

# LA CALIDAD Y LA EFICIENCIA EN EL CICLO DE VIDA DE SOFTWARE PARA DISPOSITIVOS MÉDICOS

Jordi Manzano – Diagnostic Grifols, S.A.

27-5-2009

GRIFOLS



# Agenda

## **9:15 Introducción**

*Antonio Rodríguez - Rational Systems Sales Manager - IBM*

## **9:30 Estrategia de IBM Rational para el desarrollo de sistemas tras la adquisición de Telelogic**

*Antonio Rodríguez - Rational Systems Sales Manager - IBM*

*Chuck Ratigan - Engineering Solutions - IBM*

## **10:15 Una aproximación al análisis de los requisitos de sistemas embebidos**

*Oskar Berreteaga - Desarrollador de Software para Sistemas Embebidos - Ikerlan-IK4*

## **11:30 Turning Product Development into Competitive Advantage**

*Mark Wasserman - Software Client Leader – Aerospace & Defense - IBM*

## **12:15 La calidad y eficiencia en el ciclo de vida de software para dispositivos médicos**

*Jordi Manzano - Subdirector I+D - Diagnostic Grifols*

## **13:00 Plataforma de Desarrollo y Validación de Sistemas**

*Francisco López - Rational Technical Sales Specialist - IBM*

## **15:00 Diseño y modelado de Sistemas**

*Francisco López - Rational Technical Sales Specialist - IBM*

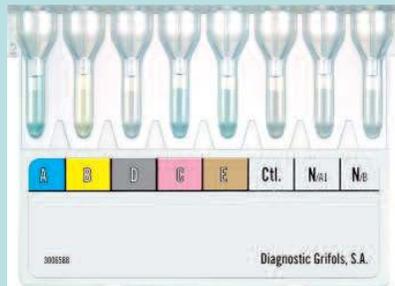
## **15:45 Gestión multi-disciplinar del ciclo de vida de productos mecatrónicos**

*Carlos de Castro - Business Development PLM Solutions - IBM*



# Actividad de Diagnostic Grifols, S.A.

Diseño, fabricación y comercialización de instrumentos y reactivos para diagnóstico *in-vitro*

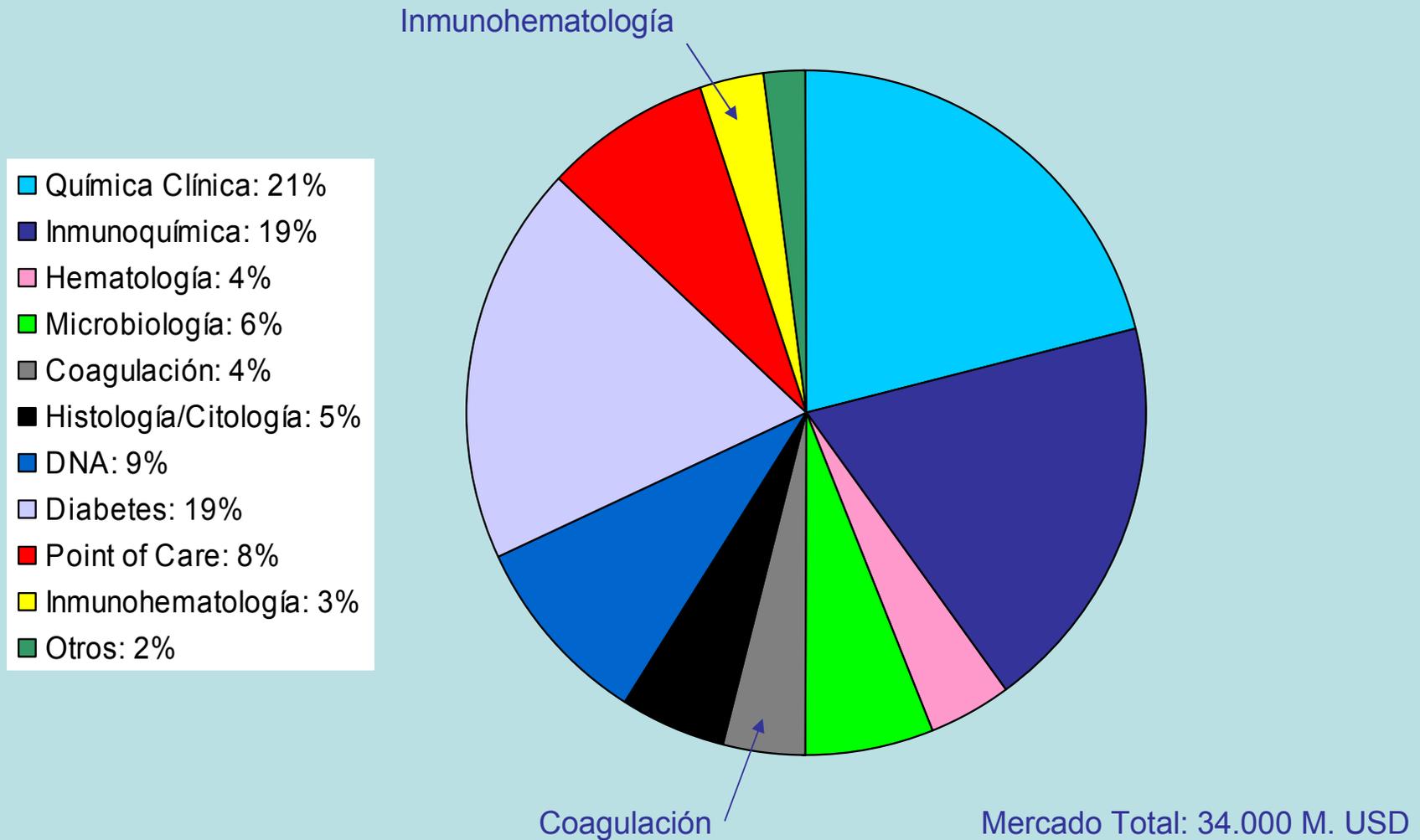


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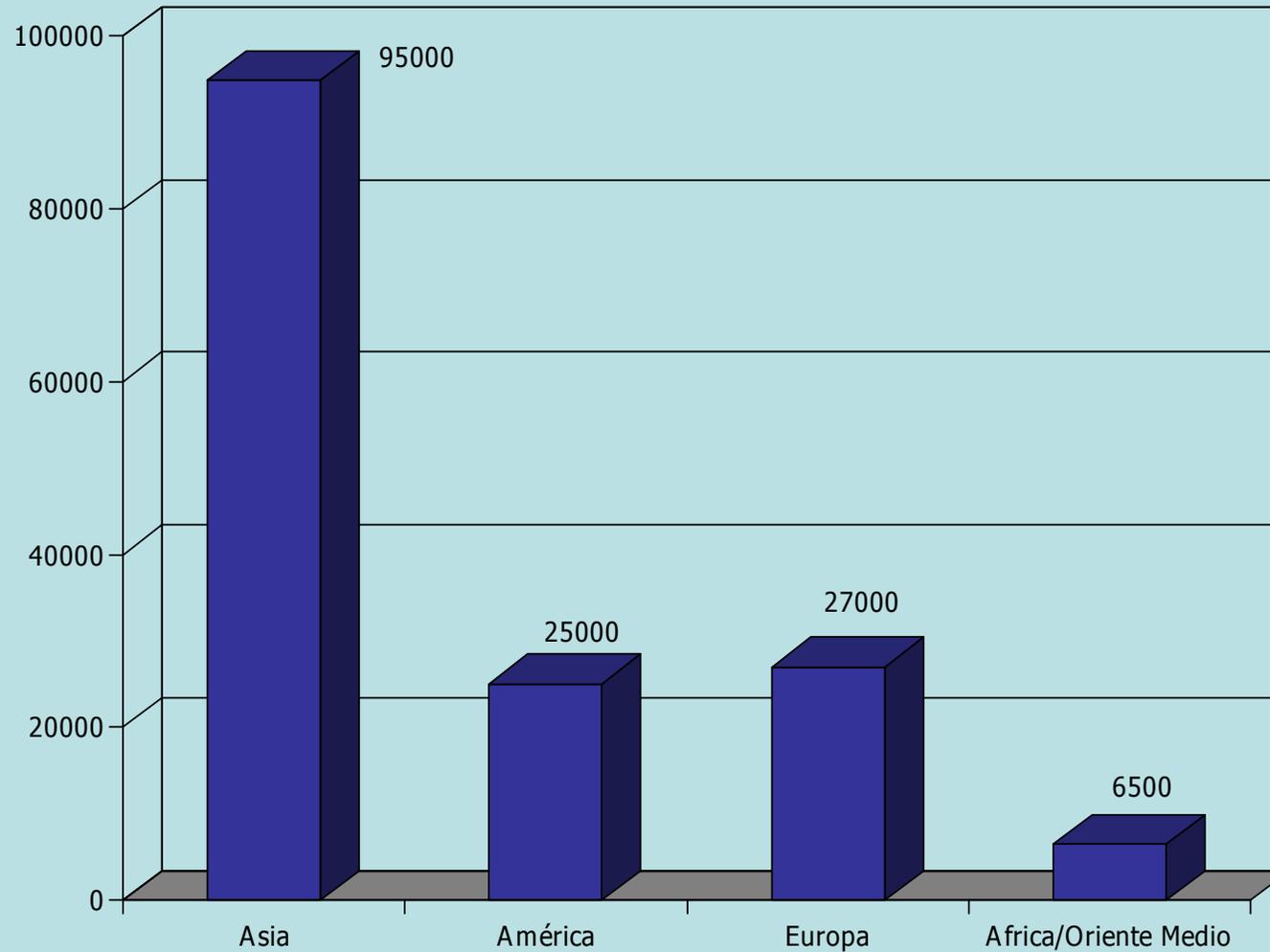
Working for health



