

# Effective validation with Modern Requirements4DevOps within Azure DevOps



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# 1 Introduction

The world in Life Science Industry is changing. Life Science is a very innovative industry where new medicines and medical devices become available every day. However, when we speak about Computer Software Validation and related quality aspects, the Life Science organisations seem to be conservative. While medicine production processes have sophisticated computer systems, the validation of these systems are often paper based. Software tools like Microsoft Azure DevOps together with Modern Requirements (MR4DevOps) can help to make a huge step forward in Paperless validation.

Applying those type of tools is not the goal for Paperless validation but creating and implementing an efficient validation is the way to go. This whitepaper will help you to define a paperless validation process for Computer System Validation. The process is based on GAMP©5 and Computer Software Assurance (CSA) and therefor highly risk based.

# 2 Strategy

Creating a paperless validation strategy shall be done in close cooperation with the company's QA department. Existing validation procedures may define a paper-based approach and very strict deliverables and templates. To be successful to implement a paperless validation strategy, people need to be convinced and existing procedures need to be updated. The new strategy can only be applied where the QA department agrees to the concept.

Another important criteria for a Paperless Validation strategy is to keep it as simple as possible. When you can automate processes, people tend to make the process more and more complex by automating all kind of exceptions that could occur but will happen only seldom. Just focus on the core process steps.

When I started to develop this strategy, I started from a paper based validation strategy in a Waterfall approach as described in GAMP. The example in Figure 1 shows a paper-based validation strategy for a Configured system (GAMP software Category 4).

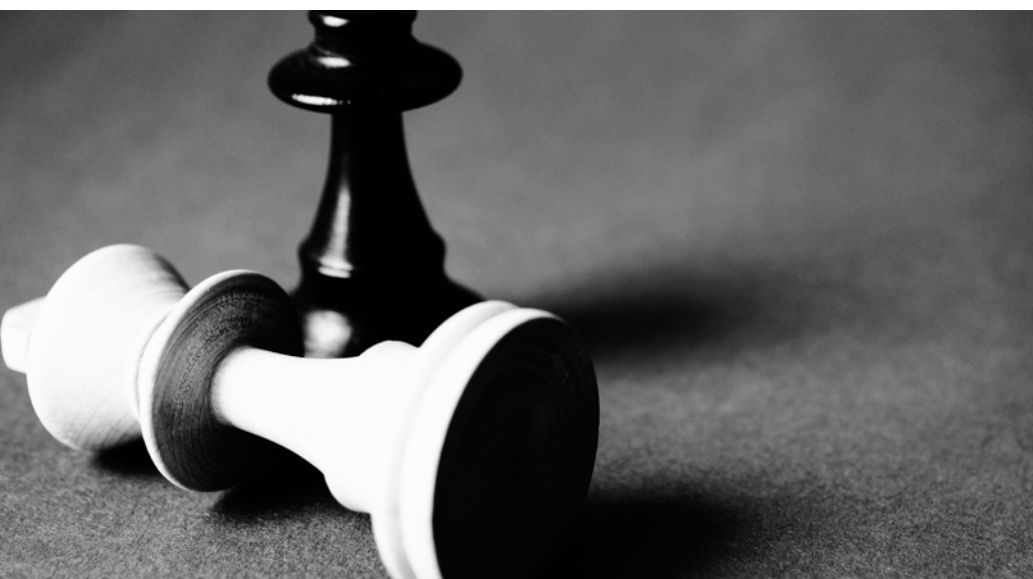
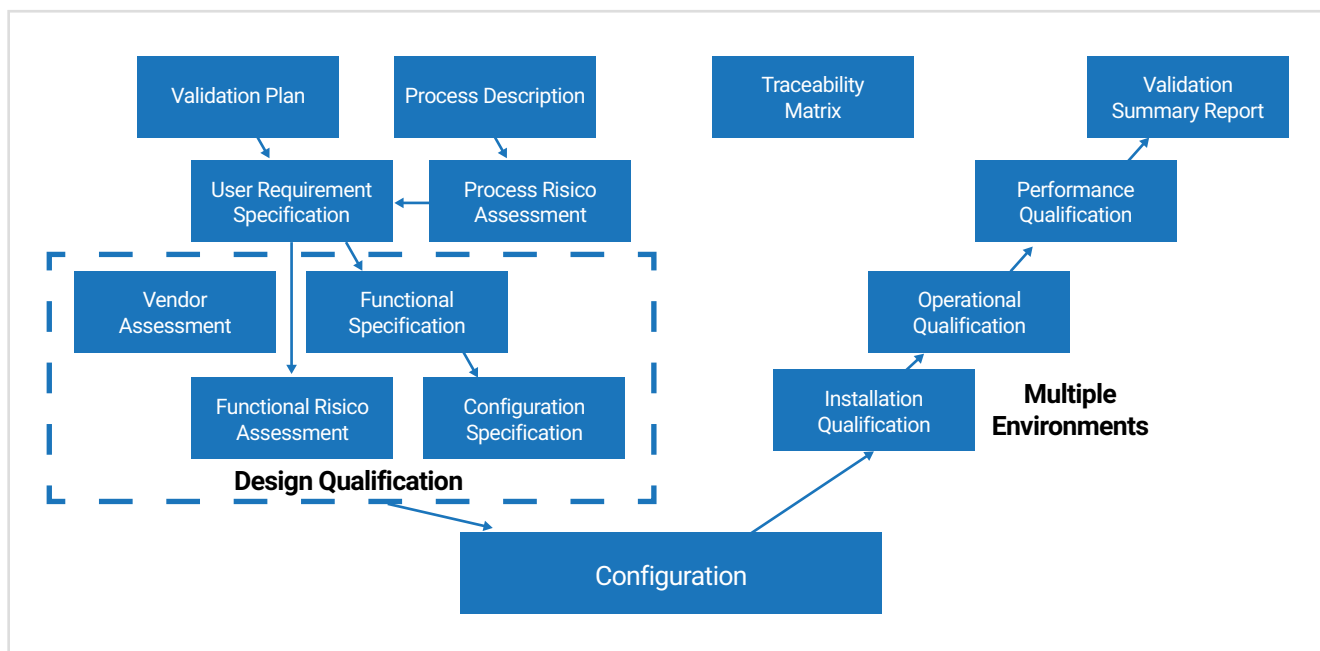


