COMPUTER VALIDATION

UPGRADE OF THE

WATS APPLICATION

BY

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Finally I would like to thank my loving husband, Mr. Paul Clarke who has encouraged and supported me everyday. Without him this course would never have been possible.

ABSTRACT

The reason I chose to complete my project on the upgrade of the WATS computer application is that one of my roles within Merck Sharp and Dohme is the WATS administrator role. As a result I am heavily involved in computer validation and the topic is of great interest to me.

The purpose of the project was to provide individuals with an awareness of computer validation and ensure that there is an understanding of the various requirements of computer validation in order to meet both the regulatory and divisional guideline requirements.

The introduction chapter aims to provide an overview of the WATS application and computer validation. It details the purpose of the upgrade and describes the differences between the application versions.

The methodological details chapter provides an overview on the regulations and guideline requirements in order to complete computer validation accurately, effectively and within compliance. It details the WATS upgrade SLC GMP deliverables and provides a brief description of each deliverable. It details the responsibilities of both the site WATS administrator and the divisional team. It provides the details on the steps required to be completed by the site WATS administrator in order for a successful implementation of the upgrade. Each possible release strategy is also detailed in this chapter along with various plans which were required to be executed as part of the rollout of the upgraded application version. These include the SOP update plan, the upgrade version training plan and the PC rollout plan.

The results chapter provides details on the results which were observed during the installation and testing of the upgrade version 3.03. This chapter includes the exceptions noted during testing; any incidents raised post release of the upgrade version and also details of the bug listing on WATS version 3.03.

The discussion and lessons learnt chapter describes a brief discussion on the findings and on the lessons learnt as a result of the installation of the upgraded version of the WATS application.

The conclusion chapter contains a brief conclusion on the findings of the upgrade, highlights the benefits of being involved in such a project and finally provides a brief summary on the future of the WATS application.

Finally a glossary of terms and acronyms used throughout the project were supplied in order for all terminology to be understood by the viewers of the project.

This project was compiled and completed on the 26th-Jan-2009 and I certify that at the time of printing all the information acquired was as accurate and up to date as possible.

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CHAPTER 1
INTRODUCTION

INTRODUCTION

This project is based of the upgrade of the World-Wide Atypical Tracking System (WATS). The divisional group are responsible for the rollout of the upgraded version 3.03 to all sites in EMEA (Europe, Middle East and Africa). It is the responsibility of the site administrator to ensure that this version is installed as required under the guidelines and requirements listed in the methodological details section of this project. The divisional and site administrator responsibilities are also listed in that section.

This project provides information on computer validation and details the requirements for completion of the upgrade. The most important aspects of this project are the sections which deal with the findings post upgrade such as lessons learnt and incidents post implementation. In order to understand this project is it important to have an understanding of the following;

1.1 WATS Overview [1]

The World-Wide Atypical Tracking System (WATS) is a Merck Manufacturing Division (MMD) developed tracking system. Its application is primarily in the area of manufacturing process atypicals, cleaning investigation Reports (CIRs), Customer Complaints, Supplier Complaints and Raw Material Deviations.

The system is a regional based client server application. The client is installed on the local users PCs, while the oracle database is hosted on a UNIX server which resides and is maintained by IS EMEA in Brussels. Merck Sharp and Dohme (MSD) Ballydine has no access to source code which remains the responsibility of the QRIS.

The WATS client runs on the standard MMD Ecore image running Microsoft XP. Within the WATS application organisations can be established based on individual business process. The three organisation set ups available at MSD Ballydine are the Atypical, CIR and Raw Material Deviation organisations. The OOS organisation has been built however is not yet activated.

The WATS System is classified as GMP Direct [SC5] as the information is used to make product quality related decisions. When a process deviation occurs in a production or supporting laboratory area, an Atypical Process Report (APR) needs to be generated to evaluate the circumstances of the process deviation and to evaluate the effects of the process deviation on product release.

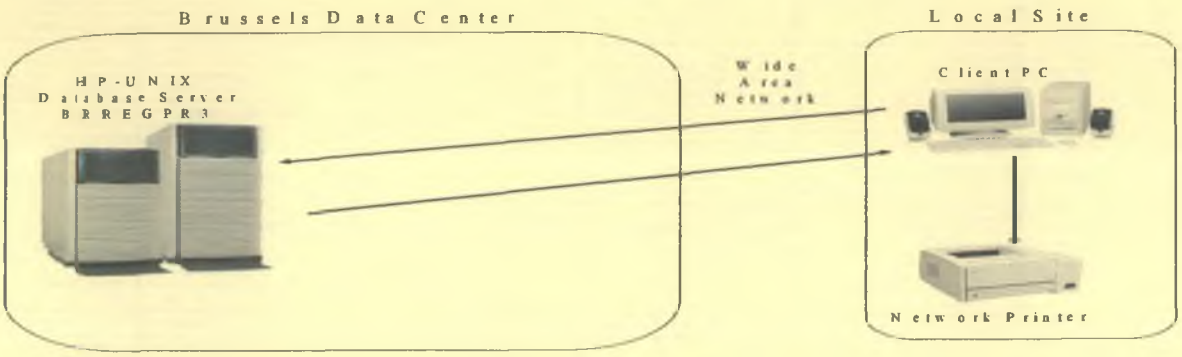
The APR would be distributed to a predetermined list of APR reviewers to obtain the appropriate technical evaluations in order for Product Release to determine the status of the affected lot (i.e. release, quarantine, or discard). Merck policies and guidelines as well as federal regulations (cGMPs) require that the APR must be documented, investigated and corrective actions taken as appropriate

The Worldwide Atypical Tracking System is an administrative tool to automate the process of generating, administering and managing Investigations (APR) involving multiple reviewers. This system is also used for cleaning failures and raw material deviations at Ballydine. The system will provide information on the people and tasks associated with the resolution of each Investigation to automate the review, tracking and close-out process. WATS is also utilized for trending purposes.

1.2 SERVER ARCHITECTURE [1]

The diagram below (Figure 1) represents the server architecture for the WATS Application and shows the interaction between Brussels and the site.

Figure 1 WATS Server Architecture

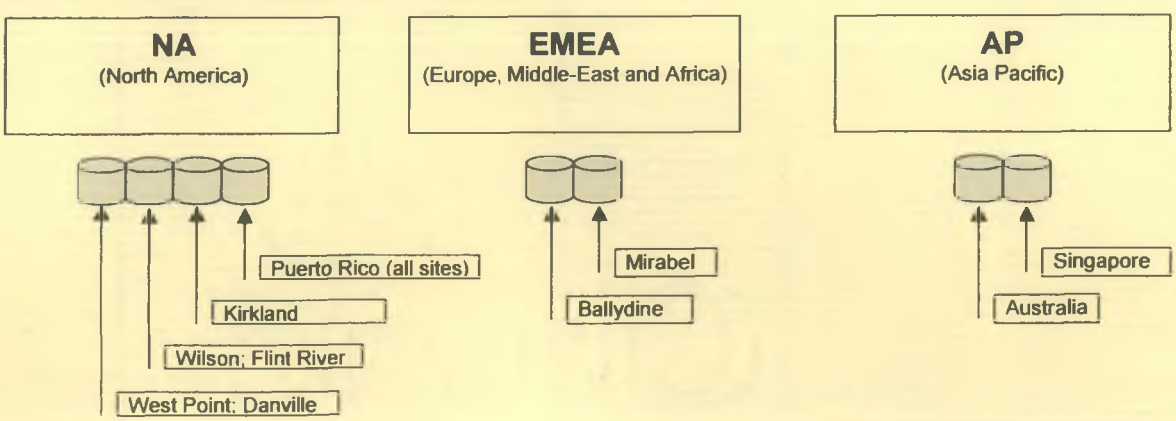


1.3 SYSTEM PHYSICAL ARCHITECTUR [1]

The Physical architecture of the system that makes up the WATS system is described as follows:

- Merck Standard Ecore PC (desktop or laptop)
- Merck Wide Area Network
- Oracle 9i, Visual Basic 6.0 and Crystal Reports 8.0
- Windows XP Professional (version 2002) SP1

Figure 2: System Physical Architecture



1.4 WHAT IS COMPUTER VALIDATION? [2]

At a high level Computer system validation (CSV) is the documented process of assuring that a computer system does exactly what it is designed to do in a consistent and reproducible manner. The validation process begins with the system proposal / requirements definition and continues until system retirement and retention of the e-records based on regulatory rules. The validation requirements are discussed in detail in the methodological details section.

