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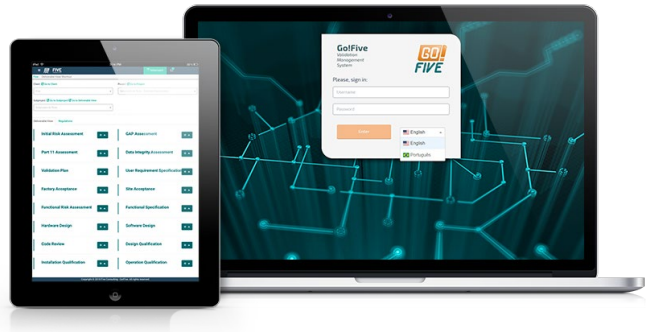
GO! FIVE®

VALIDATE FROM ANYWHERE

SOFTWARE - EQUIPMENT - PROCESSESS



Our purpose

Minimize the risks of products and services that impact the health and well-being of families

Remote validation, the theme of this e-book, is related to our purpose. If your company seeks patient and / or consumer safety, compliance, data integrity, quality of life to your employees, better management, and efficiency in the validation processes, you are in the right place. We hope you like it!

Your Validation professional can be anywhere in the world

Your worker can be anywhere in the world validating software, equipment, and processes remotely, while you monitor all activities, in real time and from wherever you are!

Remote validation has arrived to modernize the way of working and to allow projects to be carried out remotely, for the safety and health of professionals with the additional gain in reducing costs with travel and stays by service providers.

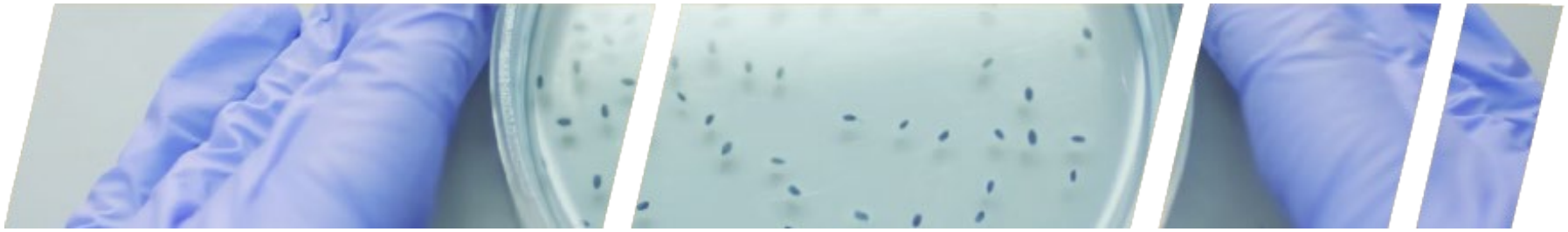
Digital and Cultural Transformation

Companies are beginning to realize that a company's complete digital transformation begins with cultural transformation. It is noticed that the top management wants the processes to be increasingly efficient and automated, however it is been realizing that the mindset of digital transformation involves mainly people.

Top management is not responsible for implementing the digital transformation itself but needs to care for and manage the people who care for the people who implement the process automation. If this mindset is not a clear strategy of the company, it is likely that the professionals responsible for operationalizing the efficiency of the processes will not have the same vision.

Therefore, it is common to see large companies with the highest layers of fully automated management processes, but the manufacturing and quality processes are still outdated.

Digital transformation begins with cultural transformation.



Risks of site contamination - it is possible to reduce circulation of service providers and validation professionals

With remote validation, it is possible reduce the risk of contamination by reducing the circulation of service providers in your company and the handling of folders and papers through 100% paperless validation.

For embedded systems without an internet connection, some on-site professional is needed but the circulation of people on the company's premises decreases, which directly decreases the possibility of virus contamination in the company, safeguarding its own employees and and production. Innovation for less human interaction, less risk and greater compliance.

Easy management of global teams in real-time of validation tasks in multi-site

The visualization of tasks performed on multi sites by global teams in real time is a necessity because we can imagine how many software, information technology infrastructure, equipment, utilities and processes need to be managed, as well as the progress of each validation cycle.

But we still have to consider that the demand for software is increasing due to the following main factors: the need for remote work that companies started to adopt because of acceleration of digital transformation, which shows us that companies are increasingly automating their processes. More systems will have to be validated.

