SAP Digital Manufacturing in Regulated Environments
Quality and Compliance

Contents

Life Science customers must independently assess the use of the [SAP Digital Manufacturing](#) product. SAP is a technology provider of back-end business processes designed for general availability. SAP provides this document for informational purposes only. Any information outlined in this document may change at any time at SAP's discretion.

1. Abstract

This document outlines SAP's efforts to support life science customers [Life Science Customer(s)] subscribing to SAP Digital Manufacturing (White Paper). Life Science Customers must comply with sector-specific regulatory requirements, including laws and recommended practices per industry, or GxP. Industry-related GxP includes GLP for Laboratories, GMP for Manufacturing, and GCP for Clinics.

Life Science Customers must adequately assess the security and quality management services of SAP Digital Manufacturing. This White Paper provides information that Life Science Customers operating in GxP-regulated security environments may use in their side of audits/inspections.

Cloud computing, also known as Software as a Service (or SaaS, and further described below in Section 5, in addition to standard GxP complexities, brings an additional element of consideration as it becomes an increasingly crucial technical solution across industry sectors. Customers seek highly scalable, reliable, and secure solutions, and Life Science Customers are no exception. Due to its efficiencies and value, cloud computing is steadily receiving a higher priority.) SAP Digital Manufacturing, a SaaS solution, is likewise a robust cloud computing solution.

This White Paper outlines practices Life Science Customers use, including internal quality and development practices critical for GxP compliance.

The following outlines each party's focus on GxP requirements:

SAP's Focus	Regulated Company Focus
Overview of SAP Digital Manufacturing	Cloud Strategy
SAP Digital Manufacturing Quality Management Systems (QMS)	SAP Digital Manufacturing Validation
Digital Manufacturing Software Development and Operations Lifecycle (SDOL)	Potential impact on existing QMS
SAP Digital Manufacturing Team Training	Qualification SAP Digital Manufacturing

2. About SAP Digital Manufacturing

SAP Digital Manufacturing provides a manufacturing execution system (MES) of near real-time data and analytics on critical processes to promote a fully integrated manufacturing environment. Life Science Customers can use SAP Digital Manufacturing to optimize resources, enforce quality goods, and enhance operations. Due to the sensitivity of this data, security and quality management of such processes are essential to ensure the health and safety of Life Science Customers' products. Accordingly, such data's confidentiality, integrity, and availability are essential.

3. SAP Digital Manufacturing in a Regulated Environment

Life Science Customers are subject to strict regulatory surveillance. Life Science Customers must prepare themselves to demonstrate their compliance efforts with regulators

Although Life Science Customers are solely responsible for assuring compliance with GxP laws and practices, SAP ensures that GxP- guidelines are followed to demonstrate minimal viable compliance

SAP summarizes specific GxP-relevant information for SAP Digital Manufacturing, as follows:

- The technical and procedural measures and controls,
- Its institutional knowledge to develop and operate SAP Digital Manufacturing in a controlled state,
- How SAP ensures the confidentiality, integrity, and availability of customers' data.

Such information enables Life Science Customers to assess their compliance with GxP.

To make this information more accessible, this White Paper consolidates and further highlights GxP-relevant aspects, like SAP Digital Manufacturing's Quality Management System (QMS), Software Development Operational Lifecycle (SDOL), and IT Operations and Services.

4. Certifications and Attestations

, SAP supports specific certifications and attestations to achieve specific assurances. SAP Digital Manufacturing and its services are audited regularly by independent third parties for SOC 1, SOC 2, ISO/IEC 27001, or other equivalent standards. Additionally, SAP certifies the software development, and support of SAP Digital Manufacturing software per ISO 9001. Life Science Customers can find the latest attestations and certifications on the Trust Center, Compliance section.

5. Country-Specific Laws and Regulations

EU, UK and GDPR

Since May 25, 2018, Regulation 2016/679 of the European Union (EU), also called the General Data Protection Regulation (GDPR), has been in effect. GDPR is an EU law with mandatory rules for how organizations and companies process personal data. The UK GDPR derives from the EU GDPR, which has been updated post-Brexit with the Data Protection Act 2018 and the Privacy and Electronic Communications (EC Directive) Regulations 2003 (SI 2003/2426). As a processor, SAP ensures that SAP Digital Manufacturing has appropriate technical and organizational controls that process personal data in the cloud.

United States and Federal Laws

Various requirements apply to manufacturing food, drugs, and cosmetics under the US Federal Drug Administration regulations, the United States Code of Federal Regulations, the Federal Food, Drug, and Cosmetic Act, and 21 C.F.R., as applicable to Life Science Customers. These regulations concern the testing, labeling, packaging, holding, and quality control of activities of the Life Science Customer, including its use of products in manufacturing food, drugs, and

cosmetics, like SAP Digital Manufacturing. SAP follows specific quality management activities to promote quality products and services where applicable.

