



DIGITAL VALIDATION: Validation and Qualification process

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Global CSV Manager Menarini



MENARINI
group



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Francesca Merlini, Information Engineer, in Menarini since 2007. As part of the Menarini Global Quality Direction, she is the Responsible for Computer System Validation and Data Integrity. She coordinates a team of 5 members for the management of the Validation of Global Computerized Systems.



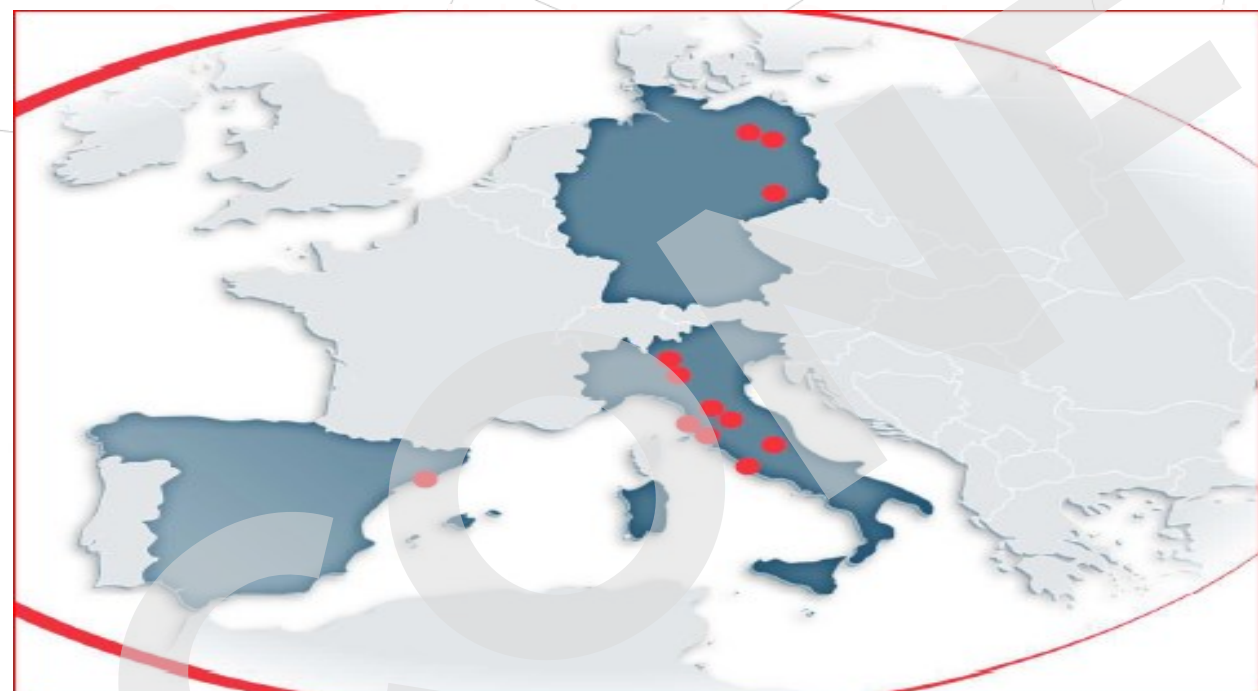
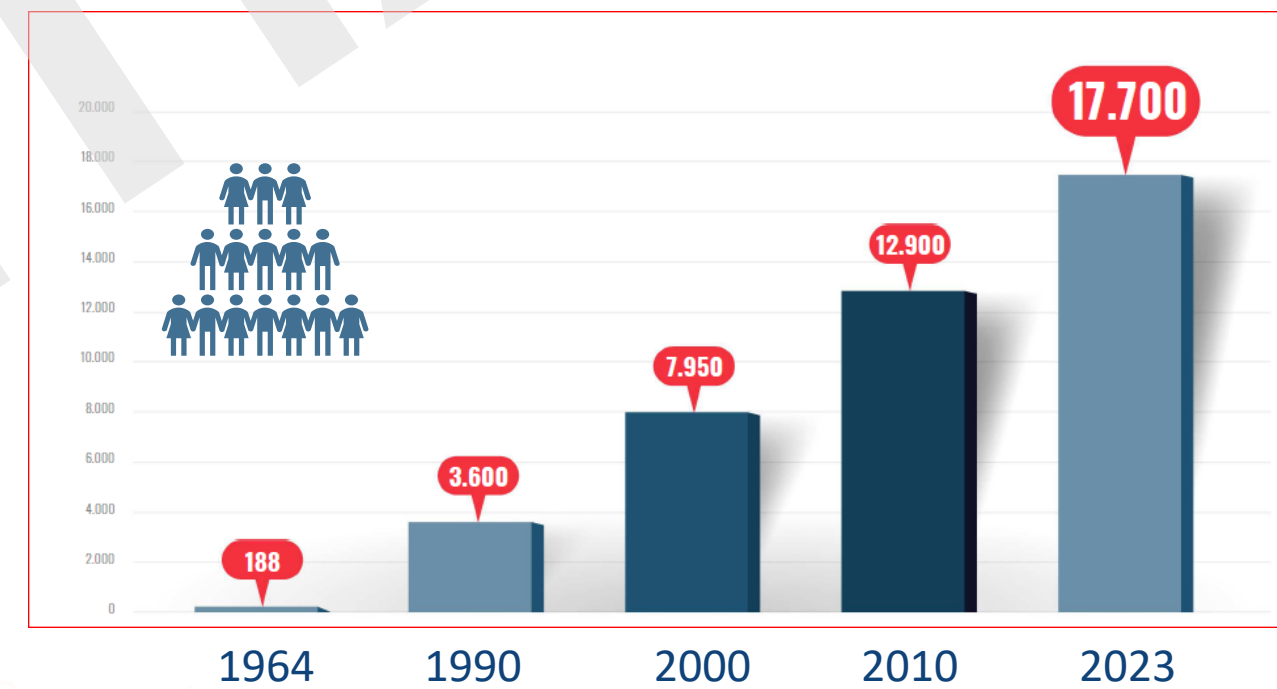
Founded in 1886, Today is present in **140 countries** (with plants, commercial and distribution affiliates)

