***Lifecycle Safety AEGIS Project –***

***Argus 7.0.2 Configuration Settings***

|  |  |
| --- | --- |
| **[X] Software [ ] Hardware** | |
| **Product Name:** | Oracle Argus Safety |
| **Product Version Number:** | 7.0.2 |
| **Document Version:** | V5.1 |
| **Document Date:** | 07Aug2014 |

**Configuration Settings Authorization**

**Author: (This signature confirms that the configuration settings described in this document are complete and accurate)**

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Table of Contents

[1. Introduction 4](#_Toc365549051)

[1.1 Purpose 4](#_Toc365549052)

[1.2 Scope 4](#_Toc365549053)

[2. Argus Safety Configuration 4](#_Toc365549054)

[2.1 Workflow and Security 4](#_Toc365549056)

[2.2 Code Lists 7](#_Toc365549057)

[2.3 System Configuration 7](#_Toc365549058)

[2.4 Letter Templates 7](#_Toc365549059)

[2.5 Narrative Templates 7](#_Toc365549060)

[3. References 8](#_Toc365549061)

[4. Appendix 1 9](#_Toc365549062)

[5. Change History 12](#_Toc365549064)

# Introduction

## Purpose

The purpose of the Configuration Specification Document is to centrally group all the information necessary to configure the AEGIS Argus Safety system which is hosted on the Quintiles Infosario Safety Platform (ISP).

The ISP is a set of products and process standards associated with the use of the ISP used to capture, retrieve, report and manage safety data globally and in accordance to EMA, FDA, ICH, and/or local regulations and guidelines. The ISP platform integrates top industry products and processes for safety data management within the Quintiles environment. The ISP includes the following applications and systems.

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  | | --- | --- | | *ISP Products* |  | | *Purpose* |
| *Infosario Portal* | Quintiles hosted landing page allowing external users access to various applications within the Quintiles network. |
| *AEGIS Argus Safety System* | Oracle based platform used to report and manage safety data. |
| *dsNavigator Coding Application* | Medical Coding application integrated with the safety platform for adverse event coding and synonym management. |

## Scope

The scope of this document is limited to the following areas of Argus Safety configuration:

* Workflow and Security
* Code Lists
* Letter and Narrative Templates
* Periodic Reports

Note: PLS is not in scope for this version as it is being handled separately. The LAM module is also not in scope.

# Argus Safety Configuration



## Workflow and Security

The workflow and Security settings are derived from the Quintiles Gold Standard, updated and configured as required to meet the needs for Project AEGIS.

The strategy of how Workflow and Security Settings are configured in Argus is as per Quintiles Gold Standard.

Given below is the workflow diagram that outlines how a case will be processed within Argus.





Sites

User sites allow defining organizational or geographical entities.

When viewing worklists and similar case listings within the application, the standard user will only see cases assigned to their own user site. For example, a user assigned to a specific site will only see cases or incoming faxes assigned to that site. However, a user can also be assigned to the Enterprise Manager role on the user configuration page. This setting overrides the site assignment and allows that user to see cases from every site, not just the one the user is assigned.

*User Groups*

The user groups define the access rights for a user on the Argus Safety applications.

The user group permissions determine which cases, reports, action items or contacts will appear on the user’s worklist.

Users may belong to more than one group. A user possessing more than one privilege always maintains higher-level access whenever conflict exists between the two privileges except for restrictions on products or studies.

The table below describes user groups and its workflow state association.

User Groups and Associated Workflow State

| # | Group Name | Associated Workflow State |
| --- | --- | --- |
|  | Intake Coordinator (Central, Local) | New Case, Awaiting Follow-up, Source Document Intake |
|  | Intake Coordinator Private (Central, Local) | New Case, Awaiting Follow-up, Source Document Intake |
|  | Case Processor | Triage, Data Entry, Complete Case Processing, Final Case Review, Awaiting Follow-up, AOSE Generation |
|  | Case Processor Private | Triage, Data Entry, Complete Case Processing, Final Case Review, Awaiting Follow-up, AOSE Generation |
|  | Medical Advisor | Medical Review, AOSE Search, AOSE Review |
|  | Medical Advisor Private | Medical Review, AOSE Search, AOSE Review |
|  | Periodic Report Coordinator | N/A |
|  | Periodic Reporting Specialist | N/A |
|  | Regulatory Reporting Specialist | Awaiting Follow-up |
|  | Read Only | N/A |
|  | Coding Review Specialist (same as read only) | N/A |
|  | System Administrator | Case Deletion Pending |
|  | Super User Group | N/A |

All User Groups identified as Private will not be able to view the following sections on the case form to protect Data Privacy:

* Reporter Information
* Patient Information
* Contact Log Information

The configuration for Workflow and Security is captured and referenced under Appendix 1 in this document.

