



what makes you *
special?

IBM Softwaredag 2006



Tool Support for FDA Compliance

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Agenda

- * Introducing Novo Nordisk, Diabetes Research Unit
- * Business Drivers
- * Current usage of Rational tools
- * Hazard Analysis using Rational RequisitePro
- * Change Request types in Rational ClearQuest
- * The future

* Introducing Novo Nordisk, Diabetes Research Unit



NovoPen® 3 is the most widely used insulin delivery device in the world.



The durable Doser Innovo® is the first Doser with an electronic display

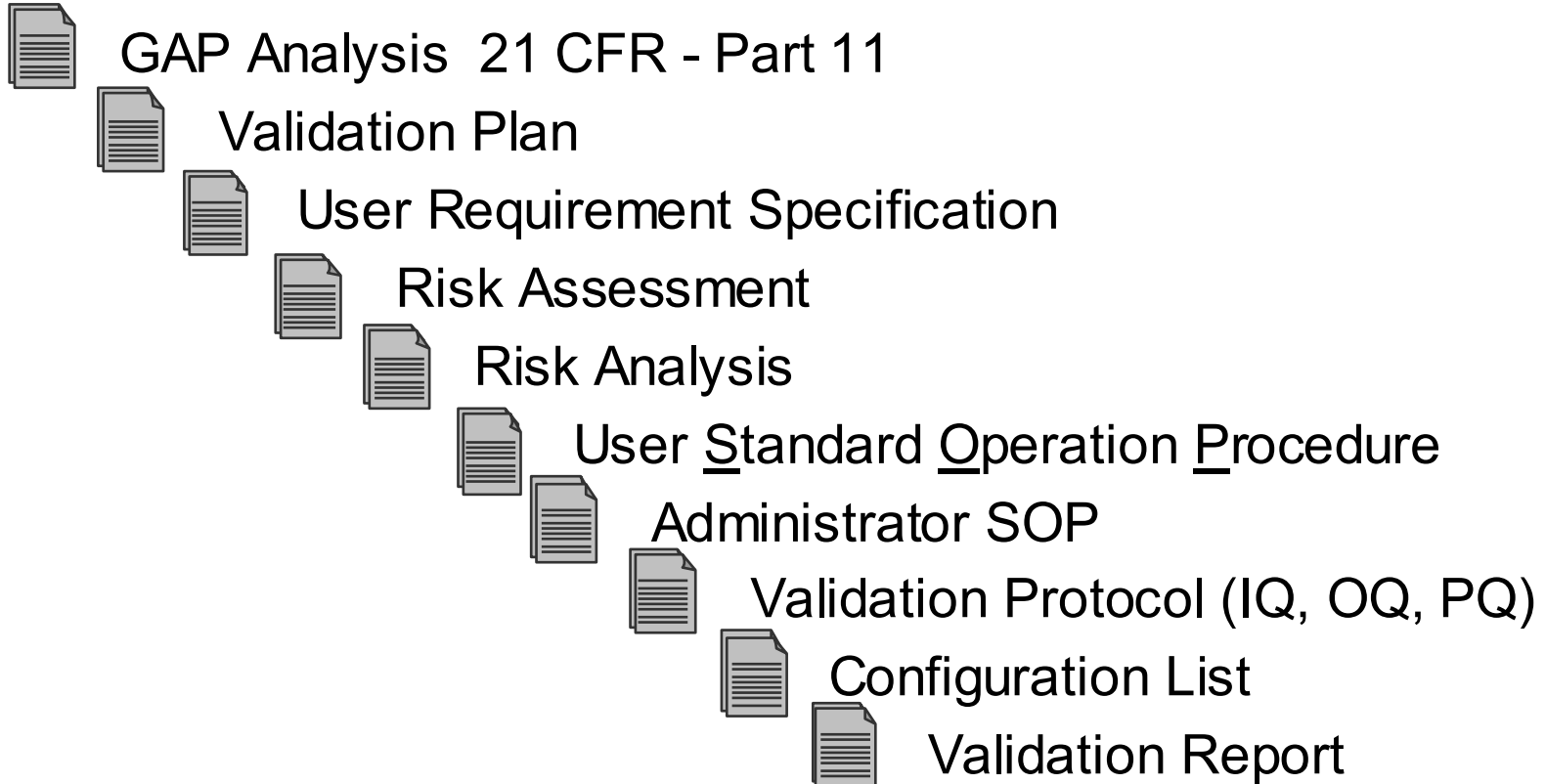


Novo Nordisk is the first company to combine a blood glucose meter with an injection device.

