White Paper

Application Delivery Management

Unleash the Power of Your Healthcare Business with Micro Focus ADM

by Ying Lei, Product Marketing Manager, Micro Focus

Healthcare and Pharmaceuticals is one of the most regulated industries, with high complexity. Therefore, it's critical to manage risk and implement a robust change management system. However, achieving and maintaining regulatory compliance creates high overhead. To remain competitive, using Agile software development has become a trend. Mobile/Cloud apps are gaining significant popularity in providing new approaches to disease monitoring, patient/doctor communication, and more. However, these apps make regulatory compliance even more challenging. Are industry CIOs ready to meet the challenge?

MICRO FOCUS

Table of Contents

page

With the consumerization of healthcare, more and more hospitals are recognizing the need for patient engagement tools, with features such as cost estimators and mobile schedulers.

What's Up in the Industry?

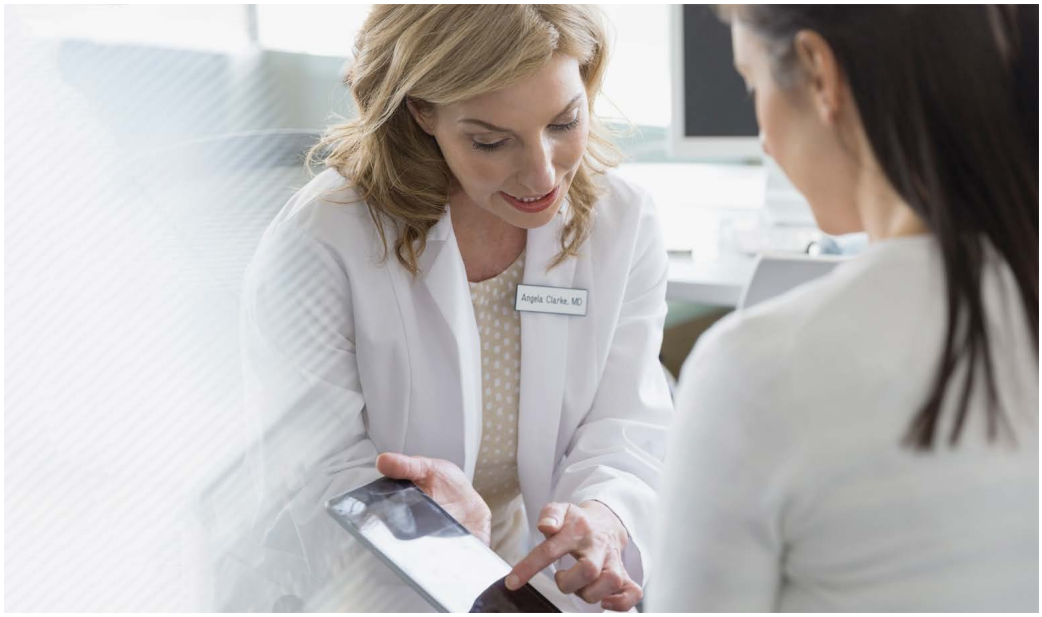
The Compliance Burden

The healthcare and pharmaceutical industry has a documentation culture primarily created by the need for compliance to regulations and providing evidence for regulatory inspections. With fears of "missing information," companies tend to document more than is necessary. However, this leads to high overhead and the likelihood of inconsistent and unsearchable documents. Some companies are still using paper-based solutions for documentation and validation, simply because they are so overwhelmed by the daily validation activities and don't have capacity to implement more efficient solutions.

New Challenges

The increasing need to develop personalized medicines and healthcare services has increased the complexity for this industry. With the consumerization of healthcare, more and more hospitals are recognizing the need for patient engagement tools, with features such as cost estimators and mobile schedulers. An aging population and insufficient funding are adding to the challenges for healthcare providers.

With only 1 in 5,000 drugs ever making its way into the market, the investment risk is tremendous. For a drug that does reach consumers, it often takes at least 10 years to develop it to the standard of quality and safety necessary. Costs can total up to billions of dollars before the drug is even licensed for use. With the ever-increasing cost of drug development, many companies can no longer afford the R&D cost. They resort to mergers and acquisitions for patents and strategic changes.



Regulations are more stringent and price controls are tighter. Payers and regulators strive to replace as many off-patent original drugs as possible with generics. These have forced many firms to find cost-saving measures.

Many healthcare and pharmaceutical companies have found it necessary to change their business models and leverage new technologies in order to cope with these new challenges.

To help companies understand and meet GMP regulations, "Good automated manufacturing practice (GAMP)" is created by industry leaders.Implementing the GAMP approach isn't easy, and leveraging the right vendor tools will make a big difference.

How Micro Focus Application Development Management Solutions Help

Regulatory Compliance

Medical device vendors, healthcare providers, and pharmaceutical companies must maintain scrupulous records on all aspects of their development, manufacturing, QA, and supply chain processes in order to comply with government regulations such as HIPPA, US Food and Drug Administration (FDA) Title 21 CFR Part 11, Part 210 and 211 (CGMP), Eudralex Vol. 4 Annex 11 (EU Annex 11), and others. Failing to comply leads to hefty penalties and damaged reputations. And while compliance is important, companies want to reduce the overhead associated with it so they can focus their energy on innovation.

