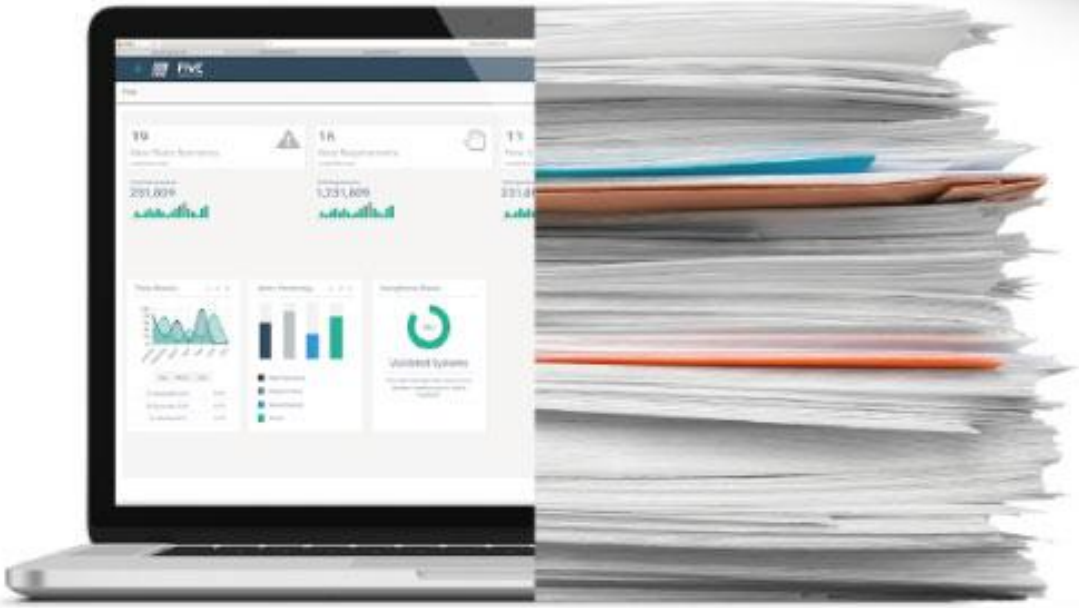
RegTech for Biopharma and Medical Devices Industries



SILVIA MARTINS and ELAINE VONG

FIVE VALIDATION

Improving health and well-being of families

OCT/2020

Validation

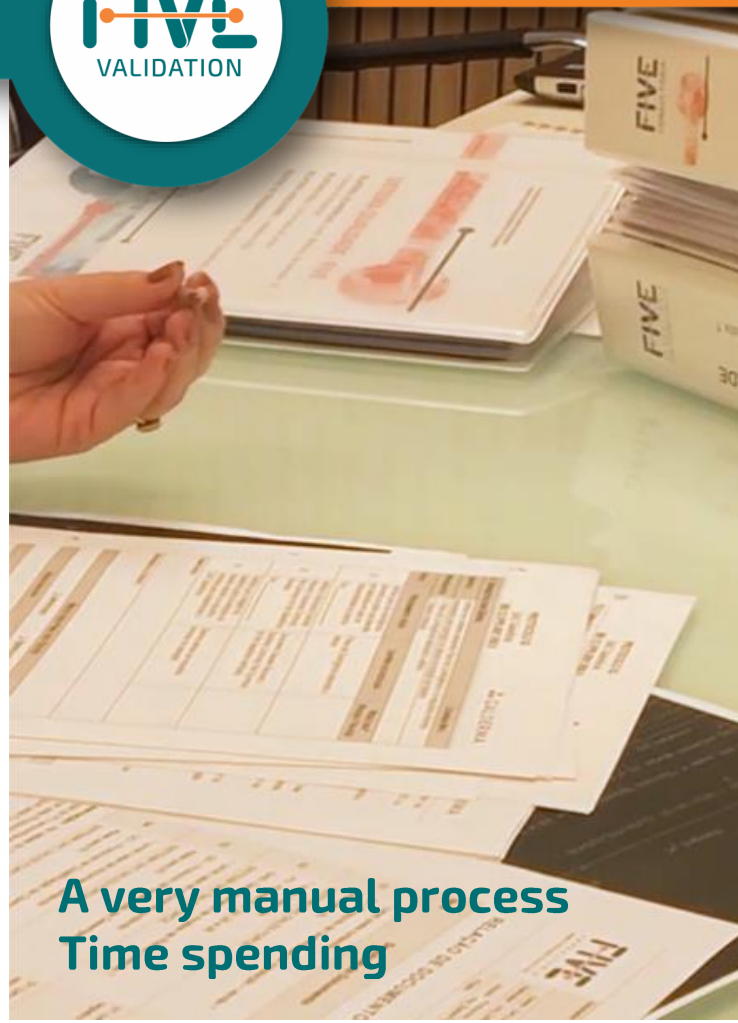
FIVE VALIDATION

Documents that confirm:

Software

Equipment

Process



A very manual process
Time spending

In compliance with global regulations

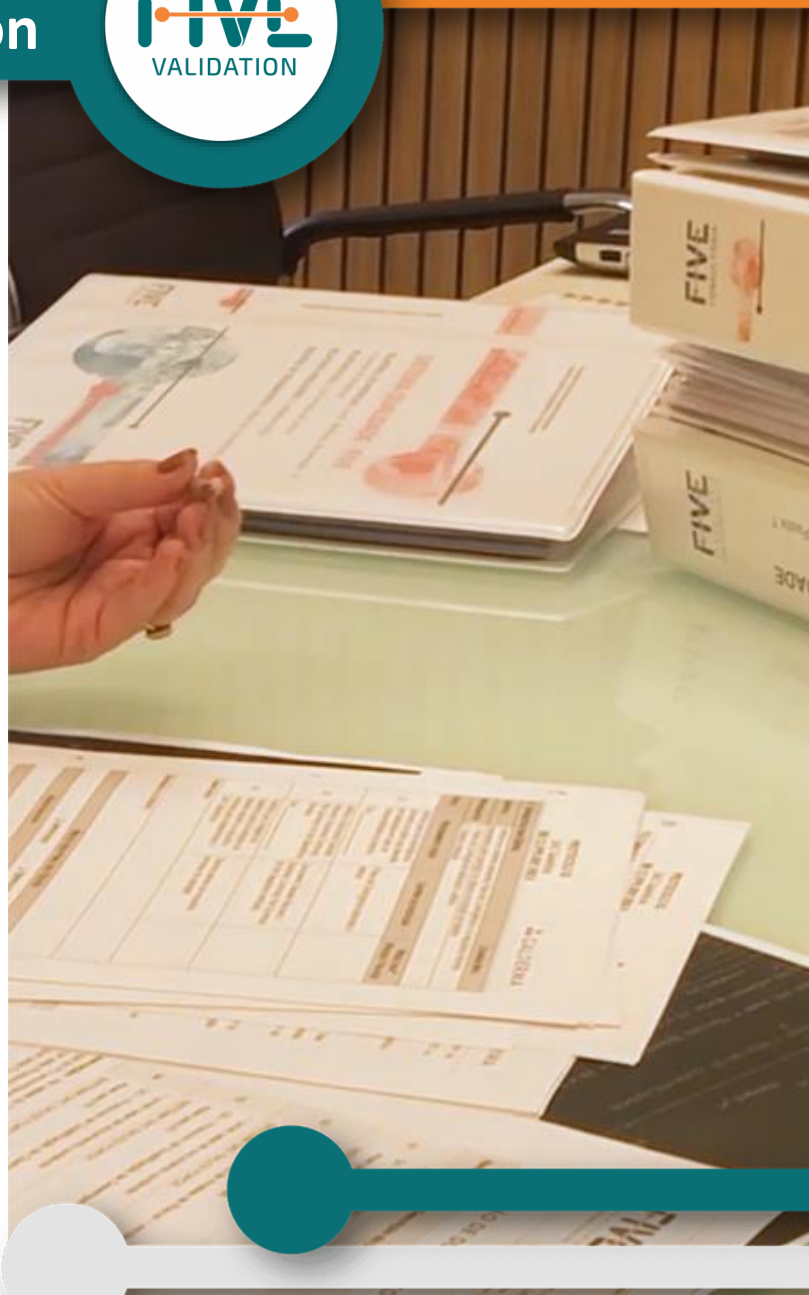
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH
An agency of the European Union

World Health Organization

FDA

* Disadvantages of Paper Based Validation

- Global shortage of skilled labor
- Time consuming and bureaucratic processes
- Slower responsiveness and agility to answer audit inquiries
- Integrity of packages - loss of data, packages or pages
- Onerous