Rest of the World

In addition to national regulations concerning quality control and good manufacturing practices, global Life Science Customers may require a comparative analysis of high common requirements among international regulatory frameworks, including guidelines and recommendations from influential groups, like international organizations, regulatory collaboration groups, standards organizations, and industry organizations. SAP as a global enterprise assists Life Science Customers with information in its possession or a mapping requirement in support of specific requirements.

Industry-Wide Recommended Global Practices

ISPE GAMP 5 Software Category 5 – Custom Applications, A Risk-Based Approach to Compliance GxP Computerized Systems is guidance by pharmaceutical manufacturing industry professionals on regulatory standards for developing custom GxP applications. Life Science Customers may use this guidance to interface with or feed data into SAP Digital Manufacturing. The ISPE GAMP, a leading professional membership organization, recommends analyzing and categorizing such custom applications as software components of GxP computerized systems. Life Science Customers must test these custom components for their intended use. To support such efforts, SAP provides information on its then-existing GxP-relevant software development controls per its SDOL.

6. SAP Digital Manufacturing as a Software-as-a-Service (SaaS)

SAP Digital Manufacturing is a software – as – a service offering. A cloud service provider, in this case, SAP, hosts these applications and makes them available to users over the internet .)

When comparing SaaS to the more traditional deployment of on-premise software solutions, service providers manage the software and underlying infrastructure of the solution. This role includes responsibility for specific security controls and compliance. Accordingly, SAP commits to providing information on its technical and operational measures within its control environment to assist the customer in assessing its compliance with GxP.
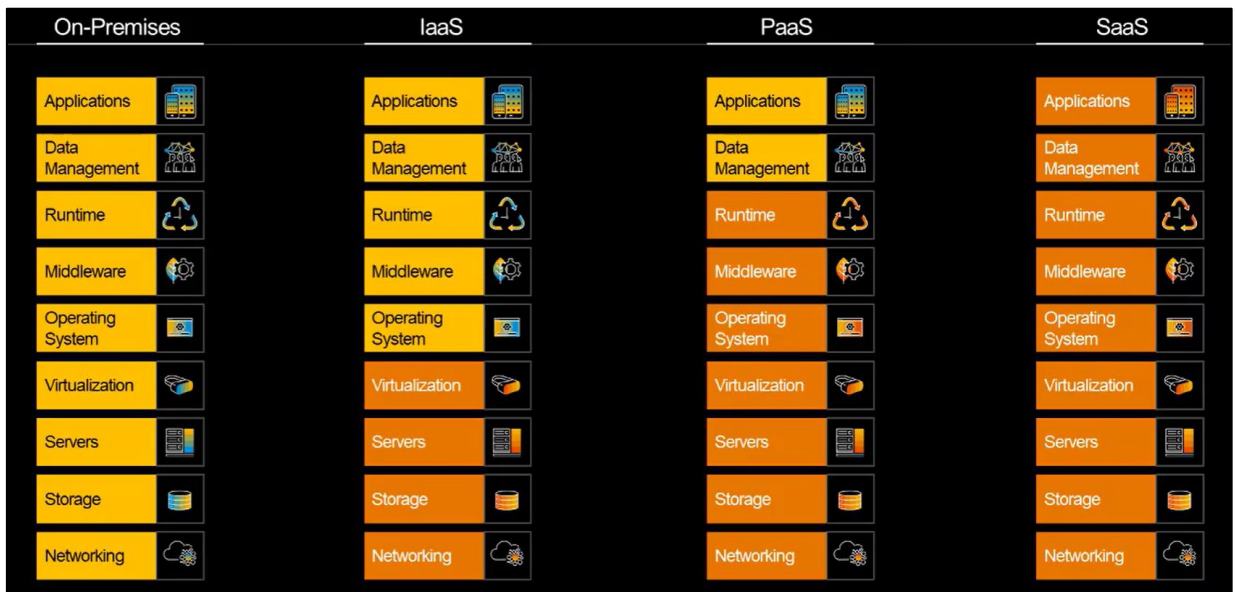
Figure 1: Responsibilities in Cloud Environments

As part of Life Science Customers' architecture governance, receiving assurances on security measures and quality management systems is an essential first step towards GxP compliance. Customers do this by checking the availability of specific certifications, such as ISO, attestations, and SOC, and reviewing various compliance requirements like audit trails, electronic records, electronic signatures, data integrity, data encryption/privacy, backups, and other controls. From a regulatory perspective, it's part of the Life Science Customers qualification process to ensure SAP Digital Manufacturing satisfies its requirements.

