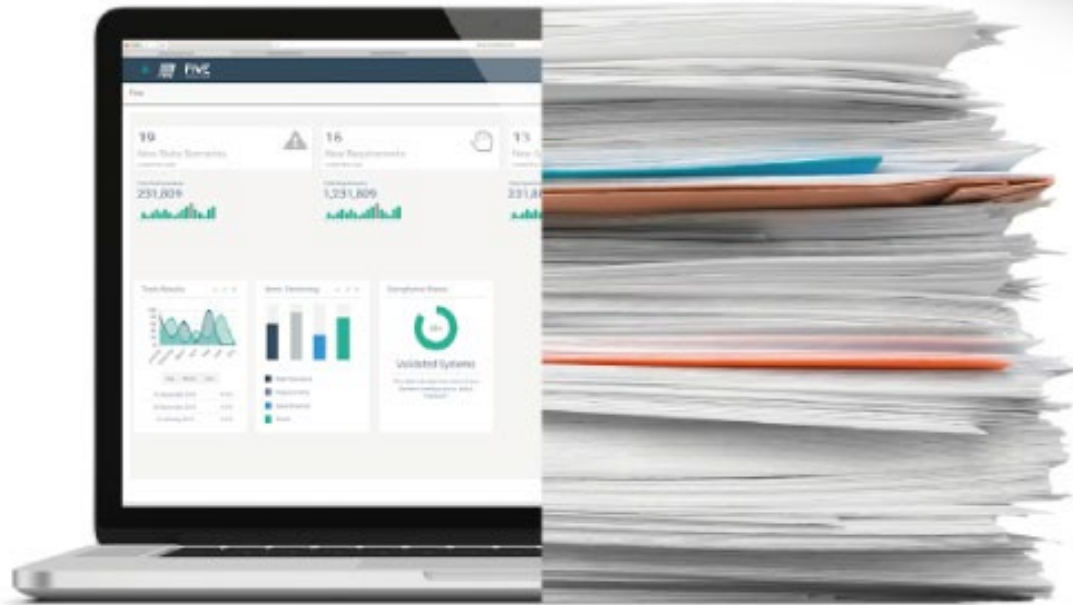


# RegTech for Biopharma and Medical Devices Industries



SILVIA MARTINS and ELAINE VONG





**FIVE**  
VALIDATION

Improving health and well-being of families

OCT/2020

# Validation



Documents that confirm:



Software



Equipment



Process



A very manual process  
Time spending

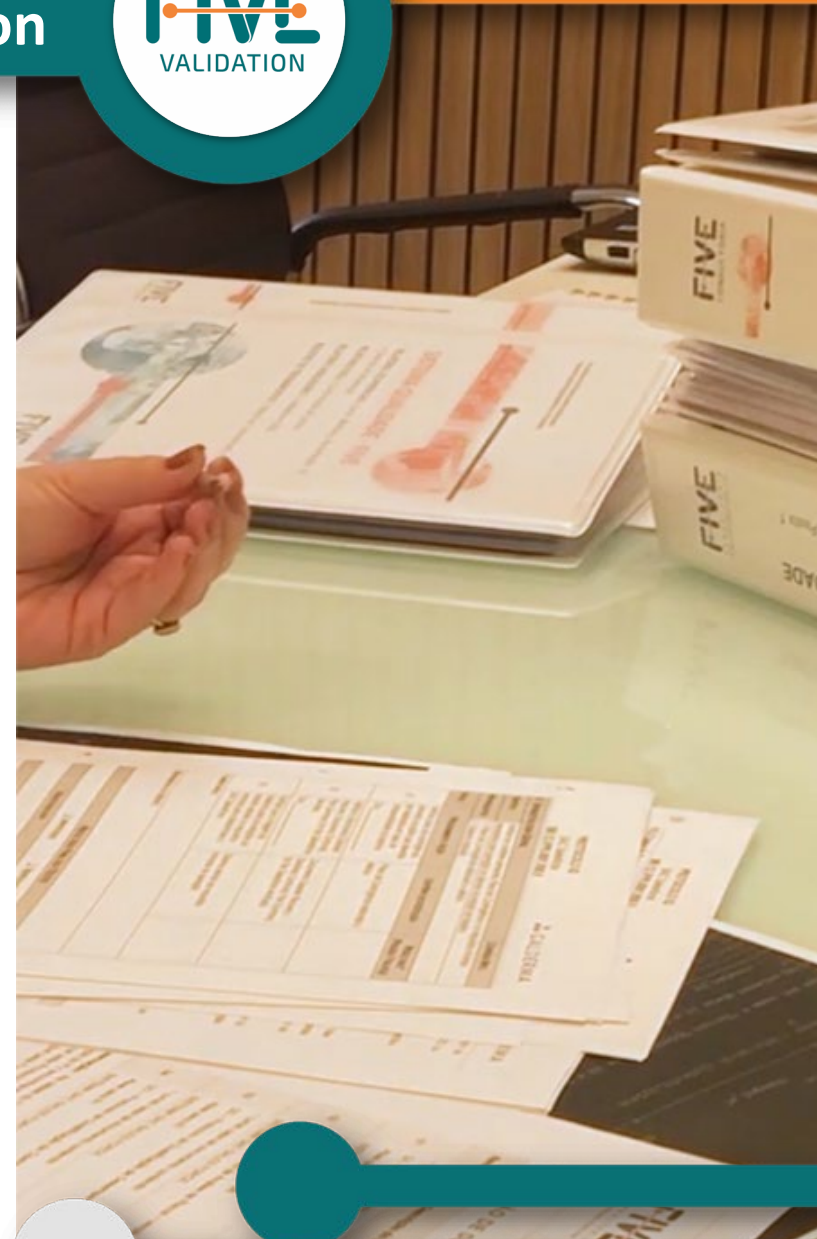
In compliance with global regulations



## \* Disadvantages of Paper Based Validation

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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

**FIVE**  
VALIDATION

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



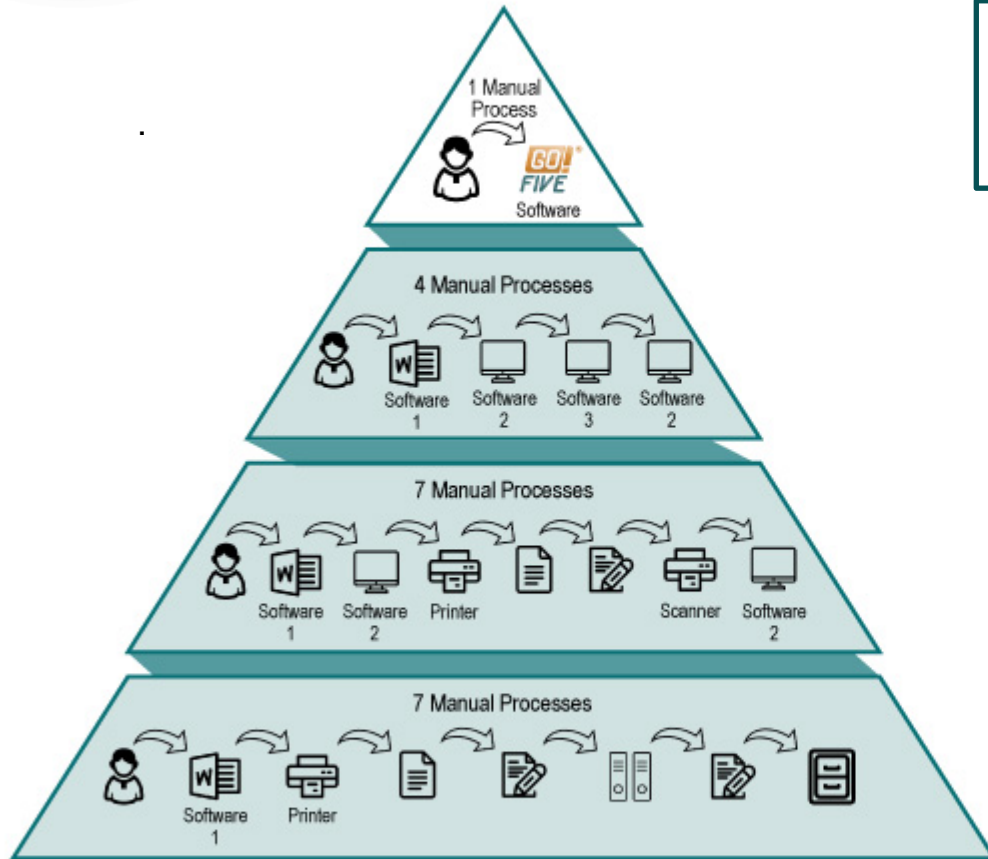
# Data Integrity in Paperless Validation



- Audit trail
- Access control
- Data security



# Automated process



Time consuming  
Costs  
Regulatory risks

Efficiency  
Data Integrity  
Compliance  
Sustainability



## 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

**FIVE**  
VALIDATION

- 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.



