PROCESS X

USDM Life Sciences

An intelligent, fully validated, GxP process automation platform built on ServiceNow

Every day, life sciences companies must deal with various events having regulatory implications and find the most efficient way to resolve them. Processes and data are often stored and managed in disparate systems and attempts at process automation often leave out intelligent or real-time insight that would bring about the desired business outcomes. Time-consuming, fragmented processes create product delays, increase regulatory risk, and result in poor business performance. Imagine a platform that enables process transformation and automation while simplifying, scaling, and maintaining regulatory compliance.
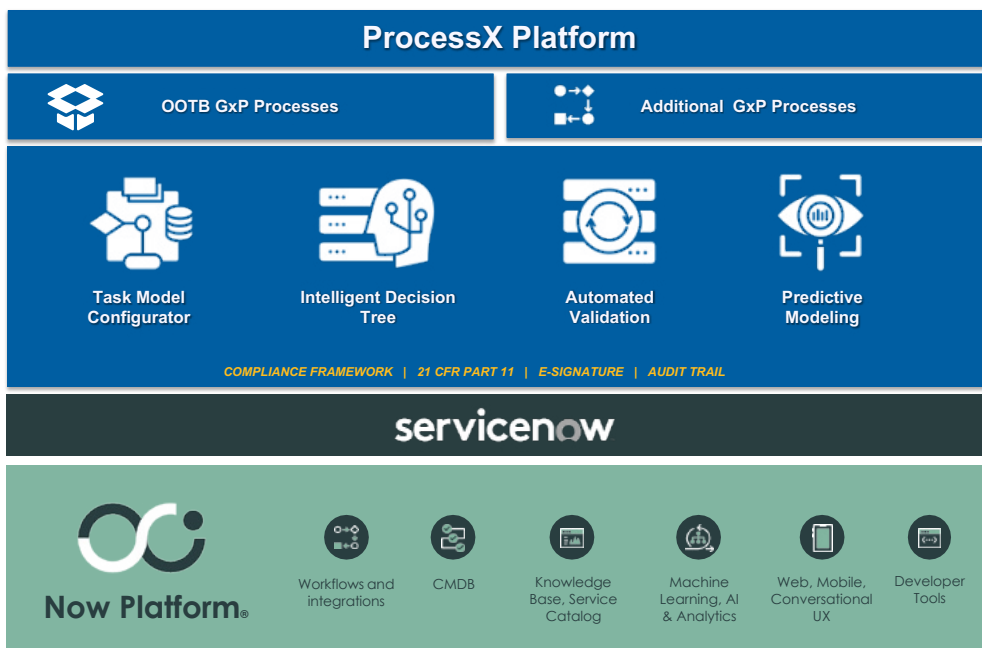
Introducing ProcessX

Today, product innovation is possible with the convergence of modern cloud technologies, development platforms, and artificial intelligence (AI). ProcessX is an intelligent, fully validated, GxP process automation platform built on ServiceNow. It simplifies regulated workflows and processes to drive greater efficiency and insight for better business decisions across your organization, and improves product quality and patient safety all while maintaining compliance. With these AI-infused capabilities, Quality and IT leaders gain greater insight into the entire product lifecycle and supply chain and minimize costly recalls or undetected systemic issues.

Built on now.

Supported Regulations

- 21 CFR Part 11
- FDA GxP
- FDA cGMP
- ISO 9000
- ISO 13485
- ISO 14000
- ISO 27000
- AS9100
- IATF 16949
- ITIL
- Sarbanes-Oxley

Built on Now means ProcessX has received the highest technical designation and certification for a ServiceNow Technology Partners application. As a native Built on Now application for the ServiceNow Platform, ProcessX has been designed and tested for fast, agile, resilient, secure, human, and connected digital transformation. Built on Now provides customers with One Platform, One Data Model, and One Architecture with the performance, security, and graphical user interface (GUI) of the ServiceNow Platform.

ProcessX Platform

OOTB GxP Processes	Additional GxP Processes

Task Model Configurator	Intelligent Decision Tree	Automated Validation	Predictive Modeling

COMPLIANCE FRAMEWORK | 21 CFR PART 11 | E-SIGNATURE | AUDIT TRAIL

servicenow

Now Platform®

Workflows and integrations	CMDB	Knowledge Base, Service Catalog	Machine Learning, AI & Analytics	Web, Mobile, Conversational UX	Developer Tools

Flexible Platform

Easily create and automate GxP processes in clicks – no code changes needed

The **Task Model Configurator** includes out-of-the-box (OOTB) quality processes to get you up and running fast. New GxP processes are easily added and automated in a few clicks using rule-based decision making to dynamically select tasks, assign team members, and create a checklist to streamline and optimize workflow routing and execution. **Intelligent Decision Tree** functionality helps you choose the right workflows, manage your regulated events, and remove any guesswork. The ProcessX **Predictive Modeling** feature helps you build a learning model to predict events and outcomes based on your unique use case parameters.

Automated Processes

Designed from 20 years of life sciences business process and regulatory compliance expertise, ProcessX is built for pharma, biotech, and medical device companies with heavily regulated requirements. With Part 11 eSignatures and audit trails built in and **Automated Validation** and testing via USDM's Cloud Assurance™ subscription, compliance is no longer the reason for your lack of innovation. Start with out-of-the-box (OOTB), pre-configured processes based on life sciences best practices. Easily add new automated processes or modify existing processes to increase productivity overnight.

Accelerated Performance

Rapidly implement new digital processes to scale your operations and gain valuable insight from your current processes and data to drive better business decisions and outcomes. Personalized homepages, dashboards, and notifications create a dynamic digital experience for each user to maximize productivity. ServiceNow's open API platform also enables robust integrations with various collaboration tools and other enterprise systems you are already using.

OOTB GxP Starter Pack

- Non-Conformance/Deviation
- OOS/OOT
- CAPA Management
- Change Management (Process & Product)
- Audit Findings Response (AFR)
- Supplier Corrective Action Request (SCAR)

Additional GxP Process

- Adverse Safety Events/Product Complaints
- Device Master Management
- Batch Record
- Inspection Management
- Risk Management
- Product Registration
- Document Management
- Record Management
- Submission Management
- Return/Recall Management
- Field Service Management

Affordable Price

By leveraging your existing investment in ServiceNow, you don't have to increase your IT footprint or overhead. The flat licensing fee helps you control IT costs and ensures access across your organization.

GxP and Non-GxP Business Processes in One Platform

R&D/Clinical	Manufacturing/ Distribution	Post-Market Surveillance	Compliance
• Record Management • Submission Management • Audit Finding Response • Change Management • CAPA Management	• Inspection Management • Change Management • CAPA Management • Batch Record • Document Management	• Return/Recall Management • Document Management • Inspection Management • Safety/Adverse Event Management	• Risk Management • Audit Finding Response • Supplier Corrective Actions
Human Resources	IT	Procurement	Legal
• Case and knowledge management • Workspace reservations • Virtual agents • Employee self-help center	• Service management • Operations management • Asset management • Agile development • DevOps	• Track service catalog requests • Create and manage purchase orders • Create and manage transfer orders • Receive assets	• Legal Counsel Center • Request intake and legal process management • Knowledge management

USDM
Life Sciences

LET'S TALK
Schedule a consultation with our team today.
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