Business Drivers

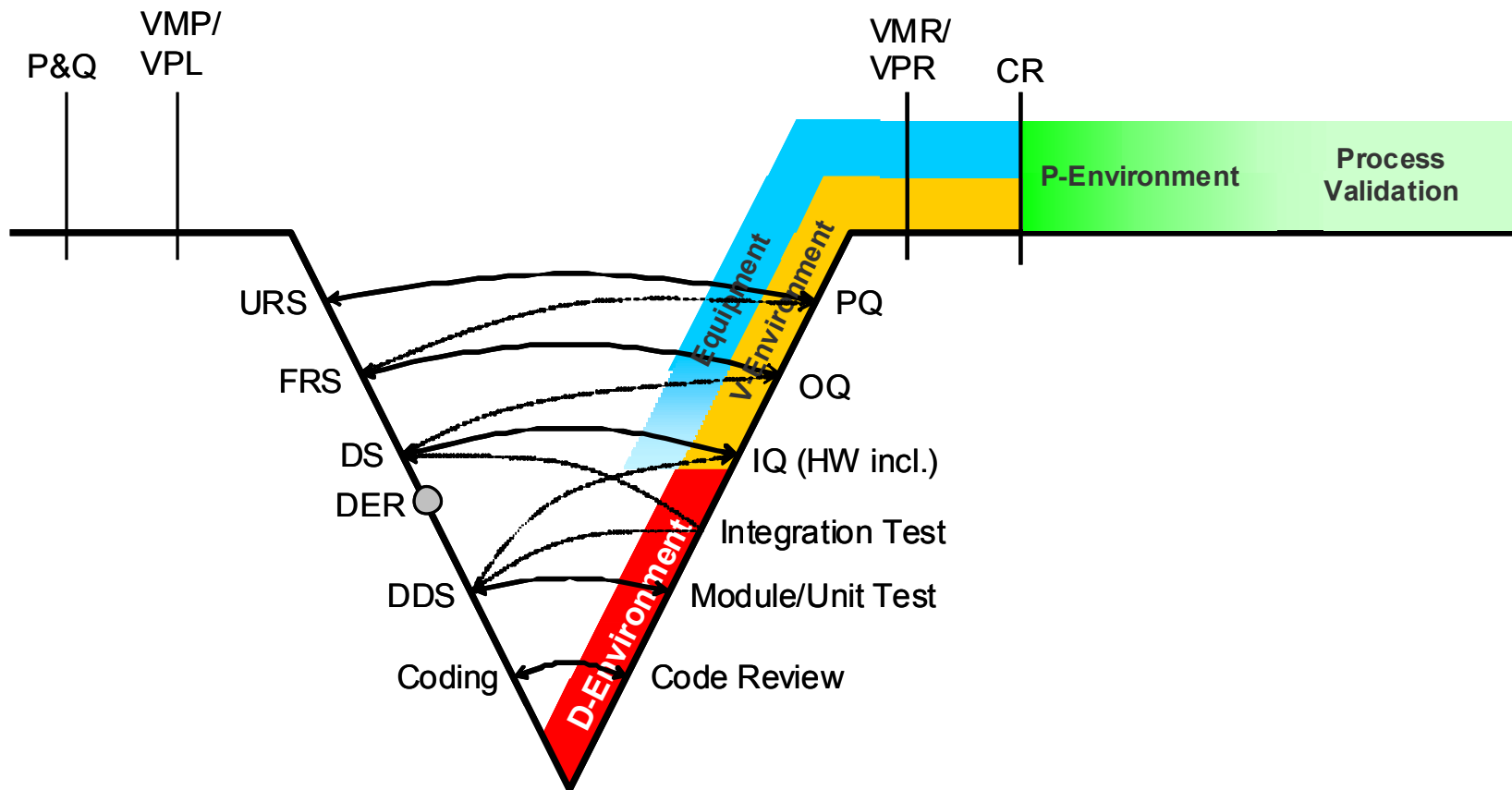
- Continue to be the world leading diabetes care company
- Changing from pure mechanical devices to a more complex world: Software + Hardware + User Interface
- Increased number of parts within each device
- Regulatory Compliance – Food & Drug Administration (FDA)
 - Validation (devices)
 - Computer Systems Validation (software tools)
 - Traceability