The way of visualizing what the validation team is delivering on each company site plus review and approval flow in electronic format are bringing agility and security for those working at home, including more efficiency in management. Currently, work must be dynamic, incorporating the innovations required by the market.

A paperless solution can bring greater engagement in quality practices to millennial professionals who may not accept working with paper-based processes well, because they were born immersed in technology.

Work from home increases retention of highly qualified professionals in your company

In addition to the benefits of performing validation from anywhere, it is possible to perform it six times faster, which allows your team to be able to absorb this demand without increasing staff. Your team can also count on pre-ready validations, collaborating with the retention of professionals and with more quality of life for you and your team.

Working from home is a privilege. For most professionals, exchanging travel time for time to spend more time with their children, going to the gym or studying a language is indeed a very positive point.

Sustainability and costs with printers

Reducing the impact that the traditional paper process brings to the environment is one of the interesting gains of paperless validation. Imagine the amount of toner or ink and printer cartridges that can become technological waste when obsolete. Not to mention costs, as it is likely that companies that pay monthly fees on printer lending contracts are potentially higher than the monthly fee for validation software.

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VALIDATION PROJECTS IN REMOTE FORMAT

It is possible to validate IT management systems, QC labs software and plant -floor automation systems that are connected on the internet, 100% remotely. In these types of systems, it is possible to carry out the validation with all professionals working remotely.

For the qualification of physical infrastructure and validation of software embedded on equipment, where it is not possible to view or access the HMI screen (Human Machine Interface) remotely, the evidence is captured through a tablet by a professional on site, while validation reports can be performed remotely.

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TYPES OF TESTS THAT CAN BE APPLIED REMOTELY

- Factory Acceptance Test (FAT)
- Site Acceptance Test (SAT)
- Installation Qualification (IQ)
- Operation Qualification (OQ)
- Performance Qualification (PQ)
- Unit Test Configuration
- Functional Testing
- User Acceptance Testing (UAT)
- Module Testing
- Integration Testing
- System Integration Testing (SIT)
- Data Migration Testing
- Requirements Testing

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HOW REMOTE VALIDATION IS PERFORMED?

1 – Risk assessment and deliverables preparation (documents)

2 - Test execution and reports

In the first phase, a risk assessment is carried out with a multidisciplinary team by videoconference. The Analyst prepares the deliverables (documents) including the Validation Plan and forwards them to the review and approval of those responsible for the project. In this step, all information about the system and other materials is also collected.

The application of tests performed by the analyst together with the key user of the software also occurs by video conference.

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HOW TO REVIEW AND APPROVE IN FULLY REMOTE VALIDATION

GO!FIVE® software developed by Five Validation is based on items that provides agility and easy maintenance of validated status.

The review and approval of deliverables (documents) is carried out within GO!FIVE® following the flow:

Preparation of deliverables (documents); creation of a review and approval package; inclusion of items developed in the package; sending the package to those responsible for the review and approval.

The review and approve process of the deliverables (documents) can be carried out in two ways:

Parallel workflow: when deliverables are sent at the same time to all those responsible.

Serial workflow: when the item package is sent to one responsible person at a time.