# Mercado Mundial Diagnóstico “in vitro” 2008



# Oportunidades - Hospitales en el Mundo



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# Amenazas – No comments

But in the US, a somewhat different mood prevails. Local companies with overseas businesses will be hit by the strengthening US dollar. Companies serving the local market are also being hit by lower spending by US hospitals on medtech equipment. An Oppenheimer analyst this week predicted that hospitals will cut spending by up to 25% in 2009, and said the severity and length of the decline may be worse than has hitherto been assumed.

Capital equipment makers' market capitalisations are dropping, and companies like surgical equipment maker Conmed are publicly saying that the weaker US economy will affect their results deep into 2009.

Indeed, with incomes falling, and lending squeezed, US citizens will have less to disposable income to pay for healthcare, and they will tend to defer seeking treatment. It is also predicted that, with job losses due to rise, fewer US citizens will have access to the health insurance that is provided through their employment.



## 微柱凝胶免疫检测法 新生儿溶血病检测

### 2. 新生儿溶血病检测卡I——

检测新生儿血型及新生儿红细胞是否在母体被不完全抗体致敏。



结果：AB型RhD阳性，直抗试验阳性

### 3. 新生儿溶血病检测卡II——

检测新生儿体内的游离抗体和放散抗体



结果：存在游离抗体、放散试验阳性



长春博迅生物技术有限责任公司 电话：0431-85073150/85073177 传真：0431-85073160

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# Marco Regulatorio

- USA: 21 CFR 820, 21 CFR 11, FDA Guidances
- EU, Japón, Canada, etc.: ISO 13485:2003 + requisitos locales
- Normativas armonizadas:
  - EN 61010-1:2001, EN 61010-2-101:2002 (Safety)
  - EN 61326-1:2006, EN 61326-2-6:2006, Directive 1999/5/EC (EMC)
  - Directives 2002/96/EC, 2002/95/EC and 2005/32/EC (WEEE, RoHS)
  - Directive 98/79/EC (IVD)
  - Directiva 95/46/CE (Protección de Datos)
  - EN 980:2003, EN 591:2001 ISO/TR 18112:2006 (Labeling)
  - ASTM D4169-01 (Shipping Containers and Systems)
  - NCCLS LIS1-A, NCCLS LIS2-A2 (LIS)
  - UL 61010-1:2004 (UL)
  - FCC 47CFR15:2003 (EMC)
  - Ley Orgánica 15/1999 (LOPD)
  - ISO 15198:2004 (QC Validation)
  - IEC 62304:2006 Medical device software - Software life cycle processes
  - AAMI TIR32:2004 - Medical device software risk management



# Sistema de Vigilancia

- USA: FDA MedWatch (Adverse Event Reporting Program)
- UK: MHRA (Medicines and Healthcare products Regulatory Agency) Safety Alerts
- Francia: Incidentes AFSSAPS (Agence française de sécurité sanitaire des produits de santé)
- ...



# Conclusión

- Productos donde la seguridad y eficacia debe quedar demostrada en proporción al riesgo
- Mercados con diferentes requisitos regulatorios
- Estrictos sistemas de vigilancia
- Auditorías periódicas de producto y sistema de calidad
- Presión de las autoridades hacia la reducción del gasto sanitario
- Oportunidades en mercados emergentes



- Calidad y eficiencia en el R&D:
  - Plataforma tecnológica
  - Suite integrada de soporte al ALM



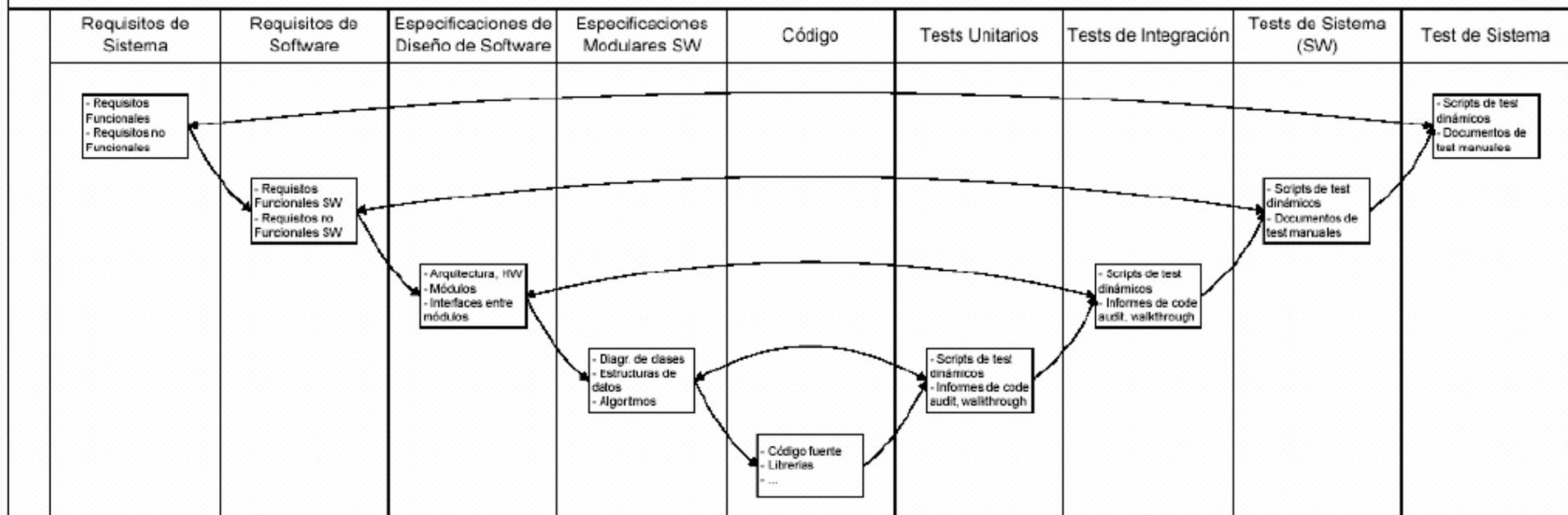
# Plataforma

- Conjunto de subsistemas e interfaces que forman una arquitectura común de la cual desarrollar una familia de productos derivados
- Cada producto tiene una arquitectura. El objetivo es hacer una arquitectura común a todos los productos
- Las plataformas no son estáticas. Deben evolucionar a medida que se integran nuevos conocimientos y tecnologías
- Algunos subsistemas son más críticos y por lo tanto deben mantenerse más estáticos mientras que otros son más periféricos y pueden evolucionar más dinámicamente