Architectural Overview

SAP Digital Manufacturing Technology Stack

SAP Digital Manufacturing runs on SAP's Business Technology Platform (BTP), a Platform as a Service (PAAS), computing environment hosted on hyperscaler infrastructures (IaaS). See the illustration below for more information.
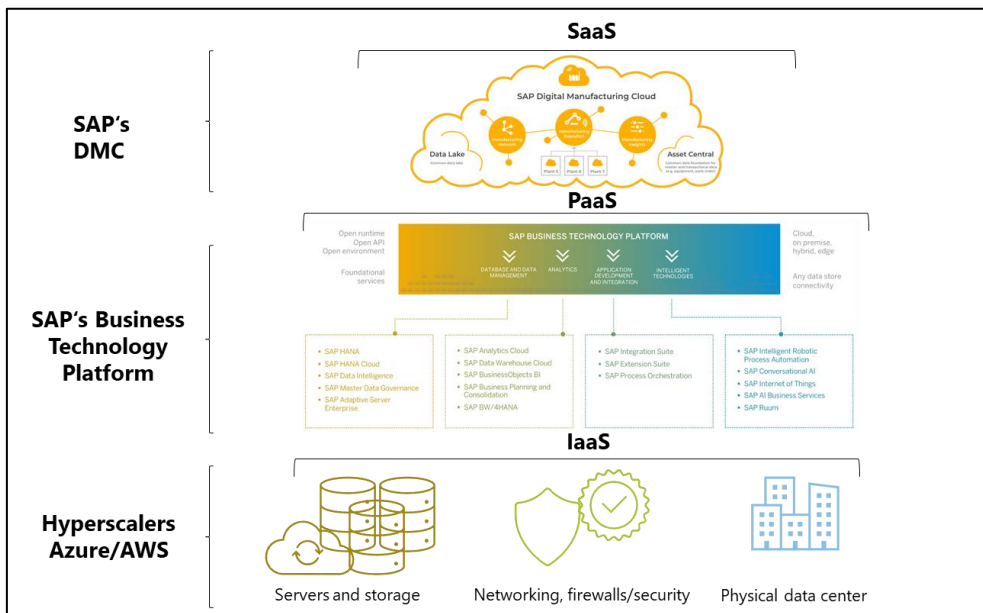
Figure 2: SAP Digital Manufacturing Architecture

SAP periodically reviews the SAP Business Technology Platform (BTP) platform services and SAP Digital Manufacturing following the applicable Standard Operating Procedure (SOP.) SAP lists and describes all platform services and tests and assesses such platform services' impact and use on SAP Digital Manufacturing.

SAP Digital Manufacturing Releases

SAP Digital Manufacturing follows quarterly release cycles for new features. After deployment to the customer test environment, customers can test the new release before deploying it to a production environment.

Figure 3: Release Cycle

SAP Digital Manufacturing Quality Management System

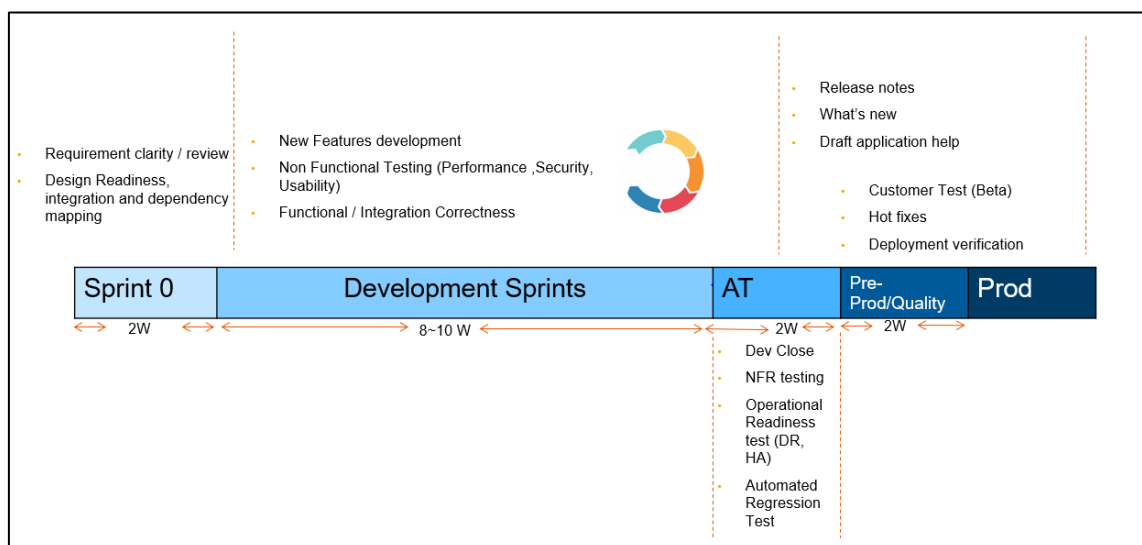The SAP Global Quality Policy* sets forth general principles for Quality Management Systems applied at SAP. The SAP Digital Manufacturing SOP scope encompasses the quality-related activities performed by SAP Digital Manufacturing teams accountable for managing SAP Digital Manufacturing.

