



# How Appian Supports GxP Principles for Life Sciences Companies

Appian is dedicated to configuring software solutions for the Life Science industry that satisfies Title 21 CFR Part 11 requirements as well as GxP (i.e., GMP, GCP, GLP, and GAMP). We recognize our life science clients must follow good practices (GxP) to ensure their manufacturing processes, clinical trials, technology transfer/scale ups, and post-marketing surveillance activities meet very specific compliance and quality requirements. Appian's core architecture includes many features that assist in validation and ensuring compliance to relevant international quality standards and best practices.

Before we review the elements of Appian's core architecture that support GxP, it is important to note how configuring applications in Appian is dramatically different from other software approaches. Applications in Appian are developed using graphical business process models instead of writing computer code. These models serve as both the documentation of the application as well as the executable artifact that performs the application's functions. In creating applications for clients, Appian's professional services team employs an agile development methodology that leverages short development cycles and constant customer and subject expert feedback to ensure the right solution is delivered as quickly as possible. Because our solutions are created on graphical models and not hand-written computer code, it is easy to share mid-stage development with business users. This evolutionary approach creates transparency in the development process and facilitates a constant feedback loop for continuous requirements validation. This results in applications that are generally delivered with higher confidence in a shorter time period and at a lower cost.

## APPIAN PRODUCT DEVELOPMENT SUPPORTING GXP AND VALIDATED SYSTEMS

Appian is committed to quality across our products and services, all areas of the customer experience, and our company as a whole. It is important that we can ensure our software platform performs to the highest standards and that the underlying technology being used to create business solutions is tested and validated before being released.

Our own internal software development process is based on industry best practices and singularly focused on the effective implementation of highly scalable, robust, and usable software. Appian's software development approach embodies many CMM (Capability Maturity Model) strategies, ensuring product quality through a rigorous software validation and auditing process. In short, Appian software is not considered Generally Available (GA) until it has successfully passed a series of validation procedures including the categorisation of defect severity and defect priority—as well as a battery of tests including endurance tests, stress tests, security, platform compatibility tests, and regression tests.

Appian has made significant investments in a complete, robust, and continuous-integration testing framework. Over two hundred and fifty thousand automated unit tests are performed, functional user interface (UI) testing scripts are run, and automated performance tests are run against each code commit. Hundreds of code commits are performed per day. A 48-hour stress test is performed every weekend, and Appian maintains a separate Rapid Response Team (RRT) focused on delivering high-priority fixes and patches independent of the standard Scrum sprint cycles.

Importantly, Appian clients are involved in the ongoing product development/enhancement process in a number of meaningful ways. We work closely with our customers and partners to incorporate their feature requests into our product road map, and our customers are encouraged to submit enhancement requests to the Appian Product Support group.

## APPIAN TECHNICAL FEATURES FOR SUPPORTING GXP AND VALIDATED SYSTEMS

The following is an overview of the technical features most important to our customers who must adhere to strict requirements for quality management systems and therefore need excellent capabilities for auditing, traceability, archiving and record retention, accountability and non-repudiation.

### Secured System Access

- **Security Mechanisms** - To help ensure accountability under GxP and in validated systems, applications must ensure that data is managed in a highly-secure manner. This section reviews specific features of our software that govern who has access to view or edit business data within applications built using Appian.
- **Secured System Access** - Appian is a 100% web-based platform which is built such that use of the industry-standard HTTPS/TLS protocol is required for all communications. By using this secure communications channel, data in transit between the user and the system cannot be altered.
- **Security Logging and Auditing** - Collecting detailed security and access information is a significant concern for many of Appian's customers. Appian's authentication layer, which complies with PCI Data Security Standard (PCI DSS) v3.1 out-of-the-box, provides detailed logs of all user access attempts, including success/failure status, username, timestamps, IP addresses, and the type of device used. Additionally, since this layer is built on top of the ubiquitous Spring Security open-source authentication and access-control framework

(by VMware), it provides additional extensibility hooks allowing for easy integration with virtually any other third-party system for further security processing, logging, or auditing, such as a Hardware Security Module (HSM), other Identity Management (IdM) system, or any other security auditing databases or applications.

- **Role-Based Application Access** - Appian applications are developed in a role-based manner, where each feature of the software is secured to users serving in a particular role. Only those users that have been explicitly granted membership into those roles by an administrator will be able to perform permitted actions.

