



Information Document



Genial Compliance Systems
P.O. Box 3751, Chester, CH1 9UF, United Kingdom
Telephone & Fax: +44 (0)1244 757155
Web: www.genialgenetics.com
Email: info@genialgenetics.com



Rainbow Scientific Inc
83 Maple Avenue, Windsor, CT 06095
Tel: 860-298-8382 Fax: 860-298-8586
Web: www.rainbowsscientific.com
Email: info@rainbowsscientific.com



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iPassport Overview

iPassport delivers a comprehensive solution for document control and compliance management for use across all disciplines. Building on this core functionality, iPassport also provides the following quality management tools:

- Comprehensive document control
- Standards/ Checklist management
- Auditing for self inspections
- Non-compliance event management
- CAPA management
- Incident report management
- Task management
- Equipment management with preventative maintenance reminders
- Staff competency
- Complaint management
- Reagent & consumables inventory control management
- Staff training event management
- Staff personnel profile management

You can take advantage of iPassport's extensive quality management tools without having to worry about system installation or maintenance support. It is a fully managed browser based application, hosted on high-capacity server clusters located at a secure data center. Data is backed-up daily and routine software updates are seamlessly provided as part of the comprehensive service, with this giving peace of mind.

iPassport delivers a comprehensive solution for single and multiple-site organizations. It standardizes and streamlines the management of policies and procedures while ensuring that your staff has access to the most up-to-date, authorized documentation.

iPassport can be accessed from any location having Internet access and is compatible with tablets and other smart devices.

The iPassport “Smart” Philosophy

We know how important your time is and have therefore designed the system to allow you to complete your objectives in the smartest way possible, while at the same time being fully compliant with regulatory requirements.

We have taken the time to streamline many processes within iPassport to make your life easier! These features include:

- Intuitive user interface with smart search and retrieve features
- **Coming Soon!** iPassport's smart start features include technology that allows you to import staff details from a database/ spreadsheet. Our smart document upload features will allow you to import hundreds of documents into iPassport in just a few clicks.



- **Coming Soon!** All system tasks, whether they are review tasks, staff knowledge events or document authorization events can be completed outside of iPassport via email.
- Smart document authorization. Medical director/ lab director doesn't have the time to log into iPassport to complete tasks? No problem, iPassport's smart authorization feature allows for another member of the team to fill in all of the initial information, while the medical director simply receives an email from iPassport and is able to authorize the document securely outside of the system!
- **Coming Soon!** Smart revision info makes it easy for staff to quickly see what's new about each revised SOP
- Smart settings including customizable landing pages and user preferences
- Smart software updates. All system updates are deployed remotely and are seamless from the end users perspective
- Continual software development plan to ensure iPassport keeps pace with evolving requirements

The Importance of iPassport

Here and now "Quality" and "Compliance" are of critical importance to all healthcare organizations large and small. Studies have shown that the cost of non-compliance can be ten times more expensive in comparison to maintaining compliance on a routine basis.

Of the 7,000+ CAP accredited organizations, approximately 7% of clinical laboratories are cited for document control system failures each year.

The following examples highlight the things that can go wrong when stringent document control is not adhered to. When test components change, for example, reagent volume may need to be altered, or when suppliers change formulations, healthcare organization may need to update their documentation in order to maintain quality. To effectively manage such changes, established best practice deems that nominated personnel should perform controlled updates to the procedures, which should then be reviewed and authorized before being used to train staff. Printed copies of previous versions of the procedure should be destroyed and the electronic copy achieved as this may otherwise lead to users accessing out-of date procedures, culminating in inaccurate or incorrect test results.

The most common inspection citations include:

- Multiple versions of the same document being available in the lab simultaneously. Staff using both
- Failure to review procedures annually
- Failure to demonstrate staff procedure & policy review
- Missing electronic signature
- Failure to demonstrate management procedure & policy review
- Failure to archive previous versions
- Failure to make complete procedure manuals available at the workbench
- Incomplete documents
- Important information missing from a procedure
- During inspections, up to 5% of laboratories are cited for failing to review their Procedure Manuals on an annual basis



Problems associated with manual document control

There are several problems associated with manual systems. The following highlights just a few.

