

iPassport

eQMS for life sciences and healthcare

G-Cloud 15

Service Definition Document

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iPassport Introduction

iPassport is a managed software service designed to help digitise, streamline and improve the day to day management of quality and compliance.

This easy to use system significantly reduces the time, frustration, costs and risk associated with achieving recognised quality standards by eliminating paper based processes, digitally centralising all relevant policies and procedures and delivering a streamlined mechanism to prepare for audits.

iPassport provides a complete suite of quality management modules, allowing you to easily keep on top of everything from controlled documents to staff training records. Modules include:

- Document Control
- Audit Management
- Non Compliance and CAPA Management
- Supplier Management
- Asset and Stock Management
- Competency Management
- Feedback and Complaint Management
- Change Control Management
- Risk Management

Service Delivery Overview

Provision of an iPassport QMS for every customer includes:

- A comprehensive suite of quality management modules included as standard
- Continual system improvements via new software releases
- Separate Live and Training accounts
- Unlimited help desk support
- Access to online user guides and knowledge base content
- Training

Optional items:

- iPassport Export Service – subscription service allowing customers to maintain an offline backup of their controlled documents.
- iPassport Validation Service – subscription service supplying quarterly system validations conducted and signed by our expert team.

User Licenses

iPassport is supplied using a concurrent licensing model. This allows users set up with administrative privileges the ability to create an unlimited number of user accounts on the system. The number of users who can access the system simultaneously is governed by the number of licenses purchases, of which there are two types:

- 1) **Editor License** – can perform any activity in iPassport which their permissions allow.
- 2) **View Only License** – can search and view records which they have permission to view, complete tasks assigned to them, raise change requests on documents, and amend their user profiles.

Implementation and Training

Genial work closely with all our customers to ensure that any implementation plan is realistic and agreed by both parties. Typically, this would start with an introductory meeting between a named, lead-trainer on the Genial side, and key personnel on the customer side who have been identified as leading on the implementation.

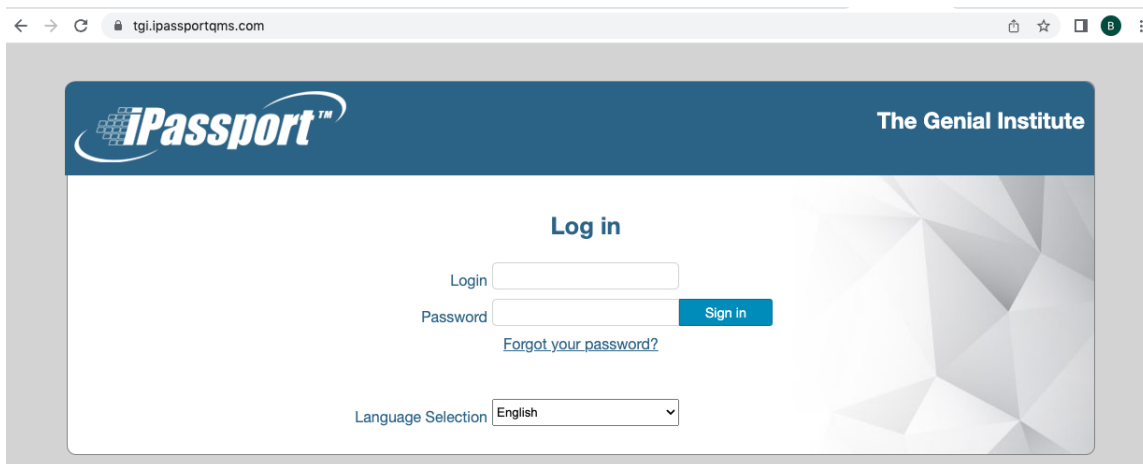
Training is then provided remotely by drawing down from pre-purchased training hours with sessions which we recommend are provided on a “train-the-trainer” approach. The aim of which is to establish local iPassport experts which can then further disseminate knowledge as needed. A typical plan would be:

- Access to the system within 48 hours
- Access to a training environment within 48 hours
- Initial discussion on implementation timetable within 72 hours
- Agree implementation timetable
- Provide details of the project lead
- Agree the module roll out plan, typically this would start with administration and then controlled documents. Once controlled documents are online we would agree the plan for the remaining modules
- Arrange administrator training/ train the trainer training
- Agree system configuration
 - o Users groups and OUs/ Departments
 - o User access controls (single sign on, password management etc)
 - o Watermark structure for controlled document footers
 - o Cover page configuration
 - o Menu language structure
- Agree role structure
 - o Groups of permissions for each access level required by the customer, this includes module and sub-module access
- Agree skilled group structure
- Agree user upload timetable, including
 - o User group membership
 - o Skilled group membership
- Agree equipment/ assets upload timetable if being used

Accessing iPassport

iPassport is accessed via a dedicated URL, specific for each iPassport account. iPassport supports Single Sign On login strategies as well as 2-Factor authentication.

The minimum requirements to run iPassport successfully is a stable internet connection and a modern web browser (Eg Chrome, Edge, Firefox).

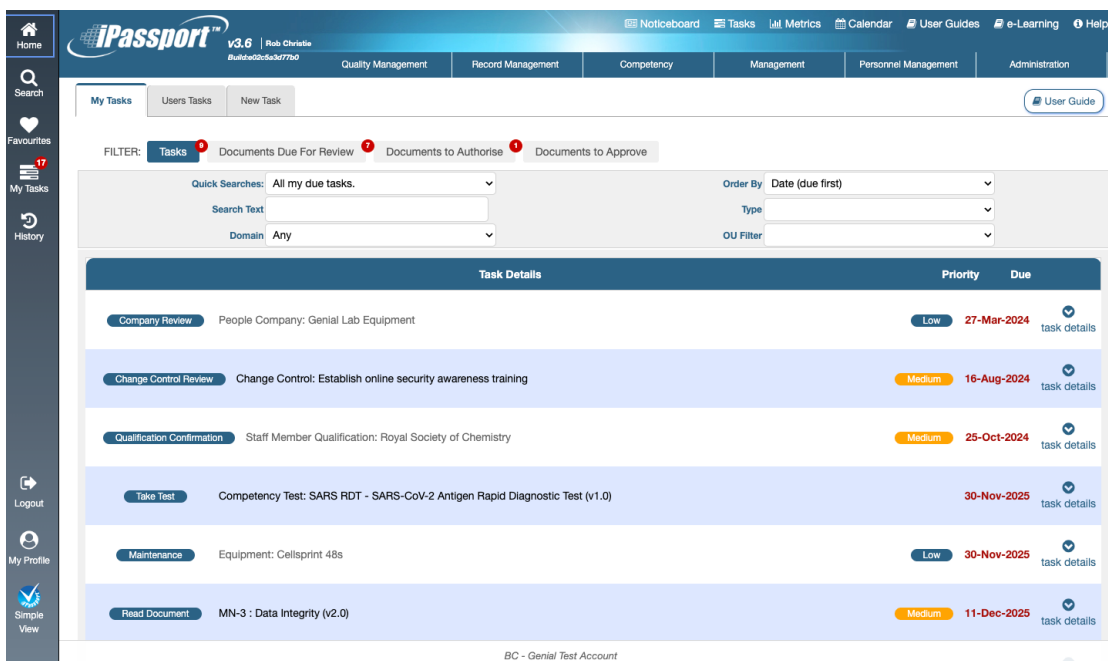


The screenshot shows the iPassport login page for The Genial Institute. The page has a blue header with the iPassport logo and the text 'The Genial Institute'. Below the header, there is a 'Log in' section with a 'Login' input field, a 'Password' input field, and a 'Sign in' button. A link for 'Forgot your password?' is also present. At the bottom, there is a 'Language Selection' dropdown menu currently set to 'English'.

Basic Navigation

iPassport has two main modes of operation, *Detailed View* and *Simple View*. The detailed view offers full functionality while the simple view has a streamlined interface, intended for occasional users who may only need to complete tasks assigned to them, or search for content.