The formal definition of validation from the US Food and Drug Administration (FDA) is as follows:

"Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality attributes."

1.5 PURPOSE OF UPGRADE

The WATS system was upgraded from version 2.1.3 to version 3.03. The purpose of the upgrade was as follows;

- To ensure that all MSD sites which implemented the WATS system would be using the same version. This eliminated the need for divisional support on numerous versions and provided consistency across the regions.
- To eliminate bugs which were identified in the previous version (2.1.3)
- To provide enhancements to the system as requested by various sites

The upgrade was required to follow Merck computer validation guidelines, Merck SLC guidelines and GAMP in order to ensure that the system remained in a validated state. These validation requirements/guidelines are discussed in detail in Methodological details section

1.6 VERSION DIFFERENCES [3]

Section 1.5 details the purpose of the WATS upgrade at a high level. This section however details the differences between WATS version 2.1.3 and WATS version 3.03. The upgrade version had numerous differences from the current version however for the purpose of this project I have listed the more important high level differences.

- The atypical process report root cause comment section now appears in the correct order. Previously this displayed after the conclusion section.
- The Revision report now shows the correct time and date for changes made to comments. Previously this was displayed in US time and not GMT.
- Changes made to closed atypicals by a Quality Manager user type now do not require approval as the Quality Manager user type was involved in closure of the investigation.
- A new report was added 'Pending Approval report'. This report displays all atypicals needing Quality Review/Manager approval.
- The Corrective Action report excludes canceled atypicals from the report as these actions are not valid as atypical was cancelled.
- Able to change default user type without getting error messages.
- The initiator of an atypical is now able to select the individuals which are required to be involved in the investigation, approval and closure of the atypical at the initiation stage.
- A warning message displays if screen resolution is not set to 1024x768 as this is required in order for the WATS application to function correctly.
- For user account administrator the status of a locked account is automatically set to Active when the reset password button is checked by administrator.

- The following fields now have an audit trail associated with them Product, Batch Number and Quarantine. Modifications to these fields are displayed using the revision report.
- In the previous version 2.1.3 there were incidents where atypicals had not moved to the next phase e.g. initiation to investigation. This version has now eliminated this bug.
- Can now add a current user to your organization when the user is part of a different organization in which you are not an administrator.
- One account now per user – no separate accounts required for different organizations.

CHAPTER 2
METHODOLOGICAL DETAILS

METHODOLOGICAL DETAILS

A number of regulations and guidelines were required to be adhered to in order for a successful implementation of the upgrade of the WATS application. By adhering to these regulations and guidelines it was ensured that the application remained in a validated state and that all regulatory requirements were met.
The regulations and guidelines which were used for the upgrade of the WATS application included;

- GAMP
- MERCK SLC
- MMD Validation Manual Guideline, VGDL 3.30, Computer System Validation: SLC Process Tailoring, Common Deliverable Content, Quality Assurance Planning & Summary Reporting, and Configuration Management

2.1 GAMP [4]

The GAMP guidance aim is to achieve computerized systems that are fit for the intended use and meet current regulatory requirements, by building upon existing industry good practice in an efficient and effective manner. GAMP provides practical guidance that;

- Facilitates the interpretation of regulatory requirements
- Establishes a common language and terminology
- Promotes a system life cycle approach based on good practice
- Clarifies roles and responsibilities

GAMP covers the key concepts; life cycle approach, life cycle phases (concept, Project, Operation, and Retirement) and Science based Quality Risk Management.

2.2 MERCK SLC (System Life Cycle) [5]

The revision of the Merck Corporate Policy #28 *'Systems Life Cycle'* in 2001 required the creation of a Company-wide process that ensured all computer systems were consistently developed and managed to minimize audit and regulatory risk, improve business productivity and provide quality assurance.

The Merck Systems Life Cycle (SLC) approach provides a common framework, methodology, and set of tools supported by a measurement system that improves the predictability, control and effectiveness of Merck's systems development processes to:

- Increase capability to deliver necessary functionality
- At the expected quality
- Within the promised time frame
- At the budgeted price

Merck SLC consists of a set of common high-level processes by which project managers, systems analysts, software engineers, programmers, and business clients can develop or acquire information systems and computer applications.

Merck SLC structure comprises of phases, each of which features groups of activities performed at predetermined points in the project life cycle; while the sequence of life cycle activities is variable to some extent, there is an implied logical sequence and implied dependencies, indicated by the process flow. Major project deliverables, suggested throughout the life cycle, are considered milestones in executing the actual project plan.

2.2.1 CONCEPT: [6]

The Concept Phase of the SLC is the period when a business area's response to a business or scientific driver triggers the identification of the need for an information technology system. This may be the result of informal discovery activities, strategic planning or collaboration on a formal business case. The high-level characteristics of a project from an information technology (IT) perspective are documented to ensure the client agrees with those definitions. Once the IT objectives of the project have been determined, the infrastructure and support areas are contacted as required to allow them to prepare for the project and identify the contribution they will be able to make concerning architecture and operational support.

2.2.2 SPECIFICATION: [6]

This phase is used to establish detailed requirements for the system solution and related infrastructure. Information is captured and discussed at a conceptual level. Technology alternatives are explored in more depth. The solution, system architecture candidates and high-level design for the Product and/or System is defined and the development path is identified (i.e., custom development, package acquisition or combination). Regardless of development path, cost estimates are detailed either internally or through evaluation of bid documents. Risk, vendor evaluations and total life-cycle cost-benefit are considered before identifying the solution. The phase starts by affirming the initial project and detailed plan for this phase, the quality assurance plans, and the configuration management plans. The phase ends with a commitment to the development path and the revised cost estimates.

2.2.3 CONSTRUCTION: [6]

The Construction Phase is the period when design details are established for how the functional requirements are to be met. During this phase, test procedures are identified, and the detailed plan describing the product's development, configuration and deployment are established. Plans are also detailed for product training design, development and delivery.

The Construction Phase also includes the installation of any necessary hardware and to build the software required for the application. In those cases where custom software development is required, the construction phase includes the actual implementation of the software components. Both custom and acquired software components are configured, tested and documented during the Construction Phase.

2.2.4 INSTALLATION: [6]

The purpose of the installation phase is to ensure that all hardware and software are tested and operational before the application is rolled out. Clients must approve the new system before it can be installed and the old system retired. The product is integrated into its operational environment and tested in this environment to ensure that it performs as required

2.2.5 OPERATION: [6]

The purpose of the Operation Phase is to ensure the application continues to function as planned and to ensure errors that occur are corrected. Version control, change control, and records retention procedures are initiated to allow adequate documentation and proper prioritization of work. The product is monitored for satisfactory performance, and modified as necessary to correct problems or to respond to changing requirements

2.2.6 RETIREMENT: [6]

The purpose of the retirement phase is to ensure that all aspects of the decommissioning effort are properly performed. These include the following;

- System decommissioning plan is created, verified and communicated
- System decommissioning plan is executed
- Decommissioning execution is approved

The upgrade of the WATS application from version 2.1.3 to version 3.03 required that the Merck SLC approach was followed. This ensured that the upgraded version was installed and operated correctly and that the application remained in a validated state.

For the upgrade of the WATS application the most applicable sections of the Merck SLC approach were the Concept, Specification, Construction, Installation and Operation Phases. The Retirement phase was not applicable. The rationale for this was that the Retirement phase will not be completed until full retirement and decommissioning of the application takes place. Retirement is not applicable for a particular version.

2.3 MMD VALIDATION MANUAL GUIDELINE, VGDL 3.30 [7]

The purpose of the Merck Manufacturing Division Guideline is to outline divisional System Life Cycle (SLC) and validation expectations for GMP systems as it relates to SLC Process Tailoring, Common Deliverable Content, Quality Assurance Planning and Summary Reporting, and Configuration Management.

This validation guideline applies to all information systems, manufacturing automation systems, and laboratory systems that store GMP data and/or control GMP processes within MMD. "Systems" use a combination of hardware and software to perform a specific GMP function. GMP SLC deliverables are direct outputs of the development of a system and/or changes to an existing system. These outputs represent system validation activities conducted for a given system to meet GMP regulatory expectations.