## DATA, ACTION, AND DECISION AUDITING

An essential element of GxP in software is the logging and auditing of all actions taken within the application whether they stem from launching new processes, manipulating the data in already-running processes, or determining how automated, rule-driven decisions were made. The following features cover these concerns.

- **Process Audit Trail** - A key reason for life science customers selecting Appian stems from our ability to comprehensively audit and trace business data. A key feature of Appian is that every action performed in a running process instance is logged into a secure audit trail. These audit trail tables also provide historical tracking of changes to all data elements, including who made the changes, at what date and time they occurred, and to what value. This information is easily available and retrieved by a System Administrator in an easy to understand format as displayed in the image below. This audit trail data is also available through reports inside of Appian and can be pushed to other reporting, auditing, or logging systems.

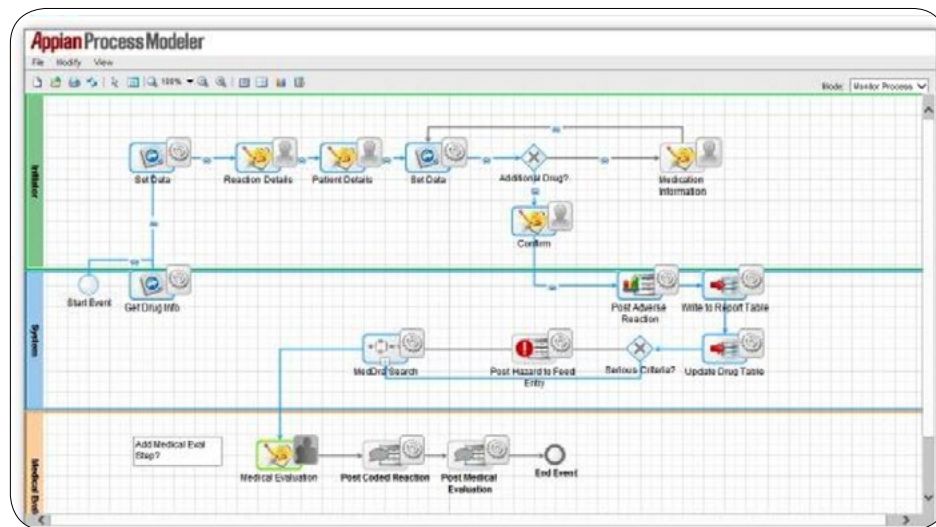
Clinical Health Assessment for Drew Sandoval				
Started by Ryan Gates on Oct 30, 2014 10:23 PM GMT+01:00. Current status is Active.				
<a href="#">Current Tasks</a>   <a href="#">Quick Tasks</a>   <b><a href="#">Process History</a></b>   <a href="#">Process Nodes</a>   <a href="#">Variables</a>   <a href="#">Sub-Processes</a>   <a href="#">Attachments</a>   <a href="#">Notes</a>				
Show [25] 100				
Date & Time	Object	Action	Actor	Properties
Oct 30, 2014 10:23 PM	Clinical Health Assessment for Drew Sandoval	Start	ryan.gates	
Oct 30, 2014 10:23 PM	appointmentData	Modify Variable	ryan.gates	Changed to [id=180, patientName=Drew Sandoval, patientPhone=(576) 159-6012, appointmentDate=12/24/2014, assignedNurse=, chaLocation=, timeframe=AM, isFlexible=, schedulingNotes=, memberInfoId=, appointmentStatus=Not Started]
Oct 30, 2014 10:23 PM	Start Event	Start	System	
Oct 30, 2014 10:23 PM	Start Event	Complete	System	
Oct 30, 2014 10:23 PM	Capture Visit Information	Start	System	
Oct 30, 2014 10:23 PM	Capture Visit Information	Assigned	System	Assigned to <a onclick="doUserDetail('ryan.gates')">ryan.gates</a>

- **Process Model and Business Rule Versioning** - Another feature enhancing the auditability of applications created with Appian is the automatic versioning of process application artifacts and the retention of process model change history. The ability to easily change and improve processes is a central benefit of using Appian. But every change technically creates a new version of an application. To negate any concerns from such flexible software, Appian maintains all historical process model and business rule versions indefinitely.

This provides not only the means for rollback during the development lifecycle, but also to review previous process models for GxP auditing or investigation purposes. Appian tracks as-is process execution regardless of what the current version of the business process model may be. Each Appian process instance is tied to the process model version it was executed on regardless of when the process was launched or how much the process model may have changed since then, Appian will display the correct version of the process model and audit trail for each individual process instance.