Detailed View



The screenshot displays the iPassport 'Detailed View' interface. The top navigation bar includes links for Home, Noticeboard, Tasks, Metrics, Calendar, User Guides, e-Learning, and Help. Below this, a secondary navigation bar lists various management areas: Quality Management, Record Management, Competency, Management, Personnel Management, and Administration. The main content area is titled 'My Tasks' and features a 'FILTER' section with tabs for 'Tasks', 'Documents Due For Review', 'Documents to Authorise', and 'Documents to Approve'. A search bar is available with options for 'Quick Searches', 'Search Text', and 'Domain'. A table of tasks is displayed with columns for 'Task Details', 'Priority', and 'Due'. The tasks listed include 'Company Review', 'Change Control Review', 'Qualification Confirmation', 'Take Test', 'Maintenance', and 'Read Document'. Each task entry includes a description, a priority level (Low, Medium, or High), a due date, and a 'task details' link. The bottom of the page shows the user's account information: 'BC - Genial Test Account'.

Main Menu Items

iPassport QMS is a module based system with the main menu items located along the bottom of the header area (displayed in blue within a live account, as above, or red in training accounts). Visibility is controlled by access preferences (whether the modules have been chosen to be visible on the account) and access permissions configured for the user logged in. If all permissions are available then it will contain the following items (it's also possible to adjust the language used according to local conventions or requirements):

Quality Management	Laboratory Records	Competency	Laboratory Management	Personnel Management	Administration
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Sub Menu Items

Hovering the cursor over any of the main menu items will reveal the sub-menu items for that module. The + icon next to a sub-menu items is a convenient shortcut to create a new record in that specific section.

Competency	
Skilled Groups	+
Tests	+
Test Designer	+
Assessments	+
Assessment Designer	+
Training Courses	+
Training Schedule	+
Staff Qualifications	+

Global Menu Items

These are features not limited to a specific area or module

 Noticeboard	 Tasks	 Metrics	 Calendar	 User Guides	 Help
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Noticeboard: Also includes system notices posted by Genial Compliance, for example advance notice of new release

Tasks: Task details for the user logged in and also a management function (subject to permissions) for searching on User task details

Metrics: An area providing a predefined set of metrics and widgets plus the ability to intuitively

create new metrics to drill down into the data, study trends and see if objectives and targets are being reached. These metrics and widgets can be organised in user configurable dashboards

Calendar: Provides a calendar view of upcoming events and tasks which the user has permission to view

User Guides: Link to access online user guides, including validation documentation and release notes

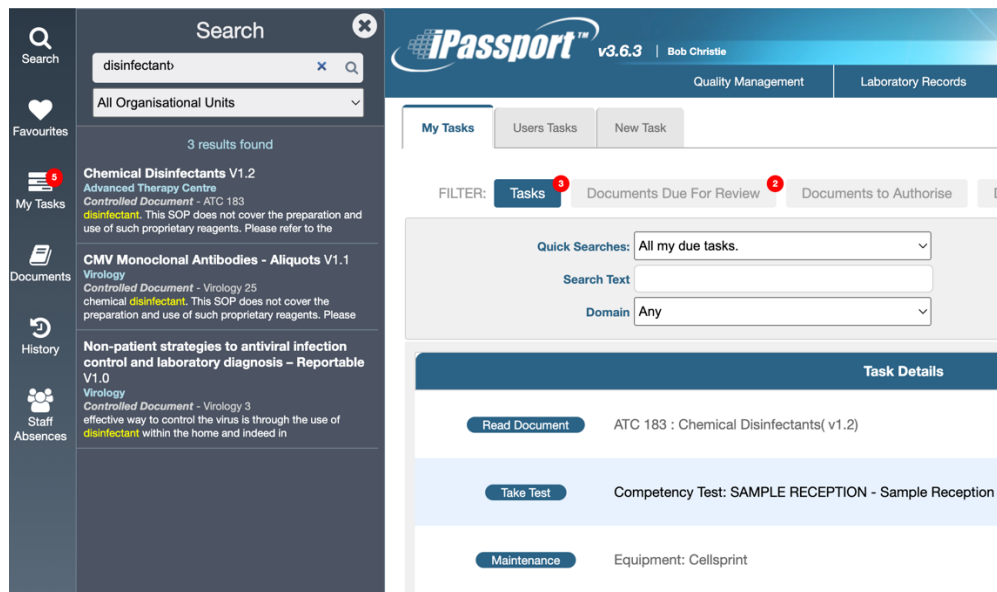
Help: Area listing local iPassport administrators and a form to submit a support request to the Genial support team

Quick Access Sidebar

The collapsible sidebar menu on the left hand side provides some quick access options for simple navigation.