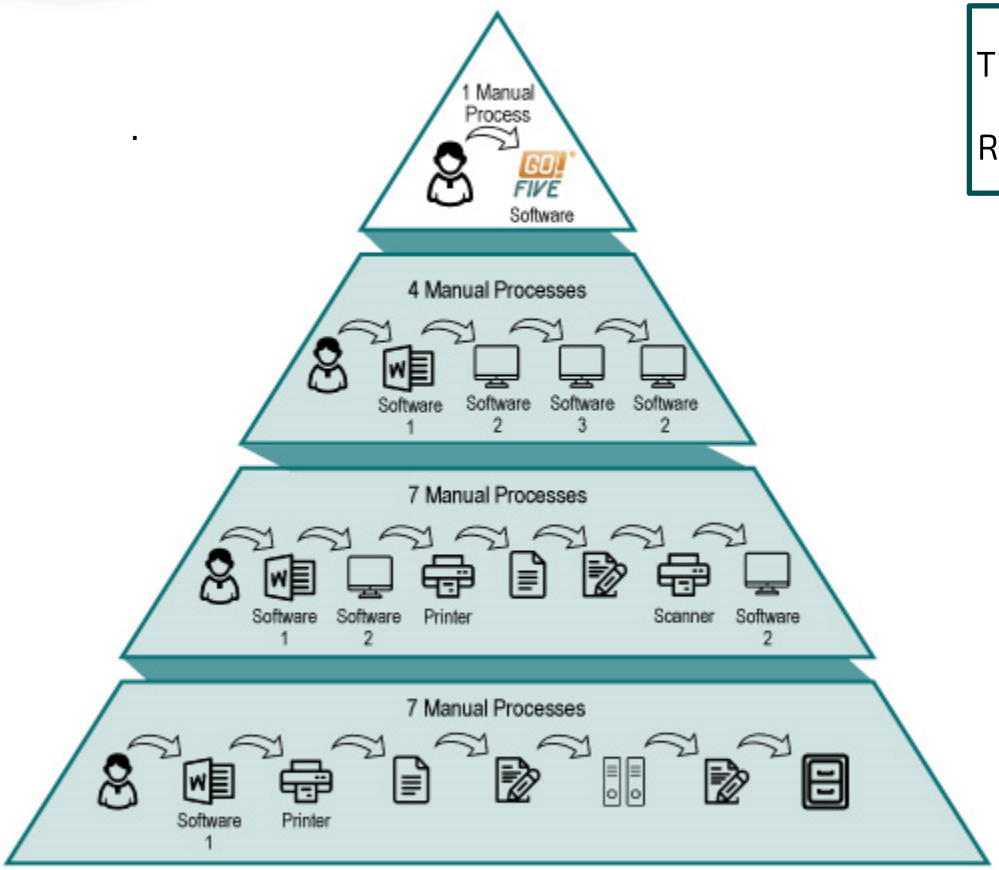
*Advantages of Paperless and Remote Validation

- Patient and/or consumer security
- Compliance
- Data integrity
- Quality of life for employees
- Better management of the process
- Efficiency

Data Integrity in Paperless Validation

- Audit trail
- Access control
- Data security

Automated process



Time consuming
Costs
Regulatory risks

LOW
HIGH

Efficiency
Data Integrity
Compliance
Sustainability

HIGH
LOW

Powered by FIVE VALIDATION

Paperless: VLMS and EDMS differences

Validation Lifecycle Management Software

≠

Electronic Document Management Software

EDMS is not sufficient because it:

Lacks mechanism for carrying out tests

Repository for documents – Nothing else!

Incapable of workflow management for validation

Cannot generate a Traceability Matrix

*Validating from Anywhere

- Your team can be anywhere in the world validating software, equipment and processes remotely
- Client monitoring of all activities, in real time and wherever you are!
- Reduction in validation costs: no travel expenses for service providers and/or professionals from other production sites

* Demands during the pandemic

- Remote work becoming the norm for companies during and after the pandemic period.
- Acceleration of digital transformation.
- Urgent need for systems to be validated due to Covid-19: vaccines, antibody therapies, convalescent plasma, diagnostics, etc.

Case: Alkaloid AD

- **Successful remote validation**

Global Team Management

- Real time – multiple sites
- Deliverables - each company site
- Employees working from home
- Dynamic environment

*Millennial Workforce

- A paperless solution can bring greater employee engagement to quality practices for millennial professionals.
- This generation of employees were born immersed in technology.
- Working with paper-based processes is not second nature, but digital systems are for this demographic.