Each of the SLC GMP deliverables required for successful completion of the upgrade of the WATS application are listed in table 1 'WATS UPGRADE SLC GMP DELIVERABLES'. This table details the Merck SLC phase, each validation document required in that phase and the associated responsible party for completion of that document/activity i.e. Site or divisional.

TABLE 1: WATS UPGRADE SLC GMP DELIVERABLES

DOCUMENT	RESPONSIBLE PARY
SPECIFICATION	
Quality Assurance Plan (QAP)	Divisional
WATS Ballydine Site QAP	Site
WATS Ballydine Site System Configuration Management Plan	Site
Configuration Management Plan	Divisional
Requirement Specification	Divisional
WATS User Requirement Specification	Site
Design Specification	Divisional
WATS System Configuration Specification	Site
CONSTRUCTION	
Acceptance Test Plan	Divisional
Source Code	Divisional
INSTALLATION	
Requirement Traceability Matrix	Divisional
Ballydine WATS Traceability Matrix	Site
WATS Acceptance Test Protocol	Site
WATS Functional Test Protocol	Site
WATS Migration Plan	Site
Divisional Change Control request and Execution	Divisional
Site Change Control request and Execution	Site
OPERATIONAL	
Quality Assurance Summary Report	Site
Six Month post Implementation Review	Site

2.4 RESPONSIBITIES OF SITE WATS ADMINISTRATOR [1]

- Responsible for the review and approval of the site installation and testing activities including the review and approval of the site Validation Summary Report.
- Responsible for reporting and investigating all deviations/exceptions that arise during the upgrade.
- Responsible for ensuring the legacy information is accurate and that all information is transferred to updated version correctly.
- Responsible for ensuring that the site follows MMDs SLC methodology throughout the life of the system.
- Responsible for ensuring appropriate SOPs are in place and used.
- Responsible for ensuring that the correct version is rolled out to each users PC
- Responsible for training of each user on the upgraded version

2.5 RESPONSIBLES OF THE DIVISIONAL TEAM [1]

- Responsible for the design, development and implementation of the computer technology that satisfies the requirements of the atypical tracking processes.
- Responsible for the development, review and approval of the Divisional Quality Assurance Plan and for ensuring that the divisional project team follows the QAP throughout the project life-cycle.
- Responsible for development, review and approval of all other required SLC documents.
- Responsible for the operation and maintenance of the application software for the WATS application.
- Responsible for the completed Validation Summary Report (VSR) for the divisional system.
- Provide Database services including Database Administrator (DBA) support.

2.6 WATS APPLICATION UPGRADE DOCUMENTATION

In order to complete the WATS application upgrade from version 2.1.3 to version 3.03 the SLC GMP deliverables listed in Table 1 of the Methodological Details chapter were required to be completed. This ensured that Merck SLC guidelines were followed throughout each stage of the project. This section of the project now provides detailed information on each of the documents and the purpose of each document.

2.6.1 Divisional/Site Quality Assurance Plan [8, 9]

The purpose of both the divisional and site Quality Assurance Plans (QAPs) were to define the techniques, procedures, and methodologies that were to be used for the project based on its project attributes and associated tailoring rules. The plan defined the deliverables required which assured that the system and its components were developed in accordance with the approved quality standards to ensure the system was in a validated state on delivery. Further, referenced procedures, as well as standard operating procedures created specifically for the project, governed the operation of this system.

2.6.2 Divisional/Site Configuration Management Plan [10, 11]

This plan defined the configuration management (CM) requirements for the development and installation of application. The CM Plan guided the development and installation activities to assure appropriate configuration management in accordance with written, approved technical standards and guidelines conforming to Merck policies.

2.6.3 Divisional/Site Requirements Specification [12, 13]

The purpose of this document was to provide a clear statement of the business requirements for the application. The Requirements Specification described in familiar terms what the completed system was intended to do. It was a description of the required functions and capabilities derived from the business needs. It formed the basis for the design of the system and subsequent system development tasks.

2.6.4 Divisional Design Specification [14]

A Design Specification was the implementation strategy for the contents of the Requirements Specification. Each Design Specification or multiple Design Specifications encompassed more technical details about how the requirements were to be met. All subsequent code development, databases, man-machine interfaces, etc. were based upon the details found in the Design Specification.

2.6.5 Site System Configuration Specification [15]

This document defined the current configuration of the Ballydine installation of the WATS system. This document defined how the user requirements outlined in the document "User Requirement Specification" were to be achieved. This document also detailed any localisation which was undertaken to better reflect the Ballydine atypical and CIR business flows. The intended audience of this document was the Ballydine WATS application manager and application administrator.

2.6.6 Acceptance Test Plan [16]

The purpose of this test plan was to describe the test activities to be performed for the testing of the project. This document was intended to be used as a reference for the project team members. This document provided guidance on completion of activities assuring the system functioned in accordance with the projects' requirements, approved standards, and the customer's expectations. The Test Plan provided the structure required to conduct formal testing

2.6.7 Divisional Source Code [17]

This document had two objectives which included ensuring that the programming standards were consistently and correctly applied and also ensured that the code was written in accordance with the design specification.

2.6.8 Divisional/Site Requirements Traceability Matrix [18, 19]

This Requirements Traceability Matrix traced all the functionality, data and performance requirement references stipulated in the System User Requirement Specification document to the corresponding test scenarios. The intended audience of this document included the developers and testers of the system.

2.6.9 Site Acceptance Test Protocol [20]

The purpose of this protocol was to test the Ballydine installation of the upgraded WATS application. It provided a set of criteria against which the user may have accepted the system

2.6.10 Site Functional Test Protocol [21]

The purpose of this protocol was to document the eCore functionality testing for the WATS application version 3.03. The objective was to ensure that the application software would operate in accordance with the functions as outlined in the protocol and that the operation would satisfy the acceptance criteria specified in this protocol

2.6.11 Site Migration Plan [22]

The purpose of this plan was to ensure that all data which was migrated from WATS version 2.1.3 to WATS version 3.03 was completely accurate and that no data was lost or corrupted on migration

2.6.12 Quality Assurance Summary Report [23]

The purpose of this document was to authorize the release of the WATS application Version 3.03 for use at Ballydine. The objective was to demonstrate that the project had been delivered versus its commitments outlined in the associated WATS Quality Assurance Plan. Where exceptions had been encountered, these has been recorded and dealt with in the body of this document.

2.6.13 Six Month Post Implementation Review [24]

The purpose of this document was to complete a review of the upgraded WATS application six months after the release date. This review would cover any incidents post release and any bugs that may have been observed by the Ballydine site or any other Merck site using this WATS version.

2.7 Site Administrator Methodological Details

In order to complete the implementation of the WATS upgrade version 3.03 on the MSD Ballydine site, the initial step required to be completed by the Site WATS administrator was to review the high level validation documentation completed by the MSD divisional team. The purpose of these validation documents were as described in section 2.6. These documents included the Quality Assurance Plan, Configuration Management Plan, Requirement Specification, Requirement Traceability Matrix, Design Specification, Acceptance test plan and Source code.

The next step to be completed post review of the divisional documentation was for all site documentation to be drawn up, reviewed and approved. The documents required to be completed included the Site Quality Assurance Plan, Site System Configuration Management Plan, Site WATS User Requirement Specification, Site System Configuration Specification and Site Requirement Traceability matrix. The validation documents listed were authored by the Site WATS administrator and reviewed and approved by the application manager, application owner and site computer validation co-ordinator.

The testing documentation was also required to be authored by the Site WATS administrator. These documents included the Acceptance Test Protocol, Functional Test Protocol and the WATS Migration Plan.

In order for the WATS upgrade version 3.03 to be installed on the site the WATS administrator raised a site change request form. This change request form provided a description of the change and the reason for the proposed change. The approval of this form by the application manager signified that the change was approved for implementation, that is, the upgrade version was approved for installation to the MSD Ballydine Site.

A change execution form was then required to be completed. This change execution form provided the proposed change design detail and the testing which was required to be completed in order for a successful implementation. Approval of this form signified that the change could now be executed.