Validation types that can be performed using the GO!FIVE® software

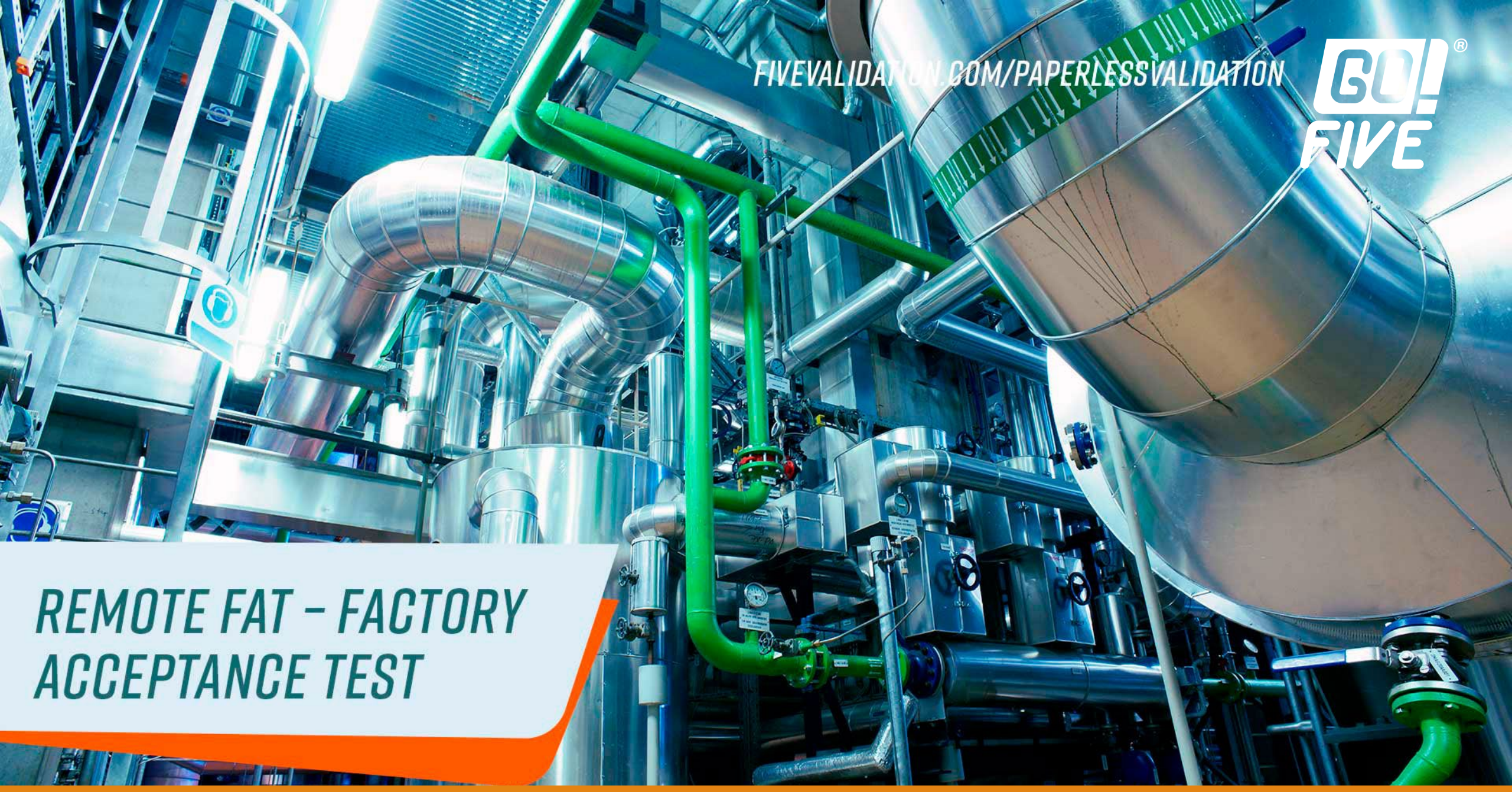
Five Validation team is recognized by the market with high expertise in the following specialties:

- (A)Computer System Validation
- (B)Equipment Qualification
- (C)Utilities Qualification
- (D)IT and OT Infrastructure Qualification, including cyber security items
- (E)Supplier Qualification
- (F)Data Integrity

Due to accumulated experience though years, FIVE team built (and continue to build continuously) within software, a library of knowledge and content that facilitates and streamlines validations through sets of requirements items, risk scenarios and tests that make up ready-made validations, as if they were templates for each type of system or equipment.

However, GO!FIVE® platform was developed to manage all validation types. The ‘custom deliverable’ feature allows you to build templates the way you want, making it possible to use the software according to the company's internal procedures in other disciplines:

- Process Validation
- Cleaning Validation
- Validation of Analytical Methods



REMOTE FAT – FACTORY ACCEPTANCE TEST

The viability of remote FAT reduces costs and streamlines the process

The new and recent approach to running FAT tests remotely is smart and sustainable. Long-distance travel due to the acquisition of equipment imported from other countries has its days numbered. Remote FAT looks like a trend that is here to stay.

Most large industrial automation companies are launching technologies by combining software with 3D glasses or high-definition cameras to make remote FAT feasible. Until a recent past, there was no alternative to the face-to-face activities of this verification and testing phase.

In general, FAT is required for partially or fully customized equipment and normally occurs at the supplier's factory before being dispatched to its destination. During the visit to the supplier's premises, the customer's team conducts documented tests to verify that the equipment was built according to the agreed specifications.