Business Drivers – Computer Systems Validation



IQ: Installation Qualification - OQ: Operational Qualification - PQ: Performance Qualification

* Business Drivers - Validation



Current Usage of Rational Tool

- Rational ClearCase
- Rational ClearQuest
- Rational RequisitePro
- Rational SoDA
- Rational Rose
- Rational Team Unifying Platform

* Current Usage of Rational Tool – ClearCase - Used for configuration and version control



Used for Technical File
& HW SW documentation



ClearCase Database

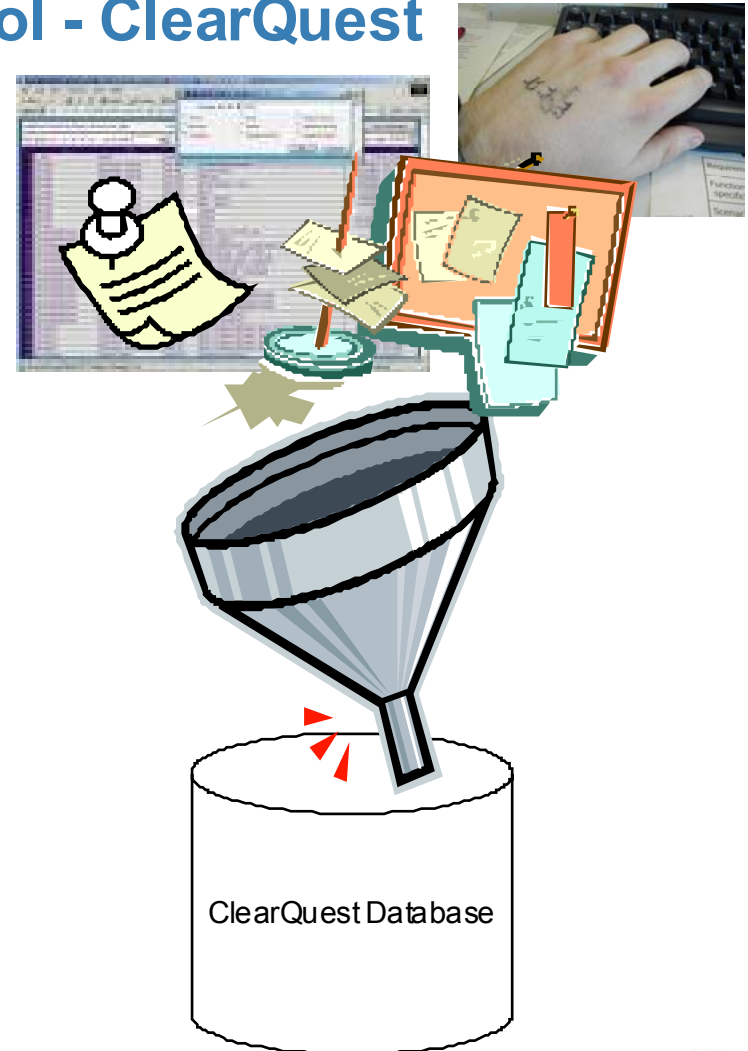


Reduced risk of **quality** or **compliance** problems:

- Right knowledge for decision making
- Less human errors
- One place for Technical File
- Efficient follow up, overview & control

* Current Usage of Rational Tool - ClearQuest

- Scope for using ClearQuest in the projects
- History from last milestone
- One place for Observations/failures & Change proposals



* Current Usage of Rational Tool – RequisitePro - Used for Requirements, Traceability and Risk Analysis

Key pain: Traceability system for mechanical devices:

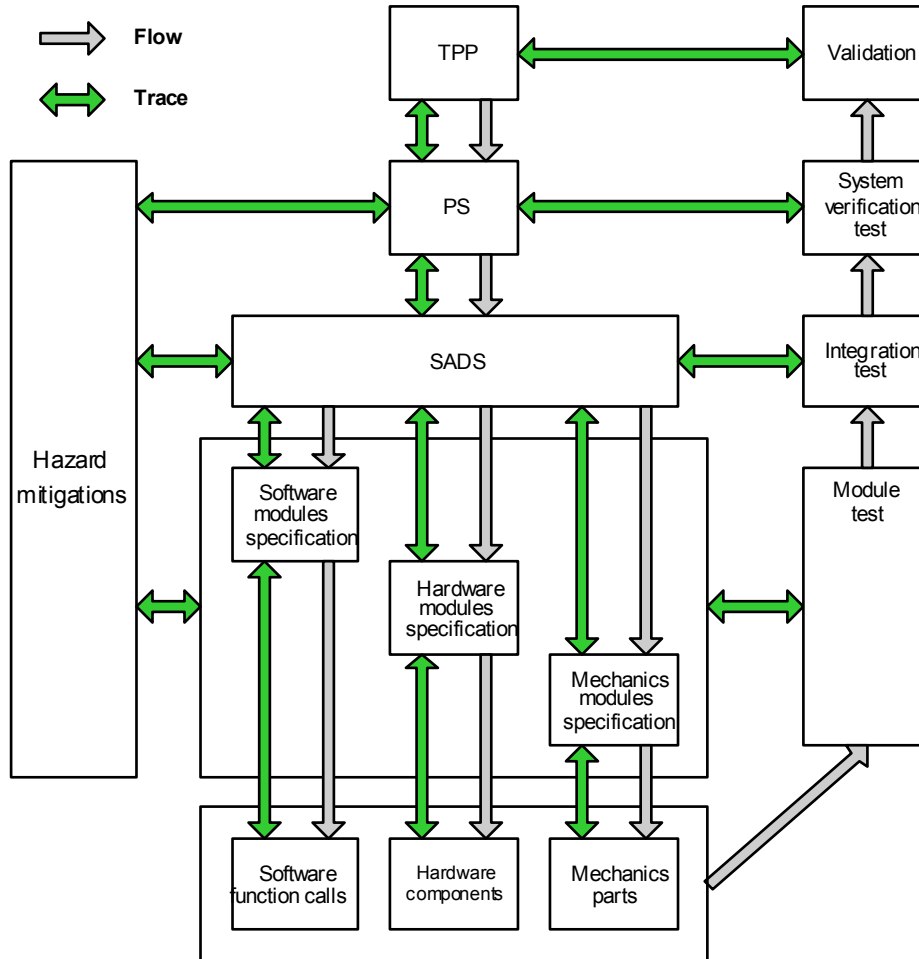
Manual process, costly, difficult follow up & control.

Example: 27 components in NovoPen4®

- V&V Plan:
241 rows in Excel
- Risk analysis
800 rows



* Traceability using Rational RequisitePro



Hazard Analysis using Rational RequisitePro

- Why using RequisitePro for Risk Analysis
 - FDA requires traceability
 - All requirement documents resides inside RequisitePro



Hazard Analysis using Rational RequisitePro

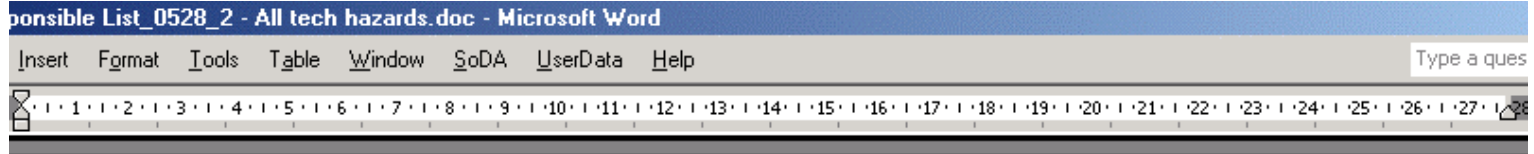
Requirements:	Failure mode/	Failure Cause	Consequence, tech	Consequence, user	S	Pd	Pi	Ph final	RPN	Risk class	Traced-to
HAZ826:	Inspection of insulin not possible	Material error: Reservoir opaque	If insulin fibrillated the user will not be able to detect it	Under dose (25-75% of set dose delivered in >12 hrs.	S4	P1	Pn0	P1	1E0	ALARP	MIT11
HAZ827:	Inspection of insulin not possible	Material error: Reservoir opaque	If insulin fibrillated the user will not be able to detect it	Under dose (>75% of set dose delivered in >12 hrs.	S3	P1	Pn0	P1	1E-1	Accept	MIT11