Once the upgraded version was loaded by the divisional team to the server the site WATS administrator was responsible for testing the application to ensure that all data was available and accurate in the upgraded version and that the historical data migration was successful. Also that all previously existing and new functionality was working correctly and as described in the functionality protocol. This involved execution of the following validation documents as described above;

- Site Acceptance Test Protocol
- Site Migration Plan
- Site Functional Test Protocol

Once the testing was completed by the WATS administrator and validation documents approved the change execution form was required to be approved by the WATS application manager. The closure section detailed the actions taken to implement the change. Once the change execution form was approved then the change request form could be closed and the system released for use. The release strategies that could have been chosen are described in section 2.8.

Additional plans were required to be executed by the site WATS administrator prior to release of the upgraded version of the WATS application. These plans included the SOP update plan, the upgrade version training plan and the PC rollout plan. The methodological details of these plans are described in sections 2.9, 2.10 and 2.11.

2.8 UPGRADED VERSION RELEASE STRATEGY

A system's capabilities and its benefits to the user may be delivered at different intervals depending on the project. There are four distinct release strategies available. Each of the four release strategies are detailed below.

2.8.1 Once Through Release Strategy [25]

The simplest release strategy is one which attempts to identify all the requirements up front and delivers a product which offers all the capabilities are identified. This is referred to as the once-through release strategy (IEEE). For computer system products, this is appropriate for single use applications and simple systems but is otherwise not the norm.

2.8.2 Incremental Release Strategy [25]

One way for a project team to better address the constraints of time and resources is to separate the requirements by priority so that the functionality most valued by the client is released first and additional functionality provided over time via subsequent releases of the product. This is referred to as the incremental release strategy (IEEE).

2.8.3 Evolution Release Strategy [25]

A more realistic scenario is that requirements may not be fully known nor understood until a product has actually been produced, released and used by the end user. New requirements can come as a result of engineering improvements, feedback from the user/consumer community as well as business and regulatory drivers external to the product team. This accommodation of new requirements after the product's release is known as the evolutionary release strategy (IEEE).

2.8.4 Progressive Release Strategy [25]

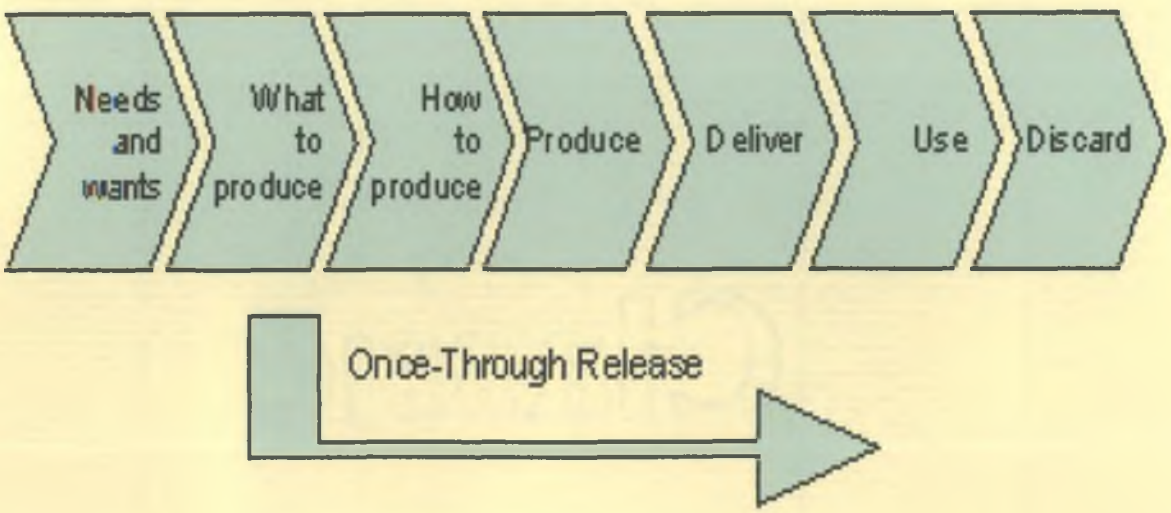
Perhaps most reflective of actual computer system life cycles is the release strategy which recognizes that time and resource constraints require a incremental release of capabilities and that new requirements will emerge through the use of the product. This is known as the progressive release strategy.

2.8.5 WATS Upgrade Release Strategy

The release strategy chosen for the upgraded version of the WATS application was the "Once Through Release Strategy'. The rationale for choosing this strategy was that the WATS application could be considered a single use application and simple system. There were no complicated systems or functionality added to the application as a result of the upgrade. The changes included the addition of simple functionality and improved reporting.

The diagram below represents each of the stages that that were required to be completed as a result of the 'Once Through Release Strategy'.

Figure 4: Once Through Release Strategy [25]



2.9 SOP UPDATE PLAN

Another activity required to be completed as part of the upgrade of the WATS application was to ensure that all procedures were updated and effective in time for the rollout of the new upgraded version 3.03.

Table 2 documents each of the procedures associated with the WATS application and whether an update to this procedure was required as part of the upgrade of the application.

TABLE 2 – WATS SOP LISTING

SOP NAME	UPDATE Y/N
SQL*LIMS and WATS Roles and Responsibilities (QO SOP 220)	Y – Modifier User Type functionality updated
SQL*LIMS and WATS Site Configuration Management (QO SOP 221)	N – No change to how configuration management is handled between versions
WATS System Administration (QO SOP 246)	Y – Required update to reflect new functionality
WATS User Manual (QO SOP 247)	Y – Required update to reflect new functionality and reports
WATS Training (QO SOP 250)	Y – Required update to reflect new functionality and reports
WATS Security and Managing Users (QO SOP 251)	N – No change to security or managing users

2.10 UPGRADE VERSION TRAINING PLAN

All current users of the WATS application were required to receive training on the upgraded version and updated SOPs where appropriate. The plan for training on the upgraded WATS version 3.03 was as follows;

- Develop a training presentation to highlight all differences from version 2.1.3 to version 3.03 – Reference Appendix 1 for presentation.
- Deliver this presentation along with a practical demonstration of the upgraded version to all current users of the WATS application.
- Review changes made to each WATS procedure where current user requires training on new revision
- Lock all current WATS users accounts until training on upgraded version has been completed.
- Once training completed activate account for WATS user and ensure training form completed and filed.
- The delivery of the presentation and practical demonstration to be completed in five group sessions the week prior to go-live of the upgraded version.
- The training plan was Monday to Friday, 9 – 11 am, Employee Services Conference Room
- Site WATS administrator to deliver training to all current WATS users
- Current WATS users who are unable to attend any of the five group training sessions will not have there accounts re-activated until training has been received. This will be individual one on one training between the WATS administrator and the WATS user.

2.11 PC ROLL OUT PLAN

As previously discussed in section 1.1 What is WATS? It was stated that the WATS system was a regional based client server application. What this means is that the client (application) is installed on the local users PCs. Therefore all current users of the WATS application had the previous version 2.1.3. The PC roll out plan ensured that the installed version was updated to the upgraded version 3.03 on each PC. The plan for this rollout was as follows;

- Develop a spreadsheet listing each current WATS user name, department and PC number. Reference Appendix 2 for an example of this spreadsheet.

- Send spreadsheet link with appropriate heading to all current users in order for the fields to be populated.

- The WATS administrator then filters by department and schedules dates to install the upgraded WATS version on the current users PC by department.

- The new version is to be installed from the Merck application website 'software on demand' http://softwareondemand.merck.com/webinstallui/Home.aspx.

There were advantages and disadvantages associated with rolling out the new application version as per the plan above. These are detailed in chapter 3 'Results'.

CHAPTER 3
RESULTS

RESULTS

The initial steps required to be completed for the installation of the WATS upgrade version 3.03 was for the WATS administrator to review of the divisional documentation. All required validation documents were supplied by the divisional team in a timely manner and were reviewed thoroughly by the site WATS administrator. No updates were required to be made to these documents as a result of the review.

The next stage was the completion of the site validation documentation. This was prepared by the site WATS administrator and reviewed and pre-approved by the application manager, application owner and the computer validation co-ordinator. A number of updates were required for each document prior to approval. These updates included typographical errors, clarifications, additional testing, addition of exceptions register document and an abbreviation and acronyms section.

The next stage was to raise and approve the change request and change execution form. This was completed with no issues noted. Once the change execution form was approved the change was executed by the divisional team and the application was tested by the site WATS administrator. There were two exceptions noted during the testing phase and these are detailed in section 3.1.