EUROPE is the Production Core of the group



18 Production Plants

10 Research & Development Centers



AGENDA

- 01** Evolution of Validation/qualification management in Menarini
- 02** Aim of the implementation of a VLMS
- 03** VLMS Implementation phases and Validation steps
- 04** VLMS Rollout and Roadmap
- 05** VLMS main features
- 06** VLMS examples and details
- 07** Final considerations

Evolution of Validation/Qualification process in Menarini



Until 2020:

Validation and Qualification process completely paper based

2021:

CSV documents issued and approved in DMS system;
Test execution still paper based

End of 2022:

Equipment Qualification managed fully paperless

2024:

CSV for Global System managed fully paperless

Validation processes not harmonized among different companies of the group.

Test execution paper based

Management of printouts, evidencies, compiled forms.



Ibrid approval workflow for the management and signature of validation documentation

Delocalized archives (global/site level)

Original and scanned copy of signatures

Phisical archive for paper based documentation

Time consuming search for test cases inside single test protocols (i.e. for Audit request)

Aim of new paperless approach



1

Harmonize Qualification/Validation process and templates among different sites of the Group

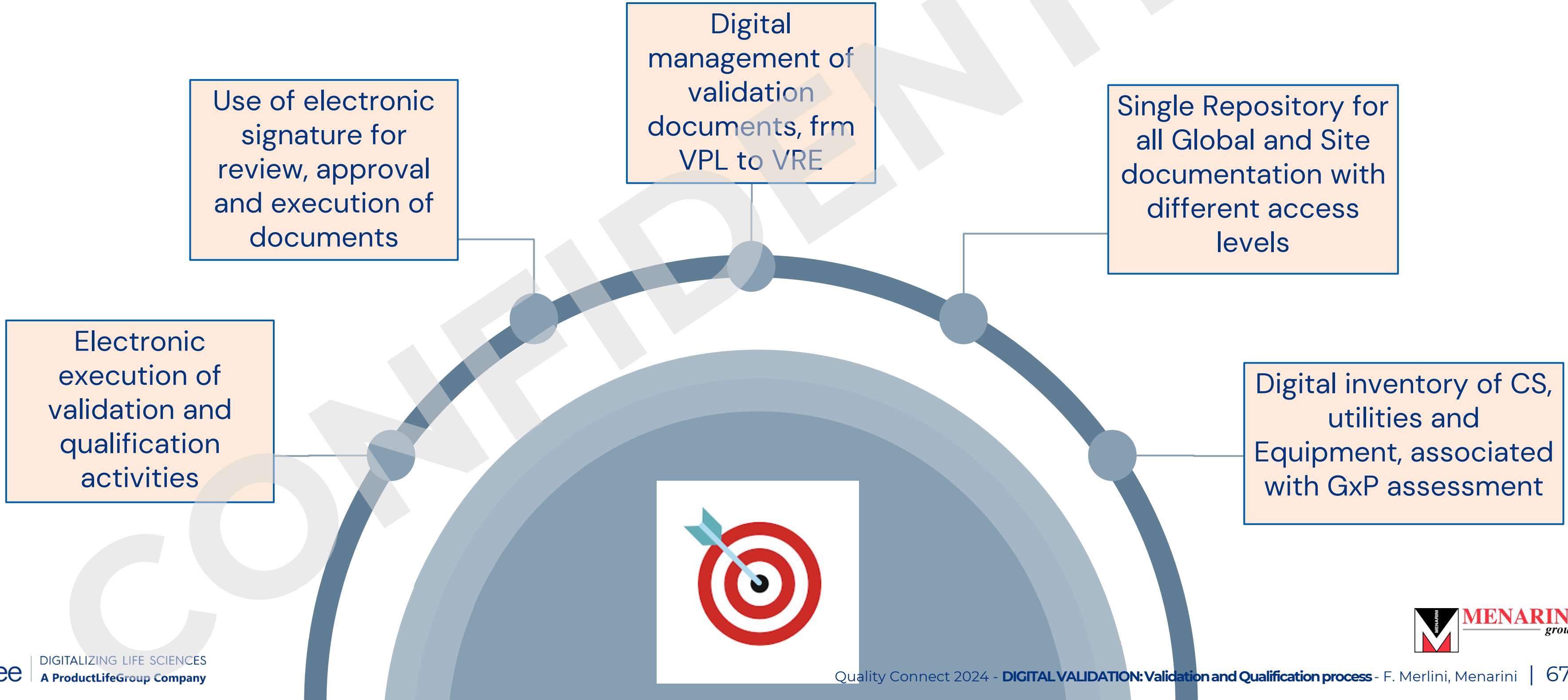
2

Digitize validation: moving to PAPERLESS validation

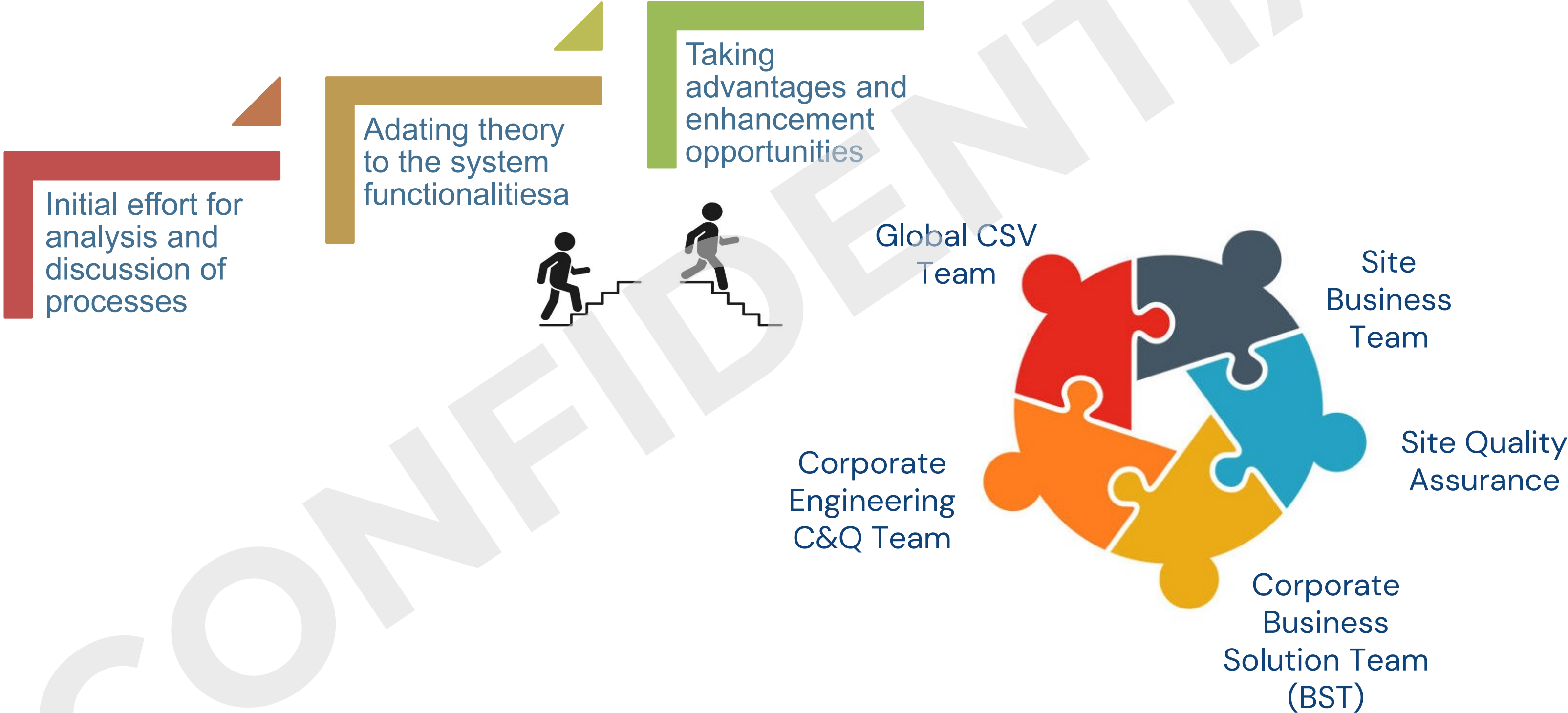
3

Electronic scheduling of periodic reviews and requalifications

VLMS: main functionalities



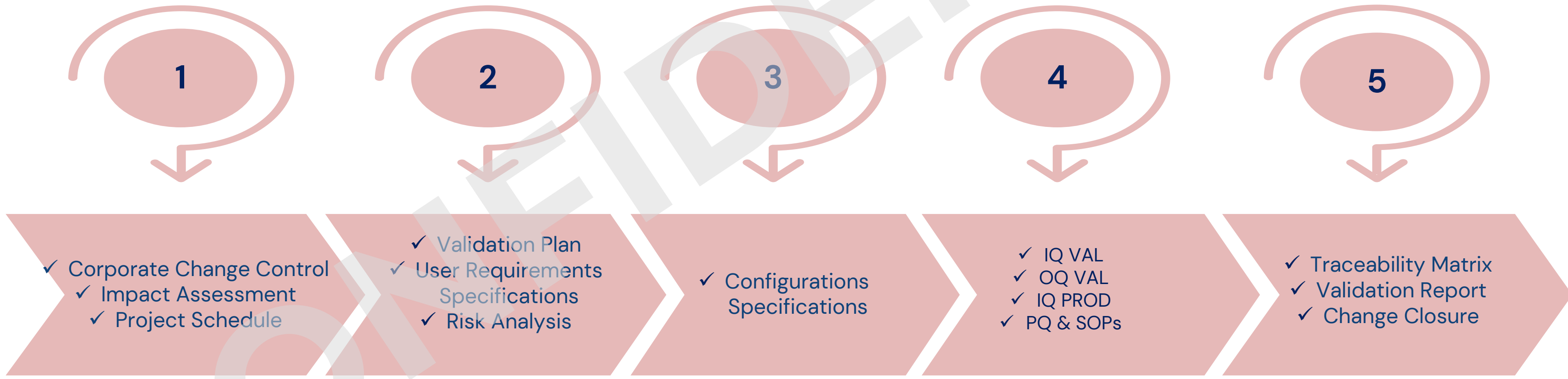
VLMS: System Implementation



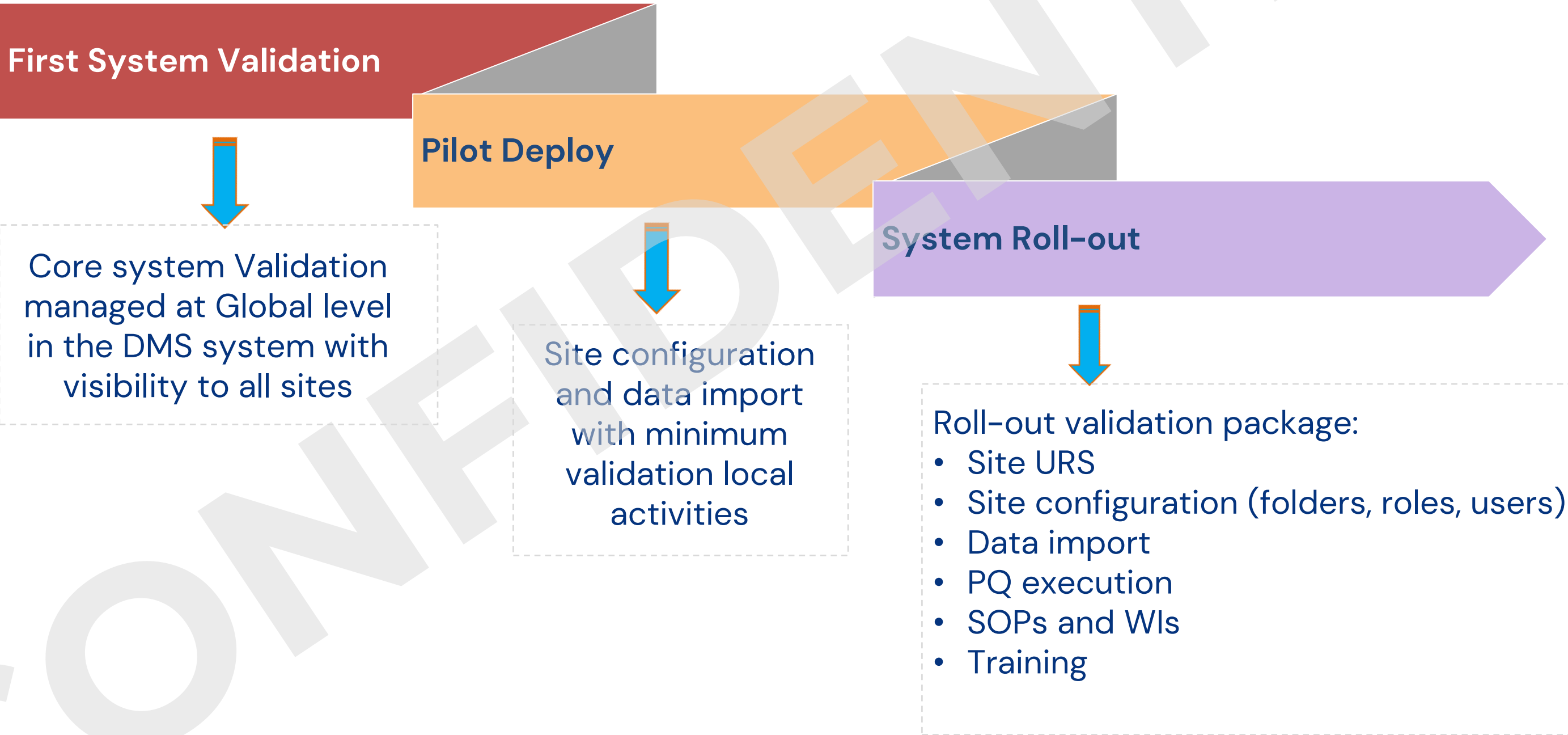
VLMS: implementation phases and validation