Search

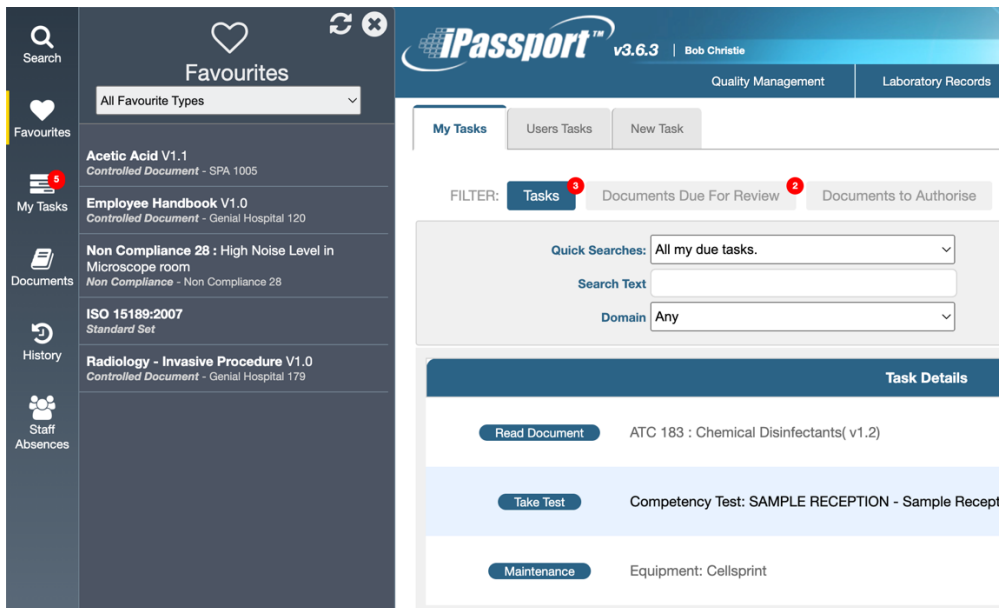
The search facility allows users to search for records from the entire account in which the user has access. The search matches on keywords including within content of records to make it as simple as possible for users to find what they are searching for.



The screenshot displays the iPassport v3.6.3 interface. On the left is a dark sidebar with navigation icons for Search, Favourites, My Tasks, Documents, History, and Staff Absences. The Search section is active, showing a search bar with 'disinfectant' entered and a dropdown for 'All Organisational Units'. Below the search bar, three results are listed: 'Chemical Disinfectants V1.2', 'CMV Monoclonal Antibodies - Aliquots V1.1', and 'Non-patient strategies to antiviral infection control and laboratory diagnosis - Reportable V1.0'. The main content area on the right shows the 'My Tasks' tab selected, with a filter for 'Tasks' and a 'Quick Searches' dropdown set to 'All my due tasks'. Below this, a 'Search Text' field and a 'Domain' dropdown are visible. The 'Task Details' section lists three tasks: 'Read Document' (ATC 183 : Chemical Disinfectants(v1.2)), 'Take Test' (Competency Test: SAMPLE RECEPTION - Sample Reception), and 'Maintenance' (Equipment: Cellsprint).