3.1 EXCEPTIONS DURING TESTING

During the execution of the validation protocols referenced in section 2.7 two exceptions were observed. These exceptions were noted during the execution of the Site Migration Plan. No exceptions were noted during the Site Functionality testing or Site Acceptance testing.

Each protocol was required to have a section for non conformances/exceptions. This section stated that in the event that an exception was encountered, the course of action was to be determined by the tester. An exception may have consisted of a single installation step failing during the execution of multiple steps. All exceptions were required to be documented in the exceptions register of the protocol.

Each protocol also had an acceptance Criteria section which required that the protocol only be approved when all steps were passing. This section allowed for the protocol approval to occur where exception(s) had been noted. These exceptions must have been investigated and deemed not to impact the validation status or intended use of the application.

The exceptions noted during the execution of the Site Migration Plan were as follows. All exceptions were thoroughly investigated and deemed to have no impact on the validation status or intended use of the application. Both exceptions were fully closed prior to final post approval of the Site Migration Plan.

3.1.1 Three extra fields observed on atypical and CIR reports within the upgraded version 3.03. These fields were organization, classification and revision. No corrective actions were required as these were new fields which were added to the report. There was no impact as all the information on the original report was identical to that on the new report [22]

3.1.2 One extra field observed on the Action, Atypical Listing, Planner, Processing Time and Quality Metrics report which the upgraded version 3.03. This field was classification. No corrective action required as this was a new field added to the reports. No impact as all information on the original reports was identical to that on the new reports [22]

Once all testing was completed and each validation document post approved the change request was closed and the system could be released to the current users. However prior to actual release there were a number of plans that were required to be executed as described in sections 2.9, 2.10 and 2.11.

In the case of the SOP update plan no issues were noted. All SOPs were updated by the site WATS administrator and the effective date of each updated SOP was the go-live date of the upgraded version of the application. All users completed training on these procedures as per the upgrade version training plan.

In the case of the upgrade version training plan, the training was provided to the current WATS application users by the site WATS administrator in line with section 2.10. Unfortunately the five sessions did not cover all departments and shifts. Ballydine is a 24X7 site and all four shifts were not present on site. Therefore resulting in numerous individuals requiring one on one training with the site WATS administrator. This was considered an area which could have been improved and was included in chapter 4 'Discussion and Lessons Learnt'.

The final plan required to be executed prior to release of the application was the PC rollout plan. This could be completed pre or post release, however, if completed post release the users would not be able to access the application immediately. This plan was extremely difficult to execute and resulted in a lot of time and resource by both the site WATS administer and the current users of the application. Out of 97 current WATS application users, 72 of these had there PCs updated on the morning of the application go live date. This equated to 74% of all users. The remaining 26% of the applications users had their PCs updated with the upgrade version over a period of four days. No user experienced any downtime as a result of this delay. The 26% of users that did not have their PCs updated in time for go-live were in-fact not on site in order for the WATS administrator to complete the update. As they returned to site the application version was updated. [23]

Once all plans, validation documents and change controls were implemented, reviewed and approved the upgraded WATS application version was installed on the MSD Ballydine site. Post release of the upgraded version a number of incidents were raised by the application users.

One of the roles of the WATS administrator is 'Incident Management'. The incident management process aims to categorize incidents to direct them to the most appropriate resources or complementary process to achieve a timely resolution. An incident itself can be categorized as an operational event which is not part of standard operation. All incidents were investigated and thoroughly documented by the site WATS administrator. Section 3.2 provides a description of each incident raised.

3.2 INCIDENTS POST RELEASE OF UPGRADE VERSION 3.03 [24]

Table 3 below documents all incidents post release of the upgraded WATS version 3.03.

TABLE 3: Incidents Post Release (WATS Version 3.03)

DESCRIPTION	INVESTIGATION	CORRECTIVE ACTION
The Quality Manager User Type within the WATS application version 3.03 reported that no CIRs appeared in the dropdown menu when the 'Open CIRs that require your approval' tab was checked within the CIR organization.	In the upgraded version of WATS 3.03 there is only one user name and password for both the atypical and CIR organizations. In the previous version 2.1.3 each user had a separate user name and password for each organization. Each department in each organization had a default quality manager name however this default name for CIRs was associated to the CIR account. Once version 3.03 was implemented this account was inactivated and so the association was inactivated.	A change control was executed to place the default name of the Quality Manager into the CIR organization for the only account now held by the user as a result of the upgrade of the WATS application. This incident was reviewed by the WATS administrator and site computer validation co-ordinator and was deemed to be an isolated incident where the corrective action eliminated the problem and no reoccurrence would be possible.

DESCRIPTION	INVESTIGATION	CORRECTIVE ACTION
If the engineer/Quality Assurance/Technical Operations/Operations Manager or Technical Manager user types close a corrective action or adds an attachment to a closed atypical or CIR, then the atypical/CIR requires revision approval by the Quality Manager user type. The issue is that the Quality Manager user type is not notified of this update to the atypical/CIR.	The WATS upgrade version 3.03 has new functionality that when the engineer/Quality Assurance/Technical Operations/ Manager or Technical Manager user types closes a corrective action or adds an attachment to a closed atypical/CIR then the atypical/CIR requires revision approval by the Quality Manager. The Quality manager user type is not notified of this revision approval and therefore all permissions are required to be modified. The proposed solution is that write access to closed atypicals/CIRs be removed from the engineer /Quality Assurance/Technical Operations /Operations Manager or Technical Manager users types and that the modifier user type should be the only user type with write access to these reports as the WATS upgrade version sends automatic e-mails to the Quality Manager user types once the modifier user types makes an update.	A change control was raised in order for the permissions to be changed for the engineer/ Quality Assurance/ Technical Operations/ Operations Manager or Technical Manager users type. Write access to closed atypicals/CIRs was removed from these users types and two QA specialists were assigned the modifier user type role in which they made all required changes to site atypicals/CIRs as this user type automatically sends e-mail notification to the Quality Manager user type once an update is made to the atypical/CIR.

DESCRIPTION	INVESTIGATION	CORRECTIVE ACTION
A CIR report was initiated within the WATS application version 3.03. The initiator box was checked by the initiator and also the notified date and person in Quality notified fields were populated (these fields are automatically populated by WATS on initiation of a CIR) however the CIR did not move from the initiation phase to the investigation phase.	This issue was investigated by the site WATS administrator however no root cause could be established. A Merckury case was raised with the divisional team in order for a divisional investigation to be completed on the issue. Post divisional investigation the team identified the issue as a bug on the application version 3.03. This bug was added to the application version 3.03 bug listing.	The CIR was cancelled and the incident number referenced in the cancellation comments section. A new CIR was raised without incident. No corrective actions will be made in regard to the bug as the WATS application will be retired in February 2010 due to the installation of SAP on site.

DESCRIPTION	INVESTIGATION	CORRECTIVE ACTION
Quality Assurance name and check missing from the investigation phase of an atypical.	On investigation by the site WATS administrator it could be seen from the atypical audit trail that the Quality Assurance check box was indeed checked by the QA group. A Merckury case was raised and the divisional team investigated. The divisional team investigation concluded that it was a known bug on the application upgrade version 3.03 and that the issue was caused by the user key in the WATS_ESIG table not matching the one in the WATS_ATYP_APPVL table.	The closed incident report was attached to the atypical within the WATS application so that in the case of an audit the deviation could be explained. No corrective actions will be made by the site or divisional team in regard to the bug as the WATS application will be retired in February 2010 due to the installation of SAP on site.
The modifier user type updated the author field on the interim memo section of an atypical. A different user was selected however once re-opened the original name still appeared	The modifier user type does not have permissions to save updates to this field. They can access to make the change however the change will not save.	Change control raised to update the modifier user type permissions for the save field. Change control was successful and no further update was required. This was deemed an isolated incident where the corrective action rectified the issue.

DESCRIPTION	INVESTIGATION	CORRECTIVE ACTION
When the 'Print Atypical/Attachment' button is selected in some cases not all attachments present print	On investigation by the site WATS administrator it was clear that once the atypical remained open that all attachments printed. However, the individual was printing the atypical with attachment and as soon as the print icon stopped the individual closed the atypical however with the upgrade version 3.03 the atypical cannot be closed until all attachments have printed.	All application users and the divisional team were notified of the application version bug.