- **Process Monitoring** - A feature that is also commonly used to assist in illustrating the auditability of Appian is the Monitor Process view. Any Appian process instance can be viewed in Monitor Process mode inside Appian's Process Modeler. This provides another view into the audit trail of the process instance and displays the process model for that particular instance's version, regardless of when it is viewed. The modeler will show highlighted in blue the path that the process has taken. The nodes where the process is currently waiting (if it is still a running process) are highlighted in green as noted in the image below.

Additionally, the end-state values of the process data can be easily viewed..



- **Saved Task Forms** - Appian also provides the ability to save a read-only snapshot of the exact state of any task form as it was submitted by the user, which can then be viewed at a later time. This gives administrators yet another tool to demonstrate what exactly occurred during a process instance's execution.

## AUTO GENERATED PROCESS DOCUMENTATION

An important facet of following GxP is being able to tie system documentation to its implementation. Appian's Process Modeler provides a feature to automatically generate highly detailed process documentation for any process model version. This allows Appian administrators to more accurately retrieve documentation for any process version at any time in the future. By being able to produce the process instance data and audit trail, along with the complete documentation for that given model version, those responsible for GxP auditing or investigation can quickly produce the artifacts they may need. The image below shows a sample of auto generated documentation.

## AUTOMATED PROCESS ARCHIVAL

Data retention is critical of any system. Appian has answered this concern with very powerful but easy-to-use automated process archival features. Each individual Appian process model has configurable settings for automatic archival of completed process instances as shown in the image below. Processes are written to disk in archival files and include all process data and the full audit trail from beginning to end. Archival files are typically written to secure media such as a SAN, computer tape, or other data storage medium, and are stored according to customer's data retention policies. If ever required, Appian's archive files can be un-archived back into Appian, which can then be viewed using the various tools mentioned previously such as the audit trail reports and Process Modeler in monitor mode.

**Appian**

### Clinical Trial Parent

**1 Process Model Properties**

Process Display Name: "/Clinical Trial Parent: "Spv/uid  
Model Id: 3508  
UUID: 000229e6-1c07-8000-ae7b-080000000000  
Last updated: Jun 1, 2013 9:13 PM CEST by elizabeth.ecstein@appian.com

**2 Process Model Diagram**

The diagram shows a process flow starting with 'Initiate Transition to Site Monitoring'. It branches into two paths. The top path includes 'Add Items to SCP', 'Set Site Rules and Monitoring Schedule', 'Post New CTR to Feed', and 'Confirmation Follow-up Letter Template'. The bottom path includes 'Get Trial Details from DB', 'Set Top Level Folder', 'Modify Process Security', 'Update DB', 'Spin off Site subs', 'Update Status', and 'Post Completion to Teams'. A separate section at the bottom shows a flow starting with 'Quick Tasks Ready' leading to 'Reassign Lead CRA', 'View All Queries for Trial', and 'Update DB', ending with 'END Event'. A 'Trial Ending Timer' is also shown.

**Automatic Process Clean-Up** Selected configuration will apply to all versions of this process model [Help](#)

- Use system default (currently: Auto-archive processes 30 days after completion )
- Archive processes 30 days after completion or cancellation (0-999 days)
- Delete processes 0 days after completion or cancellation (0-999 days)
- Do not clean-up processes

## DOCUMENT MANAGEMENT AND CONTROL

Appian's built-in Content Repository provides all of the essential features for managing documents throughout the running of business processes in a validated system. The Content Repository allows users to upload and download documents which can be "attached" to running process instances. All access to documents in the Content Repository is logged, and check-out / check-in capabilities ensure that document changes are tracked and managed without losing any critical information. All files in the Content Repository are versioned, so the exact state of the file at a particular snapshot in time can be retrieved to assist in auditing and review related activities.

## PROCESS AND BUSINESS RULE TESTING

To ensure compliance with GxP, applications must be easy to test to ensure they perform as intended. Appian includes several features for testing process flow and rule execution to help ensure that the system behaves exactly as intended. Appian provides a mechanism for testing business process models by running processes in a debug mode to test behavior. In addition, Rules that support decisions and dynamic logic in processes all have the ability to define automated tests. Rule tests with custom test assertions may be run in bulk to validate behavior after any change.

