DATA SHEET

Scitara Digital Lab Exchange DLX™ Validation

Scitara Delivers Next-Generation Validation

Scitara DLX, is an Integration Platform as a Service (iPaaS) for Science that enables a 'no instrument or application left behind' concept and promotes innovation and digital transformation in any lab environment. Software validation is a regulatory requirement in the pharmaceutical industry. Unfortunately, validation is sometimes viewed as a burdensome exercise by decision-makers and system users alike. This view leads to resistance toward implementing new products and processes, where the required validation activities are believed to be disruptive or to lead to delays and unacceptable time-to-market. However, when you partner with Scitara, we provide you with an Out-of-the-box Validation Package to ensure your validation requirements are easily met.

Major highlights of this are:

- Qualified Infrastructure
- Qualified Scitara DLX platform
- 24x7 infrastructure maintenance and customer support per written procedures to maintain the integrity of controlled environments
- DLX cloud services (24x7 monitoring and infrastructure reporting for security threats or anomalies)

The overall framework for Information security management system (ISMS) and IT Quality management system (QMS) is designed in accordance with:

- ISO27001 and SOC2 - Scitara has identified the risks, assessed the implications, and put systemized controls resulting in increased reliability and security of systems and information
- ISO9001:2008
- ITIL V3, GAMP, ICH, and other such best practices

The Scitara QMS incorporates the latest regulatory guidance principles from around the world and our redesigned QMS is implemented across all IT processes within Scitara. Software development and deployment services and support all follow the robust Scitara QMS.

A Comprehensive Validation Offering

QA Environment

Scitara's Next-Generation Validation approach establishes a solid foundation for achieving compliance while offering custom validation tailored to specific compliance requirements.

The AWS Cloud infrastructure is established through the utilization of Infrastructure as Code (IaC) scripts, specifically referred to as DLX iPaaS Scripts. After the inception of this infrastructure, a series of security assessments, encompassing Threat Modeling and Vulnerability Assessment and Penetration Testing (VAPT), are systematically carried out. Concurrently, the installation of Scitara DLX Core and Connectors is executed on the iPaaS infrastructure.

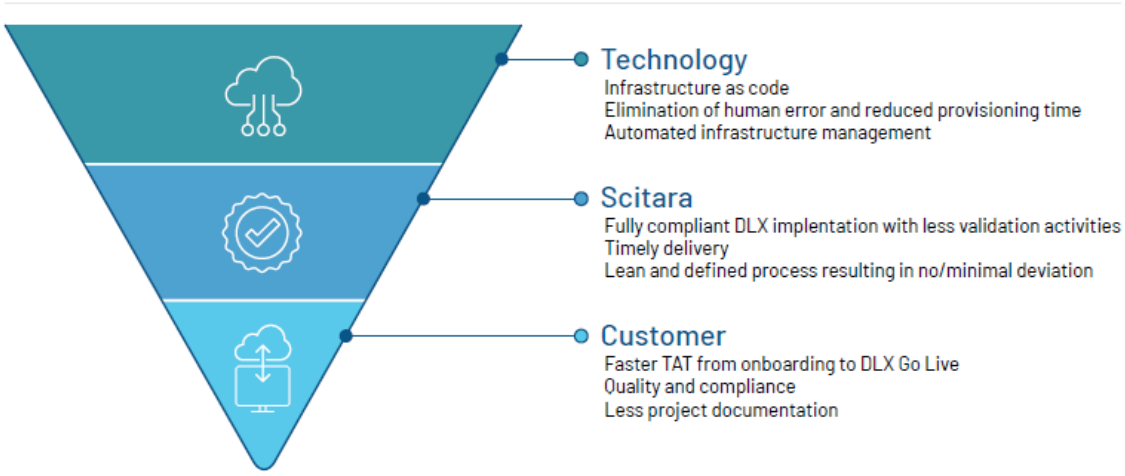
Following this phase, the infrastructure undergoes a comprehensive qualification process, encompassing both the installation and operational qualification of Scitara DLX Core and Connectors. This fully qualified environment is called the QA environment and is a controlled environment within the Scitara framework. The DLX iPaaS Scripts are referred to as 'Gold Scripts' and are utilized to configure customer deployments.