In general, this phase has costs associated with travel expenses of travel from this team from the country or place of origin to the supplier's factory, often involving obtaining visas making the process expensive and time-consuming.

It is noteworthy that the giant's industrial automation companies have been investing in tools seeking information security for sharing documents during the testing phase. We do not recommend the use of corporate video conferencing tools for industrial use, as these were not normally developed with all the security requirements for the OT (Operational Technology) environment and do not meet the requirements of IEC-62443 which deals with a series of standards focused on control systems and industrial automation - IACS (Industrial Automation and Control Systems). The set of standards provides a series of systematic practices for adopting cybersecurity for industrial systems.

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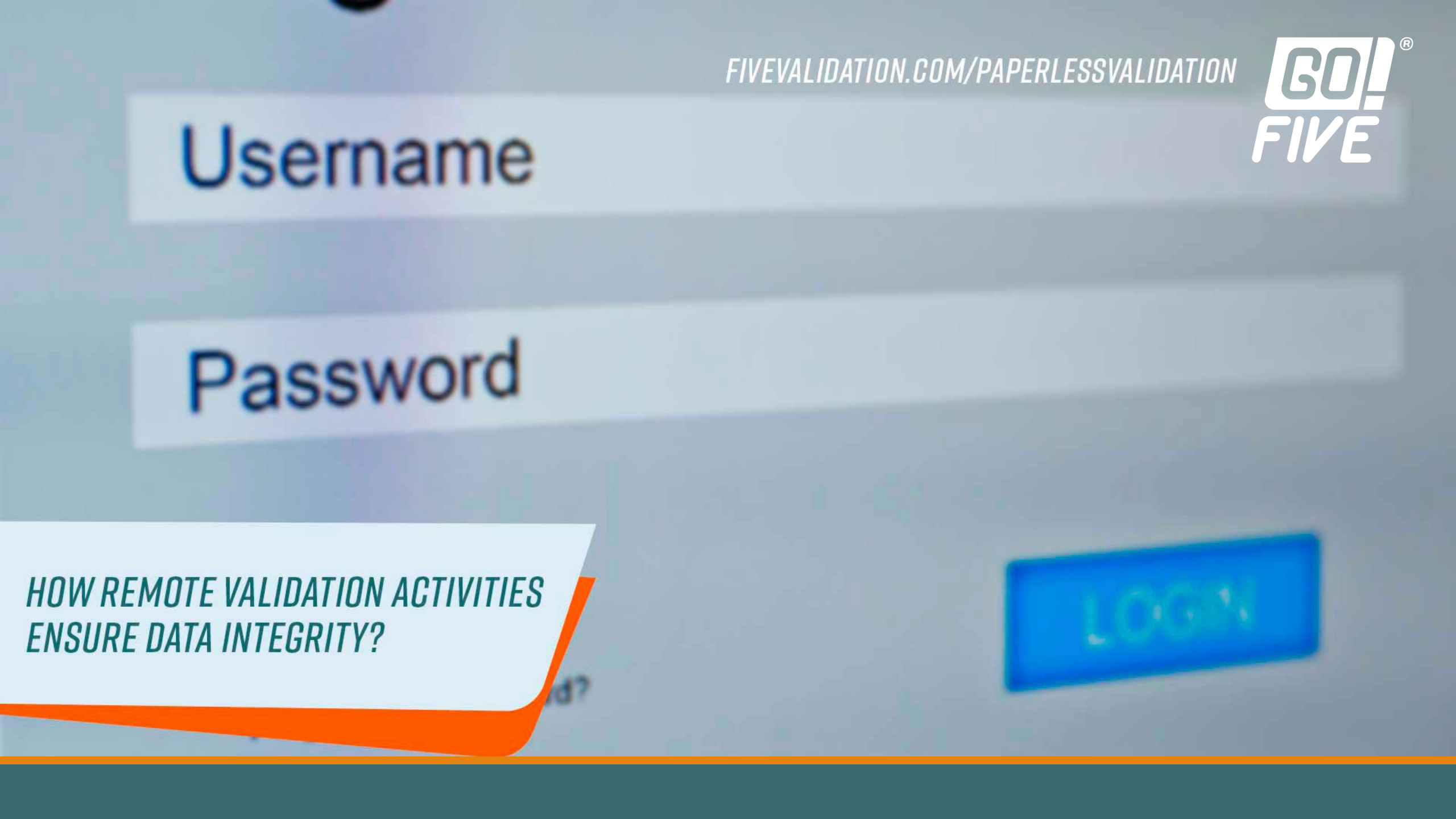

HOW REMOTE VALIDATION ACTIVITIES ENSURE DATA INTEGRITY?