SAP Digital Manufacturing Quality Management System (QMS) is the organizational structure, processes, procedures, responsibilities, and resources for implementing effective quality management per applicable regulations and standards.

the SAP Digital Manufacturing QMS has many similar core elements to those of SAP's customers operating in regulated environments. These elements include (i)a clearly defined organizational structure with roles and responsibilities, (ii) documented procedures, and (iii) SOPs, all of which govern internal processes that guide resources toward achieving SAP's quality objectives.

SOPs, including the policies and procedures governing QMS, are stored and managed electronically in a controlled document management system (DMS). DMS is an e-signature-enabled SharePoint site that automates version control and user access management, allowing authorized individuals to access such documents.

In addition, SAP follows QMS-specific procedures for SAP Digital Manufacturing (May apply to SAP Digital Manufacturing Edge as expressly outlined below), as shown in Figure 4.

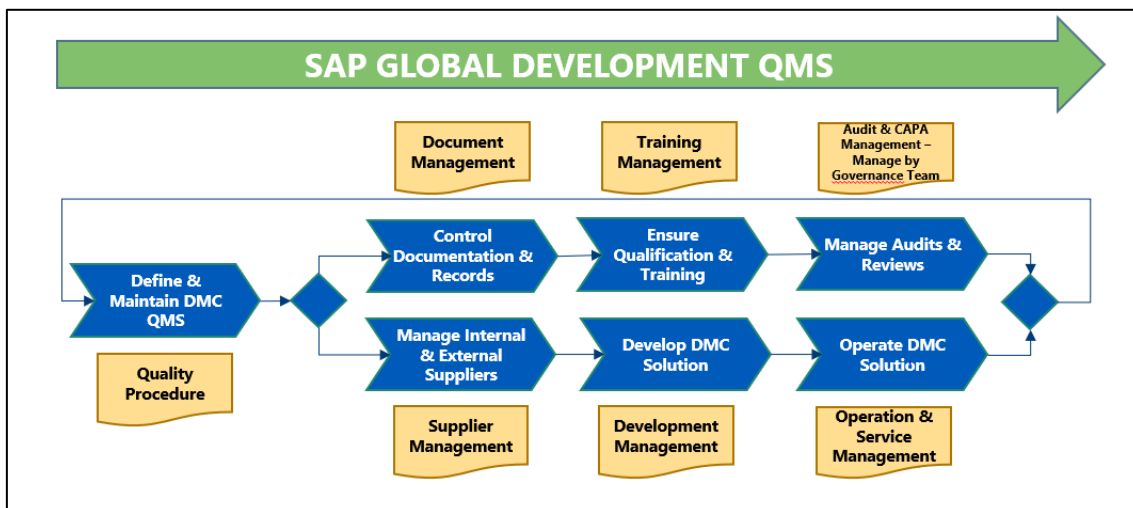**Figure 4: SAP Digital Manufacturing QMS**

In **SAP Digital Manufacturing QMS**, the following Procedures are available:

- SAP Digital Manufacturing quality procedures covering:
  - SOP Supplier Management – Management of external and internal suppliers
  - SOP SDLC
  - SOP Operations and Service Management:
    - o Incident Management
    - o Problem Management
    - o Operational Change Management

- o Monitoring Management
- o Backup & Restore
- o Provisioning and De-Provisioning
- o Hotfix Release Process
- o Security Management
- o High Availability

SAP Digital Manufacturing installed a GxP Quality Management Center. This GxP Quality Management Center is a team responsible for defining, managing, and controlling SAP Digital Manufacturing's Computer System Validation (CSV).

The primary responsibilities of this GxP Quality Management Center include the following:

- Manage overall GxP-relevant quality aspects of SAP Digital Manufacturing and work closely with the SAP governance team;
- Manage SAP Digital Manufacturing GxP-relevant procedures and practices;
- Manage GxP training for the SAP Digital Manufacturing team in all domains;
- Consult customers on the GxP aspects of SAP Digital Manufacturing. Assist in SAP Digital Manufacturing customer audits;

Document Management

System lifecycle documents, including policies, procedures, SOPs, designs, and other important data, are maintained in DMS. SAP restrict access to DMS system documentation to the respective authorized SAP Digital Manufacturing personnel based on their job roles.

Documents are approved according to the SAP Digital Manufacturing review and approval matrix and reviewed periodically to ensure accuracy. SAP keeps and maintains such records following SAP's corporate retention policies.

As part of the SAP Digital Manufacturing team, the SAP Digital Manufacturing document owner is responsible for correct, complete, current, and consistent content. The document owner must ensure such content is consistent with related procedures or verified per SAP information handling policies. Once in order, the document owner signs the first version as the author and usually every new /updated version.

After SAP releases the SOP by signature, SAP saves the SOP-related templates and forms in the GxP Quality Management Center asset repository for SAP Digital Manufacturing. The DMS repository retains all signed and published SOPs presented in awareness training (first version and relevant process changes) as assets.