Hazard calculation created by extending RequisitePro:

- S: Severity of hazard (S1 – S5)
- Pd: Probability of the hazard to occur (P1 – P6)
- Pi: Probability of the user not recognizing the hazard (Pn0 – Pn7)
- Ph: Probability of harm. Calculated: $Pd \times Pi$
- RPN: Risk Priority Number. Calculated: $S \times Ph$
- Risk Class: Based on RPN values: Acceptable, ALARP, Intolerable

(ALARP: As Low As Reasonable Practicable)

* Hazard Analysis using Rational RequisitePro & SoDA



Hazard Responsible List		Date: 22 August 2006	
		Page: 1 of 1	

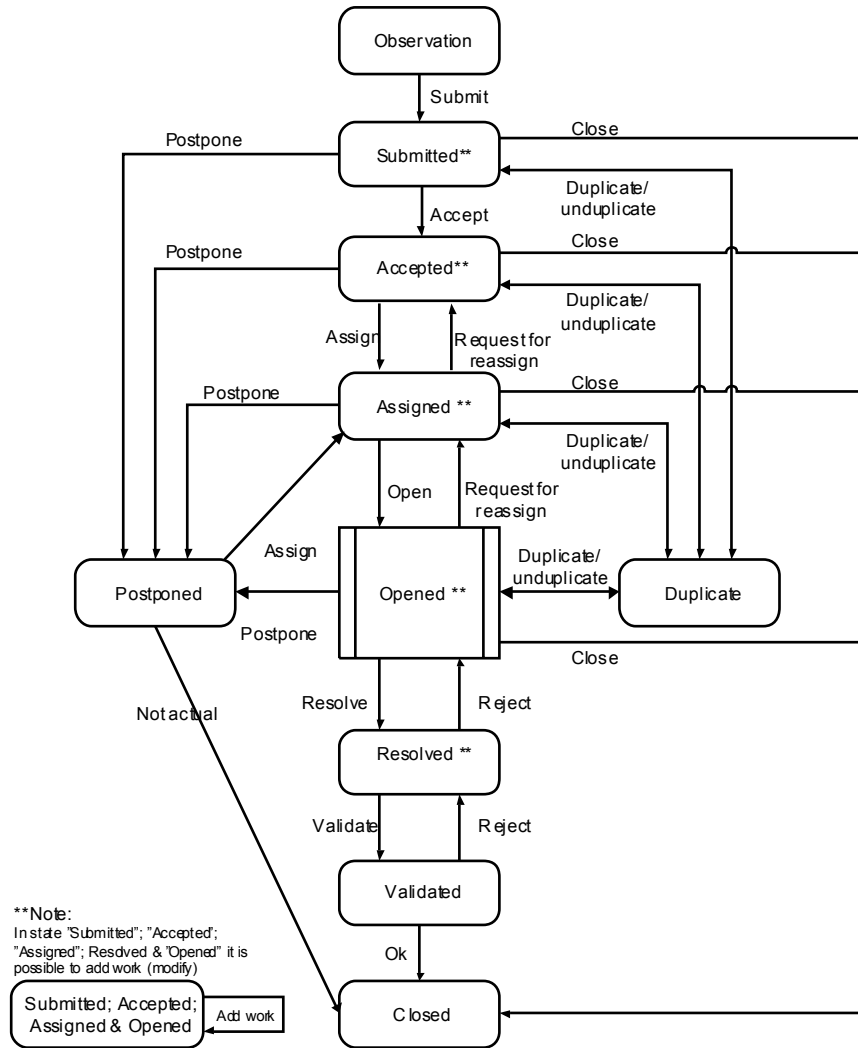
Responsible Group <HAZRequirement.ResponsibleGroup>		Person <HAZRequirement.ResponsiblePerson>	Status <HAZRequirement.Status>	Lib creation time 2006-03-20 15:18:00	HAZ ID <HAZRequirement.TagNumber>				
Device Name <HAZRequirement.DeviceUnitName>	ReqName		Order Rank Invoiced		Analysis Name	Function Invoiced			
	Usage state <HAZRequirement.Usagestate>			Handling action <HAZRequirement.HandlingAction>					
Failure Mode / Deviation <HAZRequirement.FailuremodeDeviation>					Failure Cause <HAZRequirement.FailureCause>	MEMI <HAZRequirement.MEMInterface>			
Consequence, Technical <HAZRequirement.Consequencetechnical>					Consequence, User <HAZRequirement.Consequenceuser>				
S	P _i	P _j	P _i & P _j Comments <HAZRequirement.PdPiComments>		P _i	RPN	Risk Class <HAZRequirement.Riskclassintem>	TB - HB <HAZRequirement.TBHB>	Comments <HAZRequirement.Comments>
<HAZRequirement.Requirement.Pd>	<HAZRequirement.Requirement.Pi>				<HAZRequirement.Requirement.Phntem>	<HAZRequirement.Requirement.RPNReport>			

