Identification of Supporting System Documentation

Signatures below indicate agreement and/or approval of this Supporting System documentation which are stored in Windchill. The author and approver names and functions are identified in the change documentation (e.g., change number) or project plan.

|  |  |  |
| --- | --- | --- |
| Document Prepared By: | | |
| Name and Function | Signature | Date DD-MON-YYYY |
| Author  Vidhyalakshmi Kalyanasundaram | REFER TO WINDCHILL | REFER TO WINDCHILL |

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| Adam Peterson  Support Owner | REFER TO WINDCHILL | REFER TO WINDCHILL |

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| --- | --- | --- | --- |
| **Document Version Number** | **Document Revision Date DD-MON-YYYY** | **Change Request ID** | **Change Summary (Reference section[s] changed)** |
| A(Windchill) | 16-JUL-2020 | 90656259 | Initial Version |



1.1 Table of Contents

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2.0 System Development Methodology

The system development methodology for the EDC Rave system follows BTS SLC Process.

| **Document #** | **Document Title** | **Location** |
| --- | --- | --- |
| AQ09.A | Validation (Policy) | M-Files |
| AQ0905.A | Computerized System Life Cycle (Process) | M-Files |
| AQ090504.A | Computerized System Life Cycle Procedure | M-Files |
| AQ090506.A | Computerized System Defect Management Procedure | M-Files |
| BTSQC09.05 | BTS IT Computerized System Life Cycle (Process) | M-Files |
| BTSQC09.05.002 | BTS IT Operational Testing Procedure | M-Files |
| BTSQC09.05.004 | How to Create a System Risk Classification Document in the Validation Management (VM) system (Procedure) | M-Files |
| BTSQC09.05.005 | How to Create a Change Request Document in the Validation Management (VM) system (Procedure) | M-Files |
| BTSQC09.05.006 | How to Create a Managed Document in the Validation Management (VM) system (Procedure) | M-Files |
| BTSQC09.05.008 | BTS SLC Maintenance Procedure | M-Files |

3.0 Software Development Standards and Practices

EDC Rave is a SaaS system. The vendor is responsible for Software Development Standards and Practices.

4.0 Change Control and Configuration Management

| **Document #** | **Document Title** | **Location** |
| --- | --- | --- |
| BTSQC9.05 | BTS IT Computerized System Life Cycle (Process) | M-Files |
| BTSQC09.05.004 | How to Create a System Risk Classification Document in the Validation Management (VM) system (Procedure) | M-Files |
| BTSQC09.05.005 | How to Create a Change Request Document in the Validation Management (VM) system (Procedure) | M-Files |
| BTSQC09.05.006 | How to Create a Managed Document in the Validation Management (VM) system (Procedure) | M-Files |
| BTSQC09.05.008 | BTS SLC Maintenance Procedure | M-Files |
| BTSQC09.05.GL004 | Data Integrity Guidelines | M-Files |
| BTSQC05.10.003 | BTS Change and Release Management Procedure for Applications | M-Files |
| BTSQC05-MA-002 | Use of ITSM in Change and Release Management for Applications | M-Files |
| |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | |  |  |  |  | | --- | --- | --- | --- | | 90534640 | 90534640 |  | 90534640 | | 90534640 | | Design Specification | Windchill |

**5.0 Operation Instructions**

EDC Rave is a SaaS system. The vendor is responsible for recovery planning processes/procedure.

6.0 Supplier/Vendor Evaluation

| **Document #** | **Document Title** | **Location** |
| --- | --- | --- |
| BTSQC11.01 | Information Technology Vendor Risk Management Process | M-Files |
| BTSQC11.01.001 | Information Technology Vendor Risk Management Procedure | M-Files |
| BUS2083786 | EDC System Account Administration and Management Process | Viewpoint |

**7.0 User Documentation**

| **Document #** | **Document Title** | **Location** |
| --- | --- | --- |
| 753 | 753 Rave Application Handbook | M-Files |

8.0 Procedure for Installation/Qualification/Maintenance of Hardware/Software

EDC Rave is a SaaS system. The vendor is responsible for Installation/Qualification/Maintenance of Hardware/Software.