Be Careful: a VLMS must be validated itself!!



VLMS: Deploy and roll-out phases



VLMS: process and features

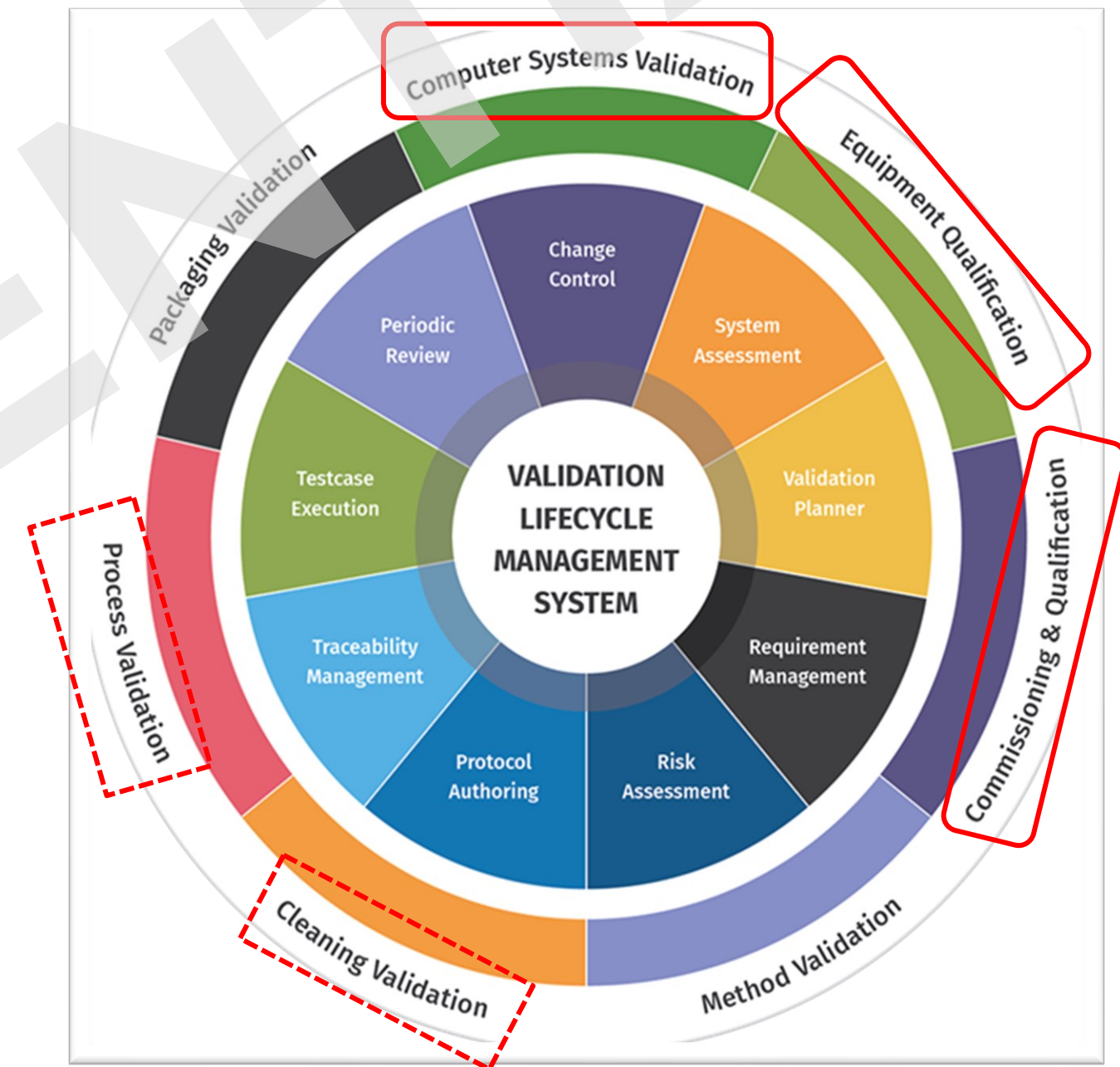


Currently Menarini has implemented the following processes:

- Commissioning & Qualification
- Equipment Qualification
- Computer System Validation
- Computer System Periodic Review

With the support of the following features:

- Digital System inventory
- System Assessment
- URS Risk Assessment
- Protocol authoring and approval
- Paperless Testcase Execution
- Automatic Scheduling



VLMS: Inventory management



Digital Inventory of:

- Equipments
- Utilities
- Computerised Systems

The screenshot shows the 'Inventory Manager' interface. At the top, there are tabs for 'DEFAULT', 'PROJECT', and 'CCR'. Below that, there are tabs for 'Entity', 'Favorites', and 'History'. A search bar shows 'Global QA CSV' and 'L'Aquila' is selected. The main area displays a tree view of entities under 'L'Aquila', including folders like 'Site Documents', 'New Entity', 'Black Utilities', 'Clean Utilities', 'Computerized System (L1)', 'Computerized System (L2)', 'HVAC', 'Laboratory Equipment', 'OSD Bulk Equipment', 'Capsule Filling Machines', 'Coaters', 'Combined Granulators/Dryers', and 'Granulatore a letto fluido (GRES-02)'. The 'Granulatore a letto fluido (GRES-02)' folder is expanded, showing sub-items like 'Approved', 'Calibration Summary Report', 'Design Qualification Report', 'Design Specification', 'Equipment Calibration Plan', 'Installation Operational Qualification', 'Legacy System Report', 'Periodic Qualification', 'Site acceptance testing', 'Traceability Matrix', 'User Requirement Specification', 'Validation Plan', 'Validation Plan Report', 'Conditionally approved', and 'Inactive/Terminated/Suspended'.

The screenshot shows the 'Entity Details' interface. It displays a table of entity information:

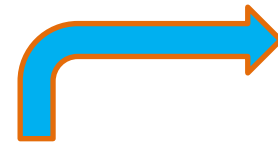
Site	Global QA CSV
Intended Use	Quality processes management
Entity Validation Status Alert Group	Global Quality
Category	Computerized System (L3)
Sub Category	Quality Assurance
Entity	TrackWise
Entity No.	QA-002
Entity Type	Legacy System - CS (L1 - L2 - L3 - L4)
Validation Status	Validated
Software House	Sparta Systems
System Assessment Result for Legacy System	The System has GxP impact. System Nature is Information System. The System is classified in GAMP Software Category 4 - Configured. The System Scope is Corporate. The System is Closed. The System manages Electronic Signature based on Username and Password.
Business Application Manager	Francesca Merlini
Application Software System Administrator	Laura Giuntini
System Integrator	LifeBee
ICT Infrastructure	Data Centre Luxembourg
Validation Framework ID	CSV-VF-0006.01

- No more Excel inventory to be maintained
- Possibility of search/queries/export

VLMS: User Requirements management and evaluation



Word-alike issuing of URS with special tags



CODE	REQUIREMENT TITLE	REQUIREMENT DESCRIPTION
WF.URS.CHC.004	Open a Change Control	Originator, Originator - Approver and QA will be able to create a new Change Control record in <i>Opened</i> status.
WF.URS.CHC.005	Cancel a Change Control	Originator, Originator - Approver and QA will be able to perform the Cancel activity to change the status from <i>Opened</i> to <i>Closed-Cancelled</i> . An activity summary is required.
WF.URS.CHC.006	Submit a Change Control	In <i>Opened</i> status, Originator, Originator - Approver and QA will be able to perform the Submit activity, in order to move the record to <i>Manager Evaluation</i> status.
WF.URS.CHC.007	Request More Info	In <i>Manager Evaluation</i> status, the person selected as <i>Department Manager</i> (in <i>Opened</i> status) will be able to perform the Request More Info activity, in order to move the record in <i>Opened</i> status. An activity summary is required.
WF.URS.CHC.008	Cancel a Change Control	The person selected as <i>Department Manager</i> (in <i>Opened</i> status) will be able to perform the Cancel activity to change the status from <i>Manager Evaluation</i> to <i>Closed-Cancelled</i> . An activity summary is required.
	Department	In <i>Ma</i>



A URS risk analysis is compiled directly in the system with std rules and classification. The result will indicate how to mitigate the risk.