# Requisitos de la Suite de Soporte al ALM (I)

Requisitos ALM Grifols



# Requisitos de la Suite de Soporte al ALM (II)

Matriz de Trazabilidad

FR	FRS	DSS	MSS	Code	UT	IT	ST (SW)	ST
FR 1.12								TestCase TC_FR1.2
	FRS 1.8						TC_FRS1.8	
		DSS 3.1						
	FRS 3.10							
		DSS 3.1						
		DSS 3.1.2						
			MSS 1.1	class DataStorage	Class Test_DataStorage			
			MSS 3.1	class DataStorage	Class Test_DataStorage			
		DSS 3.1.7						
			MSS 3.1	class DataStorage	Class Test_DataStorage	Class Test_I2		
	FRS 3.11							
		DSS 3.1						
		DSS 3.1.2						
			MSS 1.1	class DataStorage	Class Test_DataStorage			
			MSS 3.1	class DataStorage	Class Test_DataStorage			
		DSS 3.1.7						
			MSS 3.1	class DataStorage	Class Test_DataStorage	Class Test_I2		
FR 2.17								
	FRS 9.15							
		DSS 3.1						



# Requisitos de la Suite de Soporte al ALM (III)

## **Requerimientos para los requisitos y especificaciones:**

- (1) Numeración única, a ser posible reseteable por proyecto.
- (2) Campos de título, versión, descripción (texto, tablas, imágenes y diagramas UML).
- (3) Baselines de items (bloqueados, a ser posible con firma CFR 11). Comparación & merge de baselines.
- (4) Volcado fiable y flexible a documentos Word (imágenes en su sitio, bien visibles, anidamientos, etc.).

## **Requerimientos para el repositorio de código:**

- (5) Check out & check in locked y atómico, control de versiones, etiquetas de builds, branch & merge, herramientas de comparación de archivos.
- (6) Integración con herramientas de integración continua.
- (7) Conforme a requisitos CFR 11 de conservación de registros electrónicos.

## **Requerimientos de trazabilidad:**

- (8) Trazabilidad entre requisitos y especificaciones.
- (9) Trazabilidad a código.
- (10) Trazabilidad entre código, especificaciones modulares y tests unitarios.
- (11) Trazabilidad entre tests de sistema y requisitos.
- (12) La trazabilidad debe poder valorarse en cualquier instante.
- (13) Flexibilidad en el nivel de anidamiento de las matrices de trazabilidad.

## **Requerimientos de tests:**

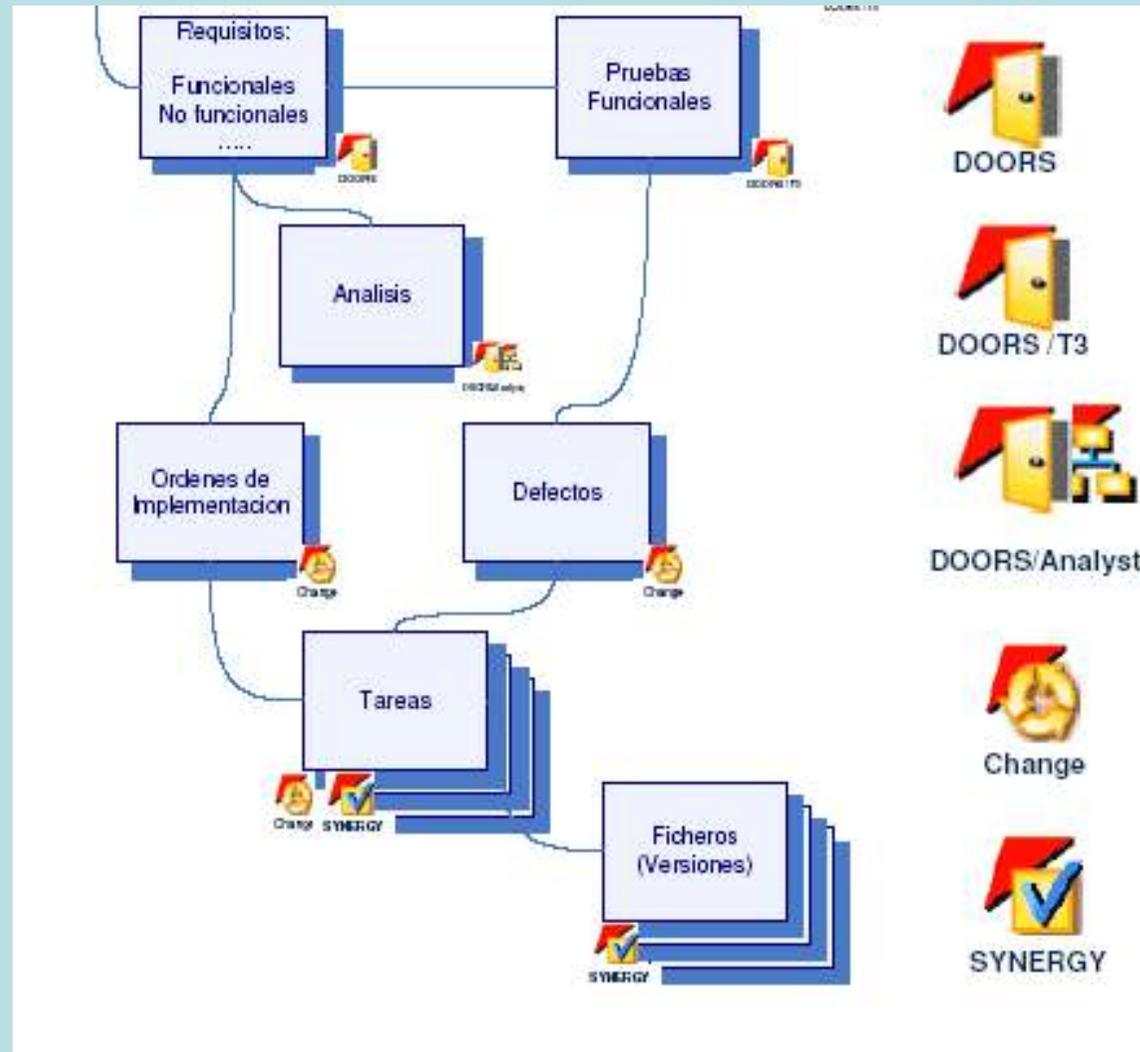
- (14) Reporte de tests redactados, ejecutados, pasados, no pasados, en sospecha, etc. por versión de build. Métricas (% redactados, ejecutados, pasados, no pasados, etc.).
- (15) Integración con herramientas de test automático para importar estos datos.
- (16) Asistencia a la redacción y ejecución de pruebas manuales.

