

Application Managed Services: GxP Release Management Support for Oracle Cloud Applications



Today’s businesses are under pressure to transform rapidly – most likely your company has begun to leverage more diverse and complex enterprise application and technology portfolios. Inevitably, this makes managing your applications more complicated and consumes additional resources.

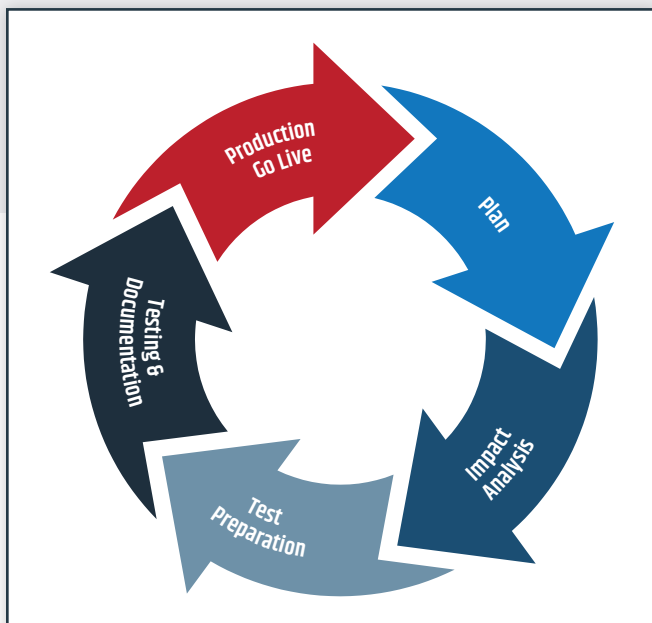
There are additional considerations required when operating in a GxP compliant environment.

What are those considerations?

- Evolving Government Agency Regulations regarding Computer System Validation / Computer Software Assurance (CSV/CSA) Processes.
- Continuous System updates - Quarterly/Monthly Updates are applied to Oracle Cloud applications for continual function and feature improvements, requiring proper analysis and testing to validate GxP compliance.
- Interpretation of Release Notes.
- Time and skill to maintain requirements, configuration, testing, and trace documentation necessary for FDA compliance.
- Time required to complete regression testing and address any issues prior to production deployment.

Apps Associates has been successfully executing a Release Management Service to address these challenges.

- Computer Software Assurance expertise provided by subject matter experts – Apps Associates maintains a validation support staff that is experienced in life science industries and CSA available to assist Release Management services in ensuring compliance with current FDA CSA guidance.
- Proactive planning, analyzing, testing, validation and support of Oracle updates and new feature implementation - GxP compliance.
- Technical skills to interpret Release notes and provide summary of new features.
- Maintenance of CSA documentation to align with new feature implementation.
- Risk based CSA approach to eliminate inefficient workflows and maximize testing critical functions. Reduced time of regression testing through test automation.



The full cycle of planning, analyzing, testing, documenting and supporting new software releases prior to Production deployment is covered through a proactive approach using **GxP Release Management Services**.

Services include:

- Assessment of Oracle Release Notes, preparation of Impact Analysis
- Recommendations of relevant new features
- Preparation of Change Control & Validation strategy for new features
- Update of Requirements, Design Specification, Configuration Specification
- Performing GxP Risk Assessment
- Preparation of Risk based Test strategy & Test plan
- Building client specific testing scenarios & Trace Matrix
- Creation of manual and automated test scripts for new features
- Execute / Record required new scripts

Leave It To The Experts...

With Apps' deep expertise in supporting and testing multiple customer environments in Life Sciences, you will get a breadth of knowledge that is simply unmatched.

Apps' has subject matter experts with many years experience supporting life science companies with Computer System Validation and Computer Software Assurance. If there is a specific scenario that requires additional attention, we will collaborate with your compliance team to ensure that your regulatory and business needs are met.

What does this mean for you? Benefits include:

- ✓ Proactive approach for proper preparation and execution of Oracle quarterly updates
- ✓ Efficient and complete coverage of mission critical applications
- ✓ Clear and complete analysis of updates and the impact to Cloud applications
- ✓ Expertise in Life Sciences and in Risk-based CSA approach to software validation.
- ✓ Full suite of test scenarios and scripts for covering GxP compliance and more
- ✓ Breadth of expertise across application footprint.

We act as an extension of your IT, Validation, and Compliance teams so that you can focus on your business. Ready to learn more? Visit us online [here](#), or call +1.855.466.5066.

Our Strategic Partners



About Apps Associates

Apps Associates delivers a breadth of services, unwavering dependability and unparalleled agility that drives ROI. Apps Associates is a trusted partner for the management of critical business needs, providing strategic consulting and [managed services](#) for Oracle, Salesforce, [integration](#), [analytics](#) and multi-cloud infrastructure.

We differentiate through our relentless attention to delivery excellence and customer care. Apps Associates is an [Oracle Partner](#), a [Premier Consulting Partner with Amazon Web Services](#) with competencies in Oracle and Managed Services, a [Salesforce Silver Consulting Partner](#), [Snowflake Select Partner](#) and [Boomi Partner](#). No one has managed more Oracle to Cloud migrations than Apps Associates, giving us deep-rooted expertise that is second to none.

Operating in the North America, Europe and India, we've maintained long term partnerships with our customers as a result of the high quality solutions that our experts design, deploy and manage. These solutions are developed using our proprietary global delivery model under the ITIL. Our consultants work closely with our customers to create solutions from concept to deployment leveraging Oracle technology to improve their business performance through streamlined processes, improved insight, and an integrated IT environment.