ENTITY : TRACKWISE

ENTITY No.: QA-002

Doc.No.: CSV-QA-002-URS-001.01

Approval

Document Title :User Requirements Specification – Change Control

Doc. No. :CSV-QA-002-URS-001.01

Authoring

#	Author	Title	Functional Role	Authored on
1	Mattia Baldi [baldim]	Global CSV Specialist	N/A	11Apr2024 11:14:46 AM Time Zone: (CEST)

Review

#	Reviewer	Title	Functional Role	Reviewed On
1	Laura Giuntini [giuntini]	Corporate BST Specialist	System Administrator	11Apr2024 11:01:27 AM Time Zone: (CEST)

Approval

#	Approver	Title	Functional Role	Approved On
1	Luca Lazzeri [lazzeri]	Corporate BST Coordinator	System Owner	11Apr2024 11:21:11 AM Time Zone: (CEST)
2	Francesca Merlini [merlinif]	Corporate QA CSV Manager	Quality Approval	11Apr2024 12:03:18 PM Time Zone: (CEST)

Doc.No.: CSV-QA-002-URS-001.01 Approved On 11Apr2024 12:03:18 PM (CEST)

View Risk Assessment

Site: Munich

Task Type: New Revision

Risk Assessment Name: Requirement RA ERP Module 5

Risk Assessment ID: MUC-RA-2022-0019.01

Risk Assessment Template: Standard Form

Change Implementation Details: N/A

Additional Fields

Risk Based Approach: Requirement Level

Risk Model: FMEA Risk Assessment [RMM-MUC-0003.01]

Doc No: URS_1-ERP M5-0001.01

Select Risk Level

No.	Requirement	Severity	Probability	Detectability	Risk Class	Risk Priority Number	Process Condition	View
1	URS_1 This is the new requirement for the esystem.	1-Low	1-Unlikely	1-Easily Detected	1-Low	1-Low RPN	Low Risk [RP-MUC-0001.01]	
2	URS_2 System will have a web based user interface compatible with Microsoft Internet Explorer 7 or 8 or 9.	2-Moderate	2-Probable	2-Somewhat Detectable	4-Moderate	8-Moderate RPN	Medium Risk [RP-MUC-0002.01]	
3	URS_3 Access to the system will be through ValGenesis. Users with permissions to the esystem functionality will be able to carry out appropriate work.	3-High	3-Likely	3-Undetectable	9-High	27-High RPN	High Risk [RP-MUC-0003.01]	
4	URS_4 Specific functions can be turned on through the configuration	1-Low	2-Probable	1-Easily Detected	2-Low	2-Low RPN	Low Risk [RP-MUC-0001.01]	

Approval Required: Yes No

VLMS: Test protocol and execution



Table 7: Test case 1

Test Step	Test Action	Expected Result	Actual Result Attachments	Pass / Fail	Reference	Signature and date
1.	Login into TrackWise. In the top of the page click on +Create button and open a new Complaint record. Compile, at least, all the mandatory fields. Click on Save.	The system correctly opens a new Complaint empty form. A new Complaint record is correctly created. The record is in <i>Opened</i> status.			GE.URS.CMP.001,G E.URS.CMP.002,GE. URS.CMP.003,WF.U RS.CMP.004,GC.UR S.CMP.027,PR.URS. CMP.030,UP_URS.C MP.036,NC MP.05	
2.	Open the Complaint record in <i>Opened</i> status. Select the "Submit" activity. Verify that the mandatory fields and the Electronic Signature are	The system requires an electronic Signature to save. The record is correctly moved in <i>Investigation Definition</i> status.			WF.URS.CM O.URS.CMP URS.CMP.05 RS.CMP.027 S.CMP.0	