This approach brings the following benefits:

- Validation by design
- Out-of-the-box Validation
- Qualified Scripts for customer deployments
- Reduced documentation needs for customer environments thus minimizing effort and shortening project schedules

Benefits of QA Environment Approach

Combined Benefits



Key Deliverables for Out of the Box Validation

Inception Phase	Elaboration Phase	Construction Phase	Transition Phase	Reporting
• DLX iPaaS Specifications (User requirements & Functional) • Validation Plan • Risk Assessments (Initial & Functional)	• Design Architecture Document • Configuration Specifications • Threat Model • Scheduled VAPT Audits	• Qualification Planning (Infrastructure Qualification, Scitara DLX and Connector Installation and Operational Qualification)	• Infrastructure Qualification • Scitara DLX and Connector Installation Qualification • Scitara DLX and Connector Operational Qualification	• Qualification Reports (Infrastructure Qualification, Scitara DLX and Connector Installation and Operational Qualification) • Requirement Trace Matrix • Release Notes • Validation Report

Scitara also provides custom validation services to its customers as per their business requirements.

Key Deliverables for Custom Validation Package

Planning	Requirements	Validation	Reporting
• Validation Plan • Impact and Risk Assessment	• Customer Specific Business Requirement Specifications • Customer Specific Configuration Specifications • Technical Specifications	• Customer Specific Operational Qualification Plan • Customer Specific Operational Qualification Scripts • Execution of Customer Specific Operational Qualification Scripts	• Requirement Trace Matrix mapped to customer's business requirement specifications • Summary Report

Support And Maintenance

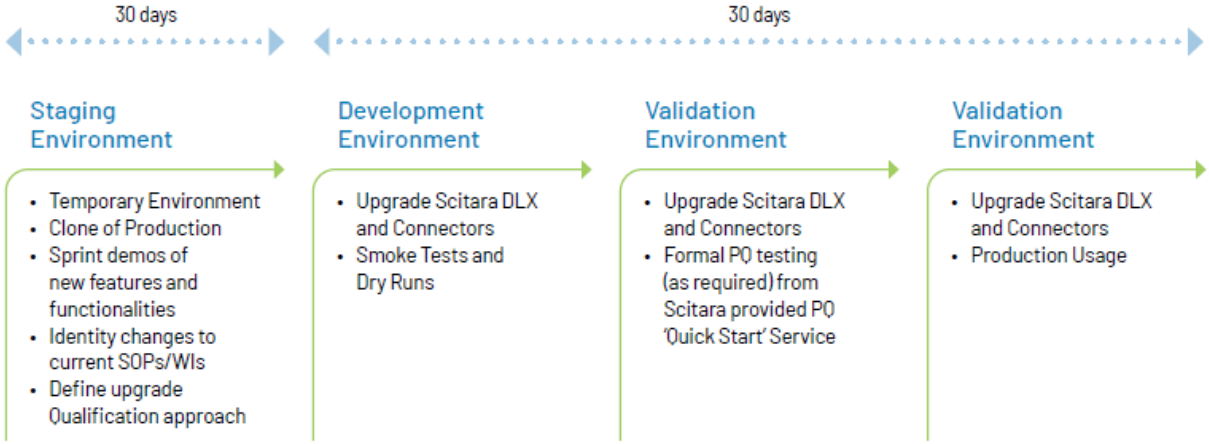
Any changes requested in the customer's-controlled environment follow a robust change management process, which is an integral part of Scitara QMS. All changes are done on a development environment, tested for accuracy, replicated on validation, and qualified/documented before applying to the production environment.

Scitara DLX and Connector Upgrade Process

With each release of Scitara DLX Core and/or Connectors, the QA environment undergoes an update or upgrade. A temporary staging environment is established, containing all configurations identical to the production environment. Within this environment, new features and functionalities can be tested and showcased to customers. Any potential impact on the customer's existing work instructions or standard operating procedures (SOPs) is documented, and necessary updates are applied to this environment.

This staging environment is accessible for a duration of 30 days. Following this period, the development environment is upgraded, and a trial run of validation scripts, if needed, is executed. Subsequently, the validation environment is upgraded, and a formal validation process is conducted as required. After the successful upgrade of the validation environment, the production environment is updated with the latest version of Scitara DLX Core and/or Connectors.

The entire upgrade procedure is completed within a 60-day timeframe, starting from the initiation of the staging environment.



Up to two upgrades per year required on a schedule

- 60-day lead time for review
- Access to IQ/OQ documentation
- Optional (recommended) services for PQ documentation and execution

Just like the implementation stage, the validation process for the Scitara DLX Core and Connector upgrade is executed in a manner that minimizes its impact on the customer environment. This is achieved by initially conducting the validation in the QA environment before releasing it to customers.