Good manufacturing practice (GMP) guidelines have been created to provide guidance for manufacturing, testing, and quality assurance in order to ensure that a manufactured product is safe for human consumption or use. GMPs are enforced in many countries. To help companies understand and meet GMP regulations, "Good automated manufacturing practice (GAMP)" is created by industry leaders. Implementing the GAMP approach isn't easy, and leveraging the right vendor tools will make a big difference.

AUDIT TRAILS

Electronic Record Management is a key requirement by FDA 21 CFR Part 11. Records need to be accurately generated.

If any data record changes were made, the history should be recorded and no one can alter the history. With Micro Focus® ALM /ALM Octane, this can be easily achieved —the audit log displays the date and time of the change and the name of the user who made the change to any entity in the system. Audit log is automatically generated and cannot be manipulated by anybody.

ELECTRONIC SIGNATURE

The regulatory compliance activities also involve people in many different roles. One of the most critical requirements is to ensure that authorized individuals have authenticated all test results with an electronic signature. Many e-signature solutions are separate from the ALM tool; they have higher cost overhead and a greater likelihood of issues with integration and maintenance. Micro Focus offers its ALM e-signature solution built on top of the ALM workflow mechanism, which makes it fast to implement and easy to maintain.

Micro Focus Application Lifecycle Management (ALM) has been selected by many healthcare industry companies for the purpose of regulatory compliance because of its end-to-end traceability and its reporting capability.

END-TO-END TRACEABILITY

A main reason for the difficult nature of regulatory compliance audit and reporting is that the linkage between records is difficult to find. Weaving pieces of information into an audit report is a daunting task. Micro Focus Application Lifecycle Management (ALM) has been selected by many healthcare industry companies for the purpose of regulatory compliance because of its end-to-end traceability and its reporting capability.

From requirements to source code, test cases, test runs/results, defects, and executables, all information is saved in a central repository and is inter-linked. Drilling down to any detail is very easy.

GAMP emphasizes a lifecycle approach in computer system validation. Being a lifecycle management tool, Micro Focus ALM and its Enterprise Agile version ALM Octane fit this need well.

EFFICIENCY

The core of GAMP is risk-based quality management. The risk-based approach allows you to assess the risk of each part of the system, and focus on testing the high-risk areas. This makes the validation effort more efficient. Micro Focus ALM has built-in feature of risk-based quality management, which lays a good foundation for your GAMP implementation.

GAMP uses the V-model to demonstrate the relationships between each phase of the development lifecycle and its associated phase of testing. Steps in the V-model are sequential, following the arrows, and every next step should only be started when the previous one is completed. If your whole project is done with this sequence, it becomes Waterfall approach, and is likely to suffer from the problems such as late discovery of issues.

A more efficient way is to treat each agile sprint as a separate "GAMP V-model". This way, you can perform validation while the software is being developed. Micro Focus ALM Octane is your choice to execute the GAMP guideline with Agile. ALM Octane is not just an agile management tool with Requirement Management, its BDD (Behavior Driven Development) feature turns requirements into test cases, because it uses Gherkin language to describe test cases in near-natural language. And with the BDD test automation framework such as Cucumber, Gherkin tests can be automated very easily. The combined effect of agile, test automation and continuous testing is significant.

Manual processes and separate, multiple tools are also a primary cause of overhead in compliance activities. Micro Focus has a full set of Application Development Management (ADM) tools to help you automate manual processes. The key is integration, linking them together. These tools help you automate all types of tests, overcome the challenges of preparing the test environment, and gain insights from a large amount of test results.

By adopting Micro Focus ALM or ALM Octane as a single, centralized, automated quality management tool, healthcare providers and pharmaceutical companies benefit from a higher return on investment,

higher quality, and shorter test times and release cycles. ALM /ALM Octane enables you to boost efficiency through standardized processes, automated workflows, reusability, and automated data collection. Moreover, the analytics it performs on the development and test data gives you actionable insights into the status and trending of your computer system. With that, companies benefit from preventing problems rather than spending time reacting to them.

SECURITY

Another critical compliance requirement is security. Computer system security is a topic that spans many areas. Vulnerabilities in software are among the top causes of security breaches. That's why Micro Focus ADM tools include security testing as an integral component. Micro Focus's expertise in this area is reflected in its own software development. Its ADM and ITOM business units are ISO 27034-1 certified (the industry most advanced and demanding application security standard), which demonstrates proactive integration of security as part of Micro Focus software development lifecycle. Such expertise is built into its ADM tools.

By integrating with Micro Focus Fortify Static Code Analysis and Fortify Web Inspect, security tests are performed earlier and more frequently. Detecting security issues in the early stages helps companies to avoid the high cost of remediating code late in the cycle. It also significantly reduces the risk of a damaged reputation caused by security breaches.

By integrating with Micro Focus Fortify Static Code Analysis and Fortify Web Inspect, security tests are performed earlier and more frequently. Detecting security issues in the early stages helps companies to avoid the high cost of remediating code late in the cycle. It also significantly reduces the risk of a damaged reputation caused by security breaches.