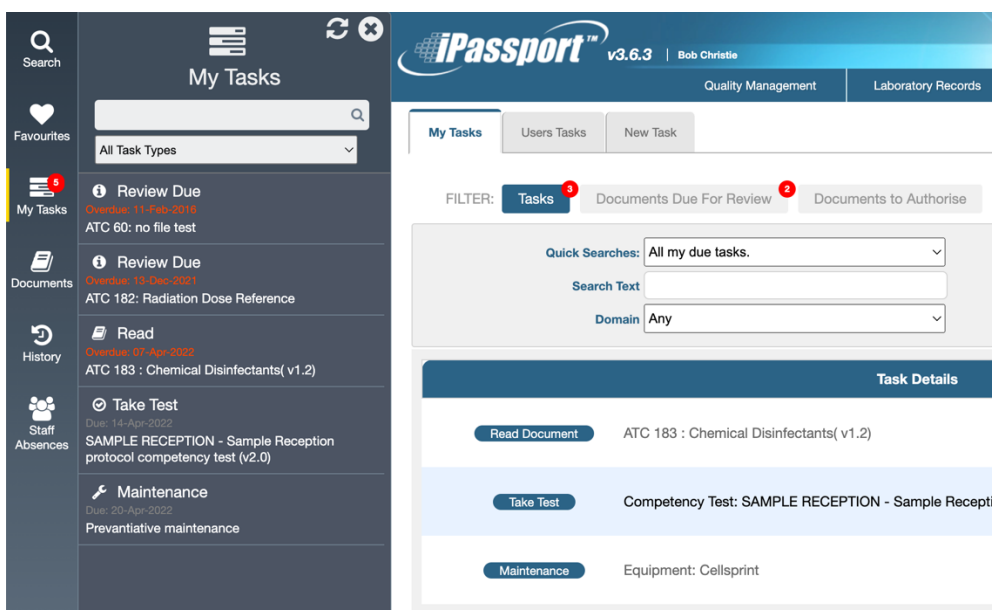
Favourites

A user configurable favourites area designed for quick access to frequently accessed records.



My Tasks

Quick access to the user's due tasks and includes a search facility within to filter by task type and search for specific tasks.

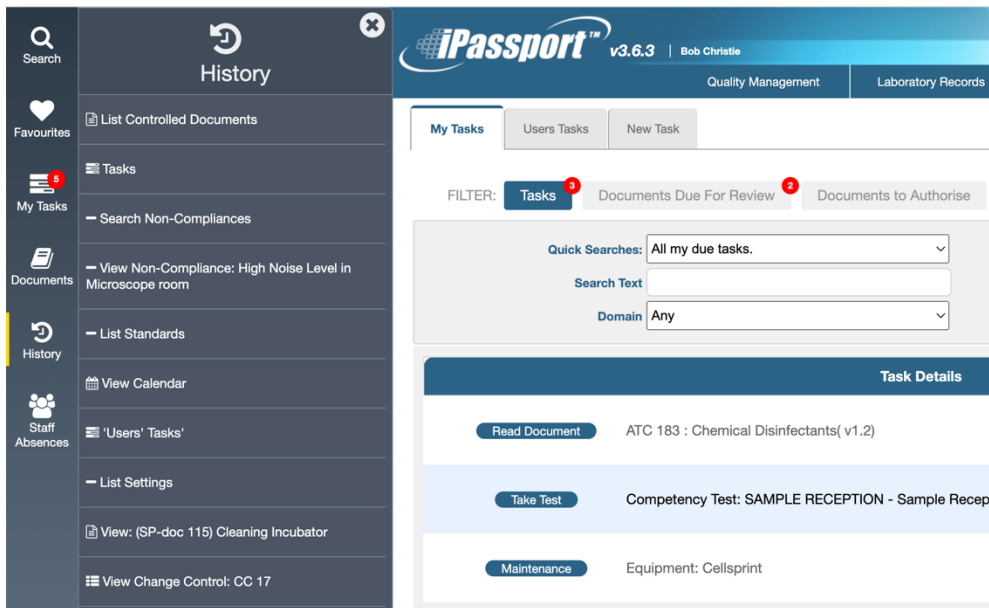


Documents

A quick access link to the Controlled Documents search area (similar to Main Menu > Laboratory Records > Controlled Documents).

History

Quick access to previously visited records.



Staff Absences

Allows a user to view a summary of absences of staff in the system (which they have access to view). Broken down into 'Today', 'Tomorrow', and 'Next Week'

Logout

Logs the user out of iPassport. Important as iPassport is a concurrent license based system. When a user is logged into iPassport, they are using a license. When they logout (or logged out automatically by the configurable inactivity period) the license is returned and available for another user to use.

My Profile

Access to the user's personal preferences to view/adjust their details, request leave and view their training and competency records.