## Code Lists

The Code List(s) settings are derived from the Quintiles Gold Standard, updated and configured as required to meet the needs for Project AEGIS.

The strategy of how Code List(s) are configured in Argus is as per Quintiles Gold Standard.

The configuration for Code Lists is referenced under Appendix 1 in this document.

## System Configuration

The System Configuration settings are derived from the Quintiles Gold Standard, updated and configured as required to meet the needs for Project AEGIS.

The strategy of how the System is configured is as per Quintiles Gold Standard.

The configuration for System Configuration is referenced under Appendix 1 in this document

## Letter Templates

The Letter Templates are derived from the Quintiles Gold Standard, updated and configured as required to meet the needs for Project AEGIS.

The strategy of how Letter Templates are configured in Argus is as per Quintiles Gold Standard.

The configuration for Letter Templates is referenced under Appendix 1 in this document.

## Narrative Templates

The Narrative Templates are derived from the Quintiles Gold Standard, updated and configured as required to meet the needs for Project AEGIS.

The strategy of how Narrative Templates are configured in Argus is as per Quintiles Gold Standard.

The configuration for Narrative Templates is referenced under Appendix 1 in this document.

# References

| Document Type | Document Title/Description |
| --- | --- |
| Quintiles Gold Standard | **CSD\_Finalv26.doc** – This document describes how artifacts are configured in Argus. In addition this document also captures the Quintiles Gold Standard Configuration. |
| Validation Report | AEGIS Validation Report |

# Appendix 1



| **Sr. No.** | **Configuration Item** | **File** |
| --- | --- | --- |
|  | Workflow and Security  **See “Change History” V5.1** |  |
|  | Code Lists  **See “Change History” V5.1** |  |
|  | System Configuration  **See “Change History” V5.1** |  |
|  | Aggregate Reports  **NOTE: No change from Iteration 5** | <https://ata.quintiles.com/sites/IPS/2012001/Quintiles%20Confidential/Business/Periodic%20Reporting/05-Design/Argus%20CSD/Aegis%20Argus%20Safety%20Aggerate%20Report%20CSD%20-%20Iteration%205.1.xlsx> |
|  | Periodic Reports  **NOTE: No change from Iteration 5** | <https://ata.quintiles.com/sites/IPS/2012001/Quintiles%20Confidential/Business/Periodic%20Reporting/05-Design/Argus%20CSD/Aegis%20Argus%20Safety%20Periodic%20Report%20CSD%20-%20Iteration%205.1.xlsx> |
|  | Pre-Save / F\_CUSTOM\_ROUTINE\_BEFORE\_COMMIT  **See “Change History” V5.1** |  |
|  | Post-Save / F\_CUSTOM\_ROUTINE\_AFTER\_COMMIT  **See “Change History” V5.1** |  |
|  | Letter Templates  **NOTE: No change from Iteration 5** |  |
|  | Auto Narrative Configuration – Templates  **NOTE: No change from Iteration 5** |  |
|  | Auto-Narrative Configuration – Configuration  **NOTE: No change from Iteration 5** |  |
|  | Global Configuration  **NOTE: No change from Iteration 5** |  |
|  | EMA Auto-Serious Event List  **NOTE: No change from Iteration 5** |  |
|  | Consolidated Device Configuration  **NOTE: No change from Iteration 5** |  |
|  | Product Mapping for TA Alignment  **NOTE: No change from Iteration 5** |  |
|  | Product Security (Argus Group Product Restrictions)  **NOTE: No change from Iteration 5** |  |
|  | Study Configuration Registries  **NOTE: No change from Iteration 5** |  |
|  | Product-License-Studies-Reporting Rules (PLSR)  Note: Informational templates for future use.  **NOTE: No change from Iteration 5** |  |
|  | Event Group (Watchlist)  **NOTE: No change from Iteration 5** |  |
|  | Advanced Conditions – Library  **See “Change History” V5.1** |  |