## **Requerimientos de gestión de cambios e incidencias:**

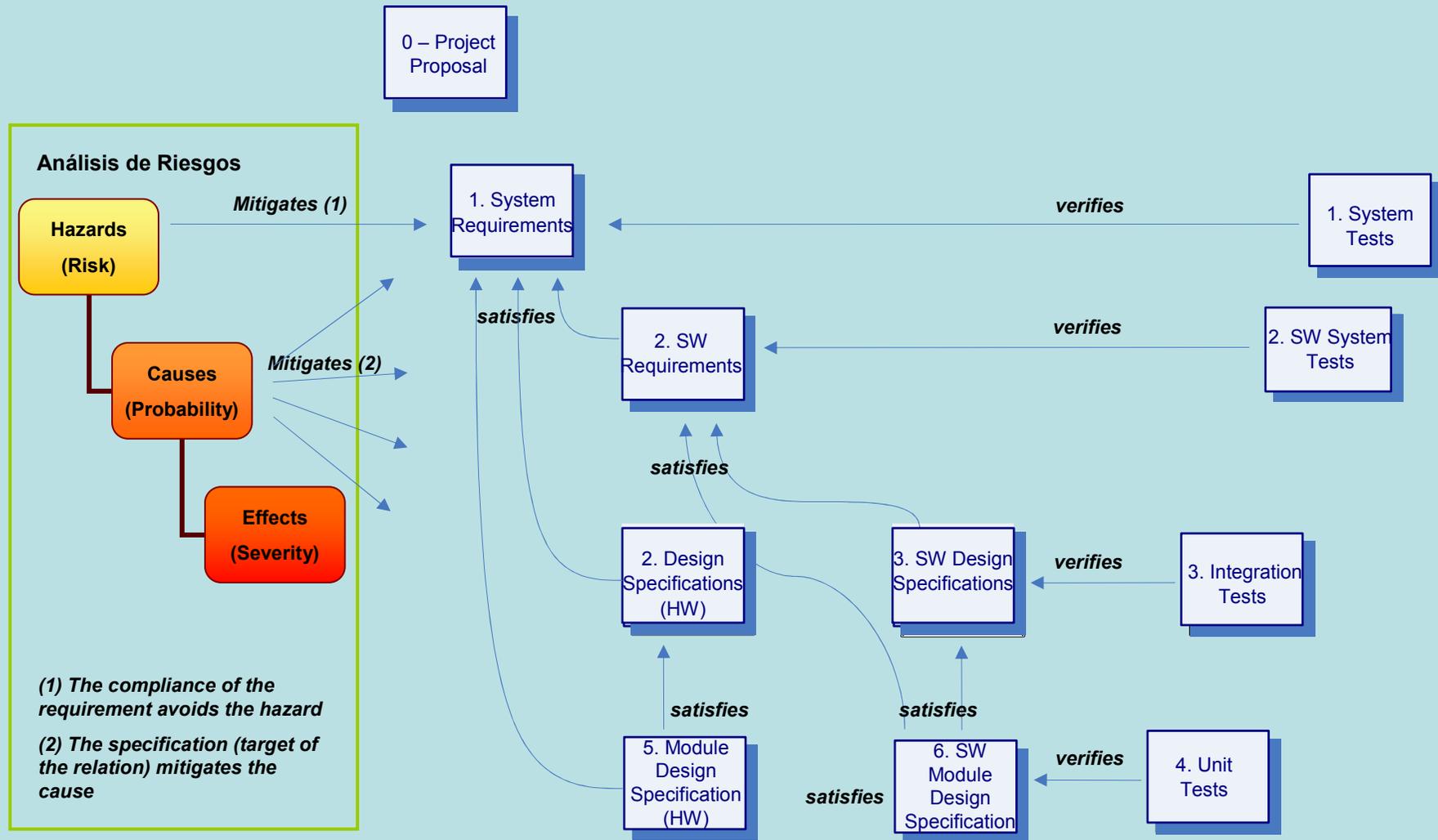
- (17) CRs, tareas con campos personalizables y workflow definido.
- (18) Clasificación de los CRs, tareas por clase. Vinculación con otros items (archivos del repositorio, requisitos, etc.).
- (19) Métricas (nº de CRs / tareas por tipo abiertas y/o cerradas por periodo, promedio de tº en cerrar CRs / tareas, etc.).



# Solución Integrada DOORS - Analyst – Change - Synergy



# DOORS



# DOORS

The screenshot displays the DOORS Database application window. The title bar reads "DOORS Database: /DG-XXX - DOORS". The menu bar includes "File", "Edit", "View", "Favorites", "Tools", and "Help". The toolbar contains various icons for file operations. The "Location" field shows "/DG-XXX".

The left pane shows a tree view of the database structure:

- DOORS Database
  - CURS DOORS
  - DG-421
  - DG-510
  - DG-512
  - DG-59
  - DG-Common
  - DG-XXX**
  - Link modules
  - Proves

The right pane displays a table of design artifacts:

Name	Type	Description
5. Detailed Design Specifications - ...	Folder	5. Detailed Design Specifications - D...
6. Detailed Software Design Specifi...	Folder	6. Detailed Software Design Specifica...
7. Design Verification - DV	Folder	7. Design Verification - DV
9. Trace Matrix	Folder	9. Trace Matrix
9.1 Software Trace Matrix	Folder	9.1 Software Trace Matrix
0. Project proposal	Formal	0. Project proposal
1. Product Requirements Specificat...	Formal	1. Product Requirements Specificatio...
2. Design Specifications - DS	Formal	2. Design Specifications - DS
3. Software Requirements Specific...	Formal	3. Software Requirements Specificati...
4. Software Design Specification - ...	Formal	4. Software Design Specification - SDS
8. Risk Analysis - RA	Formal	8. Risk Analysis - RA



# DOORS

**DOORS Database: /DG-510 - DOORS**

File Edit View Favorites Tools Help

Location /DG-510

**DOORS Database**

- CURS DOORS
- DG-421
- DG-510**
  - 5. Detailed Design Specifications - DS.×××
  - 6. Detailed Software Design Specifications - SDS...
  - 7. Design Verification - DV
  - 9. Trace Matrix
- DG-512
- DG-59
- DG-Common
- DG.×××
- Link modules
- Proves

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9. Trace Matrix	Folder	9. Trace Matrix
0. Project proposal	Formal	0. Project proposal
1. Product Requirements Specification - PRS	Formal	1. Product Requirements Specificatio...
2. Design Specifications - DS	Formal	2. Design Specifications - DS
3. Software Requirements Specification - SRS	Formal	3. Software Requirements Specificati...
4. Software Design Specification - SDS	Formal	4. Software Design Specification - SDS
8. Risk Analysis - RA	Formal	8. Risk Analysis - RA

Name	Type	Description
Detailed Design Specifications - DS.FLU	Formal	Detailed Design Specifications - DS.F...
Detailed Design Specifications - DS.PIN	Formal	Detailed Design Specifications - DS.P...
Detailed Design Specifications - DS.PRE	Formal	Detailed Design Specifications - DS.P...
Detailed Design Specifications - DS.PWA	Formal	Detailed Design Specifications - DS.P...
Detailed Design Specifications - DS.ROA	Formal	Detailed Design Specifications - DS.R...
Detailed Design Specifications - DS.RTW	Formal	Detailed Design Specifications - DS.R...
Detailed Design Specifications - DS.×××	Formal	Detailed Design Specifications - DS.X...
PCA Detailed Design Specifications - DS.pBKP510	Formal	PCA Detailed Design Specifications - ...
PCA Detailed Design Specifications - DS.pPIN	Formal	PCA Detailed Design Specifications - ...
PCA Detailed Design Specifications - DS.pPRE	Formal	PCA Detailed Design Specifications - ...
PCA Detailed Design Specifications - DS.pPWA	Formal	PCA Detailed Design Specifications - ...
PCA Detailed Design Specifications - DS.pWAD	Formal	PCA Detailed Design Specifications - ...
PCA Detailed Design Specifications - DS.p×××	Formal	PCA Detailed Design Specifications - ...

Name	Type
Copy of Detailed Software Design Specifications - SDS.PIN	Fo
Detailed Software Design Specifications - SDS.PIN	Fo
Detailed Software Design Specifications - SDS.PRE	Fo
Detailed Software Design Specifications - SDS.×××	Fo
New Module	Fo



# DOORS

Print view

All levels

Product Requirements Specificati

- [-] 1 General Information
- [-] 2 Design Inputs
- [-] 3 Document change history
- [-] 4 Functional Requirements