- The main problem with manual systems is that adherence to document review cycles for policies and procedures is not strictly followed. Invariably therefore some reviews are missed and having just one “uncontrolled” document in circulation can be sufficient to generate a citation.
- Manual systems are often ineffective at leading staff to read and sign-off on the latest versions of documents as they become available.
- When updating documents, user notifications are difficult to manage in manual systems as inevitably, some staff are overlooked and are therefore not made aware of the availability of new versions, thereby increasing the likelihood of working to obsolete documents.
- Unapproved document content changes are a common occurrence in manual systems.
- Manual systems make it difficult to maintain an accurate and up-to-date review history.
- Track Changes in Word™ is generally considered to be a useful tool for updating document content in some environments. It is, however, unsuitable for the clinical laboratory review process because there is no retention of superseded versions of the document as the same document is continually evolving; and once change suggestions are accepted or rejected, they are implemented or deleted but significantly not recorded. The document review history is therefore lost.

Through the use of a dedicated “Review Task” feature, iPassport addresses these shortcomings. The Review Task links a person to a document, and with its date and time stamped activity logs, a full and accurate review history for every document is maintained by iPassport.

- Manual systems make it difficult to maintain a full audit history.
- Forgetting to destroy associated documentation such as “job aids”, “cheat sheets” and “bench copies” can also lead to citations.
- Failing to make documents available at their point of use. Manual systems often struggle to provide controlled copies of documents to all those who simultaneously require them.
- Giving controlled access to the most recent document version as well as controlled access to superseded documents is also difficult to achieve in a manual system. Secure document retention is a CAP requirement
- A simple common server approach to making documents available to staff can often be an ineffective approach to maintaining accurate document control. Manual systems inevitably lack essential tools for reviewing, printing & tracking, controlling updates and more.



- Customization of such common server systems is expensive, time consuming and often produces a system that is inefficient and inaccurate to use.
- Common server systems lack essential compliance tools for standards management, auditing & CAPA.
- Lost Opportunity Factor: time, energy and cost invested in the development and maintenance of common server solutions is often lost upon discovery that manually developed solutions lack the sophisticated tools found in iPassport. Implementing iPassport from the outset provides access to advanced tools in a system that keeps pace with healthcare requirements.

The above problems are fully addressed by iPassport as it provides a precise systematic approach for implementing, modifying, and reviewing documentation in an easy to follow format for every policy and procedure. Standardization throughout all departments is achieved through iPassport's disciplined approach to maintaining controlled policies and procedures, with this resulting in sustained and continual performance improvements.

iPassport Benefits

Document Control Benefits

iPassport improves compliance and employee knowledge by allowing secure web access to relevant documentation from any location.

iPassport stringently controls user access to information within the system. For example, staff access to policies and procedures can be restricted to documents relevant to their job descriptions. Moreover, iPassport administrators can, for example, grant permission to only allow certain users to make changes to procedures.

Document Population & Retrieval

- The "Browse & Upload" feature allows you to import your existing policies and procedures into iPassport with ease.
- iPassport's comprehensive search engine allows you to quickly identify and easily retrieve documents

Document Review

- Comprehensive document review features. Comply with national and international regulations!
- Task management for document review events – schedule policy and procedure reviews for individuals/groups of people with email notifications
- Advanced communication technology - Users are notified/reminded of new and outstanding review tasks via email as well as within iPassport's centralized task management area.
- Complete flexibility of task notification release dates. This feature allows managers to pace the release of iPassport tasks and helps technical staff to prioritize workload.



- Keep everyone involved in document tasks up-to-date with automated notifications following change requests, approvals and task completion
- At-a-glance search feature for forthcoming reviews
- Automated future review reminder notifications

Document History

- Automatic document History feature – all major document events are automatically recorded within each individual document record. Each event is date, time and user ID stamped.