3.3 BUG LISTING FOR WATS UPGRADE VERSION 3.03 [26]

From the incidents discussed in section 3.2 it is clear that the upgrade version 3.03 had a number of bugs present. This section lists the bugs which were identified by all sites for the WATS upgrade version 3.03 and are controlled by the divisional team.

- When the Quarantined Comment is removed and a new comment is added the information displayed on the revision report (audit trail) displays the deletion only but not the addition.

- When the 'Print Atypical/Attachment' button is selected the atypical must be kept open until all attachments have printed.

- Atypicals/CIRs remain stuck in a particular phase – Initiation/Investigation/Investigation approval or Quality approval.

- Atypical approval check boxes – check does not remain in approval box after it has been saved.

- Error appears when running open, closed, cancelled atypical report – this error is intermittent and does not appear every time the report is run.

- The processing time report displays investigations twice if it was sent for revision using the modifier user type.

- When creating an atypical the deactivation third level root cause options still appear as available

CHAPTER 4
DISCUSSION AND LESSONS LEARNT

DISCUSSION

As a result of the implementation of the upgraded version of the WATS application to version 3.03 all steps required to be completed by both the divisional team and site WATS administrator were completed successfully. On a whole the installation of the upgraded version was a complete success and the application remained in a validated state.

However, it was extremely clear from this implementation that a number of improvements could be made for future updates or for the installation of new computer systems on site. These improvements were seen throughout the entire project lifecycle. A number of these were also in the rollout plans such as the training and PC rollout plan. Section 4.1 below discusses a number of these in detail;

4.1 LESSONS LEARNT

Table 4 below details each of the lessons learnt/improvements observed by the WATS administrator;

TABLE 4: Lessons Learnt/Improvements

LESSONS LEARNT/ IMPROVEMENT	BENEFIT	COMMUNICATED
Execution of validation and rollout of upgraded version to be completed during a shutdown period or weekend	• Eliminates downtime of application to users • Eliminates resources required for execution of validation documentation • Provides efficiency	To the Ballydine Automation Validation Committee

LESSONS LEARNT/ IMPROVEMENT	BENEFIT	COMMUNICATED
Pool resources between all Merck Sharp and Dohme sites which are been upgraded	• Develop regional validation documentation which could be executed by all sites rather than each individual site developing their own version. • Provide consistency in the approach to the upgrade. • Reduce resource time required by each site. • No differences would be observed by Divisional auditors in the validation documentation which would result in reduced number of observations.	This lesson learnt was communicated to the divisional team so that future rollouts could be improved

LESSONS LEARNT/ IMPROVEMENT	BENEFIT	COMMUNICATED
Automated PC rollout of the upgraded application version	• Efficiency and consistency • Reduced time for current users and WATS administrator • Any problems with the application version would need to be reported to the WATS administrator. This would result in an incident report which could be used to eliminate problems in future rollouts	To the Ballydine A&ITs department
Back up administrator to assist with the issues or questions post release of the upgraded version	• Reduces downtime experienced by application users • Provides efficiency • Speeds up resolution time • Provides awareness training for back up administrator	To the Ballydine Automation Validation Committee

LESSONS LEARNT/ IMPROVEMENT	BENEFIT	COMMUNICATED
E-Learning Training Package with competency based testing	• Eliminate the need for numerous group sessions • Reduce WATS administrator time for execution of rollout • Competency based testing ensures each user is aware of all changes whereas classroom session with no test does not provide this assurance • Improved efficiency • Training can be completed at convenience of the user and not to suit training schedules • Automated report documenting completion provided to WATS administrator in order for accounts to be re-activated	To the Ballydine Training department
Rollout out training (whether e-learning or classroom based) at least two weeks prior to go-live	• Ensures that all shifts have time for completion of training • Provides time for users to query the updated functionality	To the Ballydine Training department

LESSONS LEARNT/ IMPROVEMENT	BENEFIT	COMMUNICATED
Training environment of the upgraded version	• Application users have access to the system prior to go live • Application users can familiarize themselves with the updated functionality and reporting • Application users can test the system and ensure that no issues are observed prior to completion of validation activities	Divisional Team
Completion of the application Annual Performance Monitoring Report prior to go live of upgraded version	• Eliminates confusion between the two versions • Provides efficiency in completion and approval of the report • Annual performance monitoring report now only covers one version	To the Ballydine Automation Validation Committee

CHAPTER 5
CONCLUSION

CONCLUSION

Prior to commencement of the upgrade of the WATS application from version 2.1.3 to version 3.03 the system resided in a validated state. The aim of the upgrade was to ensure that the new functionality and improved reporting was installed correctly but most importantly that they system remained in a validated state.

By following and adhering to the requirements of GAMP, Merck SLC and the Merck Validation Guideline 3.30 this was completed successfully. The WATS version 3.03 was fully integrated into the Merck network and was deemed to be working in a validated manner prior to release to the application users. All Merck SLC GMP deliverables were completed in a timely manner and all exceptions were fully investigated and closed out prior to approval of validation documents and issuance of the final Quality Assurance Summary Report.

As part of the WATS upgrade various plans were required to be executed. These included the SOP update plan, training plan and PC rollout plan. Post execution it could be seen that various improvements could have been made in the planning and execution of these plans. Each of these improvements was noted in chapter 4 'Discussion and Lessons Learnt'.

Chapter 4 also identified various improvements that could be made in other upgrades or other divisional computer validation exercises. This chapter is and will be extremely beneficial for other Merck system administrators. This section was shared with the Ballydine Site Automation Validation group so that all administrators on site would be aware of the potential improvements that could be made in relation to divisional computer validation projects.

Overall the project was a complete success. No unscheduled downtime was experienced by the application users and the system functions as required and as validated.

The benefits of working on a divisional project are that one learns to work cross functionally as you are not only implementing a system for your department but all departments on site. All areas of interest and all department requirements must be considered. As this was a divisional upgrade it also provided the opportunity to work with other sites and to observe their work practices which resulted in sites sharing their best practices.

The WATS application is a fundamental part of the MSD Ballydine system and it ensures that the site remains in compliance with all deviation management regulations and guidelines.

The WATS system is due to be retired in February 2010 due to the implementation of SAP. SAP has a Quality Notification system which will replace the WATS functionality.

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GLOSSARY OF TERMS

Acceptance Test – a formal test conducted to determine whether or not a system satisfies its acceptance criteria and to enable the end users and system owner to determine system acceptability.

Application Software – software written to configure or use general purpose computing solutions and their associated operating system elements for a particular use or application (FDA Compliance Policy Guide 7132a.11).

Atypical – any unplanned, unexpected or out of specification production, packaging or testing event or result that may affect product quality.

Change Control – A formal process by which qualified representatives from appropriate disciplines review proposed or actual changes to a computerized system. The main objective is to document the changes and ensure that the system is maintained in a state of control.

Computer System – A system containing one or more computers and associated software.

Configuration Management – a systems engineering discipline in which a system is logically broken down into the smallest components for which defining, tracking and controlling key parameters or elements is important. Such components for which the defining characteristics and parameters will be identified, tracked and controlled are known as Configuration Items.

Division – as used in this document, terms such as "the Division", "Division-Level" or "Divisional" refer to the Merck Manufacturing Division.

Existing System – any software component(s) and required hardware which is operational or becoming operational within the computing environment at the start of the project.

Hardware – the computer CPU and its peripheral equipment such as printers, work stations, disk/tape drives, I/O equipment, communication equipment, etc.

Installation Qualification (IQ) – a documented verification activity to provide evidence that all key aspects of system installation adhere to hardware and software installation specifications, facility and electrical codes are as required, resource and support provisions have been satisfied, etc.

Operational Qualification (OQ) – a documented verification activity to provide evidence that the installed system software is configured and functional in accordance with developer specifications.

Software – the collection of programs, routines, and subroutines that control the operation of a computer or computerized system.

System – a collection of all hardware and software components providing a specific computing function or set of functions for real time process control or information management.

System Life-Cycle – the entire life span of a system and all the activities and tasks associated with it. The System Life-Cycle is broken down into distinct phases that begin with the Concept Phase and continue through the Requirements, Design, Construction, Installation and Operations phases. Retirement is also considered a formal phase of the life-cycle. Formal methodologies are associated with the system life-cycle that defines quality assurance, developmental and operational procedures.

System Software – software for general purpose computing functions and associated operating utilities for system support.