- Successful remote validation



- 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

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:

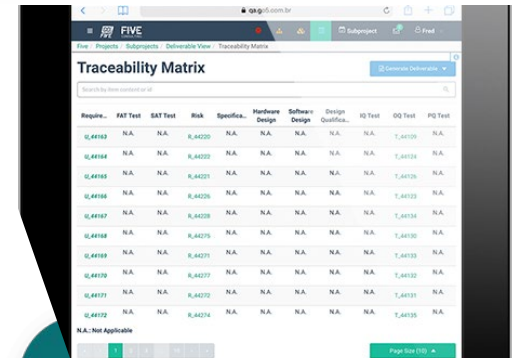
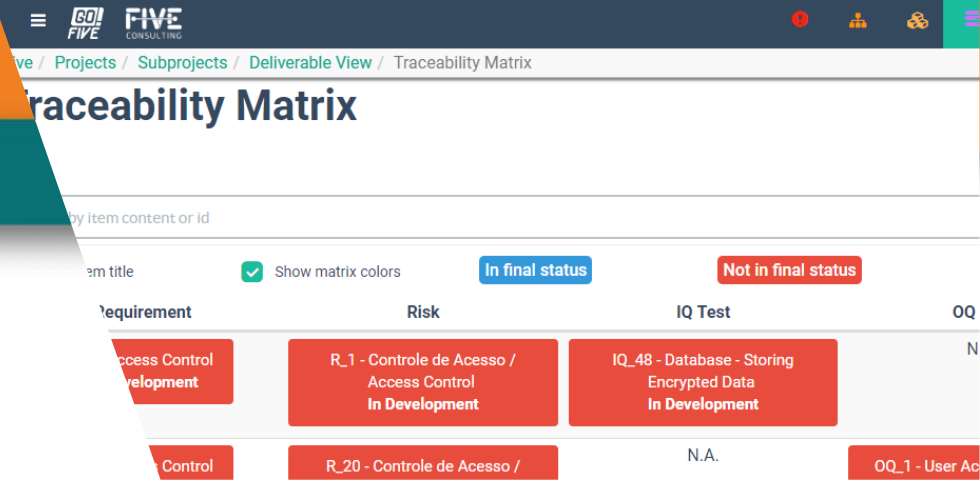
- Evidence is captured through a tablet
- There is no need for both professionals to be present.



# GO!FIVE main features



- SaaS platform
- Streamlines validations in electronic format
- Approval workflow
- Libraries
- 7x faster



# GO!FIVE structure



CURRENT MODEL



GO!FIVE AGILE MODEL

## 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

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



## Traceability Matrix

Generate Deliverable

Traceability Matrix | Structure Items | Deleted | Audit Trail

Clear Filters

Search

Search by item content or id

Show item title

Show matrix colors

In final status

Not in final status

U	R	IQ	OQ	PQ	Order
U_37 - Support Infrastructure In Development	R_50 - Infrastructure Approved	IQ_44 - Infrastructure - Network point certification Approved Post	N.A.	N.A.	↓ ↑
U_38 - Support Infrastructure Approved	R_52 - Infrastructure Approved	IQ_2 - Date and Time - DST Approved Post	N.A.	N.A.	↑ ↓
N.A.	R_2 - Access Control In Development	N.A.	N.A.	PQ_20 - Vendor access Approved Post	↑ ↓

English

# Export PDF format



## Master Validation Plan

Client: Five

Title: Master Validation Plan

Printed: 21/JUL/2020

Page: 2 of 3



## 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



Navigation icons: Home, Error, Play, People, Gear, Grid, Window, Mail, Laptop, Notification (42), Profile (Silvia Martins)

Five / Projects / Subprojects / Deliverable View / Run / Execution

Data To Be Recorded \*

Confirmed manufacturer label: Pharmatech, tag T-435 verified. ✓

Transfer(Paste) Area

Paste an image here (E.g. Print Screen + Ctrl+V)

Attachments

Step Evidences

## Electronic Signature

Cancel

Save

Please enter your password for electronic signature:

silvia.martins

••••••••

Cancel

Sign it!

# Test PDF format export



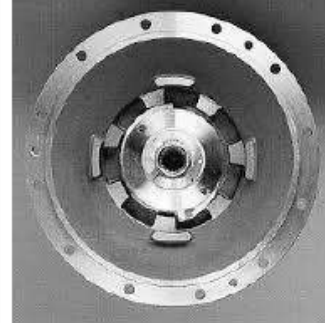
Document:	<b>Installation Qualification - Script</b>
Client:	Five
Title:	Installation Qualification - Script
Printed:	07/24/2020
Page:	1 of 8

## 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

**GO!**<sup>®</sup>  
**FIVE**

**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!



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**Silvia Martins:** silvia.martins@fivevalidation.com



[http://bit.ly/Webinar\\_OCT\\_28\\_2020](http://bit.ly/Webinar_OCT_28_2020)