Document Approval Authorization

- Each policy and procedure can be approved for use by the appropriate authority within the laboratory
- Comprehensive document authorization – includes fully compliant electronic signatures
- Flexible document authorization options – medical directors can receive secure emails from iPassport containing a copy of the document for final review purposes prior to authorization – all done without even logging into the system!

Controlled Document Printing

- Controlled and fully traceable document printing - iPassport includes intelligent tracking technology to prompt system users to remove superseded documents from the point of use.
- Essential document control information, including titles, signatures, document status, revision number and dates are automatically inserted into all document footers

Controlled Document Updates

- Controlled document updates – fully controls the user's ability to update documents
- iPassport offers full control of document status such as "Draft", "Authorized", "Under Review" and "Superseded" - all corresponding to a specific stage in the document control process
- Comprehensive version control with corresponding version number increments
- Automated notifications for technical staff for each and every document update. To maintain accountability, staff are required to read and sign-off on having understood the content of the latest document version

Additional Document Control Features

- iPassport's "Calendar Feature" provides an at-a-glance view of all iPassport events, including forthcoming document review and audits



- Secure Document Emailing facility – provides a controlled link to the document to be sent to external organizations. iPassport will then automatically monitor remote access to the document
- iPassport ensures that technical staff have access to the most recent and controlled documents only, therefore improving compliance while reducing the inherent risk associated with out-of-date documentation.
- True document retention – all superseded documents are archived within iPassport, access to which is highly restricted to those having relevant system permissions.

Compliance Management Benefits

The feature list below allows your organization to easily monitor compliance to any regulatory standards, to perform audits, to assess compliance, and to take action to address any non-compliance issues.

iPassport system administrators can control exactly which areas of the system their colleagues can access, as well as setting their permissions within those areas.

Checklists and Standards Management

- iPassport includes functionality to allow the upload of all regulatory standards, checklists and surveys.
- The system's Import feature sorts checklists and standard sets so that each question/standard is displayed in its own individual record within iPassport.
- Individual standards/questions can be linked to relevant policies, procedures, staff profiles, training events etc. in order to build an evidenced-based audit trail for compliance.
- Linked evidence of compliance provides rapid and easy access to supporting documentation, allowing the audit process to be simplified and streamlined.
- Fully traceable user tasks may also be associated with individual regulatory items to aid compliance management prior to and following accreditation inspections.
- iPassport also incorporates an "Attachment Engine" that allows files held outside of iPassport to be uploaded, to be associated with a specific record within the system and can be accessed from any location by those who have relevant system permissions.
- Each individual accreditation regulation can be labeled as "Not Started", "Non Compliant", "In Progress", "Partially Compliant" and "Compliant".
- Electronic searches can be conducted to generate lists of standards/questions by category.

Audit Management

- iPassport's dedicated internal auditing facility allows clients to conduct compliance assessments as well as maintaining inspection readiness.



- Audit lists can be easily generated within iPassport allowing you to design the content of your audit.
- Audit lists can be used on a singular or recurring basis.
- Audits can be scheduled to take place on a specific date.
- Audit Lists can be printed from within iPassport to allow observations to be recorded on the move. Alternatively, record audit results and observations can be recorded within iPassport via your tablet or smart device!
- Audits can be scheduled to take place on a singular or recurring basis.
- Audits review features.

Non Compliance & CAPA Management

- Implement a culture of proactive problem solving rather than reactive trouble shooting
- Create non-compliance events and their associated CAPA management tasks via auditing, or as standalone events.
- Assign both corrective and preventative action (CAPA) management tasks to any non-compliance event to help identify and implement a corrective action plan.
- Assign corrective actions to staff members.
- Ability to create and assign preventative actions for avoiding non-compliances, these again can be assigned to staff & monitored through the central tracking area.
- The “Automated History” feature records all events and actions throughout the process.
- All completed corrective action tasks set to address non-compliances are returned to the authorized staff member for verification of completion to a satisfactory standard.
- Identify underlying problems and implement continual improvement through root cause (trend) analysis and reporting.
- A comprehensive non-compliance reporting system allows key information to be exported from the system in either PDF and/or .csv format
- iPassport’s “at-a-glance” tab summarizes all recent non-compliance events showing the status of any related CAPA tasks.