Type:ID	Text																																																																																																																																																
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	<b>4.1.4.2.1 Reagent containers</b>																																																																																																																																																
PRS-1093:	<p><b>Bottles</b></p> <p>The characteristics of the different ELISA kit reagent bottles that shall be used in the analyzer are the following: Diluent and pretreatment sample solution bottles</p> <table border="1"> <thead> <tr> <th>Manufacturer</th> <th>Volume</th> <th>Closure</th> <th>Material</th> <th>Reference</th> <th>Length</th> <th>Diameter</th> <th>Inner opening</th> </tr> </thead> <tbody> <tr><td>Schott</td><td>20 ml (26 ml)</td><td>Crimp</td><td>Glass</td><td>VC020-20C</td><td>56</td><td>29,25</td><td>12,75</td></tr> <tr><td>Schott</td><td>30 ml (37 ml)</td><td>Crimp</td><td>Glass</td><td>VCDIN30R</td><td>75</td><td>30</td><td>12,6</td></tr> <tr><td>Schott</td><td>50 ml (65 ml)</td><td>Crimp</td><td>Glass</td><td>VCT050-20C</td><td>68</td><td>42,5</td><td>12,6</td></tr> <tr><td>Schott</td><td>20 ml (26 ml)</td><td>Crimp</td><td>Glass</td><td>V010-20C</td><td>58</td><td>32</td><td>12,6</td></tr> <tr><td>Schott</td><td>30 ml (38 ml)</td><td>Crimp</td><td>Glass</td><td>V010-30C</td><td>62,8</td><td>36</td><td>12,6</td></tr> <tr><td>Schott</td><td>50 ml (60 ml)</td><td>Crimp</td><td>Glass</td><td>V010-50C</td><td>73</td><td>42,5</td><td>12,6</td></tr> <tr><td>Nalgene</td><td>30 ml (34 ml)</td><td>Thread</td><td>HPDE</td><td>2002-0001</td><td>61</td><td>34</td><td>14</td></tr> <tr><td>Nalgene</td><td>60 ml (65 ml)</td><td>Thread</td><td>HPDE</td><td>2002-0002</td><td>85</td><td>37</td><td>14</td></tr> </tbody> </table> <p>Conjugate, substrate and stop solution bottles</p> <table border="1"> <thead> <tr> <th>Manufacturer</th> <th>Volume</th> <th>Closure</th> <th>Material</th> <th>Reference</th> <th>Length</th> <th>Diameter</th> <th>Inner opening</th> </tr> </thead> <tbody> <tr><td>Nalgene</td><td>15 ml (18 ml)</td><td>Thread</td><td>HPDE</td><td>2002-9050</td><td>58</td><td>25</td><td>14</td></tr> <tr><td>Nalgene</td><td>30 ml (34 ml)</td><td>Thread</td><td>HPDE</td><td>2002-0001</td><td>61</td><td>34</td><td>14</td></tr> <tr><td>Polyvials</td><td>10 ml</td><td>Thread</td><td>HPDE</td><td>3071420</td><td>48</td><td>25</td><td>17</td></tr> <tr><td>Polyvials</td><td>20 ml</td><td>Thread</td><td>HPDE</td><td>3071400</td><td>60</td><td>27</td><td>17</td></tr> <tr><td>Polyvials</td><td>30 ml</td><td>Thread</td><td>HPDE</td><td>3071430</td><td>60</td><td>32</td><td>17</td></tr> <tr><td>Schott</td><td>10 ml (13,5 ml)</td><td>Crimp</td><td>Glass</td><td>VCDIN10R</td><td>45</td><td>24</td><td>12,6</td></tr> <tr><td>Schott</td><td>10 ml (15 ml)</td><td>Crimp</td><td>Glass</td><td>V010-10C</td><td>53,5</td><td>25,4</td><td>12,6</td></tr> <tr><td>Schott</td><td>20 ml (26 ml)</td><td>Crimp</td><td>Glass</td><td>VC020-20C</td><td>56</td><td>29,25</td><td>12,75</td></tr> </tbody> </table>	Manufacturer	Volume	Closure	Material	Reference	Length	Diameter	Inner opening	Schott	20 ml (26 ml)	Crimp	Glass	VC020-20C	56	29,25	12,75	Schott	30 ml (37 ml)	Crimp	Glass	VCDIN30R	75	30	12,6	Schott	50 ml (65 ml)	Crimp	Glass	VCT050-20C	68	42,5	12,6	Schott	20 ml (26 ml)	Crimp	Glass	V010-20C	58	32	12,6	Schott	30 ml (38 ml)	Crimp	Glass	V010-30C	62,8	36	12,6	Schott	50 ml (60 ml)	Crimp	Glass	V010-50C	73	42,5	12,6	Nalgene	30 ml (34 ml)	Thread	HPDE	2002-0001	61	34	14	Nalgene	60 ml (65 ml)	Thread	HPDE	2002-0002	85	37	14	Manufacturer	Volume	Closure	Material	Reference	Length	Diameter	Inner opening	Nalgene	15 ml (18 ml)	Thread	HPDE	2002-9050	58	25	14	Nalgene	30 ml (34 ml)	Thread	HPDE	2002-0001	61	34	14	Polyvials	10 ml	Thread	HPDE	3071420	48	25	17	Polyvials	20 ml	Thread	HPDE	3071400	60	27	17	Polyvials	30 ml	Thread	HPDE	3071430	60	32	17	Schott	10 ml (13,5 ml)	Crimp	Glass	VCDIN10R	45	24	12,6	Schott	10 ml (15 ml)	Crimp	Glass	V010-10C	53,5	25,4	12,6	Schott	20 ml (26 ml)	Crimp	Glass	VC020-20C	56	29,25	12,75
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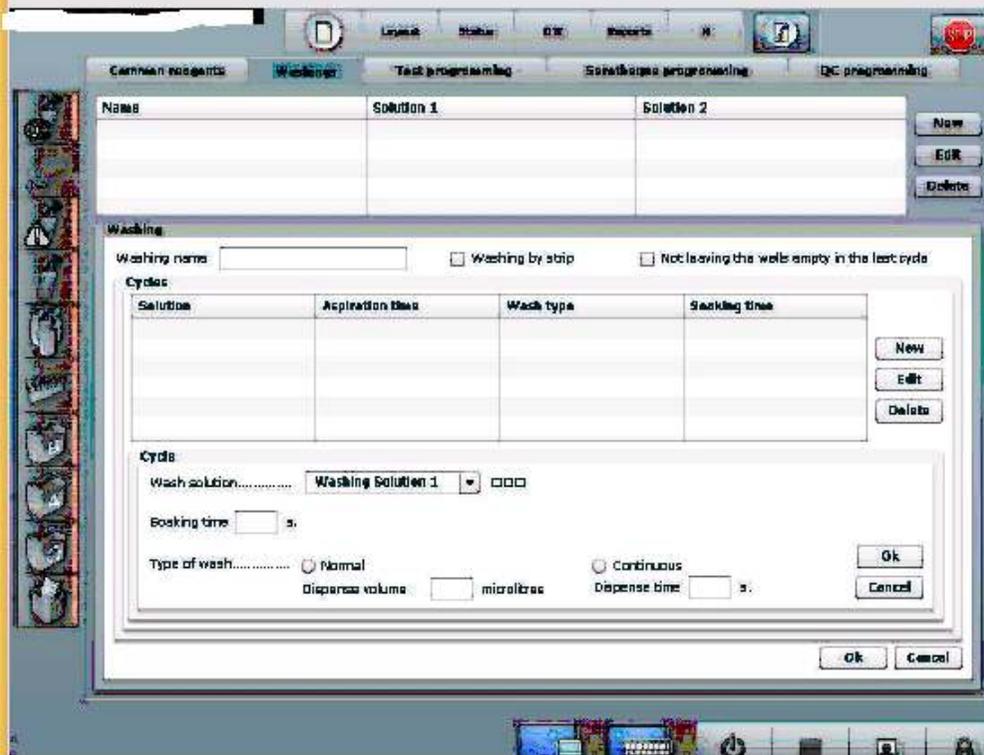
# DOORS

- ⊕ 2.1 Overall description
- ⊕ 2.2 External Interfaces Req
- ⊖ 2.3 Functional requirements
  - ⊖ 2.3.1 Programming
    - The programming st
    - ⊖ 2.3.1.1 Use Cases r
      - Programming Us
      - ⊖ 2.3.1.1.1 Use c
        - ⊕ 2.3.1.1.1.1
        - ⊖ 2.3.1.1.1.2
          - The wa
          - Micropl
          - Micropl
        - ⊕ 2.3.1.1.1.3
        - ⊕ 2.3.1.1.1.4
        - ⊕ 2.3.1.1.1.5
  - ⊕ 2.3.2 Batch manager
  - ⊕ 2.3.3 Data Warehouse
  - ⊕ 2.3.4 Reporting
  - ⊕ 2.3.5 Maintenance
  - ⊕ 2.3.6 Technical service
  - ⊕ 2.3.7 Instrument operati
- ⊕ 2.4 Non functional requirem

selected.

- Dispense time. This element shall only be enabled if the continuous type of wash is selected.
- Soaking time.

