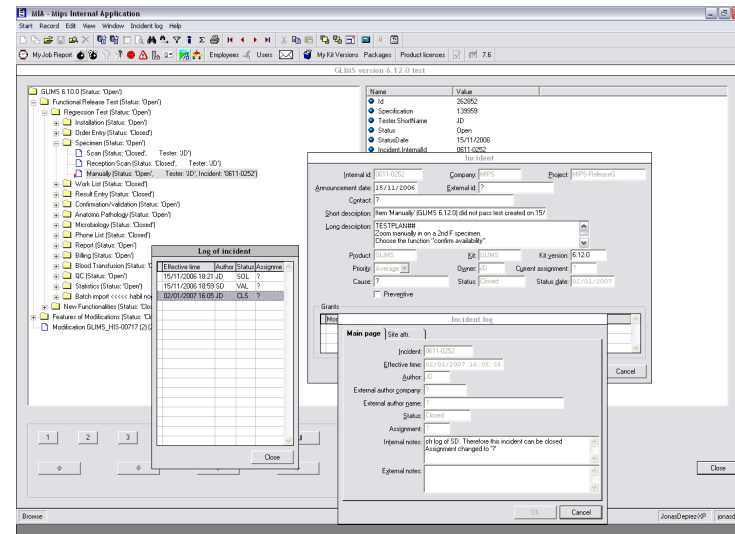


## Test Execution (2)

- Unit test fails: Solution “rejected” and send back to developer



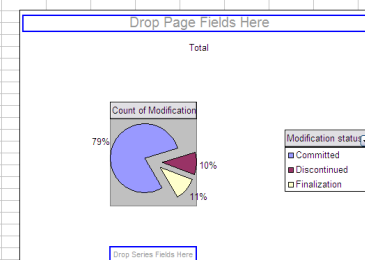
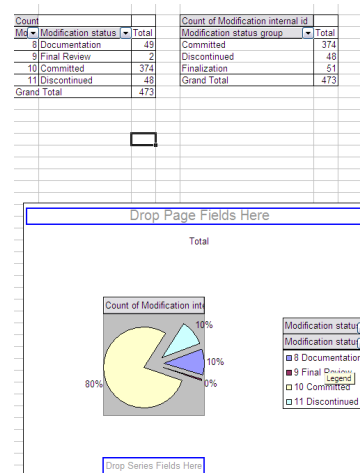
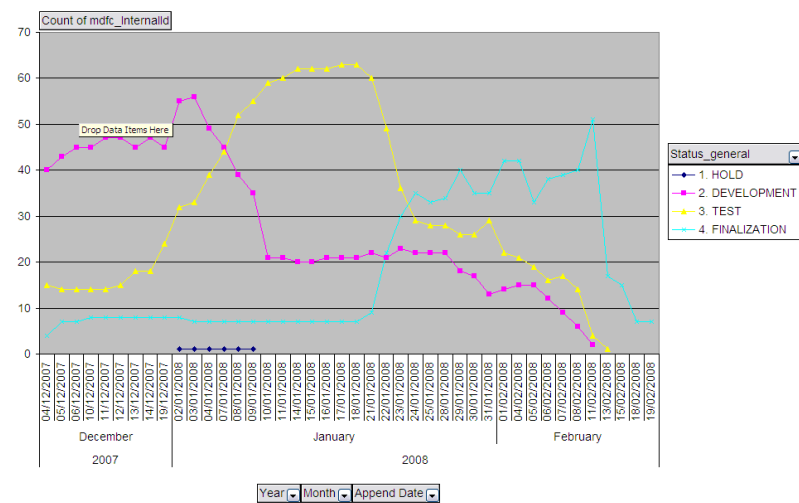
- Integration test fails: “Failure” documented and automatically generated incident



## Test Control

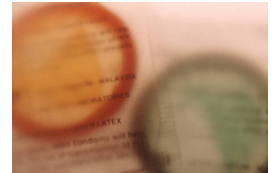
- Test Progress Reporting
- Formal Test Plan and Report (if applicable)

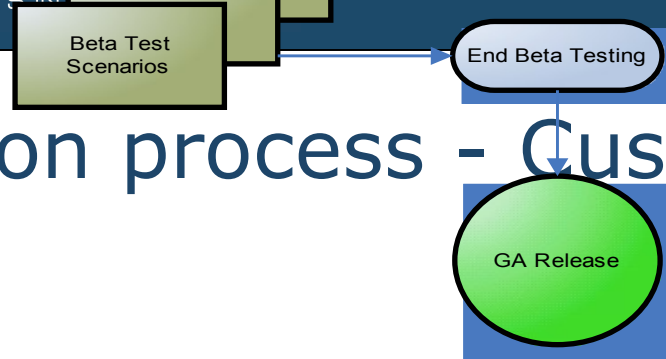
prdc\_Mnemonic GLIMS ktsv\_Label 7.8.0



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# DC: Validation process - Customer level

# Certification and audits

- **External audits:**
  - **ISO 9001 certified by ISOQAR**
    - Scope: Development, deployment, sales and support
    - MIPS Gent and MIPS France
  - **Astrazenica – bioMérieux**
- **Internal audits**
- **Procedure in place that defines who should do what in case of a major defect in the field**
  - **Customers**
    - **Corrective measures**
      - Undo the mistake
    - **Preventive measures**
      - Work-around
      - Install new version



## Conclusions



- By improving on a continuous basis it's
  - People
  - Processes
  - Products

MIPS tries to prevent any defects in his SW products

- “You get what you inspect, not what you expect...”

## Q&A