Figure 1  
Validation Strategy - Paper based



By using automated tools, the waterfall approach is still possible, but applying Agile techniques is much easier than is in a paper-based system. The most important aspect in a paperless validation strategy is to develop a different mindset. In a paperless validation strategy, you must focus on the data, not on the documents. With the tools, it is easy to generate conventional documents like the URS, but the focus must be on the requirements. In the beginning you probably would approve the documents as you were used to do; in the future you will approve the requirements with all related data. And, you will use the generated documents, just as a tool to make relations between different types of information and export the documents just as reports to show to people outside the organization, like inspectors and customers.

In this Whitepaper a strategy is created for URS, Functional Risk Assessment and Qualification testing; in future this would be extended with deliverables for Design, Configuration, internal testing. Probably a Process Description and Process Risk Assessment could be implemented as well. Documents like Validation Plan, Design Qualification, Vendor Assessment and Validation Summary Reports have no relation with the requirements. Creating these documents in the DevOps environment does not bring additional value, other than having all documents together in the same environment. I would recommend keeping these in a document management system or SharePoint. A Traceability Matrix is automatically generated by MR4DevOps.

Approval and versioning of requirements and documents is controlled within DevOps in combination with additional functionality in MR4DevOps. MR4DevOps provides a 21CFR part 11 compliant environment with Electronic Signatures.

### 3 Template design

To use a validation strategy, a process template needs to be created in the Organisation Settings of DevOps. In this Whitepaper the template Quality is created based on a Scrum default template. As an alternative Agile could be used in stead of Scrum, when it is a better fit for your organization. Be aware that this choice can hardly be corrected later, since all projects created afterwards relate to this template. It is however always possible to change the template, but this will have impact on all your requirements.