SRS-2467



SRS-130

2.3.1.1.1.3 Quality control programming

SRS-2341

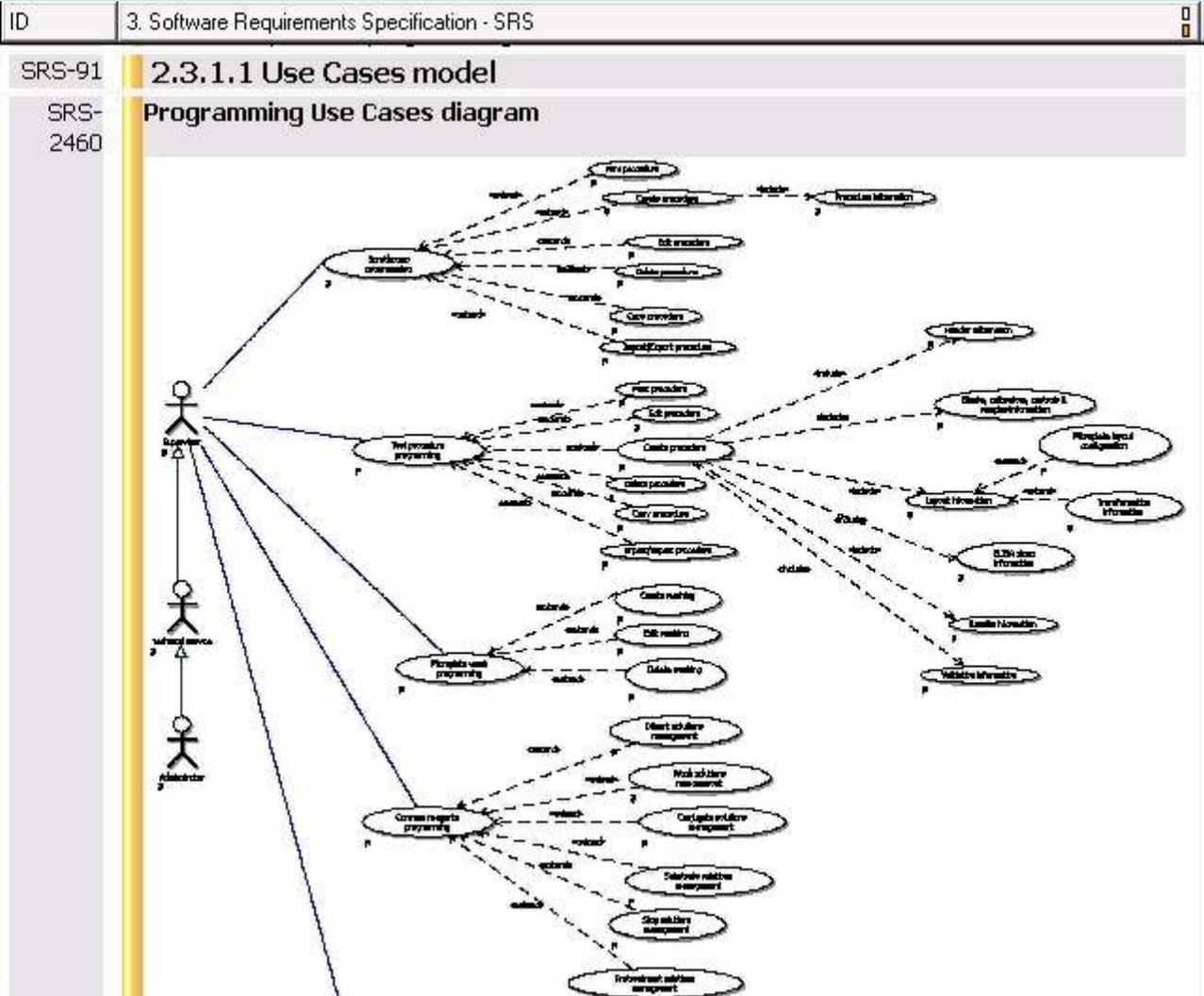
The QC protocols managing options that shall be available are the following:

- Create a new QC protocol
- Edit an existing QC protocol



# DOORS

- 3. Software Requirements Specification
  - 1 General Information
  - 2 Functional Requirements
    - 2.1 Overall description
    - 2.2 External Interfaces Requirements
    - 2.3 Functional requirements
      - 2.3.1 Programming
        - The programming software
        - 2.3.1.1 Use Cases model
          - Programming Use Cases
          - 2.3.1.1.1 Use cases
            - 2.3.1.1.1.1 Use cases
              - 2.3.1.1.1.1.1 Use cases
              - 2.3.1.1.1.1.2 Use cases
              - The way of use cases
              - Microplanning
              - 2.3.1.1.1.1.3 Use cases
              - 2.3.1.1.1.1.4 Use cases
              - 2.3.1.1.1.1.5 Use cases
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            - 2.3.4 Reporting
            - 2.3.5 Maintenance
            - 2.3.6 Technical service
            - 2.3.7 Instrument operation
          - 2.4 Non functional requirements

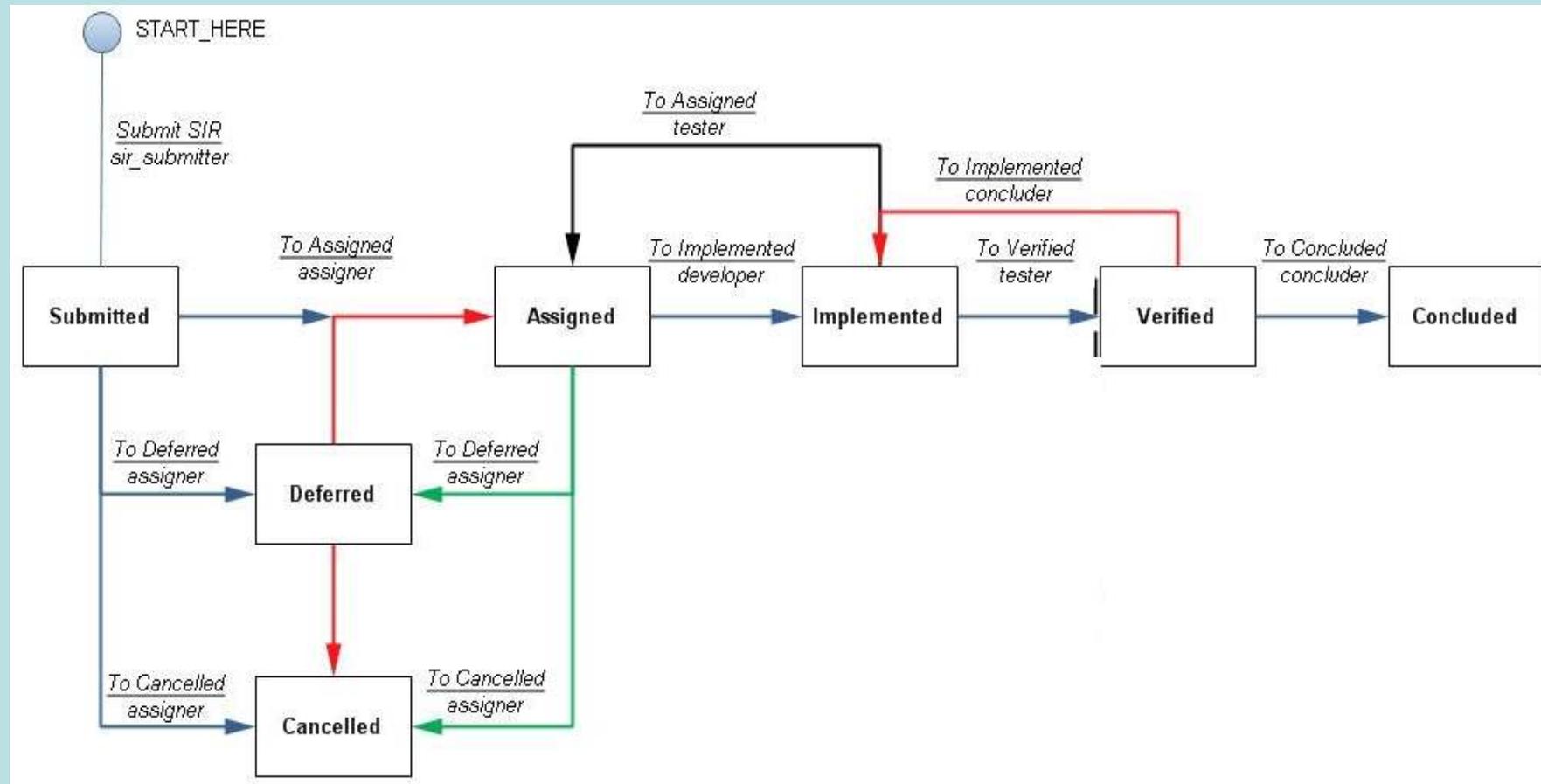


# DOORS

FR	Description	DS	Description	MS	Description	RA	Verification
PRS-1075	Automation The analyzer shall automate: Different steps of an ELISA (Enzyme Linked Immunosorbent Assay) assay in 96 microwell plate support according to the manufacturer's ELISA kit IFU Sample volume transferring process to create a Serotheque in 96 well plate support					N.A	
		DS-75	Levels The analyzer shall be vertically divided in top level and bottom level.			N.A	
		DS-93	Implementation Disposable entry shall be implemented through one guided drawer with electromechanical lock and lock status detector.			N.A	
				DS.pBKP-234	PCA DG-510 BarkPannel shall	N.A	