*Retention of professionals

- Working from home increases the retention of highly qualified professionals in your company.
- There is no work related Covid-19 exposure with no travel.
- For most professionals, exchanging commuting time for other pursuits, like spending more time with their family, going to the gym or studying a language can increase employee satisfaction.

*Sustainability

- Reducing the global impact of validation is realized through paperless validation.
- Reduction in printing costs: toner/ink, plastic cartridges and paper.
- Reduction in greenhouse gas emissions from eliminating air travel.
- Companies pay monthly fees on printer lending contracts are potentially higher than the monthly fee for validation software.
- Competitive contracts from validation companies sourced worldwide without the associated travel costs.

*Paperless Validation

- A cloud-based solution can easily help operators to run validation tests and collect objective evidence for stand-alone systems without internet connection
- Absence of service providers and validation professionals, particularly in Class 100 areas
- Lack of folders and paper impact on the facility where validation is occurring
- Occasionally, 100% remote validation is not possible

Remote Validation Test Execution - internet

100% remote validation test execution:

- Management systems
- Equipment software from the QC labs
- Manufacturing and utilities automation systems that are connected to internet

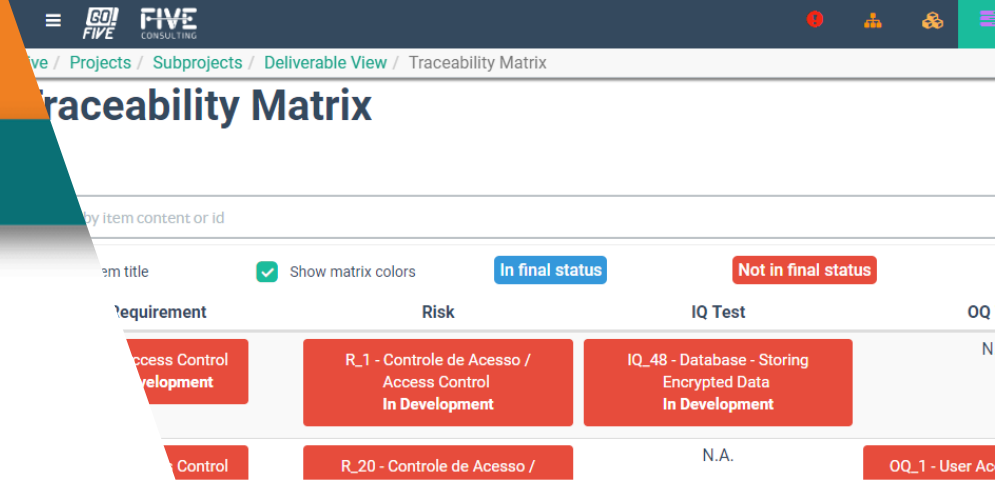
Information Security: no need to grant access of validated system to service provider.

Remote Validation Test Execution

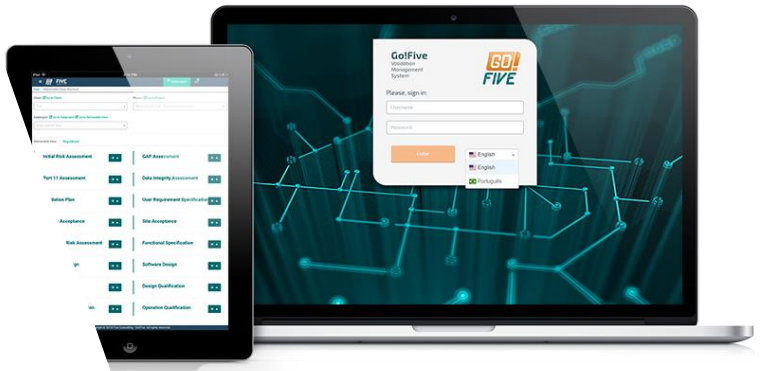
Automation systems or IT infrastructure qualification:

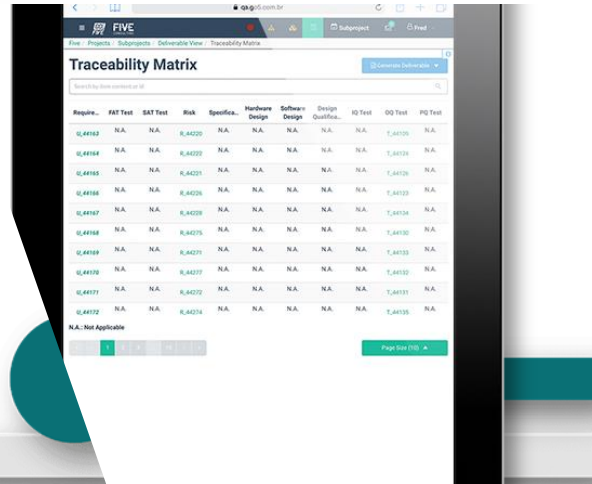
- Evidence is captured through a tablet
- There is no need for both professionals to be present.

GO!FIVE main features

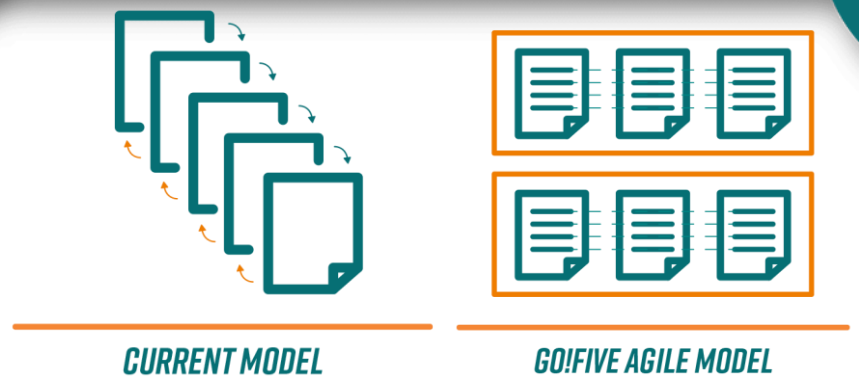


- SaaS platform
- Streamlines validations in electronic format
- Approval workflow
- Libraries
- 3x faster