# Change History

|  |  |  |  |
| --- | --- | --- | --- |
| **Version Number** | **Date of Revision** | **Comments** | **Author** |
| V1.0 | 03 Apr 2013 | Initial Version | Jayasri Vaidyanath |
| V1.0 | 03 May2013 | Updated Workflow information | Jayasri Vaidyanath |
| V1.0 | 08 May2013 | Added CSD Attachments to Appendix | Jayasri Vaidyanath |
| V2.0 | 13 May2013 | Started setup for Iteration 2 | Debra Johnson |
| V3.0 | 10June2013 | Started setup for Iteration 3 | Debra Johnson |
| V4.0 | 12July2013 | Started setup for Iteration 4 | Debra Johnson |
| V5.0 | 12Aug2013 | Started setup for Iteration 5 | Debra Johnson |
| V5.0 | 08Jan2014 | Updated Code Lists, System Configuration, WF/Security and Narrative Configuration with post-Iteration 5 updates. | Debra Johnson |
| V5.0 | 04Mar2014 | Updated Code Lists, System Configuration, and WF/Security to support Partner Case Processing, Watchlist and Groups/Product restrictions. Appendix also updated. | Debra Johnson |
| V5.0 | 14Mar2014 | Updates to address SVT issues - most related to PLSR data mapping. | Debra Johnson |
| V5.0 | 04Apr2014 | Updates to address CVT and SVT issues – Countries, Event Groups, Common Profile, Field Validations, PQC Notification letter template | Debra Johnson |
| V5.0 | 25Apr2014 | Code Lists   1. Reporting Destinations – removed Janssen Japan and Japan MHLW (per Umar R. and Amanda H.) 2. Dosage Units – removed duplicate (µkat)   Confirm config since last CSD distribution:  Country – pending confirmation  Event Groups – pending confirmation – also, added a Note re: one of the MedDRA terms was not found in the dictionary – Umar will investigate  System Configuration spreadsheet   1. Common Profile - updated MedDRA and WHO Drug Coding Methods to “Web Services” 2. Field Validations – Removed Warning and Mandatory FVs for Drug Reaction coding (SVT / QC# 657)   Workflow/Security spreadsheet   1. User Sites – moved Product Security mapping-related columns to far-right 2. User Sites – changed Confidentiality settings for Pharma Albania to match the Privacy setting 3. Users – updated Sites for Model User Names (Case Processor 1 and Medical Advisor) to match Console (chg’ed Site to “Central Case Processing”) 4. Users – updated Model Intake Coordinator User Name (removed “-Aegis”) to match Console   Confirm config since last CSD distribution:  Updated User Sites to include mapping for Prod Security Groups - pending confirmation | Debra Johnson |
| V5.0 | 27May2014 | WF/Security   1. Protect Reporter and Patient Confidentiality Default set to “Yes” per CVT issue #29   Code Lists   1. Updated Notes on Countries tab for clarification 2. Renamed letter templates (Custom Consumer and HCP; HCP) per CVT issue #178   System Config   1. Added UDF\_DATE\_12 per CNF 2. Renamed Primary Reporter FV to: FV Primary Reporter Cannot = Contact per J&J   Letter Templates   1. Renamed Custom Consumer, Custom HCP and HCP letter templates per CVT issue #178 | Debra Johnson |
| V5.0 | 30May2014 | Added “DRAFT” watermark | Debra Johnson |
| V5.0 | 05Jun2014 | Attached updated pre-commit file - added function call:  v\_fv := PKG\_CUSTOM\_IMPORT.F\_MASTER\_ROUTINE(fi\_case\_id); | Debra Johnson |
| V5.0 | 08Jul2014 | Added “Approval Draft” watermark – distributing for Approvals | Debra Johnson |
| **V5.1** | **07Aug2014** | **Completed the following updates for Iteration 6:**  **Code Lists:**  **1. Actions Type – replaced all AIs to address multiple CVT issues**  **2. Reporting Destinations – replaced per Q SME**  **System Config:**   1. **Field Validations – replaced all FVs to address multiple CVT issues** 2. **Case Priority - Update Advanced condition logic to correct Case Priority 1 - 6 errors - addresses CVT #133**   **Workflow/Security:**   1. **Multiple Tabs – updated Case Processor user/group naming convention (removed “1” from name)**   **Aegis Advanced Conditions – Library spreadsheet:**   1. **Removed “WF: Rule never met” AC (100405)- addresses CVT #129**   **Pre-Save and Post-Save files:**  **1. Per new process, these are now pulled from the CollabNet Repository.** | **Debra Johnson** |