The SAP Digital Manufacturing team publishes the assets according to the release date. The version number in the GxP Quality Management Center asset repository and the imprinted version number must match. DMS makes new versions of the SOP available as a PDF file in the approved documents section for SAP Digital Manufacturing. DMS moves the previous version of the SOP automatically to the electronic archive.

Qualification

For Cloud-based infrastructures, like SaaS, Life Science Customers have shared responsibilities with vendors and must rely on vendors for information on their quality management systems. The basic principles of on-premise infrastructure qualification apply to cloud infrastructure. Also, the

services belonging to SAP BTP adhere to the expectations of confidentiality, integrity, and availability stated by other security controls and have a mapping with the GxP controls. SAP ensures BTP qualification on the following aspects:

- Robust Supplier Qualification.
- Ensuring implementation and maintenance of SAP BTP and services using SOC 2 controls.

Risk Management

SAP's risk management policy provides a structured approach to identifying, prioritizing, and directing risk management activities for SAP Digital Manufacturing.

SAP Digital Manufacturing operates according to the applicable SAP corporate standards for risk management and covers the following steps:

1. Risk Identification
2. Risk Validation
3. Risk Analysis
4. Risk Management
5. Risk Monitoring
6. Risk Planning.

Software Development Operations Life Cycle (SDOL)

SAP develops Digital Manufacturing software per the SAP quality management system processes of its respective product standards. In the SAP Digital Manufacturing reference landscape, test strategy and test evaluations confirm adherence to the quality criteria set in the product standards. Test cases and test plans provide traceability from requirement to release, which SAP maintains in its product management tool, Jira's X-ray boards. Requirements implemented during sprint delivery, including sprint planning, are brought to requirement clarity between product management and development before the system design breaks down to epics and user stories/ backlog items and implements development tasks (Coding & Review). SAP development follows an agile methodology (SCRUM) and continuously creates test cases without composing a sequential cascade of sprint delivery. The development phase closes after in-sprint testing and respective quality gate passage of all code via continuous integration automation. Acceptance testing takes place to ensure release maturity for deployment to the customer test tenant. As part of this acceptance testing, SAP ensures the correct code transfer to the internal mirror environment. To maintain consistent quality and to meet product standards throughout the agile development process for each quarterly release cycle, the test approach relies on full test automation. Before production release (i.e., the release to the customer), SAP investigates all defects detected according to resolution priority. With the customer release, SAP publishes customer assistance documentation to verify the draft notes provided during acceptance testing. SAP continuously improves the test strategy as necessary via root cause analysis of defect reports.
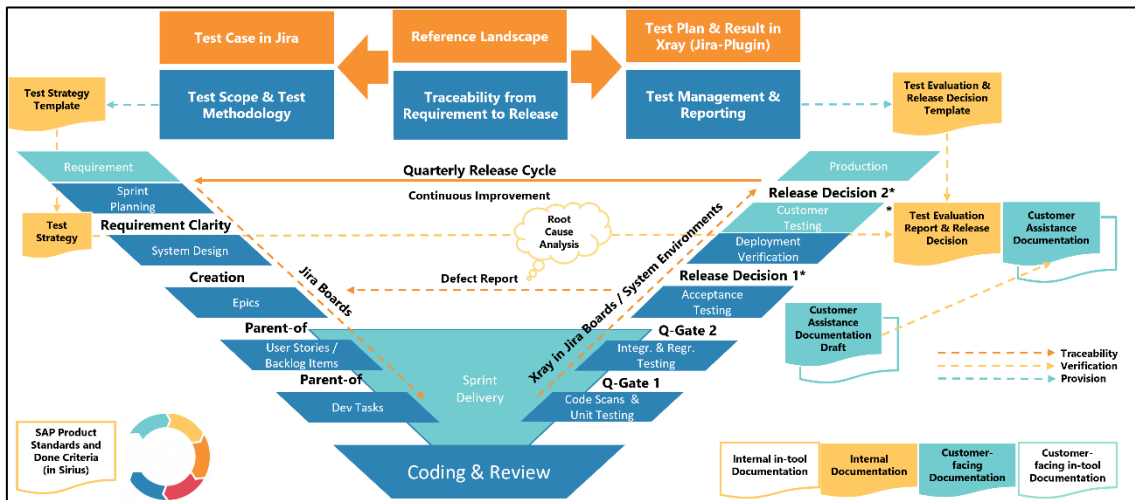
Figure 5: SDOL

The SAP Digital Manufacturing solution is (continuously) created in compliance with the SAP product standards, which define general software qualities and specific quality criteria for how to achieve them which are:

- Accessibility
- Functional Correctness
- Integration
- Language
- Performance
- Security (see Secure Software Development & Operations Lifecycle)
- Software Life Cycle
- User Assistance
- User Experience

SAP verifies product standards compliance by a test evaluation report outlining the testing results.