GO!FIVE structure



Five / Projects / Subprojects / Deliverable View / Functional Risk Assessment

Functional Risk Assessment

Attach External Document | Generate Deliverable

Risks | Structure Items | Deleted | Audit Trail

Clear Filters | Search | + Add

Search in Risks

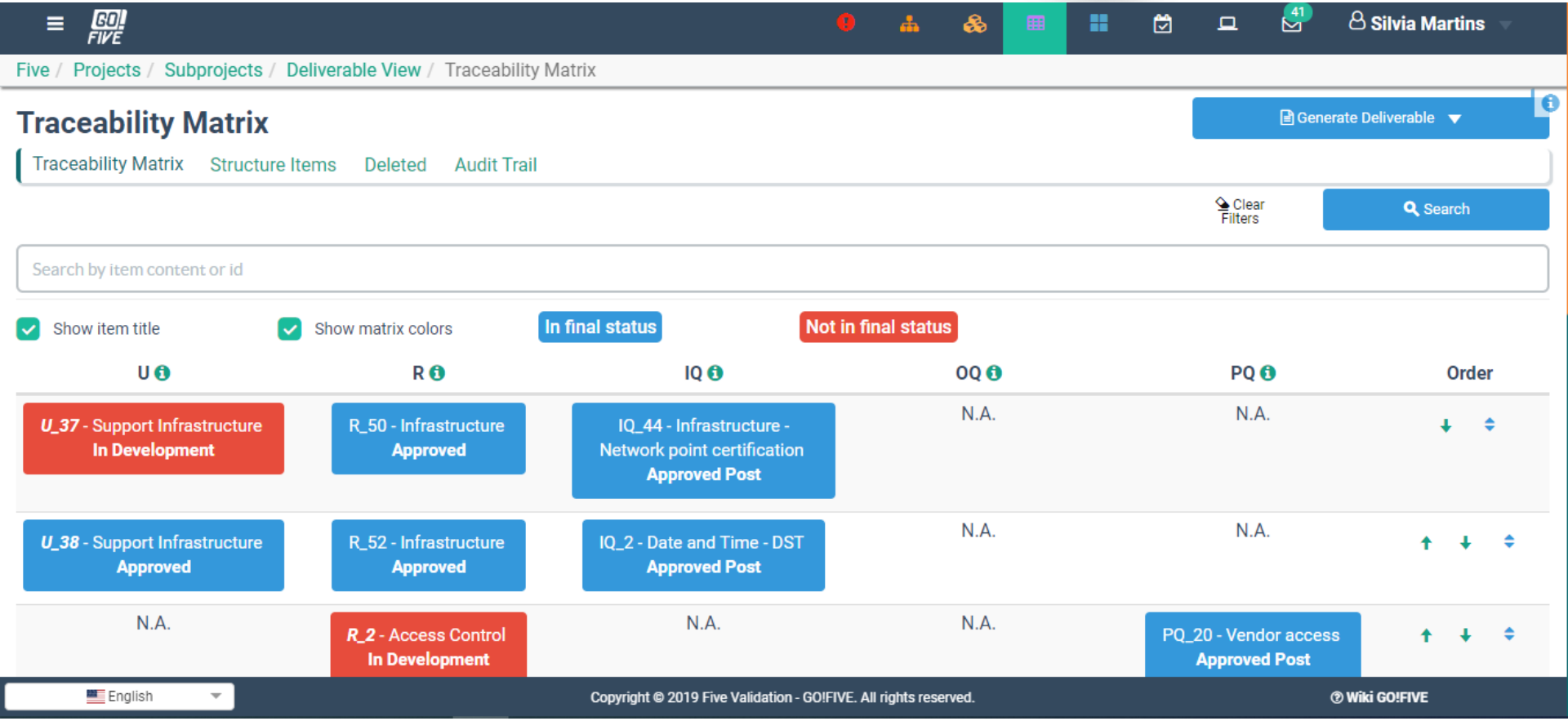
Any Risk Priority

+ More Filters

Quick view

ID	Title	Scenario	Worst-case effect	Priority	Version	Status	Actions
R_1	Access Control	Passwords are not stored in the database in encrypted format.	Lack of security. Impact on traceability.	High	1	In Development	
R_16	Access Control	Creating duplicate users (same user name)	Lack of traceability	Medium	2	In Development	

Traceability Matrix



Export PDF format

Master Validation Plan

Client: Five

Title: Master Validation Plan

Printed: 21/JUL/2020 Page: 2 of 3

FIVE VALIDATION

1. MASTER VALIDATION PLAN ITEMS

ID: 477 (Version 1)

Title: Introduction

FIVE Validation is in Sorocaba city, São Paulo state, Brazil is authorized by the FDA to import, manufacture, store, repack, distribute, export, transport: medicines, raw material, and related products.

Approver: electronically signed by: João Gomes 21/Jul/2020 at 14:56:04 UTC

ID: 478 (Version 1)

Title: Objective

The purpose of this document is to express all aspects of the validation lifecycle and the management of its activities. This document sets out Five Validation guidelines, strategies, and efforts with respect to validations.

