GO!FIVE® Data Privacy Policy

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1   Documentation Registry

DOCUMENT REVIEW HISTORY		
Version	**Details**	**Issue Date**
1	Document issued for FIVE approval.	17/MAY/2019
2	e-mail update on topic 2, from helpdesk.go5@fiveconsultoria.com to helpdesk.go5@fivevalidation.com; Addition of registered trademark of GO!FIVE™.	29/SEP/2021
3	Changes made according to occurrence 23-00056: - Change from GO!FIVE™ to GO!FIVE® throughout the document. - Formatting adjustments in the document. - Changed item A of topic 10. Data Security.	01/SEP/2023

2   General Provisions

This Privacy Policy is intended to help our customers understand what data we collect and why we collect. If there are any questions, please contact us through the following e-mail address: helpdesk.go5@fivevalidation.com.

The GO!FIVE® system has the necessary functionalities for the elaboration and execution of quality validations, assisting the user to comply, achieving with success the audits.

The GO!FIVE® system stores only data from the validation process, not patient data or company confidential data, such as production order, product data, recipes, etc. By relating the test evidence, some data entered will be true, especially if the validation is in the performance phase, whereas the system will already be in production environment. However, these data will not be made available to third parties, as there is a confidentiality agreement and the validation data are stored in FIVE's Tenant (in the case of purchase of validation executed by FIVE) or in the User's Tenant (data available only to the user in case of purchase of rights to use the system).

Though, users have full responsibility for the data they enter the system and for its truthfulness.

Note: Tenant is a section of the storage database of the contractor's exclusive use.

2.1   Our Services Include:

The provision of the right to use the platform called GO!FIVE® (validation lifecycle management system) and the online support platform called GO!FIVE® WIKI, both developed and made available by FIVE.

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3   Data Segregation

The data presented in GO!FIVE® will vary according to the access/profile that the user has.

In cases of hiring a specific Tenant, there will be another layer of data segregation, through a url (network address in which there is some computer resource, for example a web page) dedicated to it. In this url only the users registered by the contractor will have access.

If there are none FIVE employees involved in the contractor's Tenant, the FIVE will not collect any data created, edited or removed from Tenant concerned.

For FIVE to collect and use the data (anonymized way) of the contractor's Tenant, there must be a formal concession from the responsible user by Tenant.

FIVE reserves the right to create Tenants with company-specific names and make use of the data contained in the Tenants as desired, for the sole purpose of enhancing the GO!FIVE® system. The contractor will be entitled to the data of a specific Tenant only after the conclusion of a commercial agreement with the FIVE. From this moment, the contracting company will be able to choose whether to grant access to FIVE in the contracted Tenant data.

4   Data that can be Collected

4.1   Why GO!FIVE® collects Data

We anonymize and may use the data we collect for the purposes described below.

4.1.1   Data we collect when the user use GO!FIVE®

When an account is created on GO!FIVE®, the user provides us with data that includes first name, last name and corporate e-mail address. Such data are used exclusively to access the system.

We also collect, all data created and edited on FIVE's Tenant. This includes files and documents attached in the validations.

However, at the contractor's Tenant, we only collect data when formally is granted access to FIVE and its employees.

We emphasize that the data collected are anonymized (uncharacterized) and FIVE and its employees do not provide the original data to third parties. Such data are used, for example, to expand the database of the library provided by GO!FIVE®, thus generating a considerable time gain in the execution of the validation activities.

4.1.2   Location Data

FIVE does not collect data regarding the location of users.

4.1.3   Provide our services

We can use the data to improve a database called Library. This database returns suggestions that aim to help the user to prepare documentation regarding validation.

4.1.4   Maintain and improve our services

We may also use the data to make sure that our services work as expected, for example to track interruptions or solve reported issues.

4.1.5   Develop new services

We may use the data we collect on existing services in developing other services and new functionalities.

4.1.6   Provide custom services

We may use the data we collect to customize our services, including to provide recommendations, content, and personalized search results. For example, when selecting a system that has data in the library, the risks, requirements, tests and other information related to the system, it will be suggested in the documents to be developed by the user if he/she chooses to use such information.

4.1.7   Evaluate performance

We can use the data for analysis and evaluation to understand how our services are used and how we can improve them. For example, we analyze data about visits to our system to optimize product design.

4.1.8   Contact user

We may use the data we collect, such as corporate e-mail address, to interact directly with the user. For example, we may send a notification if we detect suspicious activity, such as attempting to log in to an account concurrently with the account owner.

In addition, we may inform the user about future changes or improvements to our services.

If the user contacts the GO!FIVE® support team, we will save a request record to help resolve any issues that are occurring.