	Name	isbn	Output	Assertion	Time (ms)
❌	Standard Test	9780385530828	(info_uri:http://openlibrary.org/books/OL25441336...	Output: (info_uri:http://openlibrary.org/books/OL...	
✅	Test for Bad Text	ERRORTTEST	null	No errors	224
✅	Test for incorrect characters	!@#%&'()*	null	No errors	190
✅	Test for null value	null	null	No errors	187
✅	Test for large string	ASDFGHJKLZXCVBNMQWERTYUIOPASDFGH...	null	No errors	207

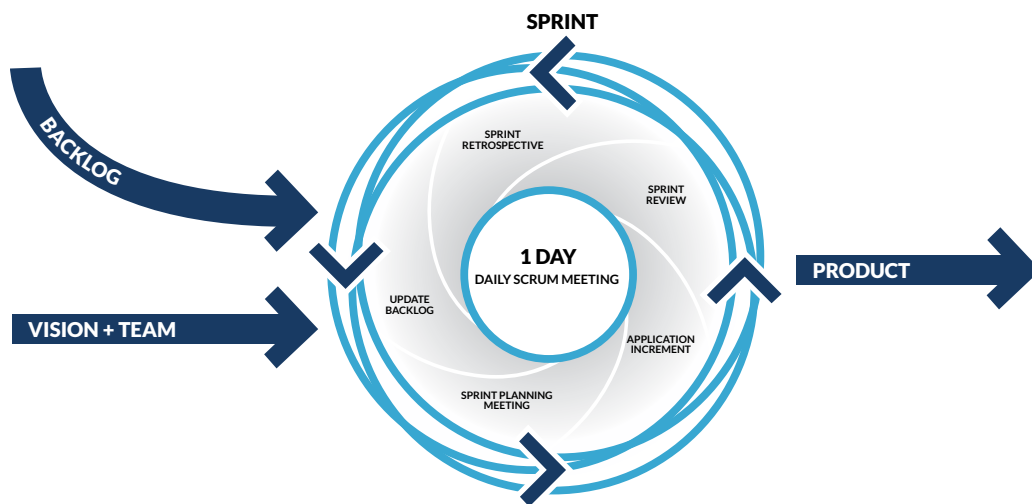
## APIAN CONSULTING FOR GXP AND VALIDATED SYSTEMS

Because Appian is a platform for creating business applications, the final responsibility for implementing GxP practices rests with those actually creating specific applications. Appian's professional services staff are experts in implementation methodology and will deploy the components and features inherent in our platform for optimal design. Appian's partner organizations are well versed in GxP principles so together we can ensure delivery of validated applications that comply with GxP.

Our implementation methodology begins with creating the solution blueprint that identifies the business program's vision and goals and the clients' requirements for compliance with regulatory and legislative controls. The operational drivers and requirements are combined with our world class BPM platform to create the functional blueprint for the client solution.

Partnering with our clients' subject matter experts, we then iterate through more detailed areas of design and elaborating on the detailed requirements, to drive out compliance requirements, validation and acceptance criteria and risk management aligning with methodology such as GAMP5.

As we move into the final solution configuration, through our agile delivery methodology, the cycle of sprints ensures a deep focus on concentrated areas of solution development and functionality that aligns configuration with acceptance criteria. Tools such as a validation test matrix will map to the sprint backlog and the testing of each sprint's releasable product facilitates the easy production of validation summary reports.



Appian is a powerful Business Process Management platform enabling our clients around the world to create solutions that meet their requirements in many regulated environments such as financial services and banking, government and public sector, as well as life sciences. The business solutions that are created will regularly either support operational compliance or themselves be under the scrutiny of controls. The key to success in this respect is having a powerful tool, with experienced consulting teams, partnering with our clients who bring the deep domain and subject expertise.

## CONCLUSION

Meeting and exceeding GxP validation requirements when developing business applications depends on security, transparency and traceability. Appian is a model-driven business application and work automation platform with advanced security and audit trail features built-in. Creating applications on the Appian Platform makes it easy to trace specific functionality to requirements and specifications. The validation steps are transparent at every step of the application build process. Building on Appian circumvents the challenges inherent in validating systems that were pre-built for generic requirements by third-party software companies. Applications created from pre-built frameworks, or packaged solutions, must be fully understood and in many instances, their handwritten computer code must be decoded and deconstructed before they can be validated. On the other hand, Applications built using Appian are fit-for-purpose and easier to validate. They are much more likely to meet specific needs by design, constructed using a modular approach, and built with the prospective users on hand in short, agile sprints, preventing the build from ever gravitating too far from the specifications and requirements.

