connect platform

Validating the Connect Platform

A Recommended Approach to Reduce the Validation Burden

A regulatory requirement within the life sciences, the validation of computerized systems has long served our industry to ensure that technology components meet their intended purpose. But the “what and to what extent to validate” remains the most significant challenge validation teams face. Additionally, the cost and time expenditure associated with the validation of GxP computerized systems can represent a significant part of the software implementation budget and timeline.

For many years, life science companies have been burdened with the complex process of validation, putting in hundreds of hours to achieve GxP compliance as non-adherence has severe consequences. Regulatory agencies have recognized this and have moved towards recommending a risk-based approach to focus validation efforts on high-risk areas and reduce the validation burden while improving quality.

Montrium’s cloud-based regulated content management system, Connect, is designed to empower clinical, regulatory and quality teams with optimized GxP processes. Behind the creation of the Platform are experienced technology experts and regulatory specialists with extensive experience in the life science industry. Leveraging years of knowledge on software implementation in the life sciences, Connect maintains alignment with industry evolution while keeping validation simple.

As part of the implementation of Connect, you have the option to either choose to leverage Montrium’s internal testing and qualification efforts or perform your own validation. Subscribers who have an in-house validation team often opt to perform their own validation, while many take our Recommended Approach to reduce the validation effort.

Is our **Recommended Approach** right for you?

Montrium's tried and tested validation methodology leverages industry best practices and standards for computer system validation to ensure all of our products meet current regulations under FDA 21 CFR Part 11 and EU Volume 4 Annex 11. To optimize the validation portion of the implementation process further and save you time, money, and stress – our Recommended Approach to qualification, testing, and validation aligns with GxP industry standards and best practices for pain-free validation processes.

Leveraging Montrium's internal testing and qualification can help reduce the time and effort that is required to complete validation on your end. We recommend this because we already perform exhaustive testing prior to market release, which is documented and maintained according to our internal procedures. When Connect subscribers use Montrium's Recommended Approach, they report significant reductions in validation cycle times.

Implementing the Recommended Approach with the proper supporting documentation, including evidence of due diligence, is the most efficient method to validating Connect. Many of our subscribers opt to take our Recommended Approach to validation to optimize the implementation timeline and reduce the validation burden.

Reduce the Burden of Validation

Validation is required for regulated content management systems such as Connect because the content stored on the platform needs to meet the requirements set forth by regulations for audit trails, electronic records, electronic signatures, and security.

Montrium's in-house validation team assists all subscribers with the management and execution of their computer system validation responsibilities, optimizing the process to relieve part of the validation burden. We assist in Connect implementation, which enables highly regulated processes in R&D, manufacturing, and quality. From the beginning, our team can help identify what risks may occur for a subscriber, then determine how to mitigate them with appropriate technical and procedural solutions. Montrium's technical, business, and regulatory experts can help you implement our Connect platform for increased efficiency, sustained compliance, and to ease your business pains.

Reduce Resource Expenditure

The time and cost associated with the validation of regulated (support GxP activities) systems can also represent a significant portion of the overall budget teams have set aside. Our in-house compliance capabilities focus on Connect products to remove most of the validation burdens from our subscribers.

As a life science software vendor, Montrium regularly performs and documents its qualification activities for each major product release and update of the Connect product. This approach is undertaken in tandem with risk assessments that determine the scope of testing required. Montrium provides subscribers with a training environment and user acceptance testing (UAT) scripts.

To maximize significant savings of validation costs, Montrium provides a validation template package for each major release of the Connect product including:

- Validation Master Plan
- User Requirements Specifications
- Test protocol(s) and validation test scripts
- Requirements Traceability matrices
- Validation Summary Report

We aim to significantly reduce the time spent and resources comprising the additional validation cost estimation to allow your organization to move quickly into new and innovative technologies within the life sciences industry.

Reduce the Risk of Non-Compliance

More inspectors expect that a risk-based framework is adopted and utilized throughout the validation process. At the core of our validation service offering, we focus validation efforts on high-risk areas (e.g., user account management, system availability & support, data protection) and mitigate inefficiencies on high-risk areas to reduce the validation burden.