Unit Testing – testing of the smallest units of a system or module to verify compliance with specifications. A "unit" is defined as the smallest compliable component of a software system.

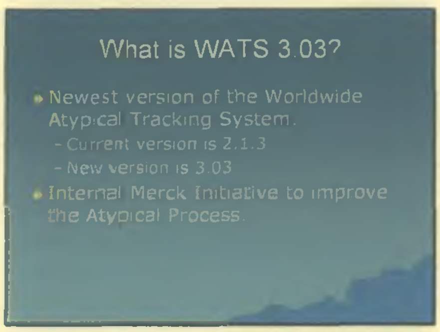
Validation Summary Report – a report written at the conclusion of all other pre-production system life-cycle activities required by the quality assurance plan and prior to placing the system into production use. This report summarizes the activities, including testing, performed pursuant to the quality plan. The report also describes any deviations from the quality plan and the impact of those deviations. Any open issues are summarized as well. Approval of this report constitutes approval to release the system into production use.

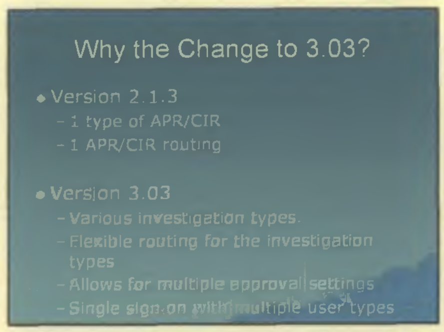
ACRONYMS

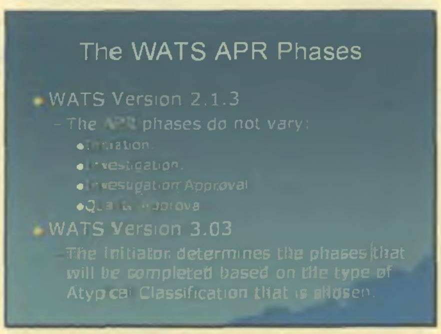
Acronym	Definition
A&IT	Automation and Information Technology
ATP	Acceptance Test Plan
APR	Atypical Process Report
cGMP	Current Good Manufacturing Practice
CIR	Cleaning Investigation Report
CMP	Configuration Management Plan
CSV	Computer System Validation
DBA	Data Base Administrator
DS	Design Specification
EMEA	Europe, Middle East and Africa
FDA	Food and Drug Administration
GAMP	Good Automated Manufacturing Practice
GMP	Good Manufacturing Practices
GMT	Greenwich Mean Time
IS EMEA	Information Services Europe, Middle East and Africa
IQ	Installation Qualification
MMD	Merck Manufacturing Division
MSD	Merck Sharp and Dohme
OQ	Operational Qualification

Acronym	Definition
OOS	Out Of Specification
QAP	Quality Assurance Plan
QO	Quality Operations
QRIS	Quality and Regulatory Information Services Group
RS	Requirements Specification
SLC	System Life-Cycle
SOP	Standard Operating Procedure
TP	Test Plan
VGDL	Validation Guideline
VSR	Validation Summary Report
WATS	Worldwide Atypical Tracking System

APPENDIX 1 – WATS 3.03 PRESENTATION







APPENDIX 1 – WATS 3.03 PRESENTATION

User Types

- For each user, you will have **ONE** user ID and password that will allow you to function at one or more user types.
  - ONE WATS ID - password will allow you to:

The WATS 3.03 User Interface

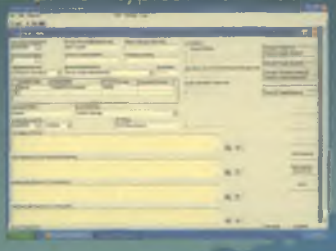
3.03 Changing User Types

The WATS APR Phases

- Initiation.
- Investigation.
- Investigation Approval.
- Quality Approval.

3.03 Creating a New Atypical

2.1.3 Atypical Interface

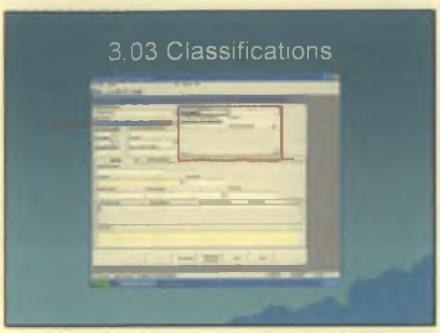


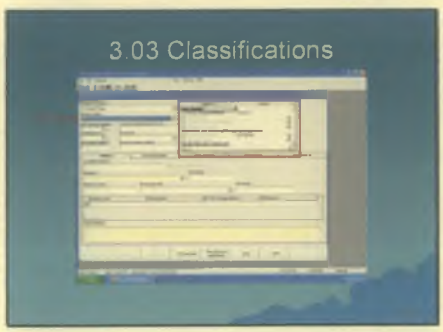
3.03 Atypical Interface

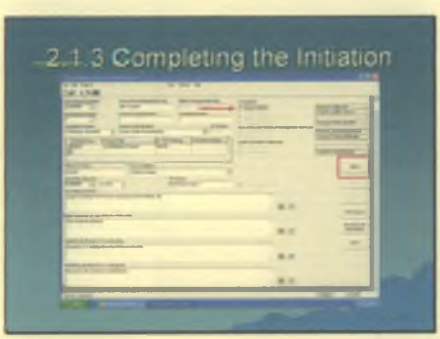
3.03 Event Summary

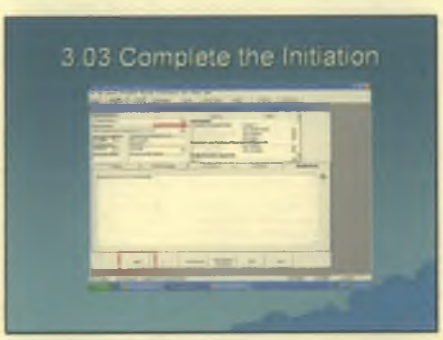
- Importance of the Event Summary
  - Important to include detailed information in the Event Summary.
  - Linked to new report
  - Not dynamically linked to the Event Description Tab information.