# Change



# Change

jmanzano (User): miktest - Microsoft Internet Explorer

**Change Request Information** Save Printer Friend

**Synopsis:** show "Hello World"

**Description:** El programa deberá mostrar por pantalla la frase siguiente:  
"Hello World"

---

**Submitter Information**

**Project:** Project A **Project Module:** ModuleA1

**Responsible:** Belen Vilaplana (bvilapla) **Resolver:** Abraham Iglesias (aiglesias)

**Release:** DG-HAL/common

---

**Priority:** High **Approval:**  [Show](#)

**Related Test:**

**Cancel Rationale:**

---

**Related DOORS Requirements:**

DOORS ID	DOORS Heading	DOORS Object Text
<a href="#">/Proyecto 1/6. Detailed Software Design Specifications - SDS.XXX/Detailed Software Design Specifications - SDS.XXX/SDS.XXX- 1</a>		El programa deberá mostrar por pantalla la frase siguiente: "Hello World"

---

**Associated Task(s):** [New](#) | [Add](#)

Task ID	Status	Synopsis
No associated tasks.		

**Links:** [Create associated CRAI](#) | [Create associated DCC](#) | [Create associated DIR](#) | [Create associated SIR](#) | [Add](#)



# Synergy

Create Task - grifols01 - Telelogic Synergy

Synopsis: Initialize v24 interface method

Description: This method will initialize all parameters to start sending date through serial interface

Release: DG510-TECHNICALSERVICE/dev

Priority: (none)

Subsystem: (none)

Platform: (none)

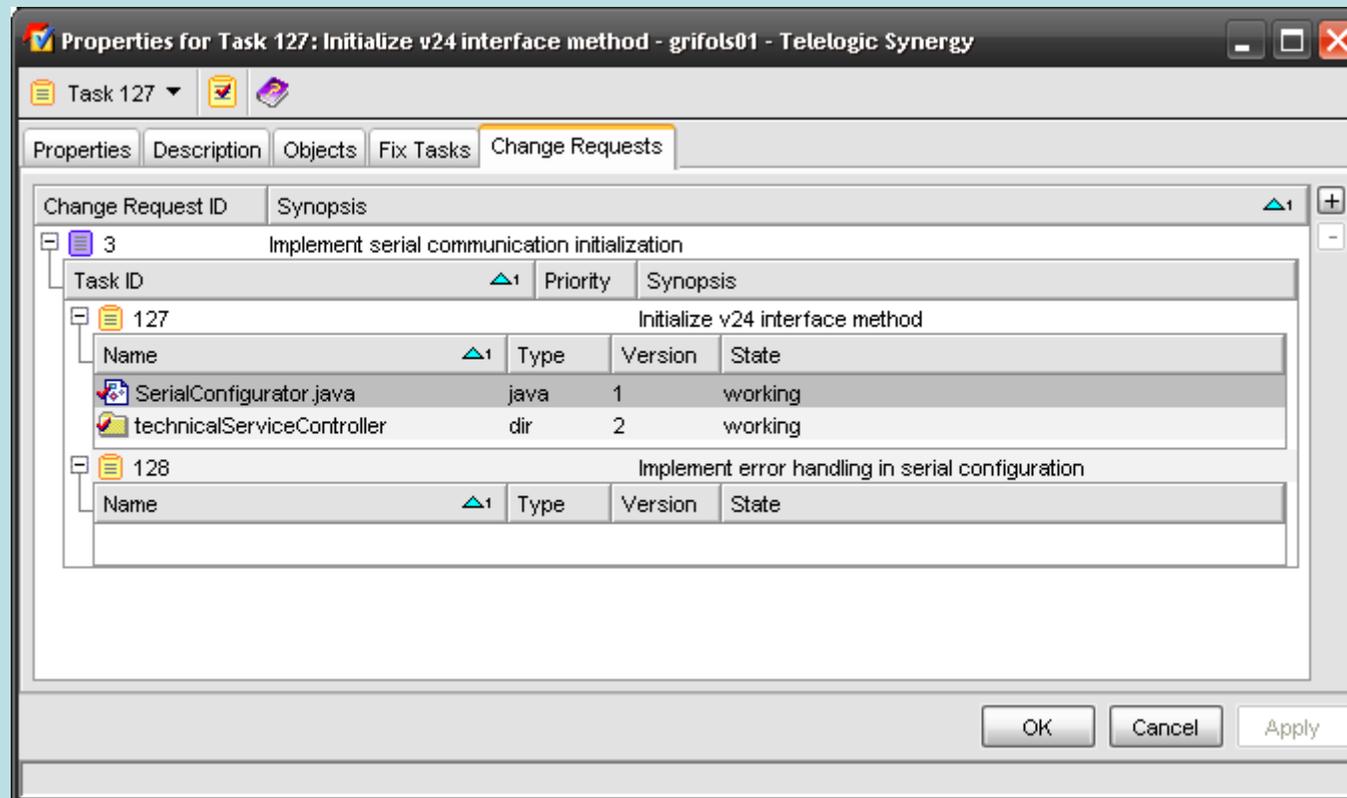
Resolver: aiglesias

Change Request: 3: Implement serial communication initialization

OK Cancel



# Synergy



# Synergy

The screenshot displays the Synergy application window titled "grifols01 - Telelogic Synergy". The interface includes a menu bar (Task, Edit, Find, View, Actions, Tools, Window, Help) and a toolbar. The main workspace is divided into several panes:

- Left Pane (Navigation):** Contains a tree view of project groupings, including "Build Management Project Groupings", "My Project Groupings", and "My Assigned SIR".
- Task List (Middle-Left):** Shows a list of tasks under "My Assigned SIR", such as "3: Implement serial communication initialization" and "128: Implement error handling in serial configuration".
- Task History (Bottom-Left):** Lists tasks completed in the last week, this week, and this month.
- Right Pane (File Tree):** Displays a detailed view of the project structure for "dg-technicalservice#ci". The tree shows folders like "src", "main", "java", "com", "dg", "dg510", and "resources", along with various Java files and configuration files.



# Synergy

Properties for dg-technicalservice v0.03 alfa 20090506 - grifols01 - Telelogic Synergy

dg-technicalservice v0.03 alfa 20090506

Properties Description Projects Tasks **Change Requests**

Change Req... Synopsis Included

1 Create project and import existing code Fully

Task ID ▲1 Priority Synopsis

107 Create Maven project for technical service

Name	Type	Version	State
.classpath	ascii	1	integrate
.project	ascii	1	integrate
.settings	dir	1	integrate
classes	dir	1	integrate
dg-technicalservice	dir	3	integrate
java	dir	1	integrate

2 Add maven plugins Fully

Task ID ▲1 Priority Synopsis

123 Add maven plugins

Name	Type	Version	State
.checkstyle	ascii	1	integrate
.project	ascii	2	integrate
.settings	dir	2	integrate
ADPComposite.html	html	1	integrate
ADPComposite.html	html	1	integrate
ADPConfiguration.html	html	1	integrate

OK Cancel Apply



# Historia de un Cambio

- Equipo de evaluación de herramientas (3) con usuarios clave.
- Caso de prueba con solución implementada en la misma.
- Sesiones específicas con especialistas en cada una.
- Calendario del proyecto de evaluación con objetivos e hitos.
- Cambio de toda la suite para aprovechar la integración entre herramientas.
- Implantación progresiva y asistida (workshops, cursos, propuestas de solución, ayuda a la implantación).
- Migración DOORS autónoma y “smooth”.
- Change y Synergy para nuevos proyectos o nuevas versiones.



