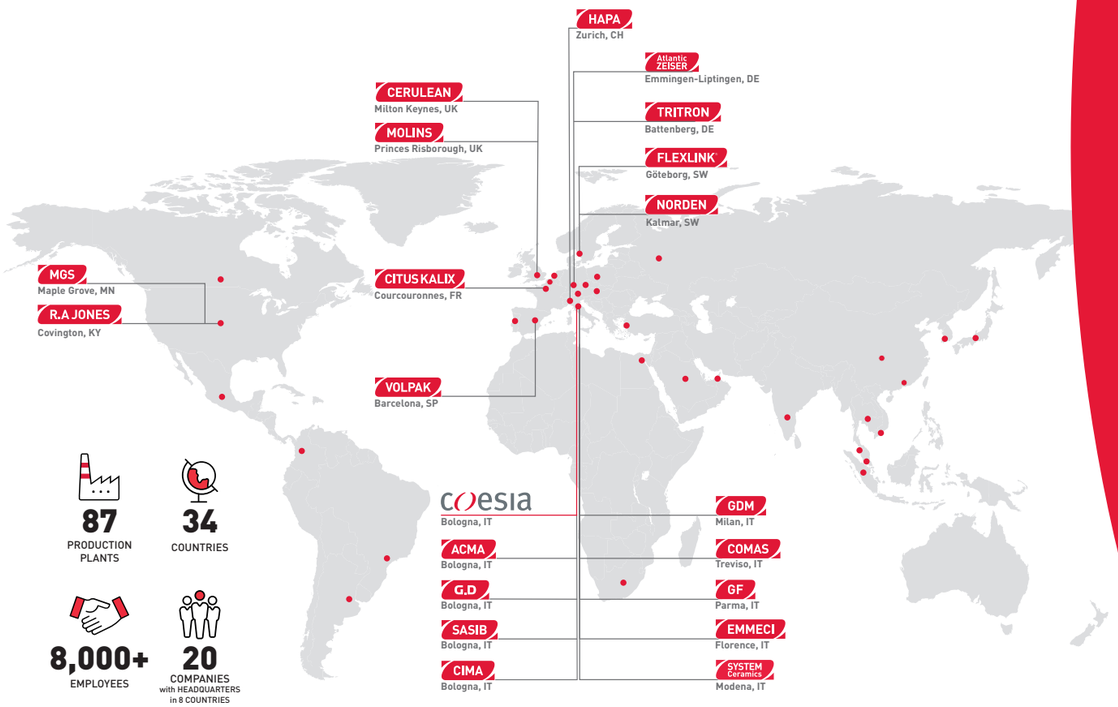
Coesia Group in the world



COESIA is a group of innovation-based industrial and packaging solutions companies operating globally, headquartered in Bologna, Italy.

Coesia's companies are leaders in the sectors of:

- **Advanced automated machinery**
- **Industrial process solutions**
- **High-performance transmissions**

Coesia's customers are leading players in a broad range of industries, including Consumer Goods, Tobacco, Healthcare, Aerospace, Racing & Automotive and Electronics.

Volpak S.A.U
Pol. Ind. Can Vinyalets
C/ Can Vinyalets 4
08130 Santa Perpètua de Mogoda
Barcelona, Spain

