# Next Generation Validation

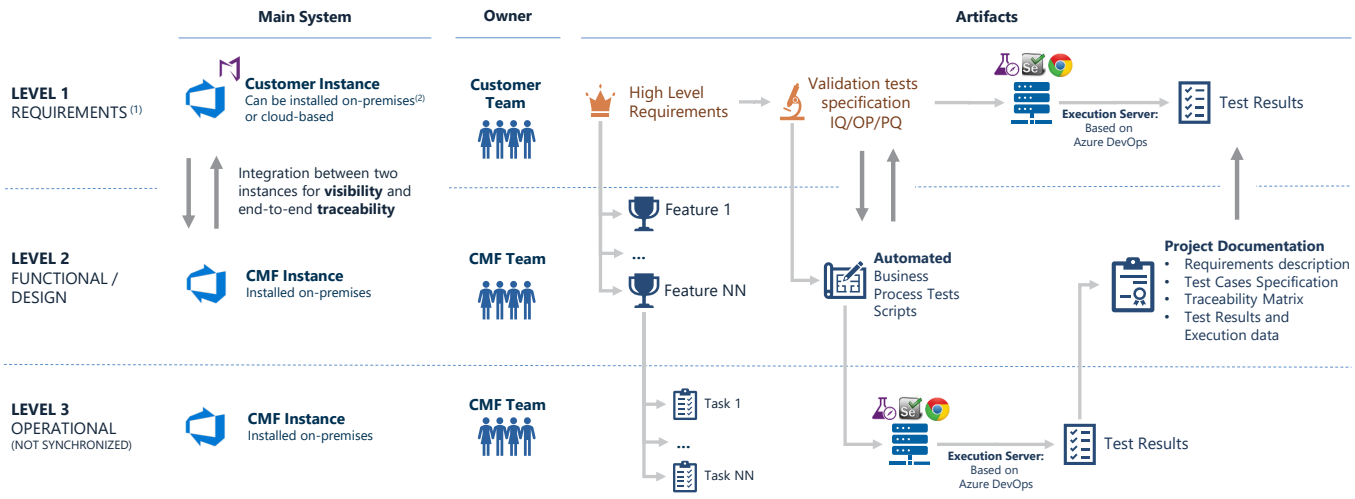
## Provides out-of-the-box automated support for the validation process

### Overview

For Medical Devices Manufacturers, system validation is of utmost importance due to strict regulatory requirements and quality standards enforced in the industry. They are required to comply with regulations such as FDA 21 CFR Part 820, ISO 13485, and other industry standards. Validation ensures that the MES system meets all regulatory and quality requirements and specifications, which proves critical for the safe and effective operation of medical devices. It also ensures that the system operates in a consistent and reliable manner, reducing the risk of errors and failures that could cause product defects.

To help medical devices manufacturers streamline their production processes, reduce costs, and increase productivity, Critical Manufacturing Next Generation Validation offers a complete solution that includes automated validation procedures; a full set of documentation for out-of-the-box Critical Manufacturing MES requirements; and a set of proven templates to be used by the customer for the product validation process in each of the qualification phases. By automating the testing and validation process, manufacturers can quickly and efficiently identify and address issues, reducing downtime and improving overall system performance.

Following an Agile project implementation mindset, the Project Backlog consists of the full set of requirements that are prioritized according to the Customer Risk Management and Minimum Viable Product (MVP). The project backlog is then implemented in sprints, delivering a validated package to the customer at the end of each sprint. Following the principles of testing early and often, the project can rest assured that validation is performed right from the very beginning of the project.




(1) Requirements baselines and versioning supported by a third-party ADO Extension.
(2) Integration with on-premises Azure DevOps Server requires access to remote network from CM servers

Figure 1 Next Generation solution example

Critical manufacturing 11.1



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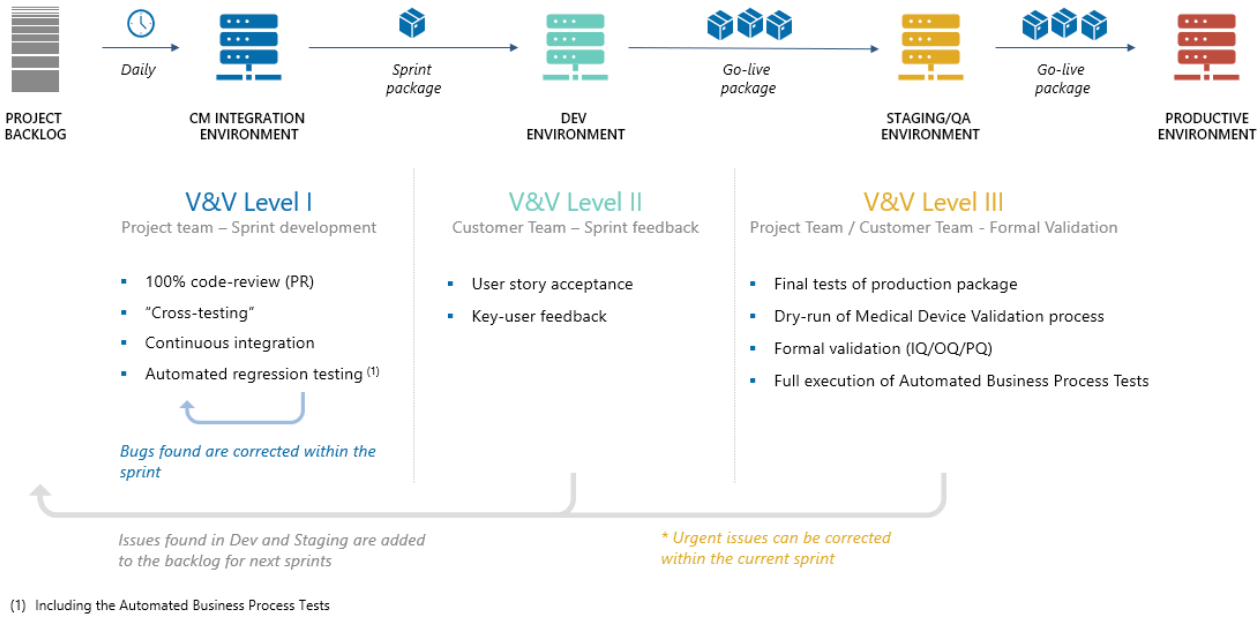


Figure 2 Validation flow for implementation projects

## Key Features

- Full set of the out-of-the-box Critical Manufacturing MES requirements, including traceability matrix between design documentation, requirements definition, test cases specification and test execution data, in a convenient PDF format
- A set of proven validation templates, pre-filled with information from the MES, for the Master Validation Plan, IQ, OQ and PQ phases
- Integration between the Customer and CMF Azure DevOps allowing bi-directional flow of information
- Support for change management during the project
- Full traceability between requirements, validation scripts, test execution and test results
- Assures that the suite of tests created for all the requirements are executed in all the releases delivered during the project implementation

## Benefits

- Leverage the data provided by CM, a CMMI L3 Dev, certified company since 2013, following FDA CSA advise.
- Integrate a full set of documentation in the Help menu of the MES, or in PDF format
- Collaborate with a high expertise team throughout the project, in every aspects, to speed up and increase the quality project and expected outcomes
- Drastically reduce the duration of the validation phase to a fraction of the time





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