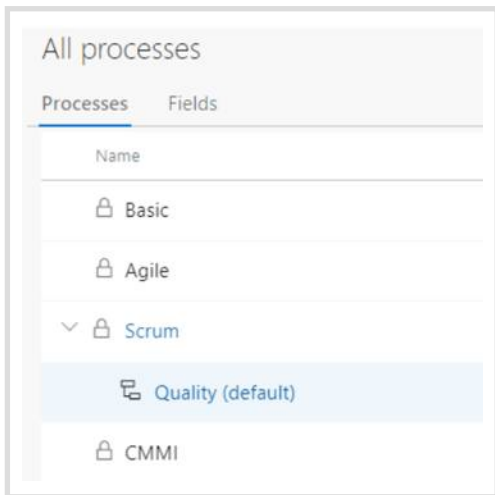


Figure 2

#### Template selection and creation

Within the template the Work Item Types are defined. Table 1 gives an overview of the most important work item types created or available in this strategy. Other Work Item Types are available (and used) or can be created where required, but don't overdo.

Figure 3 shows a high-level overview of the Paperless validation strategy used in this Whitepaper.

Figure 3

#### High level overview Strategy

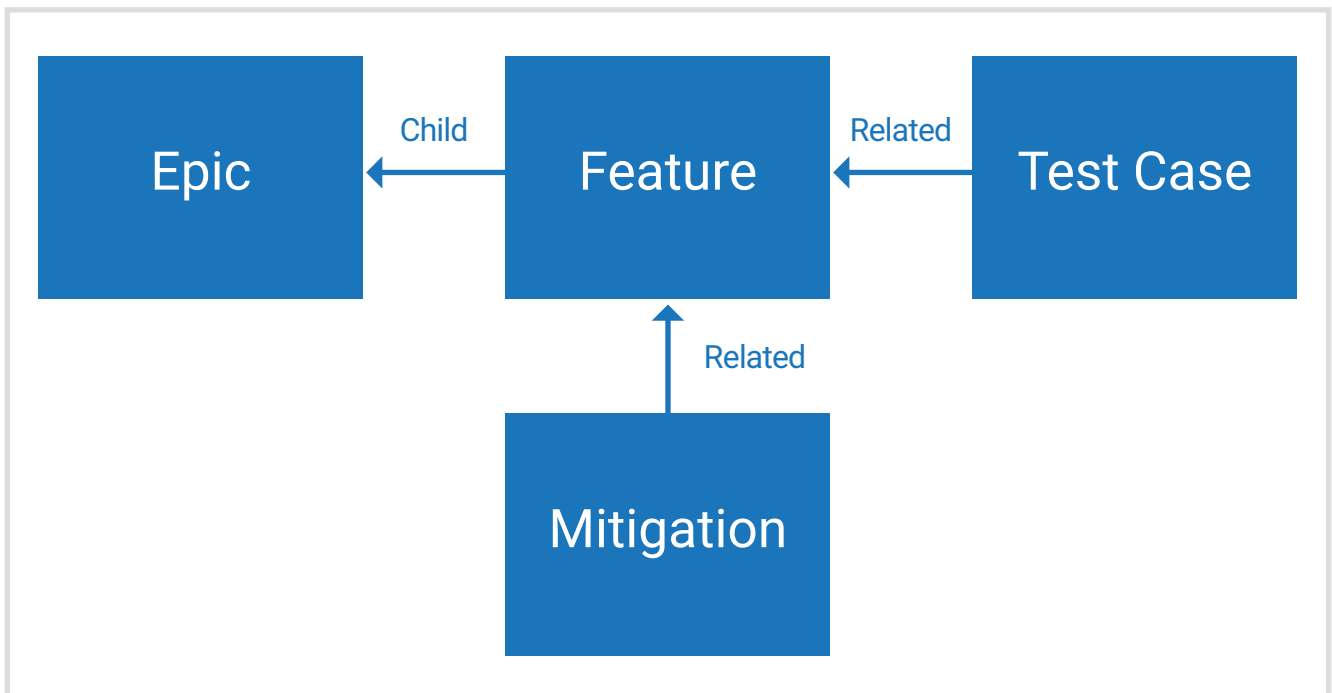


Table 1  
Work Item Types

Work Item Type	Description	Comment
<b>Epic</b>	Group of requirements	Available
<b>Feature</b>	Requirement	Available
<b>Mitigation</b>	Mitigation action for Risk Assessment	Created
<b>Document</b>	Document used in the strategy	Created for MR4DevOps
<b>Section</b>	Text section in a document	Created for MR4DevOps
<b>Test Plan</b>	Qualification Plan	Available
<b>Test Case</b>	Test Case	Available