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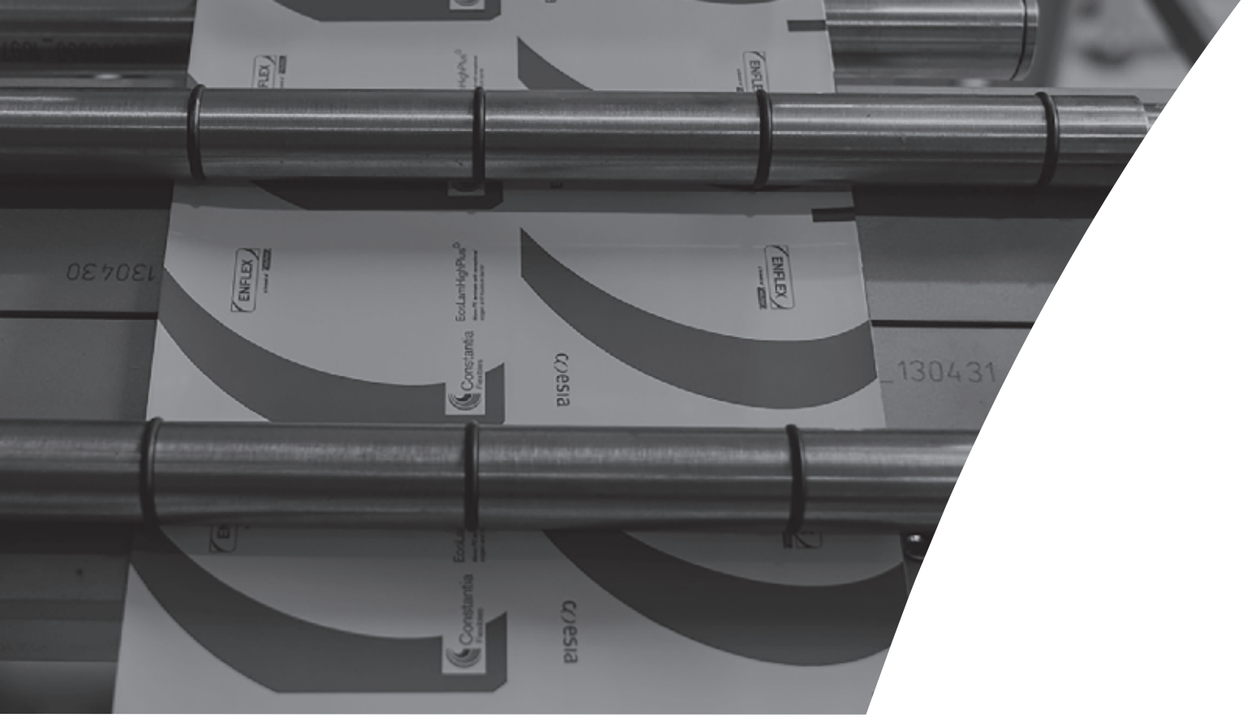
Validation & qualification packages



Packages

Qualification and Validation: modular packages of documentation

- Enflex has a **specific team** dedicated to the creation of **validation** documentation and the **qualification of equipment** for GMP environments
- On the support of **external consulting firms** with extensive experience in the pharmaceutical sector
- Validation & Qualification documents in **modular packages**, to meet the simplest to the most complex needs

Basic

- Installation Qualification (IQ)
- Operational Qualification (OQ)

Plus

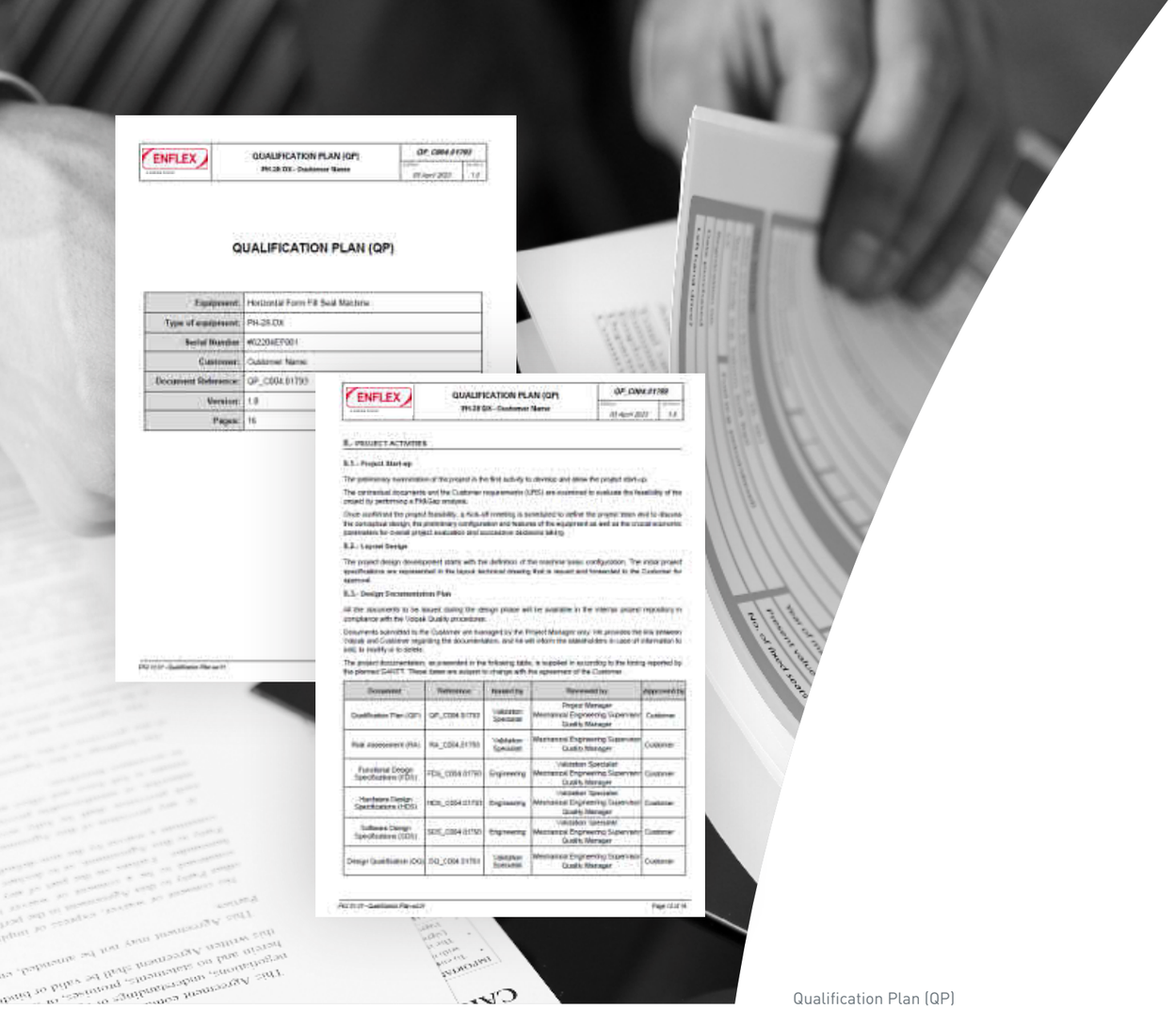
- Pharma Factory Acceptance Test (FAT)
- Site Acceptance Test (SAT)
- Installation Qualification (IQ)
- Operational Qualification (OQ)