Change Request types in Rational ClearQuest

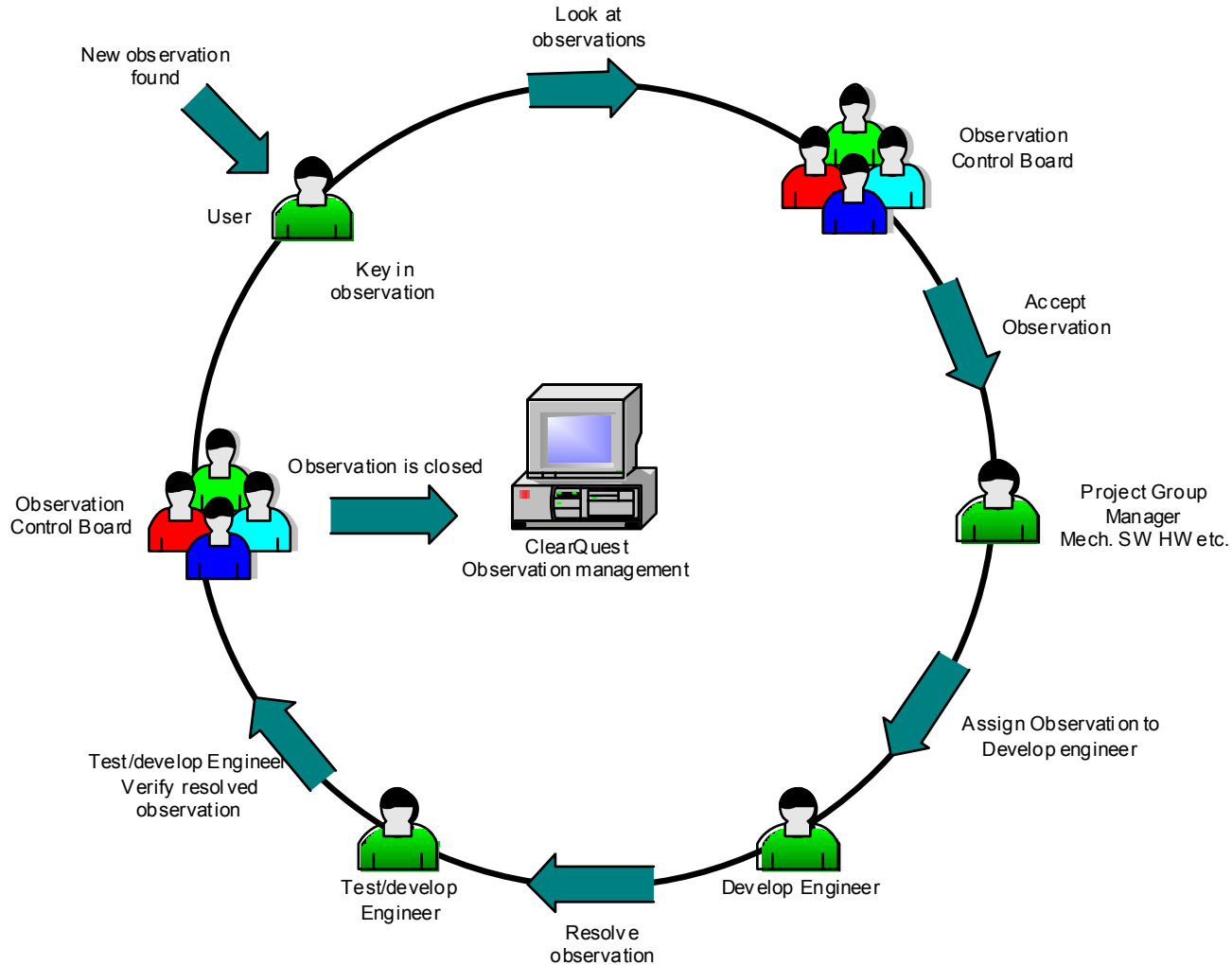
- **Observations**
 - Defects during System Verification Tests, Integration Tests and Handling Tests etc.
 - Change Proposals for document changes
- **Tasks**
 - actions in minutes of meetings