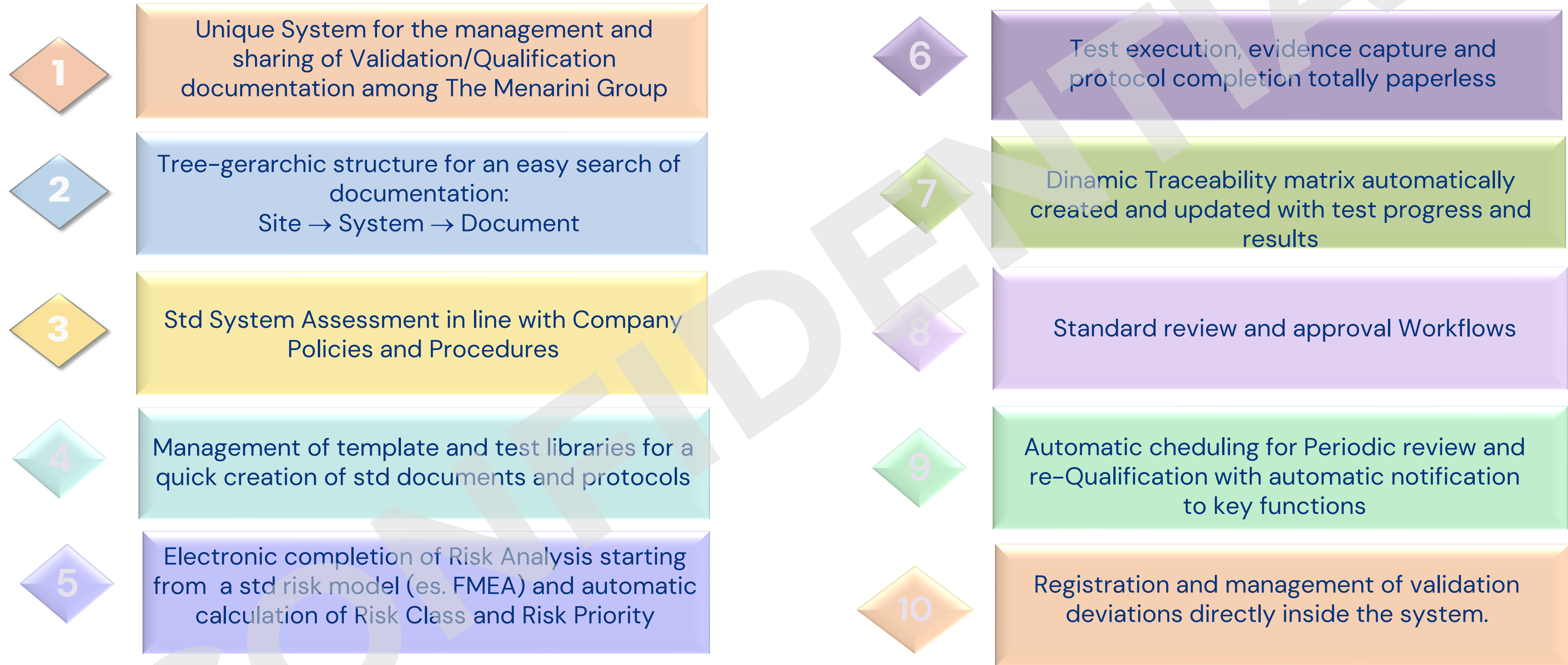
Step by step description of test cases with special references to URS (huge work!)

Test execution done directly in the system with automatic timestamp registration.

The screenshot displays the 'ELECTRONIC EXECUTION' interface. On the left, there's a 'TASK DETAILS' section with a table for 'Table 3' showing test results for 'Row 4'. The table has columns for 'Pass', 'Fail', and 'N/A'. Below this is an 'Actual Results' section with a text area containing 'This is failure'. On the right, a 'Test Table' is visible, showing a list of test cases with columns for 'No.', 'Description', 'Expected Results', 'Reference', 'Actual Results', 'Pass/Fail', and 'User ID and Timestamp'. A notification window is overlaid on the screenshot, displaying 'Done, Picture Uploaded Successfully' with an 'OK' button. A blue arrow points from the table in the screenshot to the table in the table above.

No.	Description	Expected Results	Reference	Actual Results	Pass/Fail	User ID and Timestamp
1.	Login to SAP NWBC	Successfully logged into SAP system	,URS_1,URS_4	Reason for Edit: Forgot about something New Value:- Successfully logged into SAP system. Simply provide your changes. Old Value:- Successfully logged into SAP system	Reason for Edit: Forgot about something New Value:- Pass Old Value:- Pass	Reason for Edit: Forgot about something New Value:- Executed By: Mary Manager (marymuc)-18Mar2022 02:47:51 PM (CET) Old Value:- Executed By: Mary Manager (marymuc)-18Mar2022 02:42:30 PM (CET)
	Index displays "Software Management"	Index displays "Software Management"	,URS_3		Pass	Executed By: Mary Manager (marymuc)-18Mar2022 02:44:57 PM (CET) [IMGSCR_3_2_1]
	Software Management menu on the left	Displays Software Management menu on the left	,URS_10,URS_9,URS_8		Pass	Executed By: Mary Manager (marymuc)-18Mar2022 02:46:58 PM (CET) [Certificate-1]

DIGITAL VALIDATION: PRO and CONS



DIGITAL VALIDATION: Recommendation for implementation



1

Involvement of several users among the companies of the group can be time-consuming: user request/activation, training, support for first validation

2

Once rules are set: the system require them to be respected: a good design helps to be more flexible during the routine system usage

3

A strong commitment of the sponsor is recommended in order to speed up the phase of data preparation and template design to speed up the starting process

Main advantages of VLMS implementation



1

Strong collaboration among different departments and sites for document issuing and test execution

2

Backoffice job for signature collaction, test review and evidence management drastically reduced

3

Quick search of test cases and evidencies in case of Audit request

Q&A