Traceability from the requirement to release is maintained by linking all process-related information to the requirement via its issue ID in Jira's X-ray.

Before preparing systems designs and during the requirement engineering stage, the program management and development representatives refine each requirement in scope for realizability and clarity. Each system design comprises one or more epics consecutively broken down into user stories/backlog Items (containing the definition of done and acceptance criteria) and dev tasks.

During sprint delivery, SAP converts requirements to code according to user stories and dev tasks, scans for code correctness, and verifies in unit tests. After pull request, review, and approval, the code enters the continuous integration automation towards the internal deployment infrastructure for integration and regression testing as defined by quality gates (Q-Gates).

After sprint delivery (Development Close), acceptance testing occurs where SAP conducts system integration, non-functional requirements, and operational readiness tests. During the

acceptance testing phase, SAP publishes a customer/user assistance documentation draft, which provides information about the upcoming release:

- Feature Scope Description

- Application Help

- Release Notes (What's New Viewer)

- Launchpad Notes

Approval for release to customer tenants, either customer test tenants or productive tenants, requires a release recommendation provided during the release decision meeting based on the test evaluation report:

- Release Decision 1 approves deployment to the customer test tenant and an internal mirror tenant, where deployment verification occurs to ensure the correct components transfer.

- Release decision 2 approves release to the productive tenant (release to customer). At the same time, SAP publishes the customer/user assistance documentation to customers to verify the respective draft.

SAP reports defects identified up to the release to customers stage (RTC), investigated according to resolution priority (process interface to IT Operations and Services), and subject to release recommendation. SAP links defects to the respective test cases and requirements via their Jira issue ID for traceability, subject to root cause analysis (RCA). SAP details respective code corrections for defect resolution and measures to prevent a recurrence. SAP documents these corrections and measures in Jira's RCS to continuously improve the test strategy.

SAP assures software quality across all levels of testing by checking criteria specified in the SAP Digital Manufacturing test strategy.

SAP Digital Manufacturing IT Operations and Service

Regulated companies must maintain and operate SaaS systems, such as SAP Digital Manufacturing, in a demonstrable state of control.. SAP Digital Manufacturing has comprehensive procedures for maintaining control of its system throughout its operational life.

The standard operating procedures (SOP) for SAP Manufacturing IT Operations and Services are:

- Operational Change Management

- Monitoring Management

- Backup and Restore

- Provisioning and De-Provisioning

- Hotfix Release Process

- Incident Management (SAP Global)

- Problem Management (SAP Global)

The above SOP for SAP IT Operations for the SAP Manufacturing that applies to SAP Manufacturing Edge on-premise component, as an add-on or a supplement, are only:

- Incident Management*

- Problem Management*

*The limited SOP is because the Life Science Customer runs and operates SAP Digital Manufacturing Edge on its shop floor; thus, it is responsible for the provisioning, installation, and qualification required for the on-premise IT infrastructure. The Life Science Customer is also responsible for the secure operation, including specific backup and restoration responsibilities and change management of SAP Digital Manufacturing Edge. See Figure 4 above for reference.

Incident Management

An operation incident is any unplanned occurrence that prevents (or may prevent) or delays users, the system, an operation, or service from proceeding with an assigned task ('Incident'). The Incident management procedure aims to categorize Incidents to direct them to the most appropriate resource or complementary process to achieve a timely resolution. As a general guiding principle, SAP fixes priority Incidents opened against the production environment within defined timelines or service level agreements (SLA). Depending on the necessity, such fixes can lead to a Hotfix (see definition below.)

SAP Digital Manufacturing follows SAP's global standards on Incident management. The SAP Digital Manufacturing operations support team is responsible for customer support. It includes customer/internal ticket processing, service request completion, troubleshooting of service availability, and service degradation.

For Incident management, SAP Digital Manufacturing follows the following process steps:

1. Log an incident
2. Categorize an Incident
3. Investigate and Diagnose
4. Resolve and Recover
5. Validate and Close

The Support Policy For SAP Cloud Services outlines (i) information on how to report/log an Incident and (ii) customer response levels, including priority, definitions, initial response times, ongoing communication objectives, and resolution target.

Problem Management

SAP Digital Manufacturing's problem management process deals with the complete lifecycle of automated or manually created problem tickets (Problem Management.) The objective of Problem Management is to find the root cause of problems and to provide solutions to prevent future Incidents, reduce recurring customer system outages, and minimize the business impact of Incidents.

SAP Digital Manufacturing follows the Problem Management procedure with the following steps:

1. Log and Categorize a Problem
2. Diagnose and Define a Problem
3. Resolve and Realize a Problem
4. Validate and Close a Problem

Operational Change Management

SAP Digital Manufacturing follows an operational change management process with the following process steps (Operational Change Management:)
1. SAP maintains an inventory of application lifecycle management tools and services, listing the relevant software components with all necessary attributes.
2. SAP monitors upcoming component versions. There is a software component version upgrade plan for each use to ensure all software components operate under the latest version.
3. SAP implements new component versions with quarterly releases. The implementation of component upgrades follows the SDOL.

