Peacock engineering

IBM Gold Business Partner

Achieving validation in Life Sciences

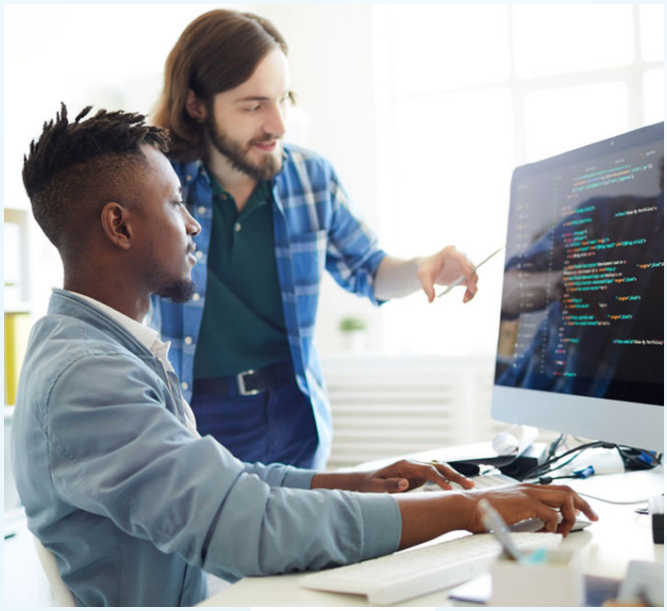
How Peacock Engineering make validation of your Maximo installation easier to achieve

Your Life Sciences organisation needs to comply with numerous regulations. When you carry out effective validation, you demonstrate that the software your company is using is doing what it is supposed to do.

At Peacock Engineering, our programming and development processes make validation easier for your business to achieve, particularly with IBM Maximo's in-built design flexibility.

The Enterprise Asset Management (EAM) system's design flexibility means that it can be used in a wide variety of business environments, including Life Sciences. This allows it to be adapted to meet your complex business needs, and provide you with the tools and functions to manage your data and information in a validated platform.

Documenting the validation exercise in how IBM Maximo has been configured is a critical activity. With Peacock Engineering's knowledge and experience, coupled with Maximo's in-built flexibility including Title 21 CFR Part 11 compliant features, validation is easier for your business to achieve.



Making validation easier to achieve

When Peacock Engineering is brought in to install IBM Maximo in your business, we will deliver this using a combination of:

- The right people
- The right tools
- The right processes

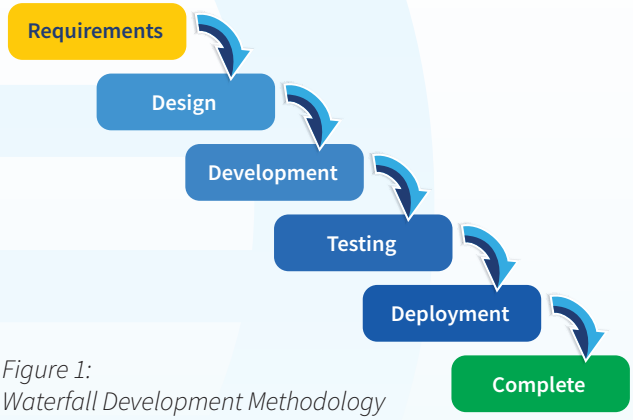


Figure 1:
Waterfall Development Methodology

We principally use waterfall delivery methodology, particularly for Life Sciences projects, as this best fits with the Validation V model approach.

Projects are delivered using DevOps tools and practices to control the production of detailed User Requirements, and their subsequent design, testing, debugging, deployment and maintenance.

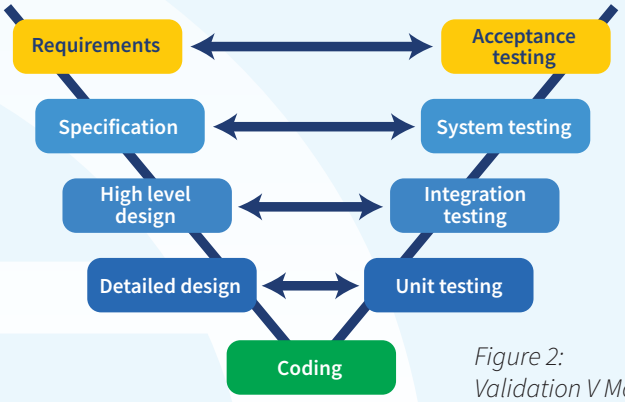


Figure 2:
Validation V Model

Using Agile Methodology in project development

Peacock Engineering also uses Agile development methodology for our Core Fingertip mobile solution, and in project development activities. This reduces our design, development and system testing effort, without impacting the validation lifecycle.

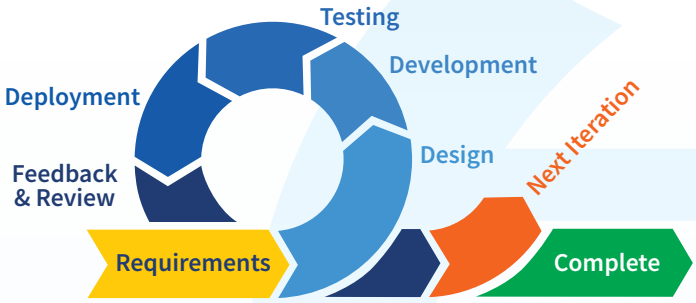


Figure 3: Agile development

Clients often begin with a **User Requirements Specification** (URS) that is carefully documented, but not always at a level that easily supports the development of the Functional Requirements Specification. However, by coupling DevOps agile tools and techniques with the Validation V model, it is possible to better manage the production of the **Functional and Detail Design Specifications** (FDS). In this way, one process complements the other.

