



The **Compliance Kit** consists of tried-and-tested, standardized validation templates that are made available to the customer. After handover, these become the responsibility of the customer and can be flexibly adapted or extended. Due to the high degree of standardization, customer-specific adaptations are only required to a limited extent. These are carried out in close coordination with the YAVEON validation team, which provides professional support throughout the entire process.

1 HLRA (High-Level-Risk-Assessment)

- ✓ YAVEON provides an HLRA template.
- ✓ Optional: Support from YAVEON during implementation.
- ✓ In addition, we provide a fully developed MS Cloud risk analysis in the form of an FMEA, which can be expanded as required and serves as a basis for argumentation.

2 Supplier qualifications

YAVEON: YAVEON provides a self-disclosure or there is the option of carrying out a remote or on-site audit. The audit report is prepared in accordance with our own QM system.

Microsoft: YAVEON provides sample Microsoft qualification documents that can be used as a basis for your own qualification. A sample audit report is also included.

3 Validation plan

- ✓ Provision of a sample validation plan with all relevant content.
- ✓ Adaptation only required to customer-specific framework conditions.

4 BPML (Business Process Master List)

- ✓ Provision of a complete process list (BPML) incl. risk analysis I by YAVEON
- ✓ Review of the assessment of GxP relevance by the customer

5 URS-Liste (User Requirements Specification)

- ✓ Contains all requirements (URSs) for the standard processes incl. risk analysis II.
- ✓ Possibility for the customer to add individual requirements

6 FS-Liste (Functional Specification)

- ✓ Includes all functions that contribute to the fulfillment of the requirements, including risk analysis III.
- ✓ Supplemented by detailed functional descriptions in the form of Word documents (specifications), which are created entirely by YAVEON – no customer activity required.

Note on individual developments:: YAVEON
YAVEON also takes care of the documentation and supplements URS and FS lists accordingly. Risk analyses are carried out together with the customer.

7 Installation qualification, function and acceptance test (IQ, OQ, PQ)

Installation qualification (IQ):

- ✓ Proof of successful installation
- ✓ Documentation incl. screenshots and approval by YAVEON

Function test (OQ):

- ✓ **Standard functions:** The functional tests are carried out as part of YAVEON product development. Separate test documentation by the customer is not required.
- ✓ **Individual developments:** Individual developments are tested by YAVEON using automated function tests. It is not necessary for the customer to carry out additional documented functional tests.

Acceptance test (PQ):

- ✓ Acceptance test plans are created individually by the customer. The customer is also responsible for carrying out the tests.
- ✓ YAVEON provides sample documents on request, which serve as a guide for the creation of test plans.
- ✓ If required, the customer can also access support services from the YAVEON team

8 Configuration documentation (export of relevant setup tables)

Documentation of GxP-relevant ERP facilities for defined statuses (e.. initial implementation, update):

- ✓ Customization possible at any time
- ✓ Data export via configuration packages (.rapidstart) in Excel format
- ✓ Provision of instructions for importing and exporting configuration packages
- ✓ Instructions also contain information on creating your own configuration packages

9 Standard-SOPs

- ✓ Provision of selected sample SOPs for direct use or individual adaptation
- ✓ Possibility to develop further customer-specific SOPs together with YAVEON

10 Validation report

- ✓ Provision of a sample validation report by YAVEON
- ✓ Addition of content by the customer (e.g. description of the validation steps, deviations, etc.)