Additional iPassport Benefits

- Equipment Management – stores important equipment metadata.



- Equipment maintenance manager. This feature provides automated reminders of upcoming events as well as a comprehensive event logging system. Evidence of each maintenance event can be uploaded in the form of documentation and can be attached to each equipment record.
- Inventory Control. Monitor the usage of materials and reagents to control inventory levels. Provides low limit and stock expiration warnings when user defined thresholds are reached.
- Training Management Features. Stores and schedules internal and external training courses. Associate CEU points with each course, recorded in staff user profiles upon course completion.
- Manage staff annual appraisal events. Management staff can set objectives and training events for individuals.
- Staff Personnel Profile Management. Any document type can be attached to a staff record including scanned certifications and credentials. Access to these records is strictly controlled to ensure only relevant managers can open and review staff progress.
- Meetings Management. iPassport's comprehensive Meetings Management facility provides users with an ideal means to record agendas and minutes for subsequent distribution. These can be linked to standards and checklists to demonstrate regular meeting compliance. Meetings can easily be tailored to the attending user group where agenda and minute notes can easily be recorded and emailed to all applicable staff.
- Comprehensive Reporting Features. Creates reports across every iPassport feature.

System Security and Backup

iPassport is a hosted web application, providing a fully managed solution. User access to data is provided via SSL to authenticate clients. iPassport is managed and maintained by Rainbow Scientific Inc and Genial staff, with data being securely held at data centers provided by Amazon Web Services EC2 machines.

The iPassport application and stored data is hosted on two sets of dual (mirrored) high capacity servers. Information held is replicated between the servers in real time so in the event that one of the servers fails the other takes over immediately to optimize system uptime. Server cluster back-ups are maintained on three different physical storage locations. A back up event takes place every four hours. Access between the data centers and client machines is through 256 bit AES encrypted SSL channels. Access to the servers for permitted Genial Genetics staff is provided through SSH using RSA keys for authentication, all logins to the servers are logged and reviewed daily.

System Uptime

We are very proud of the fact that iPassport has an exceptional uptime statistic of 99.97%. This essentially translates to approximately 1 hour of system downtime per year, which can be attributed to essential system update and maintenance events.



Why Chose iPassport?

There are so many reasons why you should entrust iPassport for your document control and compliance management requirements. Client feedback has shown that the following factors are considered to be the most important when choosing iPassport for their document control and compliance management requirements:

- A combination of performance and price makes it the best value for money solution available
- It has been specifically designed for healthcare organizations where regulations for document control and compliance are understood to be more stringent when compared to, for example, those associated with manufacturing.
- More than 10 years experience in developing and managing document control and compliance management software
- Our support team has a wealth of knowledge in ISO 15189, ISO 17025, Public Health, Hospital and Academic quality requirements
- Rapid implementation into routine clinical service
- Easy-to-use and to navigate
- Intuitive user interface
- Fully supported with dedicated one-to-one online system training
- Every customer is given access to unlimited live chat telephone support
- Supported with video tutorials
- Supported by a dedicated team of product specialists, quality managers and IT personnel
- Dedicated features that simplify the process for directors, management and technical staff
- Advanced communication and notification technology
- Separate training (sandbox) account supplied to every organization
- Large established user base
- An effective solution for single and multiple site use
- Comprehensive system security and data back up
- No need for local installation, servers and maintenance
- Seamless software updates
- Continual software development plan to ensure iPassport keeps pace with evolving requirements
- Significant savings are available by entering into extended hosting service agreements



Client Testimonials

"The addition of iPassport's electronic document control system has helped bring us to the next level of managing all of our laboratory quality requirements. This system eliminated many manual tracking steps, thus removing time and wasteful steps from our process. We absolutely love the linking feature because it allows us to link our job aids, charts, and regulations right to their procedures. We can easily track training records throughout our facility and our many off-site locations and we are one step closer to a greener, paperless system! I would recommend this system to any laboratory looking to "lean" their processes with electronic document control"

"We are just beginning to use iPassport and already are amazed at how easy it is to communicate changes and provide the proper education with documentation to prove that education was complete. No more passing around "read and signs" only to have them lost!"