Clients get the chance to confirm that User Requirements asked for match their expected outcomes, sooner. This helps to:

- Reduce the time to refine the URS
- Support the development & delivery activities
- Produce carefully scripted tests to support development

When the developers and testers produce carefully scripted tests to support the development, this in turn is used to produce the corresponding IQ (Installation Qualification) and OQ (Operational Qualification) documentation of what has been installed and verified to work correctly.

We will then:

- Rework the code & determine the Corrective Action & Preventative Action
- Document each change we make
- Verify that the code functions as designed

Then, with development complete, all modules will be merged and deployed into a test environment for pre-validation system testing. This ensures that the developed product is fit for validation.

This ensures that the validation process is:

- Easier to prepare & execute the URS, FDS, IQ and OQ documents
- Faster to develop the solution
- Most cost-effective for you

Utilising Maximo's inherent design flexibility

Utilising IBM Maximo's inherent design flexibility, including the in-built e-audit and e-signature capabilities, allows Maximo to be configured to:

- Comply with your business process needs
- Comply with your regulatory requirements
- Simplify the documentation of its configuration

By installing IBM Maximo into your business in the above way, you will benefit from a scalable, logical and methodical implementation process. This process can be adapted to meet your needs, whilst remaining sympathetic to your business, regulatory and validation requirements.

This, coupled with Peacock Engineering's efficient and reliable approach in documenting validation output, reduces business risk in satisfying the regulatory challenges including the FDA's Title 21 CFR Part 11.

Improve validation with completely accurate data

Software validation must be documented and retained for inspection if they are to continue using it. IBM Maximo retains all your data in the system by default, so that you can access it whenever you want.

This means that your data will be:

- Completely accurate
- Traceable to specific dates
- Matched with staff e-signatures where these have been configured for you

By employing e-audit and e-signature capability, this audit trail is enhanced by capturing Title 21 CFR Part 11 compliant data about specific fields and records of interest. As a result, your life sciences business will be capturing details of records that support reviews of data integrity and its validation status.

Users will also have the benefit of being able to interrogate this data, whilst having precise, 'live' data that confidently supports their operational activities.

Have regular access to industry specialists

Many life sciences organisations, including Pharmaceutical and Medical Devices manufacturers, frequently push validation towards systems integrators or third parties. These entities often do not have the product or industry specific knowledge to support this.

This can result in a solution which does not meet the user requirements and validation costs which can quickly escalate.

To overcome this problem, Peacock Engineering employs staff who are:

- Specialists who have experience in the life sciences industry
- Experienced in developing client-focused user solutions
- On-call to cater for your business needs throughout the validation cycle

This helps us to form a cost efficient and effective business partnership with you.

Our hands-on and experienced approach helps deliver your Maximo solution by ensuring that your user requirements match your expected outcomes, and that the validation exercise is successful and efficient.

Helping clients worldwide to improve validation

Peacock Engineering has extensive experience helping leaders in the life sciences industry to successfully deliver the validation of Maximo and Fingertip. Our support team works closely with your operational teams to implement IBM Maximo throughout your organisation. This helps to ensure a smooth transition, from project and validation, to actually using Maximo in your production environment.

Some of the work we have carried out in the past includes:

- Migrating a significant 90-site system from the US to the UK
- Integrating Fingertip inspections & calibrations with Maximo
- Re-aligning all date-time zones as part of a divestment
- Provisioning a new system to support ongoing needs
- Upgrading and deploying Maximo with Fingertip Calibration

Input data at point-of-work

When you implement IBM Maximo as your Enterprise Asset Management solution, you also have the opportunity to install Fingertip. This add-on solution to Maximo enables true mobile working for all your staff. Fingertip allows data to be entered at point-of-work, even when you don't have a Wi-Fi or mobile signal available. This is done by the data being synchronised automatically when you re-establish the signal.

The Fingertip mobile solution employs the same tried and tested practices of IBM Maximo, for a seamlessly integrated solution. This tight integration means that data can be captured and shared in real-time, across both platforms which helps you to:

- Streamline & unify your business process
- Simplify data capture
- Reduce duplication of work
- Eliminate paper-based processes
- Improve data quality

Peacock engineering

Successfully achieve validation in Life Sciences

Many of Peacock Engineering's experienced engineering and IT professionals provide a capability beyond software functional knowledge. We can relate the software and systems' capabilities to your actual business validation needs. This ensures that our solutions achieve true and lasting benefits for your business.

Peacock Engineering can help your life sciences business to install IBM's Maximo Asset Management Enterprise software solution, and improve your validation process.

What one of our clients said:

"Peacock Engineering was instrumental in providing valuable input with efforts associated with implementing and validating Maximo and Fingertip mobility - ultimately saving costs and still staying compliant!"

Brian Doyle , Hazardous Risk Solutions, Guerbet

More information

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IBM maximo®

Fingertip®
Knowledge where it's needed

About Peacock Engineering

Peacock Engineering Ltd was established to deliver a diverse range of Asset and Service Management solutions to asset intensive industries.

Our consulting team is made up of long standing IBM Maximo professionals, each with an average of 12 years' experience in the product and who, together, have amassed over 400 man-years of Maximo systems implementation experience.

From this knowledge and practical application, a proven and trusted process-driven methodology has emerged. With the methodology in place, the ongoing challenge is to improve delivery efficiency and provide affordable solutions, using a mix of services and systems provisioning models, to meet a broad range of industry verticals.

We can also provide bespoke training to your staff on how to use IBM Maximo effectively. We can provide bespoke training materials to educate your users, via live and online tutorials, and multimedia resources.