# Beneficios Clave

- Buena acogida por parte de los usuarios.
- Repositorio unificado en dos BB.DD. (DOORS y Synergy).
- Vistas DOORS customizables y dinámicas. Trazabilidades parciales, totales, etc.
- UML integrado y almacenado en el mismo repositorio. WYSIWYG.
- Dxl para uso avanzado (análisis de riesgos).
- Firma CFR 11 de baselines.
- Trazabilidad DOORS -> Change -> Synergy.
- Testing integrado.
- Soporte a módulos de librería.
- Change como aplicación Web, con ciclo y campos customizados y firma electrónica.
- Synergy con orientación a tareas para asegurar trazabilidad a código.
- Licenciamiento cominado tokens – flotantes.
- Fácil instalación, mantenimiento y backup de BB.DD.



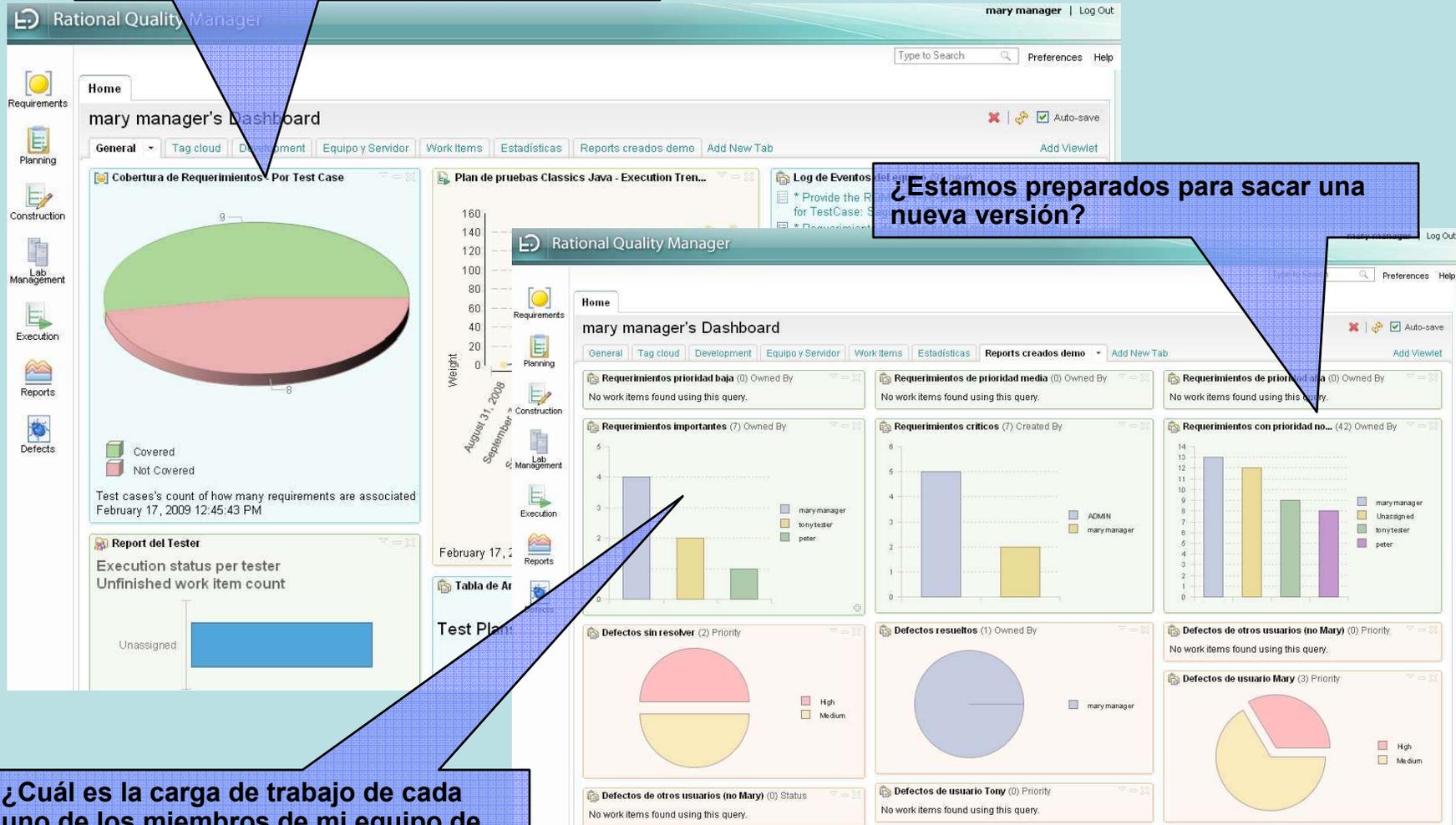
# Próximos Pasos

- Integración continua:
  - Predictibilidad en los builds
  - Mitigación de riesgos
- Dashboards estado desarrollo, calidad y testing:
  - Mayor visibilidad del desarrollo de software
  - Ayuda a la toma de decisiones
  - Mejora de la calidad del código, sin las costosas “peer reviews” -> componentes reutilizables
  - Orientación a funcionalidades implementadas
  - Mejora de la productividad



# ¿Rational Quality Manager?

Visualización del estado de las pruebas en tiempo real



¿Estamos preparados para sacar una nueva versión?

¿Cuál es la carga de trabajo de cada uno de los miembros de mi equipo de pruebas?

GRIFOLS

Working for health



# ¿Rational Insight?

Cognos Viewer - JK Enterprises Dashboard 1 - Mozilla Firefox

File Edit View History Bookmarks Tools Help

http://vega3.svl.ibm.com/cognos/cgi-bin/cognos.cgi?b\_action=dashboard&pathinfo=/om&frag\_header=true&path=storeID(%23)

## Rational Enterprise Reporting

Cognos Viewer - JK Enterprises Dashboard 1

Component Selection: Component: Core

Cognos Search: Search: Name field

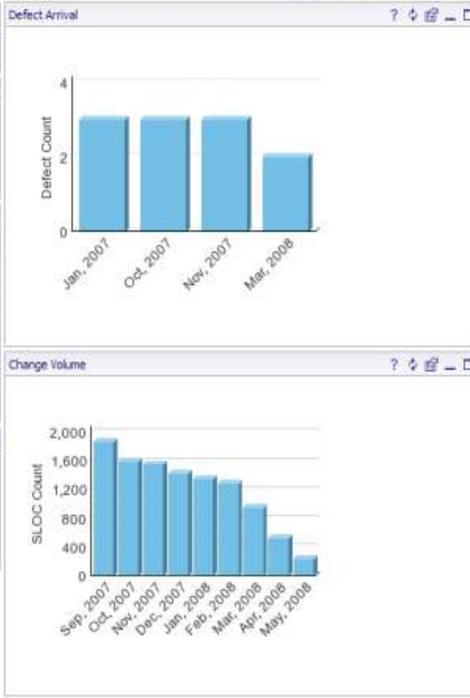
IBM DeveloperWorks

This week on developerWorks

HTML Viewer

Ready to process requests from other portlets.

Done



**Committed Tasks**

Stacked bar chart showing # of tasks by status over time.

**Approved Requirements**

Status	# of Requirements
Approved	52
Incorporated	24
No Request	186
No Test Case	186
No Test Case Execution	186
Proposed	88
Validated	3

**Test Execution**

Test Execution Status

Total TC	# executed TC	# failures	% of failures
910	16	15	94%

Requirements with Test Failures (Top)

Tag	Name	Status	# Failed T
-----	------	--------	------------

**Quality-Actuals vs. Target**

	Current	Target
# of Blocking Defects	0	0
# of Defects to Verify	70	50
% of Test Executed	12	30
% of Test Passed	100	80
Open Critical/Major Defects	27	20

**Actual Defect - Trends**

Line chart showing # of Defects over time.

**Project Performance**

Date	CV	SV	CPI
Mar 1, 2008	-198,000	-16,600,000	0.92
Apr 1, 2008	-198,000	-16,600,000	0.92
May 1, 2008	-407,000	-13,960,000	0.92
Jun 1, 2008	-550,000	-10,176,000	0.94
Jul 1, 2008	-605,000	-6,832,000	0.95
Aug 1, 2008	-874,000	-5,136,000	0.94
Sep 1, 2008	-1,321,000	-1,728,000	0.93