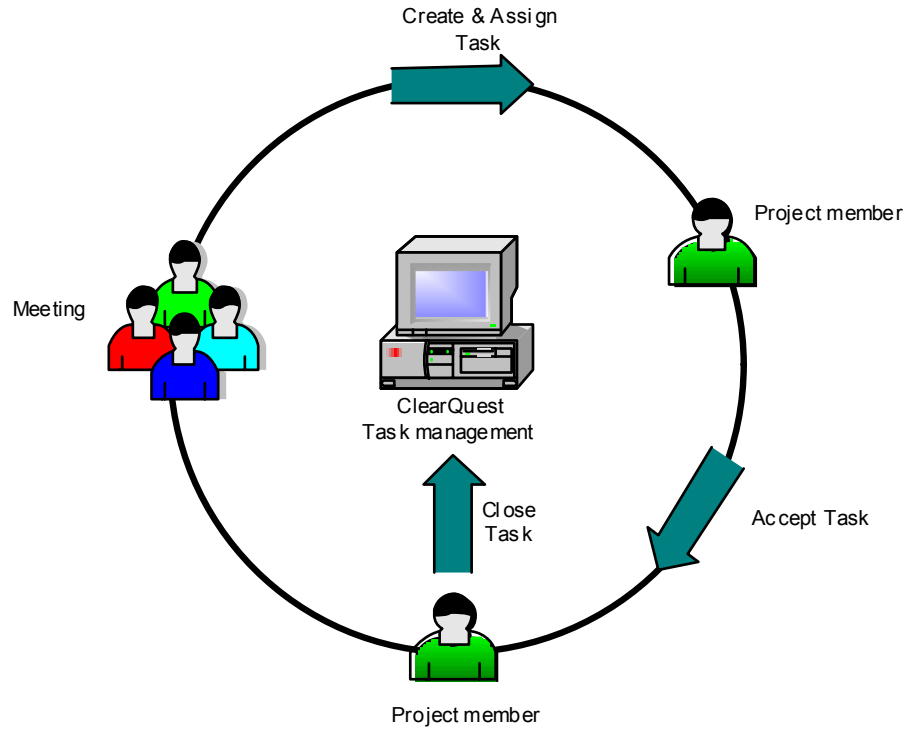
Rational ClearQuest - Observations



* Rational ClearQuest - Observations



* Rational ClearQuest - Tasks





Rational ClearQuest - Tasks

New Task NN00100000427 [] [] [X]

Main | Attachments

Task

ID:

Owner:

State:

Due Date: [...]

Meeting Number:

Headline:

Description:

OK

Cancel

Values ▼

The Future / Next Step

- ClearCase/ClearQuest Integration => controlled activity based development
- 21 CFR - Part 11 – Electronic Signature in ClearQuest
- Automated Test

Questions

THANK

YOU