Validation Deliverables for QA Upgrade

Environments

Scitara QA	Staging	Dev	Val	Pro	Scitara QA	Scitara	Customer
√	-	-	X	X	Risk Assessment	√	-
√	-	-	X	X	Upgrade Qualification Plan	√	-
√	-	-	X	X	Scitara QA Upgrade	√	-
√	-	-	X	X	Installation Qualification (IQ)	√	-
√	-	-	X	X	Operational Qualification (OQ)	√	-
-	-	-	X	X	Performance Qualification (PQ)	√	-
√	-	-	X	X	Upgrade Summary Report(s)	√	-
-	√	-	X	X	Setup and Configuration	√	-
-	√	-	X	X	Feature/Enhancement Demos	√	-
-	√	-	X	X	SOP and WI Impact	-	√
-	-	√	√	√	Customer Environments Upgrade	√	-

Customer Benefits

The management of DLX validation is significantly simplified through the utilization of Scitara. Our comprehensive validation package assesses the core functionalities of DLX, as well as customer-defined PQ, in accordance with GAMP5, EU Annex 11, and 21 CFR Part 11 regulations. While the execution of UAT or PQ scripts may require commitment from customer users, it provides them with a valuable hands-on training opportunity before the system enters production. Alternatively, customers can choose to have Scitara perform a complete validation package on their behalf.

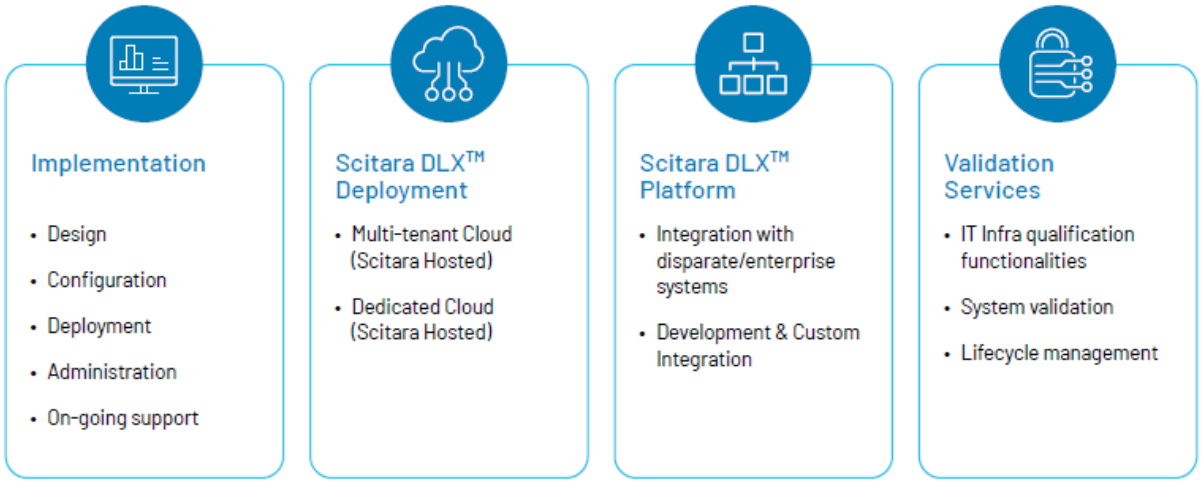
In summary, Scitara has the flexibility to offer varying levels of validation resources tailored to each customer's expectations and regulatory requirements, ensuring that DLX is indeed 'suitable for intended use.' Incorporating Scitara into your DLX validation process guarantees the achievement and maintenanceof a high-quality compliant validation with minimal disruption. This enables your users to swiftly and efficiently embrace DLX's innovative connectivity, facilitating the journey towards a fully digitally transformed laboratory.

Scitara's DLX and our associated Service's represent more than just technology and digitalization of the laboratory; they represent a new way of thinking — a new paradigm.

Key Benefits Include

- Decreased risk profile
- Reduced validation burden
- Meeting regulatory requirements
- Cost reduction due to fewer resources needed to perform validation
- Increased data quality throughout the end-to-end laboratory environment
- Driving Pharma 4.0 concepts
- Faster time to market

For more information on how Scitara can accelerate your time to market, increase data quality, and reinforce regulatory compliance, contact us today to discuss your lab automation needs.



Meet the Modern Lab™

For the very first time, Scitara's Digital Lab Exchange DLX makes it possible to create a fully connected, fully compliant lab infrastructure, enabling you to complete your lab's digital transformation and unlock true data mobility.

For more information on how to build a connected laboratory:
Request a Demo:

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revvitysignals.com
77 4th Avenue
Waltham, MA 02451 USA
P: (800) 762-4000 (+1) 203-925-4602

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