REVIEWERS

Full name User ID

Compliance Team DOC. TEAM GLOBAL IT SOP_IT1

MES Source Code Review Procedure

INFORMATION SHEET

Full name Syst ID

Written by xxxx

Main Org Unit Vaccines MES

APPROVERS

Full name User ID Date Time GMT

Content Owner x

IT Business Partnering Manager

Compliance Security Domain Manager

Operational QA Mger

GlaxoSmithKline Vaccines Page : 0/06

VERSION CHANGE REASON

FOR CHANGE

01 Creation Document Creation

02 Replacement of Links to the

relevant document repositories

Adaptation to new document

repository

§5.4 Repository change from

BioDocumentum to SharePoint

03 Update to Include following:

- References

Section 5.5 for Code Review

Report

Process Refinement

LOCAL PROCEDURE

VACCINES

ESOP NUMBER 9000082047

PAGE :

1/06

LSOP TITLE

MES OpCenter Script(s) Code Review Process

LOCAL PROCEDURE

05 pages (+ 1 page 0)

TABLE OF CONTENTS

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1 PURPOSE

The objective of this document is to describe the Code Review process for MES Opcenter

developments - scriptsor system functionality (configuration, new modules, code enhancements or

corrections) at GSK Vaccines.

2 GLOSSARY

Opcenter: Siemens Opcenter Execution Pharma - solution for complete paperless manufacturing

and full electronic batch recording enabling seamless integration between the

Manufacturing

Execution System (MES), automation and enterprise resource planning (ERP) systems.

OT: Operational technology

DEV: central MES development environment.

TEST: central MES testing environment.

MES: Manufacutring Execution System

3 SCOPE

This scope of the Code Review is all MES Basic configuration and development performed on the

MES Platform used at GSK Vaccines

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4 RESPONSIBILITIES

Developer: OpCenter consultant or GSK TECH Team

training responsible for configuration or is employed in role responsible for code

writing/modification/maintain etc according to GSK guidelines [1&2]. The developer

acknowledges that s/he is aware of, understands and performs configuration according to these

guidelines.

Code Reviewer: Opcenter consultant or GSK employee having passed Siemens Opcenter

Execution Pharma Developer training responsible for reviewing the configuration performed by

the developer. The code reviewer must not be the person who wrote the code under review.

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5 PROCEDURE

5.1 When are Code Reviews performed?

Code Review process is applied before transportation in the TEST environment followed by

informal testing. It is performed after development on the DEV environment and after unit testing.

No code will be transported without passing review.

5.1.1 How are Code Reviews initiated?

Code Review is initiated by Developer within sprint. Since all code is distributed by packages it is

the responsibility of the Developer to communicate the name of the configuration package

containing the code to be reviewed to the Code Reviewer. Additionally, release note will be

provided by the developer which will include the name and versions of the object to be reviewed

If a configuration package contains objects where changes have been made to existing code, then

for each such object it is the responsibility of the Developer to appropriately inform

Code

Reviewer.

5.2 The Code Review process

The Code Review process involves reviewing code and configuration against a checklist of items

in order to ensure that good programming practice is being followed.

The Code Reviewer checks the development compliance Programming guidelines [

1] using the

Code Review checklist [2].

The Code Review checklist [2] is divided in several logical sections and each section in several

items.

Developer will do precheck of its own code and fill up Code Review Checklist [2] that later will

be provided to Code Reviewer.

The Code Reviewer checks the compliance of each item and attributes a result

either passes

[PASS], fails [FAIL] or is not applicable [N/A].

At the end of the Code Review Checklist [2], if there are some items tagged as [FAIL], the Code

Reviewer will write a detailed explanation for each failed item.

A Code Review either passes or fails in its entirety: if anything causes a Code Review to fail then

the whole configuration is resubmitted for review.

5.2.1 Code Review PASS

If there were no quality issues in the reviewed code, the Code Review is considered as passed

and the configuration may be moved from DEV

to TEST.

5.2.2 Code Review FAIL

If there were quality issues in the reviewed code, the Code Review is considered as failed

and the developer must change the

development and then resubmit the changes for another

review.

5.3 Monitoring

Technical Product Owner monitors that the Code Review actions are performed by verifying the

status of the corresponding task.

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5.4 Code Review documentation

After Code Review process competition Code Review Checklist [2] as a part of the development

documentation, should be stored in Share point for long term retention.

5.5 Code Review Report

Every time when there is a new version of MES Validation Report [5], then a Code Review

Report will also be published as a prerequisite, based on the template ITMS Code Review Report

Template [4]

6 REFERENCES

REFERENCE DOCUMENT

TYPE

DOCUMENT

TITLE

1 Vx_MES_OpCenter_Programming_Guidelines

VQD-GUI-012473

WIKI Programming

Guidelines for MES

Opcenter Scripts and

Database Objects

2 Opcenter_Code Review_Checklist

VQD-RPT-194421

WIKI Opcenter_Code

Review_Checklist

3 Develop Source Code (SOP-IT-0290)

VQD-SOP-006151

SOP Develop Source

Code (SOP-IT-0290)

4 Source Code Review Report Template, (ITMSTEM-

010)

VQD-TEMPL-000723

TEMPLATE

Source Code Review

Report Template,

(ITMS-TEM-010)

5 Vx_MES_Validation Report

VQD-RPT-194884

REPORT Vx_MES_Validation

Report

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