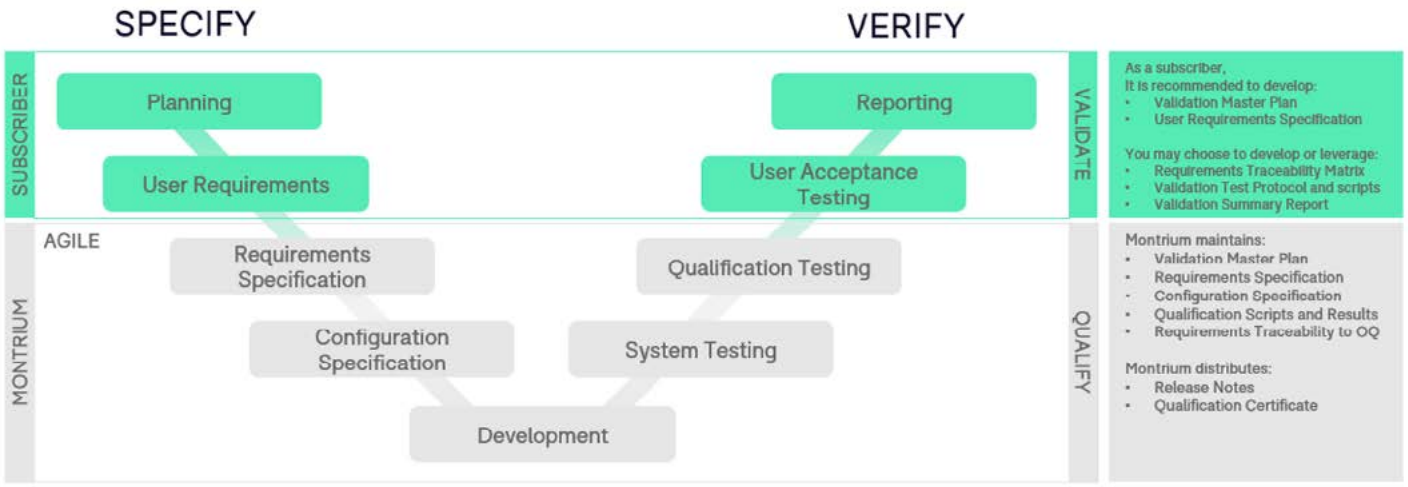
The struggle to balance time and available resources with compliance requirements often leads to insufficient testing and even project overruns, which can lead to significant regulatory risks. Recent EMA and FDA inspection documents prove that qualification, validation, and electronic records are high on inspectors' radars. Montrium executes a risk assessment of every new or updated requirement to help Connect subscribers evaluate the potential effect on their validation efforts.

Montrium's Product Specialists can help assess the impact and risk associated with each new requirement allowing Connect subscribers to make informed decisions on the scope of their validation effort. Our Specialists help you focus resources on your most significant risks, allowing you to more efficiently and effectively validate your instance of the Connect Platform. The framework described in the next section is designed to reduce the amount of documentation required for a validation effort based on the overall system risk.

GxP Software Development Practices

Montrium's significant industry knowledge, combined with GxP software development practices, enable quick and robust responses aligned with regulatory and technology trends. Our IT, product development and quality experts work together to prepare system validation activities based on industry best practices. As a result, we can accelerate your use of the Connect Platform with faster startup, transparent data transfer, and seamless integration.

Montrium's design and development methodology is inspired by ISPE's GAMP5 V-model. Per GAMP5, as a subscriber to an off-the-shelf product, you are responsible for validating a GxP-relevant system per your intended use (upper half of the V diagram below).



Infrastructure Qualification

We take active measures to maintain our hosting infrastructure in a qualified state over the course of your subscription. Connect applications are hosted in Microsoft's Azure infrastructure. Azure's secure facilities are ISO27001, 22301 and 27018 certified, FDA 21 CFR Part 11 and EU Volume 4 Annex 11 certified, with SOC 1, SOC2 and SOC3 attestations. Microsoft's Trust Center is an excellent resource to refer to for a complete understanding of their products' infrastructure qualifications. To ensure high availability, Montrium maintains redundant hardware in triplicate and backs up each copy daily to a remote location. Content and data are encrypted both at rest, using the AES 256 standard, and in transit, using the TLS 1.2 industry standard for added security.