Healthcare systems that go down because of high traffic is another security issue. The unavailability of critical information can put patients' lives in danger. The comprehensive Micro Focus testing solution covers all aspects of validation, including performance testing.

And, Micro Focus tools have helped customers to avoid regulatory penalties that can amount to billions of dollars.

Continuous Validation

Traditional validation for an on premises system can take months. The significant amount of work involved slows down healthcare and pharmaceutical companies. When changes need to be made to the system, re-validation consumes even more time. Is there a better way to do it?

Agile development has been gaining popularity in the healthcare and pharmaceutical industry for a variety of reasons. Agile leads to successful projects in terms of time, budget, and scope flexibility. In Agile practices, working code is documentation, and although continuous integration and testing lead to sufficient evidence for validation, presenting them to regulatory inspection agents can be challenging.

Micro Focus ALM Octane is a unique Agile management tool that connects the dots of all the evidence and associates them to requirements. With the DevOps pipeline set up, any change triggers the process of automatic build and test. Re-validation also occurs whenever there is change to the system, so the process can be repeated again and again without any pain.

And like other applications, functional, performance, and security testing are also needed for mobile apps. Micro Focus not only helps to automate these tests, but also provides Micro Focus Mobile Center to manage them in an integral way.

ALM Octane inherited the Micro Focus tradition of best-of-breed quality management. Its reporting capability enables you to present the information needed for validation in a clear and structured way. The Agile approach enables continuous validation of your systems.

Mobile and Cloud

Global digital transformation is changing the way healthcare providers interact with patients. Applications have become the face of healthcare companies. Patients have access to more information to help them choose healthcare providers. In this increasingly competitive industry, a good public-facing app has become essential.

And like other applications, functional, performance, and security testing are also needed for mobile apps. Micro Focus not only helps to automate these tests, but also provides Micro Focus Mobile Center to manage them in an integral way.

The variety of browsers and devices people use to run apps is huge. You can't control which devices patients use, but if your app doesn't work well on a particular device, it immediately impacts the patient's perception of your business. Thus, test automation (the capability to use one tool to manage different test types, different browsers, or devices) is critical to the success of any company's digital transformation. The number of operating systems, devices, and browser types that Micro Focus Mobile Center supports is among the largest.

Mobile app testing also includes the server side, which communicates with the app over the mobile network. End-to-end testing can be very difficult if you don't have the full environment. With tools such as StormRunner Functional, StormRunner Load, Network Virtualization and Service Virtualization, Micro Focus solves this challenge by provisioning your server machine in the cloud in just a few minutes, along with the simulated mobile network and other services your app relies on. Tests are performed in nearly the same environment as the actual one.

In addition to the Micro Focus ADM solutions, customers also benefit from Micro Focus AppPulse Mobile, a user experience management tool. It scores your app's user experience, based on all aspects of its performance—as perceived by your users. With this level of insight, healthcare companies are able to improve the user experience.

Medical Device Testing

The testing of medical devices has its own special challenges different from other software testing. Micro Focus recognizes the need for manual testing on the manufacturing floor or during onsite field testing and clinical trials, where connectivity can be limited. Managing this kind of test as part of the development and manufacturing process is not easy, especially if you want to test early and test frequently while keeping your test run information into a centralized repository.

Micro Focus meets this need with its QoT (Quality of Things) ALM client. With your whole product development managed by Micro Focus ALM, requirements and test cases are stored there. The QoT client runs on a mobile tablet or a laptop and downloads the test cases when connected to ALM server. After that, tests can be performed without consulting the ALM server. QoT generates log files to help analyze any issues later, and you can submit defects during the test. The test results and defects are uploaded onto ALM server when QoT is reconnected.

QoT enables you to test early, for example, when the medical device is still a prototype and you bring it to field testing. It also enables you to test frequently, as it makes it very easy to perform tests during different manufacturing phases, at different places and for different purposes. With all the test data consolidated in Micro Focus ALM, your products will always be ready to pass the regulatory audit. They receive certificates and hit the market in shorter time, which brings great advantage to your business.

Conclusion

Micro Focus Application Development Management solutions have helped many healthcare and pharmaceutical industry companies unleash their power to deliver better services and medicine to patients. They are designed for compliance to regulatory requirements, and deliver the following values:

- Generate accurate data and ensure date integrity and authenticity
- Timely and automatically collect data in preparing for internal and external audits
- Rule based workflow management and template driven report creation
- Compliance analysis to locate bottlenecks in the process
- Greatly improve efficiency in regulated computer systems validation
- Equip healthcare companies with top-class agile management and mobile testing tools while ensuring compliance
- Integrate with a large variety of tools/applications

Here are some customer stories that have proven these values. See how much savings and improvement they've achieved:

- Abbott
- Biogen
- UCB
- Harvard Pilgrim HealthCare
- Independent Health (Functional Testing)
- Independent Health (User Experience)
- ProHealth Care

Learn more at
https://software.microfocus.com/en-us/solutions/app-dev-test-delivery