4.1.9   Protect GO!FIVE® and our users

We may use the data to help improve the security and reliability of our services. This includes detecting, preventing, and responding to fraud, abuse, security risks, and technical issues that may adversely affect GO!FIVE® or our users.

We use different technologies to process the data for these purposes.

We use cookies for storage in cache memory related to the session that the user is in, this storage is for the system's own functioning. It is data generated by the system itself, such as storing which is the last project and subproject accessed by the user. The GO!FIVE® does not analyze or store such information for any kind of analysis.

We will require user authorization before using data for purposes not covered in this Privacy Policy.

5   Export Data

The user can export all the documents of the approved items in PDF format. We emphasize that the GO!FIVE® system does not retain such file. This should be saved on the user's server following the internal security policies of Information Technology. The GO!FIVE® stores the items data in the database. The preservation of PDF documents is not FIVE's responsibility.

6 Data Exclusion

To delete the data, the user can:

Search and delete specific items or the entire project and subprojects directly in the system.

We try to ensure that our services protect data from accidental or malicious deletion. Because of this, there may be a time gap between the moment user excludes something and the moment when copies are deleted from GO!FIVE® and from backup.

It is also possible to retire (inactivate) users on GO!FIVE®.

7 Data Transfer

We use servers located in the United States, in other words, data can be processed on servers located outside the country where the user lives. Data protection laws may vary by country, with some offering more protection than others. Regardless of where the data is processed, we apply the same protections as described in this policy.

We take care to use only infrastructure service providers that act in accordance with certain legal structures related to data transfer, such as the Privacy Shields structures between the European Union and the United States and Switzerland and the United States.

8 Data Storage and Retention

In some cases, we store the data for limited periods when it needs to be kept for legitimate business or legal purposes.

9 Data Sharing by the User

It is not allowed to share the data from the service contracted with third parties or competitors of FIVE without the formal consent of FIVE.

10 Data Security

We incorporate security into our services to protect data.

All FIVE products are developed with robust security features that continuously protect data. The insights we receive in the maintenance of our services help us automatically detect and block the security threats that reach the user. And if we detect something dangerous and worthy of notification, we will notify and guide the user about the steps necessary to keep security.

We work hard to protect the user and the GO!FIVE® from unauthorized access, alteration, disclosure or destruction of the data we hold, which includes:

A) Use of encryption on sensitive static data and use of SSL and TLS 1.3 HTTP in transit encryption;

B) use of infrastructure providers that have physical security measures to prevent unauthorized access to our system;

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C) restriction on data access by employees who need this data to process them, for example system developers. All employees with this access undergo to strict contractual obligations of confidentiality and should be disciplined or dismissed if they fail to comply with these obligations.

11 Request for help to GO!FIVE® Support Team

When there is a need for the user to request help from the support team, the FIVE's employee can access the data stored in the contractor's Tenant to understand the situation and solve the problem.

12 Infrastructure Provider

FIVE uses the cloud service provider Amazon Web Services, also known as AWS, which has been properly homologated to host GO!FIVE®.

13 Data Sharing for Legal Reasons

We will share the user's data outside of GO!FIVE® platform if we believe in good faith that access, use, maintenance or disclosure of the data is necessary to: comply with any applicable law, regulation, legal process or governmental request.

We share data about the number and type of requests we receive from governments with the impacted users.

14 In case of Merger, Purchase or Sale

If FIVE is involved in a merger, acquisition or sale of assets, we will continue to ensure the confidentiality of the data and will notify the affected users before the data be transferred or submitted to a different privacy policy.

15 About this Policy

We change this Privacy Policy from time to time and we make sure that we process the data in ways that comply with it. We will not reduce your rights in this Privacy Policy without the explicit contractor's consent. We always indicate the date on which the latest changes were posted and offer access to the archived versions for review.

16 Terms and Definitions

Cache:

Memory area where is stored a temporary copy of the data stored.

Cookie:

A cookie is a small file that contains a string of characters. It is sent to the computer when the user visits a website. When the user accesses the site again, the cookie allows the site to recognize the browser. Cookies can store user preferences and other data. You can configure

your browser to refuse all cookies or to notify you when a cookie is being sent. However, some features or services may not work properly without cookies.

Device:

A device is a computer that can be used to access GO!FIVE®. For example, desktop, laptops, tablets and smartphones are considered devices.

Personal data:

It is the provided data that identifies the user in person, such as name, surname, e-mail address.

Sensitive personal data:

This is a specific category of personal data related to topics such as confidential medical data, racial or ethnic origin, political or religious beliefs, or sexuality.

Tenant:

This is a database section of storage for exclusive use of the contractor, or FIVE, when it is designated FIVE's Tenant.