The Work Item Type Feature is the heart of the strategy. All relevant information is either in this work item or related to this work item. In the process template a page is available for the basic information and a second page is created for the Functional Risk Assessment (FRA) data. The PT shows all fields that are created or used for the validation within the Feature work item type.

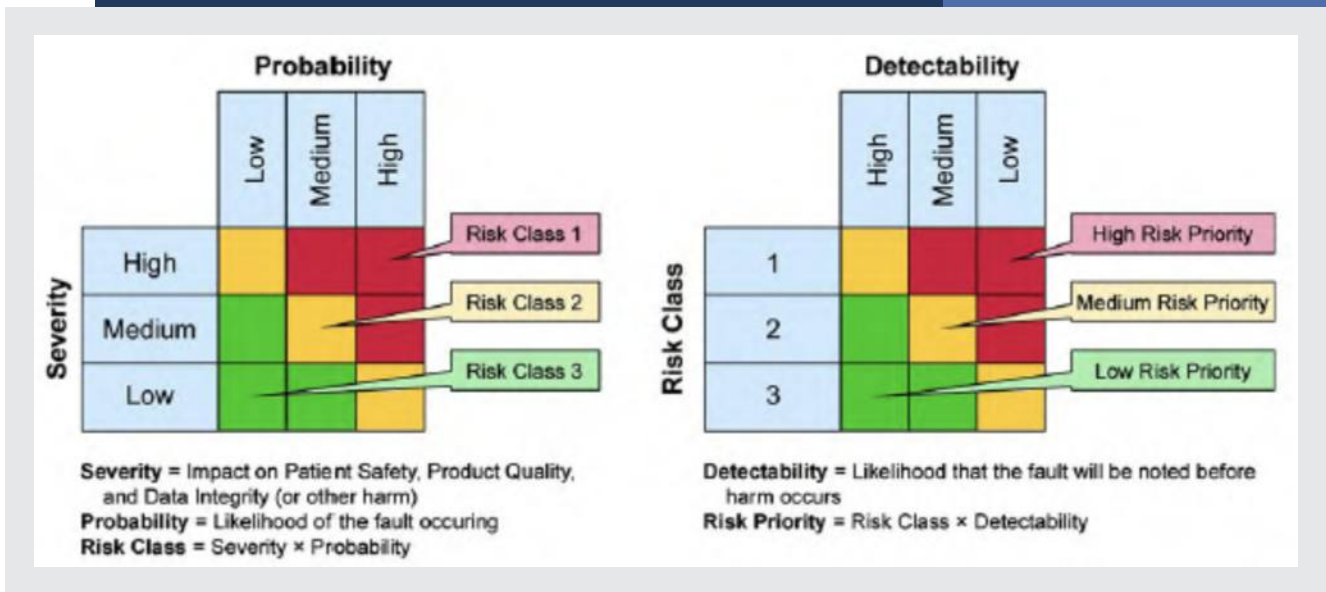
Field	Description	Type	Values
<b>Main Page</b>			
<b>Title</b>	The requirements itself	String	Text
<b>Description</b>	Optional details for the requirement	Rich Text	Text, figures
<b>GMP relevant</b>	Qualification if GMP relevant	Dropdown	Yes, no
<b>Business Priority</b>	Business Priority classification	Dropdown	Mandatory, Optional, Information
<b>Risk Assessment page</b>			
<b>Potential Failure</b>	FRA Potential Failure	String	Text
<b>Potential Effects</b>	FRA Potential Effects	String	Text
<b>Likelihood</b>	FRA Likelihood	Dropdown	High, Medium, Low
<b>RiskClass</b>	FRA Calculated Risk Class	Dropdown	High, Medium, Low
<b>Current Control</b>	FRA Current Control	String	Text
<b>Detectability</b>	FRA Detectability	Dropdown	High, Medium, Low
<b>Risk Priority</b>	FRA Calculated Risk Priority	Dropdown	High, Medium, Low
<b>New Likelihood</b>	FRA likelihood after mitigation	Dropdown	High, Medium, Low
<b>NewRiskClass</b>	FRA Calculated Risk Class after mitigation	Dropdown	High, Medium, Low
<b>New Detectability</b>	FRA Detectability after mitigation	Dropdown	High, Medium, Low
<b>New Risk Priority</b>	FRA Calculated Risk Priority after mitigation	Dropdown	High, Medium, Low