Data integrity in remote validation is ensured by software features, developed especially to meet the requirements of regulatory agencies around the world.

Audit Trail: registration of all project data and any changes that these data may undergo including date, time and responsible for the action.

Access Control: each company has a section of the database for its projects, with access control, a unique URL for exclusive access to registered users.

Data security: cloud system hosted by AWS, encryption of passwords and data in transit. cloud system hosted by AWS, passwords encryption and data in transit, with rigorous information security certifications, in addition to good internal practices and procedures practiced by qualified professionals who have access to the system data.


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REMOTE VALIDATION IS PAPERLESS
FROM START TO THE END

Remote validation is 100% paperless, all project documents are generated and administered digitally. Still, the software offers the option of exporting these documents in PDF format.

With the remote validation software, the entire project can be carried out completely paperless. An innovative approach. The documents are digitally generated and managed by the software from the beginning to the end of the project. The platform was developed to meet all data integrity requirements of global regulatory agencies and to ensure compliance at the time of the audit.

Imagine a consulting company with high knowledge in validation that develops software that includes expertise and know-how in its database. Imagine that this company is ready to conduct and support its validation remotely and/or train its team. Here we are! GO!FIVE® VLMS - Validation Lifecycle Management Software, the implementation is fast.


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EDMS VS. REMOTE VALIDATION

For the process to be paperless, it is not enough to use EDMS (Electronic Document Management System)

The EDMS software has become popular over the past decade. It is an interesting system, which should be used to manage GMP documents (Good Manufacturing Practices) such as SOP's (Standard Operating Procedures) and other quality system documents that have their life cycles controlled by this type of system, since its creation, review , approval, operation until its obsolescence. However, this type of platform was not built and designed to reduce the time involved in validation. What we want is to have a platform that automatically and electronically manages validation lifecycle, which is not limited to preparing and approving documents. It is important to manage testing phases, its incidents, and reports.

Some disadvantages in using EDMS's to manage validations:

No mechanism for test executions

In general, companies end up having to print the approved protocols before to be executed manually and digitalize them after execution (a lot of work!). Then, it is need upload all the scanned files to EDMS. The chances of human error are enormous.

Absence of automatic traceability matrix

EDMS does not automatically generate any type of traceability matrix. This type of system was not designed to link requirements and/or risks to tests. Manual building of the matrix is possible, but extremely time consuming (therefore expensive) and very subject to human errors.

Insufficient information for the management of validations

EDMS's have appropriate information for the control of quality documents as they are platforms geared towards this purpose, but they lack information necessary for decision making to management of validations/qualifications, as for example they do not show quantity of tests performed, as failed ones or open/closed incidents and management of validation status.

Lack of accelerator of validation

EDMS do not have a stored information database to contribute to the speed of the process of preparing the validation/qualification documents, as this is not the objective of this type of system.

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Risks to Data Integrity

Here are some risks associated with manually performing digital validation and its impact on data integrity:

Risk Scenario 1: Editing pre-approved test documents to include the evidence and data in the test run

It is an essential feature of data integrity to ensure that a document is not changed after it has been signed without proper change control. According to the GAMP5® Guide, systems must perform tests according to a pre-defined and pre-approved specification. This certification ensures that information is accurate, reliable, and complete. In the pre-test approval phase, the content and scope of the test script are reviewed and approved, e.g., the objective, acceptance criteria, prerequisites, action, and expected result. In the post-approval phase, the execution of the tests is reviewed and approved, i.e., if the data and evidence are recorded to demonstrate the robustness and effectiveness

of the mitigations implemented. All the work done in the previous step is called into question by allowing modification to a pre-approved test script to include evidence. This issue is because the information modification was separate from the approval, and it is impossible to guarantee the traceability of all changes.

Risk Scenario 2: Using a single signature for approval of the test phase, not approving its executions in an individualized way, and needing help to identify the failed tests.