Premium

- Qualification Plan (QP)
- Pharma Risk Assessment (RA)
- Pharma Factory Acceptance Test (FAT)
- Site Acceptance Test (SAT)
- Installation Qualification (IQ)
- Operational Qualification (OQ)

Elite

- Qualification Plan (QP)
- Pharma Risk Assessment (RA)
- Functional Designs Specifications (FDS)
- Hardware Designs Specifications (HDS)
- Software Designs Specifications (SDS)
- Design Qualification (DQ)
- Pharma Factory Acceptance Test (FAT)
- Site Acceptance Test (SAT)
- Installation Qualification (IQ)
- Operational Qualification (OQ)



Qualification Plan (QP)

Qualification Plan (QP)

The purpose of the Qualification Plan (QP) is to provide and define the qualification activities that will be performed during project execution, the responsibilities that correspond to the staff involved and the procedures that must be carried out.

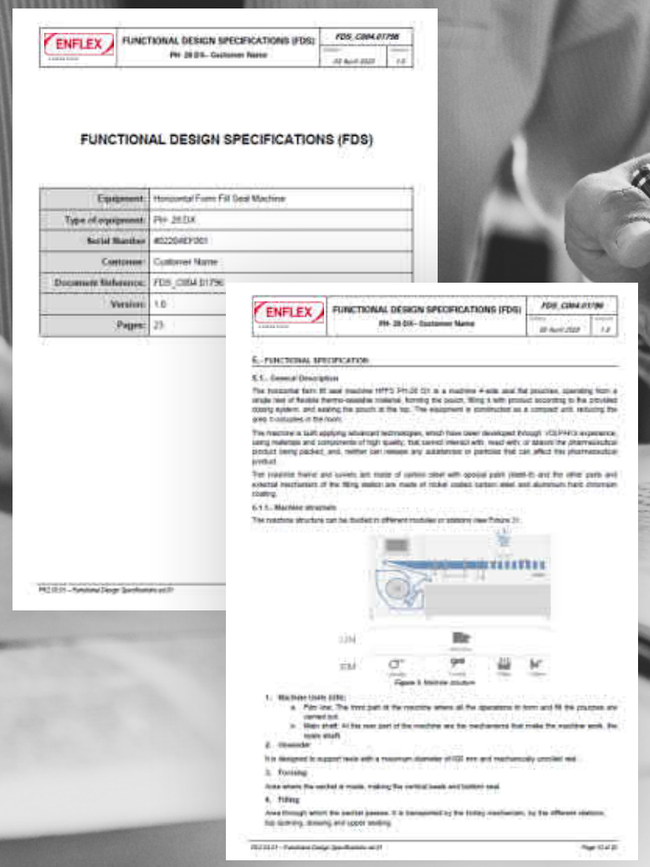
The following information is detailed in the QP:

- Project qualification strategy
- Project qualification documentation structure
- List of qualification tests.
- Methodology (management of deviations and change controls)
- Responsibilities matrix

Pharma Risk Analysis (RA)

Risk analysis methodology enables assessment of equipment features from the perspective of GMP compliance. Assessment is carried out on all aspects that may affect product quality, patient safety and/or data integrity.