Table 2  
Feature field overview

To visualize the risk priority values the free tool **Color Picklist Control** is installed and configured to show colors for the Risk Priority fields. The MR4DevOps service **MatCal** is used to calculate that the Risk Class and Risk Priority fields conform the Risk Assessment definition tables in GAMP © 5, see Figure 4.



Figure 4  
GAMP© 5 FMEA Risk definition tables



To manage the requirements the default states have been updated or created for the work item type **feature**. Table 3 gives an overview of the used states.

Table 3 **Feature State overview**

State	Description	Next state
<b>New</b>		Defined
<b>Defined</b>	Ready for Risk Assessment	Approved
<b>Approved</b>	Ready for implementation	Implemented
<b>Implemented</b>	Ready for qualification	Qualified
<b>Qualified</b>	Ready to release	Released
<b>Released</b>	Released in Production	-
<b>Obsolete</b>	Obsolete	-

Where the description of a requirement is modified, the state should be reset to Defined. The state Obsolete can be initiated from any other state.

A work item Type **Mitigation** is created for defining and tracking of risk mitigation actions. Table 4 shows the fields used for this Work Item Type.

Table 4 Mitigation field overview

Field	Description	Type	Values
<b>Title</b>	The requirements itself	String	Text
<b>Description</b>	Description of the mitigation performed	Rich Text	Text, figures
<b>Mitigation Reference</b>	Reference to the mitigation action	Rich Text	Text, figures
<b>Assigned to</b>	Person to perform the mitigation	Identity	Users
<b>Resolved by</b>	Person that performed the mitigation	Identity	Users
<b>Resolved date</b>	Date Mitigation closed	Date	Date/time
<b>Closed by</b>	Person that Mitigation verified		
<b>Closed date</b>	Date that Mitigation verified		

Table 5 Mitigation State overview

State	Description	Next state
<b>New</b>	Mitigation created	Accepted
<b>Accepted</b>	Mitigation accepted by Assigned person	Completed
<b>Completed</b>	Mitigation completed by Assigned person	Closed
<b>Closed</b>	Mitigation verified and closed	-

In addition, for the use of updating states in the Approval process, the following states are defined for Document, Epic and Section.

Table 6 Document, Epic and Section State overview

State	Description	Next state
<b>New</b>	Mitigation created	Accepted
<b>Accepted</b>	Mitigation accepted by Assigned person	Completed
<b>Completed</b>	Mitigation completed by Assigned person	Closed
<b>Closed</b>	Mitigation verified and closed	-

## 4 Approval process

With MR4DevOps the approval process can be created very efficiently and is made fully digital. DevOps maintains a version for all Work Items, but this is not easy to visualize in DevOps itself. When you are approving Work Items the approval is logged in the Discussion field of the work item and this field is also visual in the SmartDocs as a Rev.

A good way of using approval is to work with the Review & Approval function in MR4DevOps in combination with the DevOps state of the work items. Put each work item in a document in a specific state, like "Defined" when all items are ready for approval. In the review and approval request you can automatically transfer all approved items into another state, like "Approved", so it is clear for the users that the requirements or other document components are approved. In addition, you can create a Rule in DevOps to make certain field "Read Only. Change the state again when the requirement must be changed again.

It is practical, first to send a set of work items, like requirements and test cases, for review only to the core team members and update the work items accordingly, before sending it for Approval. To simplify the approval process after that, you can Approve the entire document as one entity. In the approval process MR4DevOps automatically creates a new version of the document. When new versions of documents are required, the documents can be compared with earlier versions. Ensure that you select the Electronic Signature option for the approval, where required.