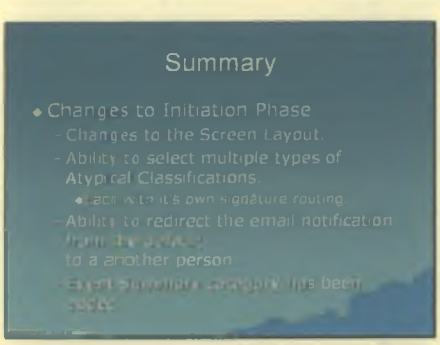
APPENDIX 1 – WATS 3.03 PRESENTATION

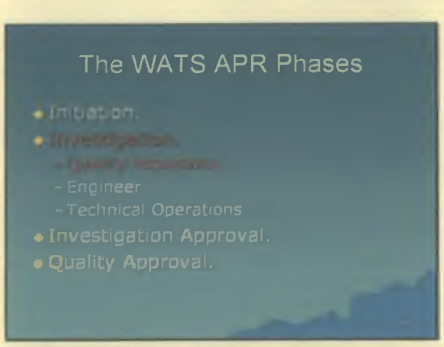


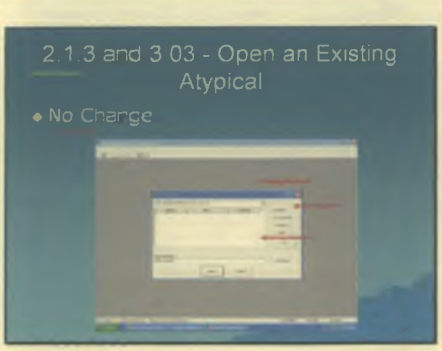


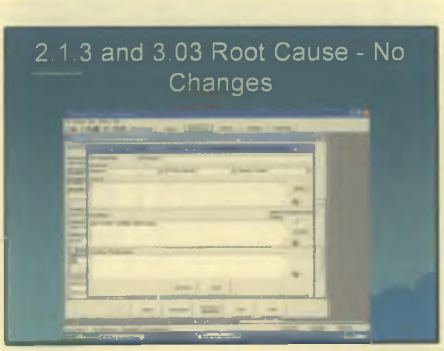












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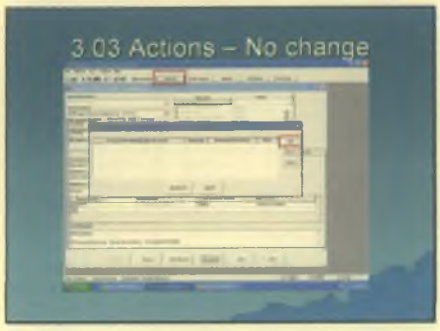
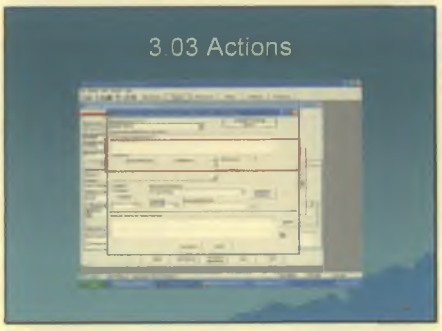
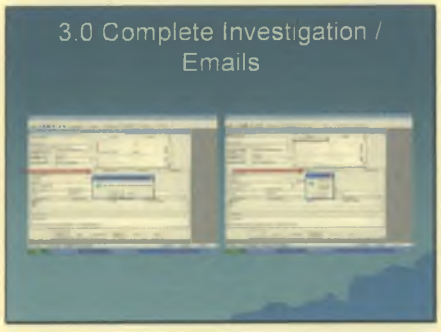
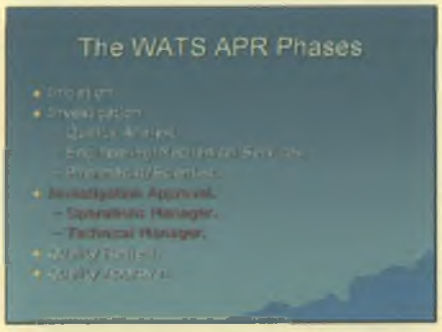
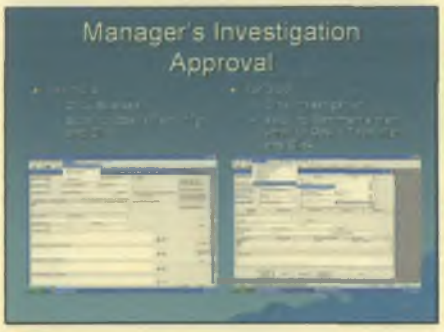
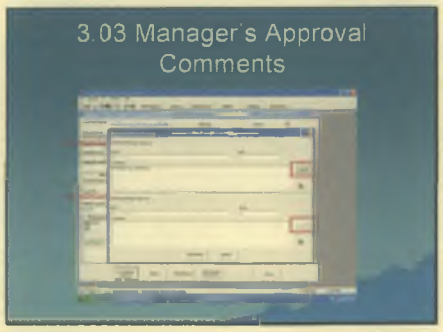


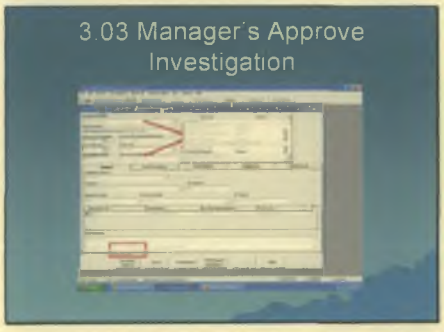




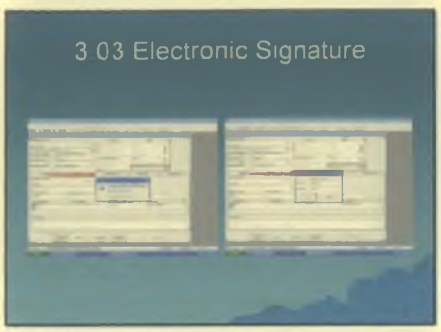


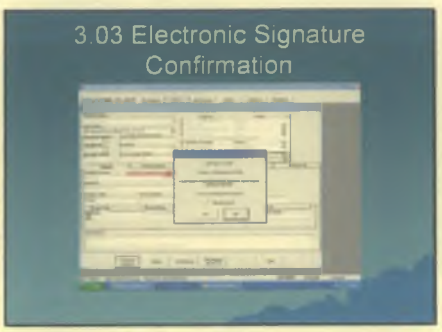


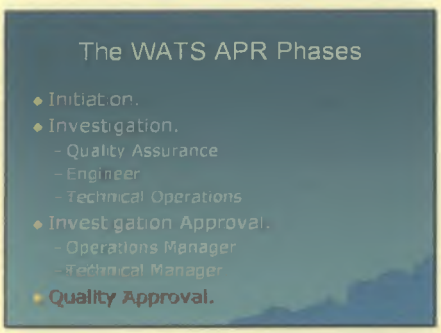


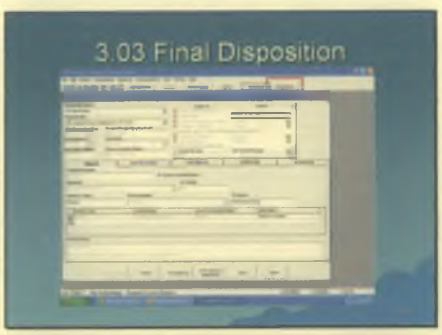


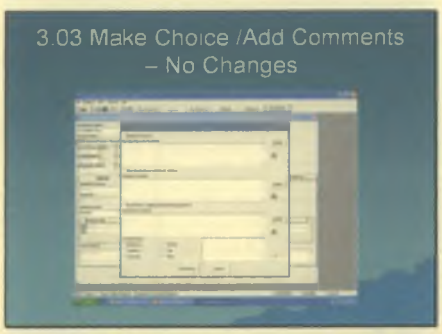
APPENDIX 1 – WATS 3.03 PRESENTATION

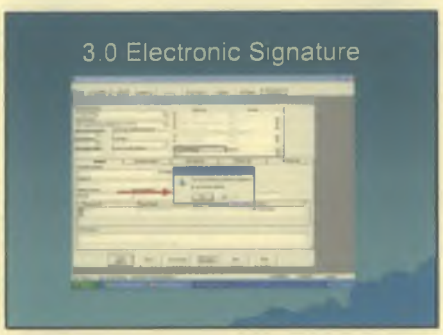


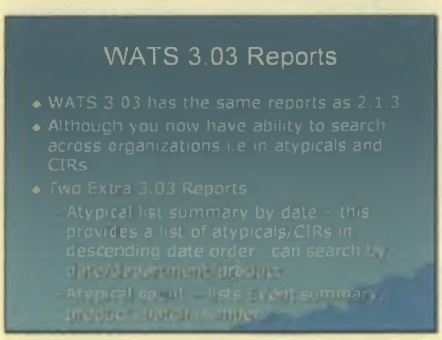


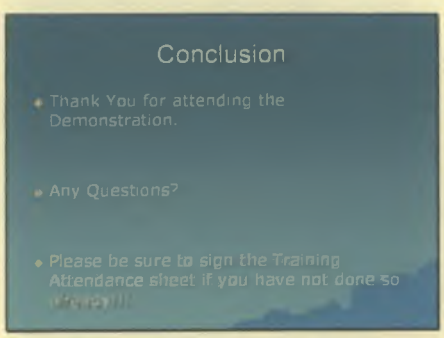












APPENDIX 2 – PC ROLLOUT SPREADSHEET

NAME	PC NUMBER	LOCATION
Jane Doe*	IEBAMM1024	Quality – CO1
John Doe*	IEBAMM1024	ADC – CO2
Mary Doe*	IEBAMM1024	PDC
Frank Doe*	IEBAMM1024	Operations – CO2
Patrick Doe*	IEBAMM1024	Safety
Alison Doe*	IEBAMM1024	Administration
Fergus Doe*	IEBAMM1024	Finance
Linda Doe*	IEBAMM1024	Human Resources
Brid Doe*	IEBAMM1024	Training
Bridget Doe*	IEBAMM1024	Maintenance
Alan Doe*	IEBAMM1024	ADC – CO1
Niall Doe*	IEBAMM1024	Quality – CO2
Kieran Doe*	IEBAMM1024	Operations – CO1
Geraldine Doe*	IEBAMM1024	Operation – CO2
Elaine Doe*	IEBAMM1024	Safety
Liam Doe*	IEBAMM1024	Maintenance

*Names have been changed for the purposes of this project