The FMEA (Failure Mode and Effects Analysis) method is used to classify the various parts of the machine, analyse potential failures and their consequences, assess the likelihood and detectability of the failure and the severity of the consequence. These three assessments reveal a risk rate which, if properly tabulated, can indicate the qualification actions required to mitigate the risk.



Functional and Design Specifications (FDS)

This document is prepared during the design phase and approved by the customer once the phase has been completed.

The FDS are set forth in two documents:

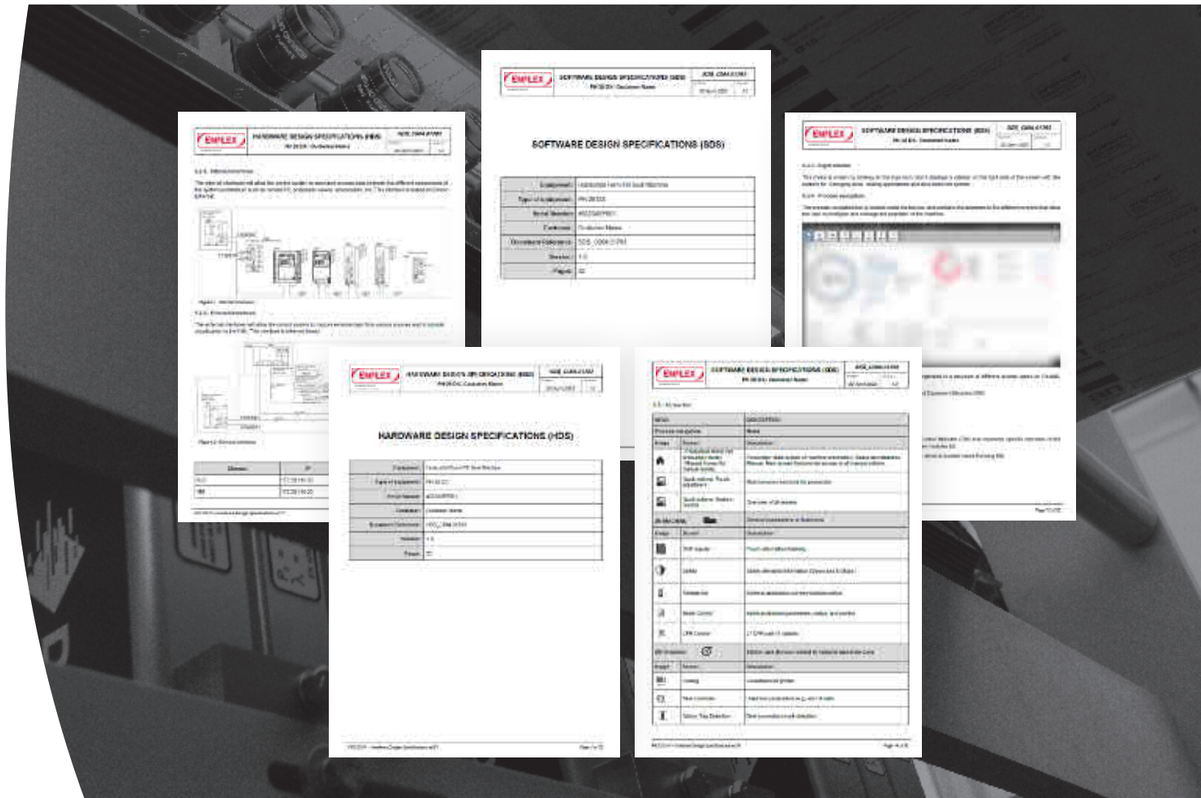
- FS: Functional Specifications – This document describes the functional design of the equipment.
- DS: Design Specifications – This document describes the mechanical, electric and programming design of the equipment.