Simple View

Simple View provides streamlined access to routine sections of iPassport, making it even easier to navigate and complete tasks for those users who may not be involved in the day-to-day management of iPassport. Simple View is also especially friendly when using mobile devices, with less information on view and larger icons for ease of use.

 Home
 Search
 Favourites
 My Tasks
 History
 eLearning

 Logout
 My Profile
 User Guides
 Detailed View



Document Control and Compliance Management

Welcome Rob

Search iPassport

All Organisational Units

You do not have any unread important notices

[View all notices](#)

My Tasks

Review Due	Cytology 1: Fine needle aspiration biopsy	Overdue: 30-Sep-2024
Review Due	Pathology 1: Antigen Typing Process	Overdue: 14-Aug-2025
Review Due	Pathology 4: Epstein-Barr (EBV) Viral Load Assay	Overdue: 27-Aug-2024
Review Due	Pathology 2: Confidentiality and Information Security	Overdue: 23-Oct-2024
Review Due	Pathology 7: Influenza Investigation	Overdue: 30-Nov-2025
Review Due	MN-3: Data Integrity	Overdue: 05-Dec-2025
Company	Company Genial Lab Equipment is due for it's approval review, please make sure that the current approval status is correct, or change it to the app...	Overdue: 27-Mar-2024
Change Control Review	A Change Control Request has been implemented and needs to be reviewed. Requested By: Sarah Miller Requested On: 18-Oct-2022 Implemented ...	Overdue: 16-Aug-2024
Confirm Your Qualification Your qualification "1: Royal Society of Chemistry" BC - Genial Test Account Please confirm that you have renewed this qualification		Overdue: 25-Oct-2025

Technical Requirements

The minimum system requirements to run iPassport QMS are, a computer with an internet connection and one of the following supported internet browsers:

- Google Chrome - version 120+
- Microsoft Edge - version 120+
- Mozilla Firefox – 121+
- Safari - version 17.2+

We recommend running the latest stable release of any of the above web browsers. iPassport enforces access through modern web browsers only which helps us keep the platform secure, reliable and also able to take advantage of the latest web technologies.

iPassport is provided as a managed service so no local servers are required.

Hosting Options and Locations

Genial utilise Amazon Web Services (AWS) as our hosting provider for all iPassport operations across the World using the AWS multi-availability zones system. Current options for data hosting include UK, EU, USA. There are no limits on storage capacity within iPassport.

Security

Genial are certified to both ISO 9001:2015 and ISO 27001:2022, both of which cover the “Development, supply, data migration, support and hosting.....” of iPassport. This ensures that iPassport meets exacting standards for design, development and security testing.

Security is built into iPassport at every stage of design and development, with particular focus on code reviews, static code analysis and penetration testing in line with the OWASP top 10.

External penetration testing is also conducted as part of our regular Cyber Essentials certification.

Special interest groups are monitored for new vulnerabilities. These are reviewed and patches applied if required.

There are numerous security controls built into iPassport at the administrator user level including:

- Block password re-use
- Maximum number of failed login attempts
- Lockout period after maximum number of failed login attempts
- Two-factor authentication via email
- Two-factor authentication period (days)
- Minimum password length
- Password complexity:
 - o Include non-alphanumeric character(s)
 - o Include a number
 - o Include uppercase letter(s)
- Password expiration period

iPassport can also operate using single sign on via SAML.

All iPassport communication between the server and the clients browser is encrypted using SHA-256 with RSA Encryption over TLS 1.2. Files stored in Amazon S3 bucket are encrypted at rest using AES-256 encryption. In addition to this the iPassport cluster is deployed in Virtual Private Cloud (VPC) which ensures logical separation of network traffic within the cluster.