| **Document #** | **Document Title** | **Location** |
| --- | --- | --- |
| BTSQC09.05 | BTS IT Computerized System Life Cycle (Process) | M-Files |
| BTSQC09.05.008 | BTS SLC Maintenance Procedure | M-Files | |
| BTSQC09.05-B | Change Request Template | M-Files | |

9.0 Incident Management

| **Document #** | **Document Title** | **Location** |
| --- | --- | --- |
| AQ03.A | Corrective Action and Preventive Action (Policy) | M-Files |
| AQ0301.A | Corrective Action and Preventive Action Process (Process) | M-Files |
| AQ090506.A | Computerized System Defect Management Procedure | M-Files |
| BTSQC03.01 | IT Exception Management Process | M-Files |
| BTSQC03.01.003 | IT CAPA/Nonconformity Procedure | M-Files |
| IT02.01.111 | MKS DIET Electronic Application Access Authorization (Procedure) | M-Files |
| QC10.13.115 | Defect, Incident, and Enhancement Tracking (DIET) System Profile Request (Procedure) | M-Files |
| QC10.21 | GIS Incident Management Process | M-Files |
| QC10.21.001 | GIS Incident Management Procedure | M-Files |
| QC10.22.004 | Incident Handling in Abbott Quality Center (Procedure) | M-Files |
| QC15.02 | Defect and Enhancement Tracking Process | M-Files |
| QC15.02.001 | Application Defect and Enhancement Tracking with DIET (Procedure) | M-Files |
| BTSQC09.05.002 | BTS IT Operational Testing Procedure | M-Files |
| BTSQC09.05-V | Incident Report Template | M-Files |
| BTSQC09.05-W | Project Release Notes Template | M-Files |

10.0 Security

EDC Rave is a SaaS implementation and adheres to Abbott Security standards and is managed by vendor’s security proceudres and practices.

| **Document #** | **Document Title** | **Location** |
| --- | --- | --- |
| 4-020 | Information Access Controls (Policy) | M-Files |
| 4-020-001 | Information Security and Access Password Controls Procedure | M-Files |
| 4-020-002 | Abbott Enterprise Logon UserID Naming Convention (Procedure) | M-Files |
| 4-060 | Network Security (Policy) | M-Files |

11.0 Training

| **Document #** | **Document Title** | **Location** |
| --- | --- | --- |
| BTSQC02.01 | BTS IT Training Process | M-Files |
| BUS2083786 | EDC System Account Administration and Management Process | Viewpoint |

12.0 Data Lifecycle Management (DLM)

| **Document #** | **Document Title (DLM Process)** | **Location** |
| --- | --- | --- |
| I1-02 | The Abbott Records Retention Schedule | M-Files |
| QC05.01 | Global Information Services Record Retention Process | M-Files |
| I1-04 | Data Lifecycle Management (DLM) Policy | M-Files |

**BTS Document Repositories**

*Retention of project documentation will be managed by the system in which it is stored.*

| **Document #** | **Document Title** | **Location** |
| --- | --- | --- |
| **WindChill** | | |
| 87115 | Create and Maintain Documents | LMS |
| 87117 | Guide to Create and Maintain Document and Part Structure | LMS |
| 87123 | Create and Manage Change Order | LMS |

13.0 DLM Assessment Unique ID Number

DLM-1180

14.0 Electronic Records and Signatures

Electronic signatures captured in the EDC Rave system or within any data assets are secured and managed, in compliance with BTSQC09.05, BTS IT Computerized System Life Cycle.

| **Document #** | **Document Title** | **Location** |
| --- | --- | --- |
| AQ090504.A | Computerized System Life Cycle Procedure | M-Files |

15.0 Business Impact Analysis (BIA)

| **Document #** | **Document Title** | **Location** |
| --- | --- | --- |
| 4-070 | IT Recovery Plan (Policy) | M-Files |
| RPT2084929 | EDC CDMS Rave BIA | Viewpoint |

END OF DOCUMENT