FIVEVALIDATION.COM/PAPERLESSVALIDATION

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with the highest layers of fully automated management processes, but the manufacturing and quality processes are still outdated.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 increasingly increasing due to the following main factors: the need for remote work that companies started to adopt during the pandemic period and the 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 three 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)

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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 following 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

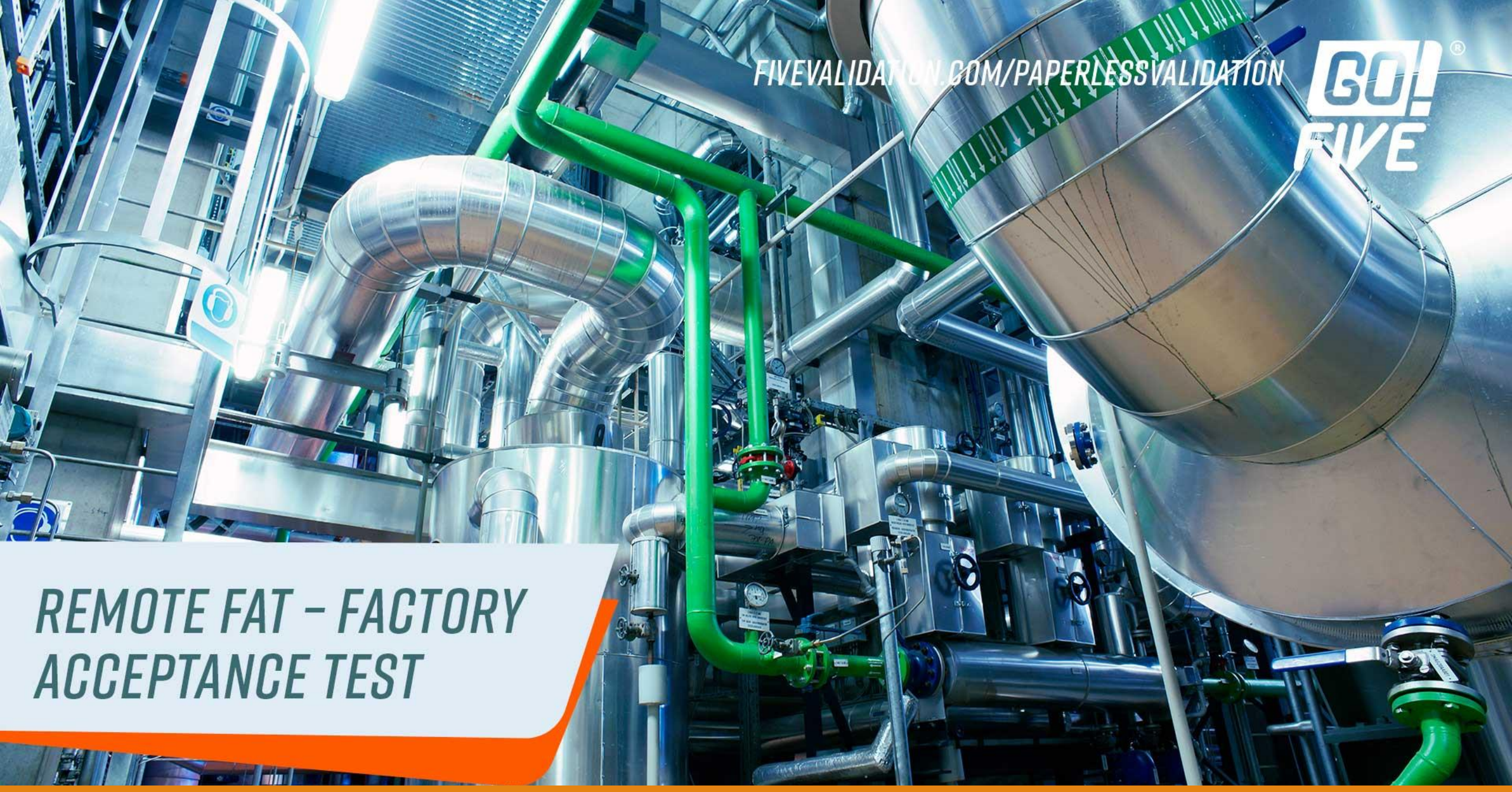
Five Validation team is recognized by the market with high expertise in the following specialties:

- (A)Computer System Validation
- (B)Equipment Qualification
- (C)Utilities Qualification
- (D)Qualification of Information Technology Infrastructure, including cyber security items
- (E)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
- Clean 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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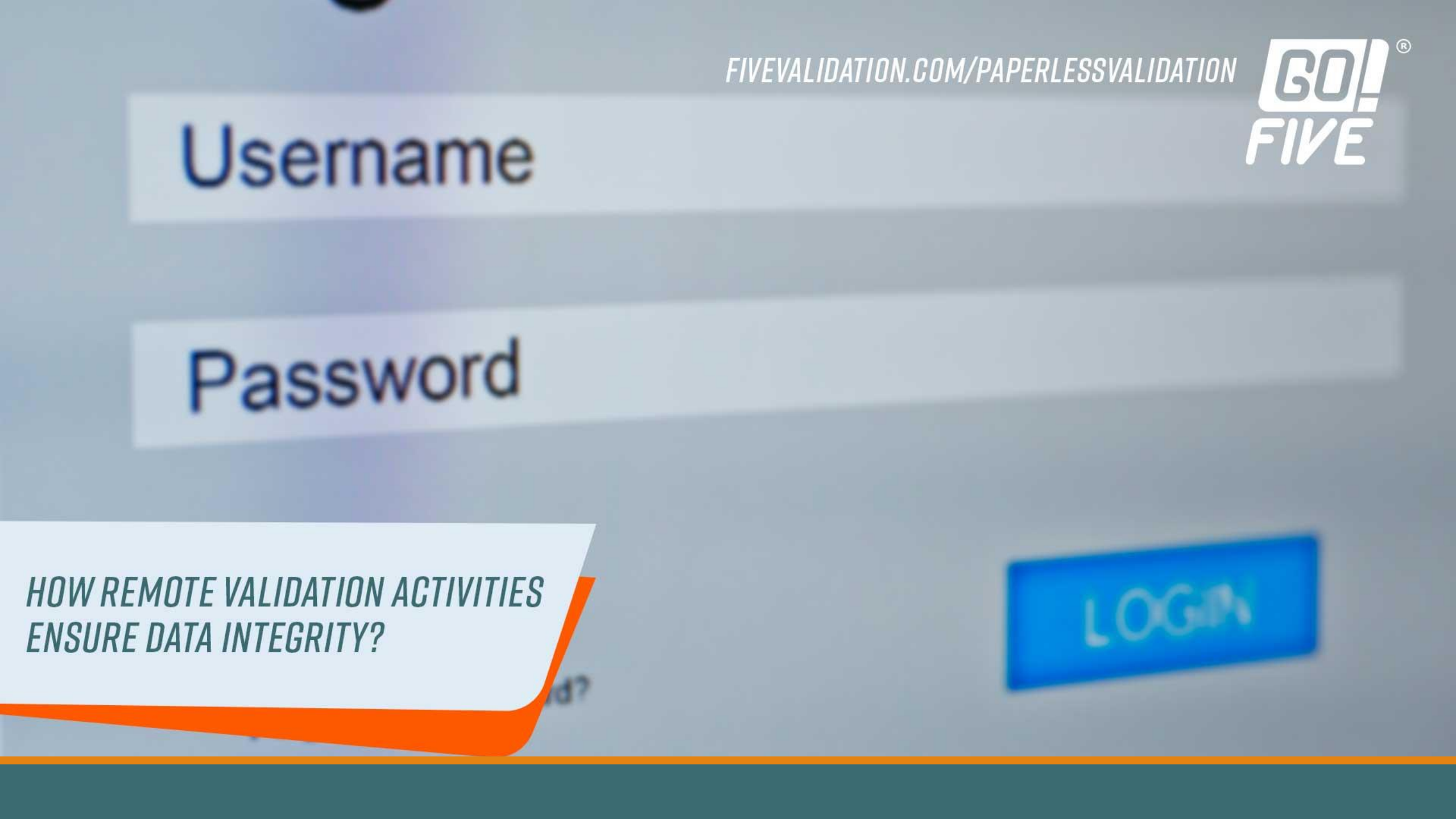

HOW REMOTE VALIDATION ACTIVITIES ENSURE DATA INTEGRITY?

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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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.

- 3x faster validations
- Revolutionary system with the possibility to handle more than one validation at the same time, fully aligned with agile work platforms
- Ready-to-use cloud platform. Projects become more agile and less bureaucratic. Access to projects from anywhere in the world via the internet
- Data integrity, security, and privacy - hosted on Amazon Web Services, in the United States.
- Zero paper. Development of fully paperless validation and qualification projects. Export of documents in PDF format
- Control / access to the productivity of the validation professional in each project (through numbers and graphs on the dashboard)
- Parameterization of review and approval flows with electronic signature - FDA 21 CFR Part 11 compliant
- Library - pre-made validations (suggestion of risk scenarios, requirements, and tests) with flexibility to edit the fields of the items.
- Responsive web interface with test execution using tablet.

Reduce costs, optimize your team, and save time by maintaining regulatory compliance for your company with faster validation and qualification documents and tests. Produce and place your final products in the market in less time (reduced time-to-market), keeping quality in compliance in line with advanced economies.

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

Click here to request yours.

https://fivevalidation.com/paperless-validation