"I wanted to let you know that we had our first CAP inspection with i-Passport last week. Everything went very well and they were both impressed and envious with the iPassport system. Thanks for all your support during the past year"

"iPassport provides excellent functionality and ease of use like no other system for on and off site working for both scientists and administrative staff. Because we work on several sites, all staff can confidently access current procedures remotely and within a secure and fully tracked system. The system is easy to manage and provides real time managerial monitoring"

"Our facility had a CAP inspection in January. This was the second inspection for this site while we've been using iPassport. One of our other facilities had their first CAP inspection using iPassport in December 2012. Both inspections went very well. Both groups of inspectors were very impressed and somewhat envious of the iPassport system. With some written instructions and a short "tutorial" about how to use the system they were all able to navigate around and find the procedures and/or other information they needed to see. As always, Thank you for all of your continued help and support with the system"

"I wanted to let you know that we are really enjoying iPassport. Long story short the lab lost its accreditation a few years back and the department retooled and changed lab management. We incorporated iPassport fully into all of our processes and last month we had an onsite visit from the evaluation team from USDA. They were very pleased with iPassport and its capabilities and the way we were using it. Before they left they gave us their assessment and are recommending that we rejoin their network. That was great news! Thank you and your team for everything you have done for us, we really appreciate it!"

"Here at the Institute we have implemented a new QMS entirely on iPassport, a complete departure from the shocking paper-based system that has been the bane of my existence since I arrived here. It has been such a success that other departments in the institute, which would not normally have a need for such a product are interested in it's use."



Minimum Specifications

iPassport only requires a minimal PC specification to run successfully. For optimal performance, we recommend the following PC specification:

- Internet Explorer 7+, Javascript and cookies enabled. HTML editor - ActiveX enabled (IE only). Page redirect security enabled.
- Adobe Reader 7+ (To view PDFs)
- Memory: 256Mb RAM
- CPU: Pentium III (or higher)
- O/S: XP, Vista, Windows 7 (or higher), OS X
- Network: TCP/IP and client access to the internet at a minimum of 20k/sec download ability
- Monitor: Display with minimum pixel resolution 1024 x 768. (1280 x 1024 recommended)

No local servers or client-side software installation is required for your hosted iPassport system!

iPassport Training & Support

Remote User Training

iPassport is very intuitive to use. To use iPassport to its maximum potential from the onset, we provide live system training. A dedicated member of the iPassport training and support team conducts system training remotely via the WebEx service. The remote training service is provided in the form of hourly training credits to be used on a draw-down basis and can be spread across different sessions on different days.

iPassport Support

The iPassport hosting service includes unlimited on-line, telephone and email technical support. iPassport also incorporates a "Contact Support" link on every screen, allowing clients to electronically notify us of any issues for our immediate attention. All issues are logged and given a ticket number for rapid processing.

iPassport Training Account

With the iPassport hosting service, we not only give our clients access to a live account, we also give them access to a training account. The training account allows our users to familiarize themselves with all the quality management tools provided within iPassport without the risk of compromising the data stored within their live accounts.

Online Demonstration

Ready for a system demonstration? The best way to learn more is via a one-hour online demonstration. Upon request, a no-obligation demonstration of iPassport can be provided to your organization via WebEx at a time that suits you. If you would like to see a demonstration, please let us know and we will be pleased to provide access details. You can contact us at info@genialgenetics.com