Data Centre Security

To provide the Hosting Service, GCS has partnered with AWS, one of the most secure computing infrastructure providers in the world. The AWS global infrastructure is designed and managed according to security best practices as well as a variety of security compliance standards, including (but not limited to):

- SOC 1/SSAE 16/ISAE 3402 (formerly SAS 70)
- SOC 2
- SOC 3
- ISO 27001
- ISO 27017

- ISO 27018
- FISMA, FedRAMP, and CJIS
- HIPAA
- DOD SRG
- PCI DSS Level 1
- ITAR
- FIPS 140-2
- MTCS Level 3

AWS's data centres are state of the art, utilizing innovative architectural and engineering approaches. Amazon has many years of experience in designing, constructing, and operating large-scale data centres. This experience has been applied to the AWS platform and infrastructure. AWS data centres are housed in nondescript facilities. Physical access is strictly controlled both at the perimeter and at building ingress points by professional security staff utilizing video surveillance, intrusion detection systems, and other electronic means. Authorized staff must pass two-factor authentication a minimum of two times to access data centre floors. All visitors and contractors are required to present identification and are signed in and continually escorted by authorized staff.

Data Storage & Retention

All data stored on iPassport is stored for the lifetime of the system. Should an account choose to leave iPassport at any point then the data is stored for a further 1 year as part of our backup cycle. Data stored in iPassport is fully encrypted at the database and file level in our secure AWS S3 bucket. iPassport is backed up at a 1-minute resolution which is in operation for one month, after this snapshots are taken twice daily on a rolling one-year schedule. After this time the data is overwritten.

Should you require the data to be purged immediately after cessation of iPassport then a request can be submitted to the Genial support team.

Support and Maintenance

iPassport has been designed to be secure and robust for our users and a 99.9% uptime guarantee is offered as part of our SLA.

There is a dedicated support team in place for both general user support and any technical support which may be required. Only dedicated members of the support team would have access to the system and any access is logged as part of our secure audit trail.

Support is provided through a dedicated link within the system and our support desk email address and contact telephone number is also provided. There is an option within iPassport to tell the system how to route support questions, which allows them to go through an internal review should the user wish, prior to being forwarded onto Genial.

The support desk operates from 09:00 – 17:30 GMT and unlimited online, telephone and email support is included.

Unlimited telephone, email and online product support is included as standard within any managed services agreement, with access to support available between 09:00 - 17:30 (GMT) Monday - Friday, excluding public holidays.

Genial will aim to respond to product related questions within one working day. Technical support requests are triaged and prioritised as outlined in our service level agreement. A short summary is below:

Severity	Failure Description	Response Time (during Support Services Hours)
1 – System Failed	Multiple users not able to access the system to perform normal work.	2 working hours
2 – System Malfunction	The system is still considered operational with some functionality disabled.	5 working hours
3 – Operation impaired	System operation is impaired, slow running or prints not being produced. Core functionality is operational.	24 working hours
4 – Data Issues	System operates normally but incorrect data items ¹ or an individual user not able to access the system etc.	5 working days
5 – Cosmetic Issues	Cosmetic error, e.g. spelling mistake, screen layout inconsistency. User enhancement request.	5 working days
Query	General advice and queries	Up to 20 working days

iPassport Updates

iPassport is provided as a SaaS product, and system improvements and bug fixes are provided as part of the managed services agreement. These continuous system updates are delivered through new releases of the software, which are remotely deployed by Genial without impacting access to iPassport.

iPassport Developments

iPassport undergoes continuous development to ensure that it remains current and innovative. This development is led by our internal multidisciplinary development group which consists of representatives from sales, support, quality and information security and the technical group. Feedback from all interested parties is also fed into the development discussions to help establish a development pathway which is mapped to a 12-month period. The design and development approach takes advantage of agile methodology and specifically sets aside time for additional items should the need arise. If this is not required, then something from upstream is developed early. Development is continually monitored and is subject to both our ISO 9001:2015 and ISO 27001:2022 certifications.

All iPassport developments undergo thorough testing prior to deployment as part of our quality and security standard certifications. This includes both manual and automated testing.

End of Contract

At the end of the agreement, the customer has a choice of how the data is handled, should the export service be subscribed to then this can be used to export data from the system in line with the service. If the export is not subscribed to then our professional services team can be engaged and the data can be provided as a data dump to the customer in a format to be mutually agreed.

Should the data need to be cleared from our servers then this can be accomplished by our technical team following a request from the end user, this can be completed in conjunction with the export and/ or data dump at the end of the agreement. Otherwise, the data would remain on our servers in line with our data retention policy (outlined above). At all times the data belongs to the end user.