Review and approval of Work Items and Documents do not require a paid license for DevOps or MR4DevOps. Using the free stakeholder licenses, that need to be defined for each user, this functionality can be used.

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## 5 Requirements definition

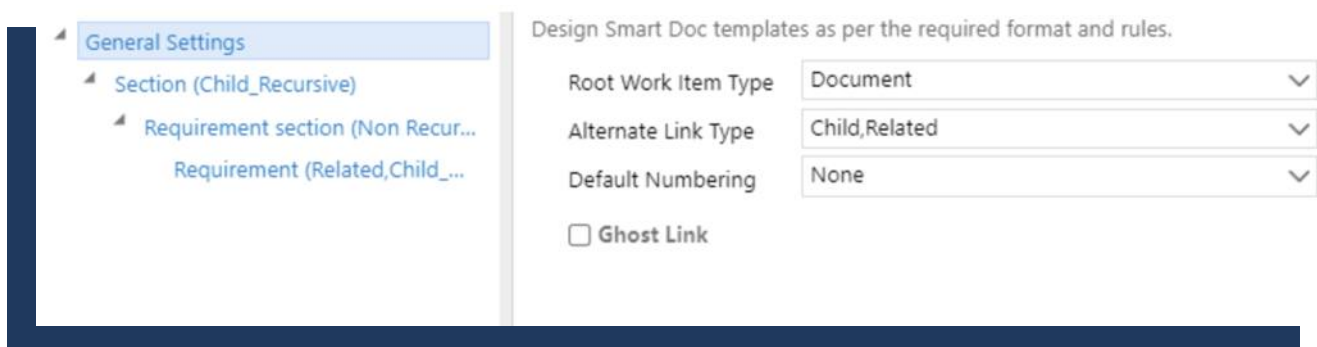
Proper definition of requirements is not easy. It requires a lot of knowledge about different aspects of the system in scope of the validation. You can find lots of information about defining requirements in GAMP © 5, appendix D1. All requirement types, mentioned in that section should be considered. In this whitepaper, the Epic is used as the requirement type. GxP critical requirements shall be indicated (in the field Feature - GMP relevant. Since many types of requirements are applicable, many subject matter experts must be consulted. The requirements define the What, not the How. The How is explained in the design of the system. The requirements need to be defined SMART (Specific, Measurable, Achievable, Realistic, Testable). Ownership of the system, including the requirements, is also vital for implementation of a system, creation of requirement cannot be outsourced to a supplier.

Before starting to create the requirements, the processes that are supported by the system should be clear and well defined in a Process Description. Many requirements will relate to these processes. In this Whitepaper the Processes are not implemented in MR4DevOps, but it is a planned as a next step, to decrease the amount of paper and increase the quality and traceability.



The best way to start building requirements is by using MR Diagrams, Mind Maps, or similar tools. Requirement from other systems can be referenced since they are probably already available in other DevOps projects. When the requirements are complete, if you are using a third-party tool, you can export them into MS Excel and transfer the requirements into DevOps for further fine tuning, however if you are using Diagram in MR4DevOps, these requirements are already saved natively in Azure DevOps. When you start with a new system, you start with creating a Project in DevOps and link that to the pre-defined template. The requirements will be added to the project during the import from MS Excel. In MR4DevOps you create a URS as SmartDoc, where you can create several Sections conform the URS document structure of GAMP © 5 Appendix D1. The Epics and related Features (Requirements) can be inserted into the Epics, using drag and drop functionality of MR4DevOps. With a SmartReport you can output a URS in the style of your company.

Figure 5  
Meta template for URS in Modern Requirements



## 6 Specifications

In a paper-based design Functional Specifications (FS), Software Design Specification (SDS), Hardware Design Specifications (HDS), Configuration Specifications (CS) and other specifications are created. In the current approach of software development User Stories and Use Cases are used in the design. In MR4DevOps Diagrams can be used to define the User Stories and Use Cases. Important is that these Work Items will always be linked to one or more requirements to ensure traceability.