In the scope of Operational Change Management are (i) upgrades (regular product increments) and (ii) corrections to the infrastructure and platform components, systems, and services, including upgrades of the platform, infrastructure components, database, runtime environment, and operating system.

Changes to the SAP Digital Manufacturing solution are not in the scope of this process. The development of quarterly SAP Digital Manufacturing releases follows the SAP Digital Manufacturing release process in the scope of SDOL.

Monitoring Management

The monitoring management process deals with the monitoring and reporting of the availability of the SAP Digital Manufacturing application, as well as handling of availability Incidents (Monitoring Management.) The objective of monitoring availability is to enable the delivery of consistent and timely service to SAP Digital Manufacturing customers (Monitoring Availability.)

The Service Level Agreement for SAP Cloud Services outlines the system availability SLA and the calculation/definition of the system availability percentage. SAP conducts Monitoring Availability for SAP Digital Manufacturing using the SAP BTP availability service, an SAP internal tool to monitor, analyze, alert, and report on the availability of services.

Customers can find the Monitoring Availability reporting on the SAP Trust Center, Cloud Availability Center section. This reporting is data center specific and is open to everyone. The Cloud Availability Center shows the availability of products/services. It provides details on the time of the incident, the status of availability, and root-cause analysis.

Backup and Restore

The purpose of backup and restore is to ensure the accurate and reproducible copying of digital assets (data and software), to protect against loss of original data, and the restoration of assets when required (Backup and Restore.) Backup and Restore are in place for SAP Digital Manufacturing persistence platform services. SAP HANA Cloud (SAP HANA DB), a database-as-s-Service offering (SBAAS) managed by BTP, is the data storage for tenant-specific relational business data. BTP also manages backups, patch management, and other platform service needs).

Provisioning and Deprovisioning

The objective of the customer provisioning process is to ensure the proper and secure set-up of the customer tenant. The objective of the customer system/tenant decommissioning process is to ensure the proper and secure deletion of customer data once the contract period ends.

The SAP Help Portal describes the onboarding process and required steps for a SAP Digital Manufacturing. The onboarding process starts after the customer purchases SAP Digital Manufacturing. During the process, the customer administrator receives emails from SAP with instructions for the next steps. If the customer does not already have a BTP global account or an SAP Cloud Identity Services - Identity Authentication tenant, the contact person is automatically assigned as the first administrator for the global account or tenant.

SAP triggers the customer system/tenant decommissioning upon receipt of the customer's request for termination or an event for the effective termination of the contract. SAP sends its customers a notification of the effective termination date upon this decommissioning. The customer must submit a service ticket to commence the data retrieval process during this notification period and has until the effective termination date to retrieve all data. If more time is needed, the customer may request an extension subject to a pro-rata fee for extended winddown activities. After the effective termination date, SAP continues completing the decommissioning process. SAP deactivates customer accounts and uses technical tools to delete customer data. The customer must retrieve all customer data before the effective termination date. SAP deletes all customer data remaining at the end of the decommissioning period, eliminating the possibility of restoring or retrieving such data.

Hotfix

Hotfixes deliver a solution for an urgent problem of a customer or a fix for a high-priority vulnerability (Hotfix.) The Hotfix release process aims to ensure the proper development, testing, and release of a Hotfix, or a Hotfix collection, which includes more than one Hotfix).

SAP initiates the Hotfix process through the Incident Management, Problem Management process and change management process. A hotfix is required to fix an urgent problem of a customer or an urgent internal incident.

A Hotfix is required when resolving a customer incident or problem requires a code change.

SAP conducts an RCA and impact analysis to implement a Hotfix. The Hotfix is QA tested, and SAP internal approver must review the Hotfix, RCA/impact analysis, and test results to approve the deployment. Once approved, SAP publishes a Hotfix Release Note.

Security Management

SAP Digital Manufacturing operates under an Information Security Management System (ISMS) per ISO 27001..

The SAP Global Security Policy applies to all businesses within SAP, all SAP employees, all external parties granted access to SAP Information, and all information and assets owned by or administered by SAP. It defines the company-wide requirements for the protection of SAP's personnel, their work, and the information entrusted to SAP by its customers

SAP Global Security policy defines the high-level requirements for:

- Preserving the confidentiality, integrity, and availability of information and assets

- Protecting assets from threats, whether internal or external, deliberate or accidental, based on an assessment of risks to the organization

SAP Security Policy is supported by various standards, procedures, and good practices.

SAP describes a set of Security Controls in applicable SOC1/SOC2 reports available in the SAP Trust Center upon request.

