

ServiceNow CORE™ for Life Sciences

Benefits

- Simplify Auditing Efforts and Quality Assessment Efforts**

Readily understand how ServiceNow supports regulatory requirements for life sciences companies leveraging cloud services.

- Improve Operation Efficiency**

Significantly reduce costs and resources typically allocated to quality auditing and assessment efforts via self-service access to key documentation in ServiceNow CORE for Life Sciences.

- Speed the Implementation of New ServiceNow Releases**

Rapidly address regulatory software validation requirements by leveraging ServiceNow software validation plans and summary reports developed for each major release.

The Business Challenge

Life sciences companies are challenged to address a growing number of evolving guidelines and regulations. Compliance efforts may produce operational inefficiencies and costly, time-consuming processes. Additionally, change control requirements can slow the adoption and implementation of new technology such as cloud services.

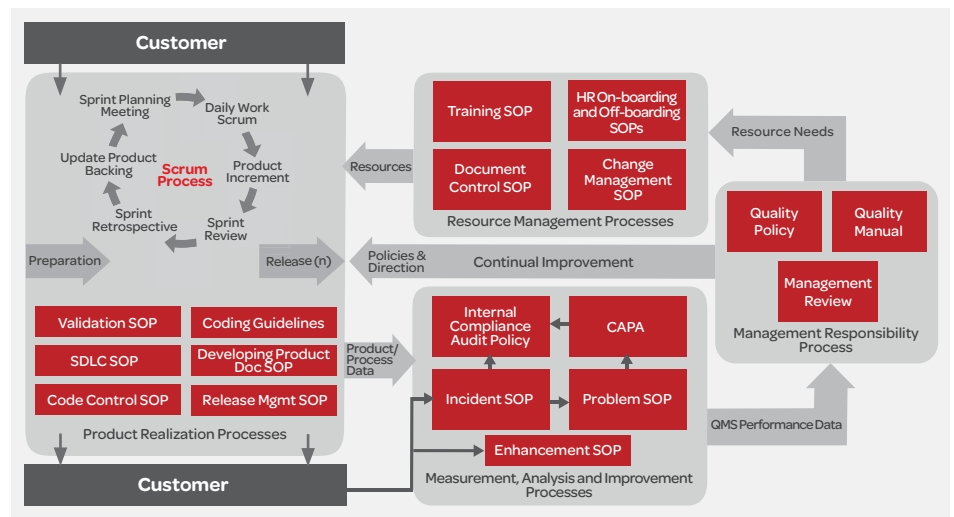
The ServiceNow Solution

ServiceNow® CORE (Compliance Operations Readiness Evidence) for Life Sciences is an extensive set of documentation that maps out how ServiceNow supports customers that need to address regulatory requirements for cloud services. ServiceNow CORE enables ServiceNow customers to readily access the documentation they need to help address their internal audit requirements, as well as FDA and other regulatory requirements, related to their use of ServiceNow.

ServiceNow CORE for Life Sciences includes:

- Overview of the ServiceNow Quality Management System (QMS)
- Overview of ServiceNow system architecture and security
- Overview of the ServiceNow software development life cycle (SDLC)
- ServiceNow software validation documentation
- Third party attestations and audit reports
- Support mapping

ServiceNow CORE for Life Sciences is regularly updated as new documentation becomes available.



ServiceNow QMS Diagram included in ServiceNow CORE for Life Sciences

ServiceNow QMS Overview

ServiceNow CORE for Life Sciences includes an overview of the ServiceNow QMS, which ServiceNow maintains to ensure the intent of the quality policy is achieved. The QMS was developed in November 2011 and is based on ISO 9001. It includes the Quality Policy and Quality Manual and describes the processes for product realization, measurement, analysis and improvement, management responsibility and resource management.

System Architecture and Security

ServiceNow system architecture and security are also described in ServiceNow CORE. ServiceNow data centers and cloud-based infrastructure are designed with high availability as a core requirement. All ServiceNow data centers are required to maintain an industry standard SAS70/SSAE16/SOC1 Type II attestation or ISO 27001 certification, or meet comparable security guidelines. Additionally, all data center providers are processed through the ServiceNow vendor risk management program. ServiceNow CORE includes descriptions such as how ServiceNow application and database tiers are completely separate so there are no pooled resources holding customer data and how data center vendors do not have logical access to ServiceNow customer data. Change management processes are described as well as single sign on and encryption options.

SDLC and Software Validation

As described in ServiceNow CORE, the ServiceNow software development procedure is designed to provide a consistent and repeatable process for developing the ServiceNow application portfolio and SaaS platform to maximize quality and user value. ServiceNow validates the out-of-the-box functionality and capabilities for each release. The release validation plan and release

validation summary report (including a traceability matrix) are added to ServiceNow CORE with each new ServiceNow release.

Attestations

ServiceNow has achieved Federal Information Security Management Act (FISMA) Moderate Authority to Operate (ATO) and ISO 27001 certification. In addition to customer audits and internal audits, ServiceNow undergoes annual third party audits and attestations to maintain its ISO 27001 certification and Service Organization Control (SOC) Reports (SSAE 16 SOC 1 Type 2 and SOC 2 Type 2). Additionally, ServiceNow obtains and conducts annual reviews of SSAE 16 Type 2 reports or ISO 27001 certificates from, or completes a security review of, third party data centers that host customer instances. Applicable reports and certification summaries for ServiceNow and its third party data centers are available in ServiceNow CORE.

Support Mappings

ServiceNow is not regulated by the FDA and is not required to be compliant with FDA regulations. To clarify how ServiceNow helps address the regulatory requirements of customers in life sciences industries, and to note gaps, ServiceNow created regulation support mappings. Currently, the support mappings address 21 CFR Part 11. Similarly, while ServiceNow is not a regulated entity under GAMP, Annex 11, 21 CFR Part 820, and has different regulatory obligations under HIPAA regulations than customers, mappings showing how ServiceNow addresses these requirements are in development. This information will be added to ServiceNow CORE as it becomes available.

To learn more or access ServiceNow CORE for Life Sciences, please contact your ServiceNow account executive.

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