## 7 Functional Risk Assessment

In a traditional Functional Risk Assessment, we assess the risk of each GxP relevant requirement using MS Excel in a Failure Mode & Effect Analyses (FMEA), using the risk tables show earlier in this paper. Using MR4DevOps we take the same approach. The main difference, related to a paper-based approach, is that all information is stored within the requirement. The calculation of the risk is also implemented within MR4DevOps by implementing the risk table calculations using **MatCal**.

For an effective and efficient risk assessment, a proper assessment team is vital. People from multiple disciplines, including QA and a strong assessment leader should be able to perform the risk assessment in several hours, dependent on the number of requirements. It is important to keep the risk assessment simple. High, Medium and Low Risk priorities can be managed, mitigated where required and used to define the test approach.

To perform the risk assessment, create a query in DevOps with all GxP relevant requirements and all required risk related fields of the requirement (Feature).

Figure 6  
Query example for FRA in Modern Requirements

ID	Title	A. State	GMP relev...	Potential F...	Potential E...	Severity	Potential c...	Likelihood	Current C...	Detectabili...	Risk Priority	New Likely...	New Dete...	New Risk ...
3	The system shall allow f...	R Defined	Yes	Less user ...	Unauthori...	High	Incorrect ...	Medium	Configura...	High	Medium	Low	High	Low
11	Users must log in before usi...	R Defined	Yes	Group lo...	Unauthori...	High	Account ...	Low	Account ...	High	Low			N/A
34	The memory of the virtual se...	R Defined	Yes	Performa...	Loss of cri...	Medium	Sizing not...	Medium	Rack spac...	High	Low			N/A
35	The processor load of the vir...	R Defined	No								N/A			N/A
36	Trend displays must be com...	R Defined	No								N/A			N/A

MS Excel will still be used as a front-end interface for the FRA. Using the integration for DevOps in Excel, the query for the FRA is executed in MS Excel, where the risks are being assessed. Since the calculation of the risk priorities is done in DevOps, this will not be directly visible in the Excel sheet, but the data can be synchronized with DevOps to update the data in DevOps and see the results in the Excel sheet. Once the FRA has been completed, you Publish the information back into DevOps to store all information with the Requirements in DevOps. From that moment you should not use the Excel file anymore. It was just used as a user interface during the FRA.

To create an FRA report and to assign mitigations for Medium and High priority risks a SmartDoc is used again. When the mitigation is defined the Risk priority can be redefined using the Excel sheet again, or directly in the requirement.

Figure 7  
Meta template for FRA report in Modern Requirements

- General Settings
  - Section (Child\_Recursive)
    - Requirement section (Non Recur...
      - Requirement (Child\_Non Rec...
        - Preventive Actions to Mini...

Design Smart Doc templates as per the required format and rules.

Root Work Item Type: Document

Alternate Link Type: [Dropdown]

Default Numbering: None

Ghost Link

## 8 Testing & Qualification

The testing and qualification approach can be used in the same way as in a paper-based validation approach. After module and unit testing by the developers, formal qualification can be done by using Installation Qualification (or Verification as used in GAMP © 5) (IQ), Operational Qualification (OQ) and Performance Qualification (PQ). The scope and approach for testing shall be based on the risk of the requirement defined in the FRA.



In the IQ the system components and configuration are verified. This will be done by Manual testing done by Subject Matter Experts (SME). For the OQ automatic testing could be used in combination with some manual testing using test scripts or unstructured testing, dependent on the type of requirement and risk.

Manual test cases can be executed in DevOps with a free license, but at least 1 user must have a Basic & Test license in DevOps. Additional tools can be used for automated testing. Screenshots and other additional evidence are stored in the test case results. It is very important that that all test cases need to be linked to the related requirements to create the traceability.

MR4DevOps has several functions to help with creating test cases and creating test protocols and reports. Test Cases can be created using Diagrams; for protocols and reports SmartDocs and Smart Reports can be used. In Smart Reports traceability is available to include Test Suites, Plans and Steps.

Mitigations should be linked to the test cases also to get the full traceability.

Figure 8 Test case Diagram

## 9 Traceability

The most valuable and time saving functionality of MR4DevOps is the Traceability functions. When all mitigations, design pats and test cases are linked to the related requirements, creating a (horizontal) Traceability Matrix (TM) is just pushing the button after creating a definition with the required columns and information once.