Data Protection

SAP Digital Manufacturing has put processes, tools, and procedures in place to support the protection of records to enable their accurate and ready retrieval, including:

- Data Segregation,
- Data Encryption
- Data Backup and Restore.

Data Segregation: SAP supports the multi-tenant architecture of SAP Digital Manufacturing, which supports security, confidentiality, privacy, integrity, and availability of data standards. SAP Digital Manufacturing was designed with the assumption that all tenants are potentially hostile to all other tenants. Security measures to prevent the actions of one tenant from affecting the security or service of another tenant or accessing the content of another tenant are in place.

The two primary goals of maintaining tenant isolation are:

- Prevent leakage of, or unauthorized access to, customer data or content across tenants
- Prevent actions of one tenant adversely affecting the service for another tenant

SAP Digital Manufacturing implemented multiple forms of protection to prevent customers from compromising SAP Digital Manufacturing services or applications or gaining unauthorized access to the information of other tenants including logical isolation of customer content within each tenant.

Data Encryption: SAP Digital Manufacturing implemented encryption methods, protocols, and algorithms to help provide a secure path for data in transit through the SAP Digital Manufacturing infrastructure, and to help protect the confidentiality of data that is stored within SAP Digital Manufacturing.

Data Backup and Restore for the SAP Digital Manufacturing persistence services is described in the chapter SAP Digital Manufacturing IT Operations and Service.

SAP Digital Manufacturing Personnel and Contractor Training

GxP regulations require adequate training and education of personnel in managing computerized systems used in the context of GxP-regulated activities.

SAP Digital Manufacturing has implemented a training program to ensure that personnel and contractors responsible for SAP Digital Manufacturing are adequately trained on applicable GxP processes and are qualified to perform their duties. New employees receive onboarding- and predetermined training requirements. SAP communicates applicable GxP policies and standards through mandatory trainings aimed at employees and external parties responsible for supporting SAP Digital Manufacturing.

SAP uses an internal learning management system (LMS) to manage critical course content and training traceability. This LMS includes a dashboard and reporting capabilities for managers to see overall training completion.

7. Glossary

Abbreviation /Term	Definition
BTP	Business Technology Platform
CSNS	Cloud System Notification System
CSV	Computer System Validation
DBaaS	Database as a Service
DMS	Document Management System
EU	European Union
GAMP®	ISPE: A Risk-based Approach to Compliant GxP Computerized Systems
GDPR	General Data Protection Regulation
GxP	Good Practices for x = C (Clinical), D (Distribution), Doc (Documentation), L (Laboratory), M (Manufacturing), etc.
IaaS	Infrastructure as a Service
ISMS	Information Security Management System
ISO/IEC 27001	International Standard on Information Security Management
ISPE	International Society for Pharmaceutical Engineering
ITSM	IT Service Management
LMS	Learning Management System
MES	Manufacturing Execution System
PaaS	Platform as a Service
QA	Quality Assurance
QMS	Quality Management System
RDM	Release Decision Meeting
RCA	Root Cause Analysis
RPO	Recovery Point Objective
RTC	Release to Customer

Abbreviation /Term	Definition
SaaS	Software as a Service
SAP HANA DB	SAP HANA Database
SDLC	Software Development Life Cycle
SLA	Service Level Agreement
SOC	Service Organization Control
SOP	Standard Operating Procedure
TLS	Transport Layer Security

8. Version History

Version	Author	Date	Change Description
1.0	Priyanka Kant Misra	26,07,2023	First Version

In conclusion, GxP compliance is an ongoing journey rather than a one-time event. SAP Digital Manufacturing is committed to a pragmatic approach to GxP regulatory compliance, understanding that becoming a GxP capable solution is of utmost importance. It should be noted that our aim is to provide a GxP capable solution, enabling our customers to place their trust in our solution and leverage our extensive documentation to minimize and optimize their validation and testing activities.

By embracing this approach, SAP Digital Manufacturing strives to enhance the reliability and trustworthiness of our solution, offering significant benefits to our customers. Through streamlined validation and test activities, organizations can achieve improved efficiency and operational effectiveness. We believe that our commitment to being GxP capable will empower our customers to meet their compliance requirements more effectively while focusing on their core business objectives.

We recognize the importance of continuous improvement to ensure our solution remains up to date with evolving GxP standards and guidelines. By maintaining robust documentation management practices, adopting a risk-based approach, and fostering a culture of continuous improvement, we are dedicated to providing a GxP capable solution that meets the regulatory needs of our customers.

We encourage our customers to consult with their legal and compliance teams to ensure compliance with specific GxP requirements, as this white paper serves as an overview and does not substitute for professional legal or regulatory advice.

At SAP Digital Manufacturing, we remain committed to supporting our customers in their GxP compliance journey, delivering a reliable and capable solution that empowers them to achieve their compliance objectives while driving operational excellence. Together, we can navigate the complex landscape of GxP compliance and ensure the highest standards of quality and regulatory adherence within the manufacturing industry.

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