AppsAccelerate
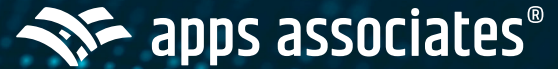
AppsAccelerate for Med Device: Validation as a Service Risk-Based Validation for Oracle Cloud SaaS Environments

apps associates®

As medical device companies shift to Oracle Cloud SaaS, maintaining GxP compliance requires a new approach. While cloud infrastructure risk is reduced compared to on-premise environments, the frequency of updates and evolving deployment models introduce unique challenges for validation teams. Leveraging the industry approved Computer System Assurance methodology, we ensure audit compliance while maintaining a streamlined approach to validation.

AppsAccelerate for Med Device: Validation as a Service is designed to help life sciences organizations build a modern, scalable validation strategy—one that supports Oracle Cloud applications while aligning with GxP requirements and your internal quality procedures.

Key Features & Benefits

1. Risk-Based GxP Validation for SaaS Architectures

Prioritize what matters most while reducing duplication and relying on Oracle's built-in compliance measures.

- Focus validation on GxP-relevant functionality only
- Leverage Oracle SOC I certifications instead of traditional IQ documents
- Maintain traceability from risk assessments to functional requirements and test results

2. Proactive Release Readiness & Change Control

Stay ahead of Oracle's frequent update cycles with structured validation planning..

- Assess Oracle Release Notes for impact on validated functionality
- Maintain reusable regression test scripts for streamlined re-validation
- Use of a dedicated UAT/validation pod to isolate and lock down tested configurations

3. Plan and Control Validation Framework

Apps Associates delivers a proven, pragmatic validation methodology tailored for Oracle Cloud SaaS.

- Create or align with Master Validation Plans and client SOPs

- Train project teams on documentation formats and Good Documentation Practices (GDP)
- Monitor deliverables to ensure alignment with validation standards.

4. Seamless Alignment with Internal Quality Systems

We integrate our approach with your existing quality processes and documentation infrastructure.

- Compatible with client document management systems
- Support for SOPs covering Change Control, Incident Resolution, and Risk Assessment
- Deliverables formatted to fit your internal validation framework

5. Flexible Add-On Services

Extend validation capabilities and streamline compliance activities.

- Validation templates and documentation accelerators
- Managed Services for ongoing SaaS patch release planning
- Integration with broader AppsAccelerate for Med Device offerings

Solution Snapshot: SaaS Validation in Action

Balance agility with compliance by adopting a validation approach purpose-built for Oracle Cloud SaaS. Focus your efforts where they deliver the most value—GxP functionality—while leveraging cloud-native tools and certifications to support your validation strategy.

Why Choose Apps Associates?

Apps Associates brings deep Oracle Cloud SaaS expertise and a long history of supporting validation for regulated medical device manufacturers. Our Validation as a Service offering delivers a risk-based, cost-effective path to maintaining compliance—without slowing down innovation.

Benefits at a Glance

- ✓ GxP-focused validation aligned with Oracle Cloud SaaS
- ✓ SOC I reliance to reduce validation overhead
- ✓ Streamlined re-validation and release impact mitigation
- ✓ Seamless integration with quality and documentation systems
- ✓ Fast implementation with ongoing support options

Contact Us Today

Learn how AppsAccelerate for Med Device: Validation as a Service can help you stay compliant, reduce risk, and accelerate your move to the cloud—without compromising quality.

About Apps Associates

Apps Associates is a premier enterprise applications and technology advisor, counseling and executing across every stage of the enterprise transformation journey—not just the destination. For more than two decades, Apps Associates has closely collaborated with decision makers across nearly every industry, offering end-to-end integration, modernization, and cloud migration services. By helping to break down the silos within today's most complex business challenges, Apps Associates is unlocking solutions and efficiencies that scale into future opportunities.

To learn more about how Apps Associates can help you align your business with the right technology, visit: www.appsassociates.com, or follow Apps Associates on social media on Youtube and LinkedIn.

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