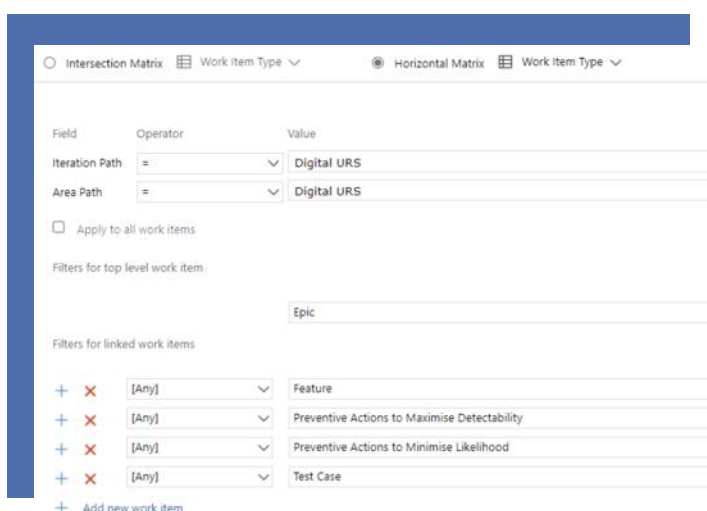


Figure 9 Traceability Definition in Modern Requirements

## Figure 10 Traceability Matrix in Modern Requirements

The vertical Traceability function can be used as a management tool to verify that each requirements has been tested, all mitigations have been performed, and many other verifications you can think of have been completed.

Epic(20)	Feature(187)				Preventive Actions To Maximise Detectability			
Title	Link Type	ID	Title	Gmp Rel...	Risk Prio...	Link Type	ID	Title
Security Requirements	Child	3	The system shall allow for at least 5 ...	Yes	Medium			
	Child	11	Users must log in before using the s...	Yes	Low			
	Related	83	Secure Remote access to the system...	No	N/A			
	Related	84	The system must be connected to t...	No	N/A			
	Related	85	Access is verified against the PQI D...	No	N/A			
	Related	86	The system must restrict logical acc...	Yes	Medium			
	Related	87	The system must provide multiple u...	Yes	High			
	Related	88	The system must require that no tw...	Yes	Low			
	Related	89	The system must have a configurabl...	Yes	Medium			
	Related	90	The system must assure that user ac...	Yes	Medium			
	Related	91	A procedure must be in place to de...	Yes	High			
	Related	92	The system must prevent data mani...	Yes	Low	Related	179	Verify user management in f
	Related	128	Remote access to the SCADA syste...	No				
	Related	133	A procedure must be in place to en...	Yes	High	Related	179	Verify user management in f
Operational requirements								
Functional requirements	Related	137	Temperature in the rooms must be ...	Yes	Medium			
	Child	137	Temperature in the rooms must be ...	Yes	Medium			
	Related	138	Pressure in the room must be meas...	Yes	Medium			

## 10 Procedures and fit for intended use

There is a lot of discussion between experts in Computer Software Validation about the level of qualification required for tools like MR4DevOps. Annex 11 of the European GMP promoted a risk-based approach. A practical approach is to create a company procedure that describes the approach for Paperless validation using these types of tools and ensure that the tools used for validation and testing are fit for use. The company QA department must be involved and needs to agree to the approach.

To ensure that MR4DevOps is fit for intended use, and that Modern Requirements can supply evidence of having the tool tested, you must first be certain that you have configured the tool as described in your procedures (and as defined in this whitepaper); and ensure that the person(s) using this tool are properly trained in using the tool the correct way. With each project register the version of the tool and manage new versions of the tool. A Simple System Description can be created to describe the tool and configuration. In addition, you can formally test the Electronic Signature component. Again, most important is to align the approach with your company QA.

I hope that this whitepaper helps you with an efficient start of creating your validation approach and environment. All companies I assisted with the validation of computer systems that are using MR4DevOps are very successful in validating their computer systems in an efficient and effective manner, and savings days of manual validation work previously done per project.



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