Data Integrity for Ensuring GxP

We help you overcome data integrity related issues by ensuring that Connect products have been appropriately tested, focusing efforts on the most critical business and compliance components to ensure data integrity and accuracy. At each step of the way, we aim and build your knowledge of the system and underlying data.

Proper Testing with Each Update

With proper testing of features that are critical to the business and regulatory compliance, Montrium ensures data integrity and helps reduce findings in cases of audits and inspections with supportive underlying data and documented risk-mitigation strategies and processes. Montrium's in-house specialists develop and execute validation scripts that are updated and re-executed with each release of the Connect product to improve quality and compliance.

At regular intervals, Montrium's team performs a comprehensive requalification of system features to ensure that no cumulative adverse impact of incremental releases has occurred on critical system functionalities. Montrium ensures the appropriate amount of testing and documentation is undertaken, saving our subscribers considerable time and money when implementing the Connect system.

Release Management and Communications

Release Notes are prepared and circulated to subscribers to inform them of the version of the product to be released, type of release (major or minor) and a description of its content. If any requirements have been impacted by the release, the Product Specialists prepare and update supporting documentation to accompany the release. This may include a Requirements Impact Analysis document. If any impact on validation is identified, Montrium recommends the appropriate validation scripts to be executed or leveraged, based on the validation approach chosen.

Validation Deliverables for Connect

As part of Montrium's onboarding, we assist subscribers in establishing and defining the scope of their validation approach, complete with risk-mitigating activities. This allows subscribers to leverage Montrium's expertise to plan, test, and manage validation activities from the start of their journey with Connect. We complete subscriber due diligence assessments regularly and can facilitate both remote and onsite reviews.

Our user requirements specification is provided to subscribers as part of Montrium's onboarding process in order to aid in the validation of the Connect product(s). Montrium provides subscribers with access to a training environment and validation test scripts that can be leveraged and adapted. The other entries that are "leverage or develop" means that we provide templates which subscribers can leverage or choose to develop their own.

Subscribers can refer to the following documentation produced by Montrium to facilitate validating Connect for your intended use:

Validation Deliverables	Montrium	Subscriber	Subscriber Action
Validation Master Plan (VMP)	X	X	Leverage or Develop
User Requirements Specifications (URS)	X	X	Leverage or Develop
Installation Qualification (IQ) Scripts and Results	X		Reference
Operational Qualification (OQ) Scripts and Results	X		Reference
Qualification Summary Report	X		Reference
Qualification Certificate	X		Reference
Release Notes	X		Reference
Configuration Specification	X		Reference
Validation Testing Protocol	X	X	Leverage or Develop
Validation Test Scripts	X	X	Leverage or Develop
Validation Summary Report	X	X	Leverage or Develop
Requirements Traceability Matrix	X	X	Leverage or Develop

A Validation Master Plan will summarize the validation strategy and User Requirements Specifications document those requirements that are applicable to your organization.

Though our internal documentation is not distributed externally, it is readily available for your review during a remote session with our QA team. To maintain the validated state of Connect following system upgrades or changes under this approach, you would continue to leverage Montrium's documentation and review Release Notes and/or the Qualification Certificate summarizing our efforts, reducing the burden of re-validation.

Maintaining a Validated State Over Your Subscription

A well-defined validation framework does not just refer to software design. It encompasses business functions to mitigate risks and achieve compliance over the entire subscription period. Montrium's subscriber experience, infrastructure and product teams work to continuously assess, monitor, test and improve systems to plan the appropriate actions.

Prior to each release and update, Montrium provides subscribers with Release Notes. When requirements are updated, a Requirements Impact Analysis is distributed to our subscribers in order to determine the impact on the validated state of their instance and the need for re-testing. To support the evolution of cloud-based systems and new policies and procedures, Montrium has adopted an approach to product updates so that all users may have the latest and greatest version available without jeopardizing our obligations and responsibilities as GxP organizations.

Our low-risk software changes are generally qualified through change control as they will not impact the validated status of the application. There is little-to-no testing on the subscriber's end, but even minor releases are tested by Montrium. Medium and high-risk changes (e.g. to user account management, system availability & support, data protection) can require additional testing and documentation based on their impact on the subscriber's use of the product.

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