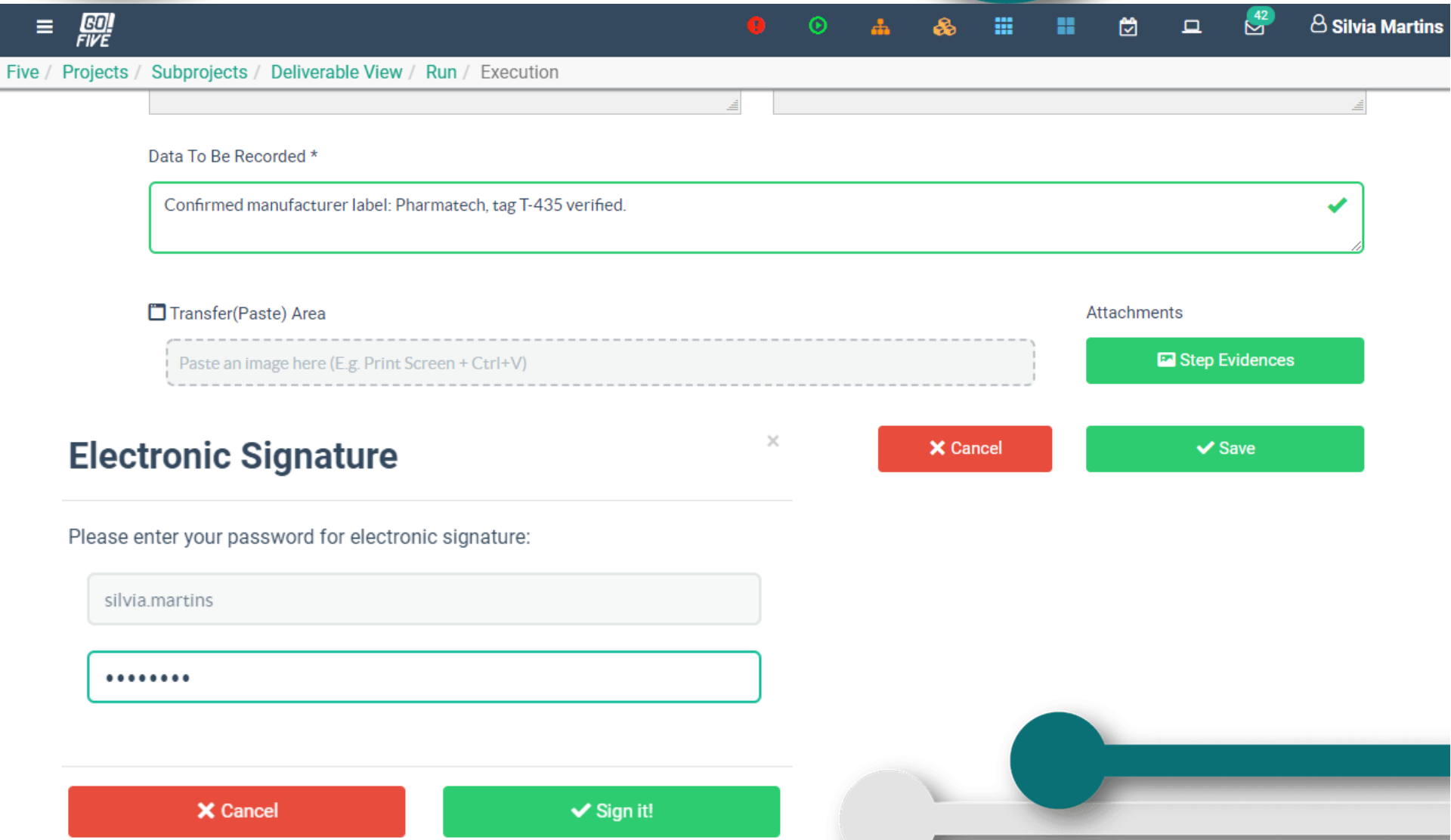
Approver: electronically signed by: João Gomes 21/Jul/2020 at 14:56:04 UTC

ID: 479 (Version 1)

Title: Scope

This Master Validation Plan (VMP) covers specific plans for all range of validation topics with GxP impact, ensuring that they all comply with applicable standards and regulations. The validation plans, covered by this VMP, contain the specific scope of activities and schedule defining all validation needs. Once validated / qualified they are subject to the change control in use by Five Validation

Test Execution



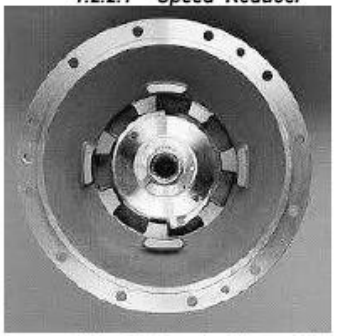
Test PDF format export

Test Scripts – Installation Qualification

Mixer Pharmatech Blender 500L EN

1.2.2. Evidences: IQ_14, Test Run: 752, Step: 2

1.2.2.1 Speed Reducer



Step 3 - Run 1 - Step status: Approved

Predecessor [Not applicable]

Action

Check if the fan used to liquid additions via spray bars (fan-type spray nozzles) is manufactured by Ventilator, model 160-A, 440Vac, frequency 60Hz.

Expected Result:

Fan data label is according to specified in action of this step.

Data to be recorded

Fan data label is according to specified in action of this step.

Executed by: Silvia Regina da Silva Martins 07/24/2020 at 1:11:23 PM UTC

Attached Files: Reducer

1.2.3. Evidences: IQ_14, Test Run: 752, Step: 3

1.2.3.1 Reducer

Team that organized this event

Elaine Vong – special thanks

Henrique Malaquias
Demetrius Rocha
Paula Campos
João Gomes
Rafael Almeida

Thank You

Special thanks to ALKALOID AD team:

Nikola Dimovski
Darko Atanasoski
Mila Palamidovska

Many thanks for your attention!

Elaine Vong: elaine@vongbiopharma.com
Silvia Martins: silvia.martins@fivevalidation.com

http://bit.ly/Webinar_OCT_28_2020