Each test scenario has an action and an expected result. According to the GAMP5® Guideline, test results must be documented directly as testing occurs and should be retained. The test executor must decide whether the test passed or failed. By executing a single electronic signature on the document, it is impossible to segregate failed tests from passed tests or record the data in real-time (non-contemporaneous signatures). Also, according to the GAMP5® Guideline, the test execution process must be flexible enough to allow the executor to decide whether to fail or pass a test and that all corrections and retests are traceable. With the use of the EDMS or electronic signature, it is not possible.

Risk Scenario 3: Informal email review of validation documents.

Email is not the best tool to make the process efficient, and it can impact the integrity and security of the information. When someone sends the document for review by email, the document is prone to loss, and the process consumes considerable time. Even if people respond immediately, each participant will make their considerations in a different document, and it is necessary to consolidate everything into a single version. Also, the traceability of comments and observations is lost.

Conclusion

Companies are automating their production processes with incredible speed to optimize time and reduce costs. But validation and qualification remain slow and susceptible to human error.

To maintain compliance requires high financial support and a lot of efforts on professional training. It takes some time and a huge amount of paperwork. There is a lot of bureaucracy and low efficiency that shortchanges validation and data integrity

FIVE has been working for over twelve years in the regulated market and correctly understand the size of the challenge because, in general, the process is extremely manual.

On one side, companies have high performance with quality through technological processes and digital transformation. On the other side, there is a low efficiency due to the delays in the manual processes of validation and qualification with increased regulatory risks.

To solve this problem, we have developed GO!FIVE® – an innovative software that streamlines validation and qualification activities, increasing efficiency and maintaining compliance.

We list 11 reasons to consider Paperless Validation:

1. More compliance: decrease regulatory risks for companies and data integrity;

2. Faster time-to-market: without validation, biopharmaceutical and medical device industries cannot register or produce their products;

3. More efficient work: 'right the first time;' decrease time to compliance, make projects agile, and have a knowledge database;

4. Decrease validation costs: faster work, avoid paperwork, no printers, no physical space to store documents, no scanning of documentation;

5. Agile Framework: Embrace agile validation practices aligned with FDA, EMA, and WHO guidelines, granting you flexibility in your project deliveries. Consider the option to release projects incrementally, such as systems, modules, and processes, allowing you to leverage previously tested and validated components before completing the entire project;

6. Sustainable: no paper, no printers, no cartridge disposal;

7. Remote work: healthier employees and quality of life, online management, team connection between several countries;

8. Easier maintenance of validation status: decrease the time to maintain the validation status with constant updates and periodic inspections;

9. Easier audits: immediate availability of data;

10. Standard documents: maintenance of good documentation practices according to GMP guidelines, GAMP5®, for example;

11. Easier management: immediate availability of data (online management);

We list 16 distinctive features for you to choose GO!FIVE®

1. Validations 7 times faster compared to paper or manual electronic models = 7 times more efficient team and/or 7 times cheaper validations;

2. Off-the-shelf system, ready for use;

3. Quick deployment, validate from day one. No need to load legacy data to start using;

4. Free deployment;

5. Pre-built validations: Access a wealth of pre-existing requirement scenarios, patient and/or product risk assessments, and comprehensive tests derived from various validations and qualifications. These resources are readily available and fully customizable to suit your specific requirements, accessible from both public and private libraries;

6. Artificial intelligence capabilities for seamless organization, formatting, and generation of PDF documentation. This includes evidence indexing and automatic index construction, streamlining your validation process;

7. Generation of updated validation documents (in PDF format):
    a) Complete validation package including the changes;
    b) Segregated by sprint, change, and/or process.

8. Test replication: in industrial automation projects, it is possible to increase efficiency by creating and replicating tests for all sensors and alarms with just a few clicks;

9. Unlimited user registration, payment only for concurrent access licenses;

10. Our monthly payment package encompasses round-the-clock support, ongoing training sessions, and access to test and production environments. Moreover, the monthly license includes a bundle of GO!FIVE® system validation documents, consistently updated with each new version, ensuring you stay up-to-date and well-supported;

11. Set of documents facilitating the paperless solution validation process at the client included in the subscription, along with updates with each new version;

12. For consulting firms, and system and equipment suppliers: client data segregation at no additional cost;

13. Automatic traceability of all changes;

14. Automatic filling of blank fields;

15. Freedom and flexibility for access control configuration;

16. Excellent cost-benefit ratio.

FIVE is ready to demonstrate our software for remote validation and its advantages.

Click here to request yours.

https://fivevalidation.com/paperless-validation