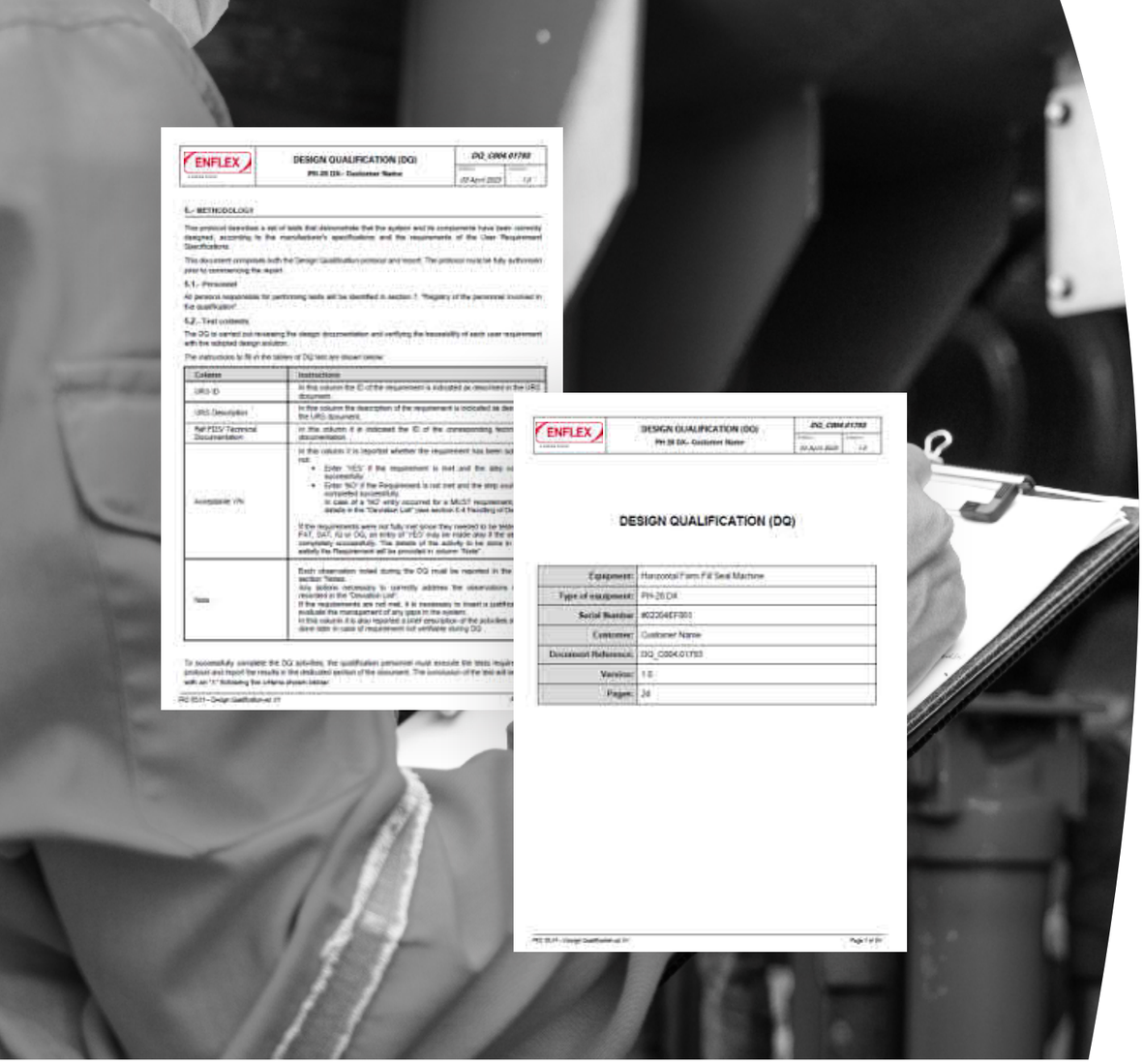
Hardware Design Specifications (HDS) & Software Design Secifications (SDS)

The HDS and SDS are the documents that detail the design of the equipment's computer and control system.

These documents serve to complement the FDS by including specific details of automation design, such as:

- Arquitecture
- User interface (HMI, SCADA, pushbuttons, printers
- PLC
- Inputs and outputs
- Sensors and instruments
- Safety devices
- Power supply systems
- Communications (network)
- Operation, shut down and emergency modes
- Servomotor controls
- Alarms
- Access levels
- Critical parameters and configurable parameters (setpoints)
- Electronic records and Audit Trail





Design Qualification (DQ) Protocol

Design Qualification (DQ) Protocol

The purpose of DQ is to verify that the points described in the design documentation (FDS, SDS, HDS) comply with the requirements set out in the URS and/or offer.

DQ execution and conformity mark the starting point for equipment construction.

Pharma Factory Acceptance Test (FAT) Protocol

The purpose of the Pharma FAT protocol is to verify that the machine has been installed and is operating according to the customer's requirements (URS) and/or the design parameters set out in the offer or order. These verifications are carried out in the Volpak plant with the aim of accepting the equipment before it is delivered to the customer's facilities.

The following tests are included in the FAT protocol:

- Document verification (Draft version)
- Conformity of the plans (Draft version)
- Conformity of the components
- Verification of the parts in contact with the product (the material certificates of the components that are in contact with the product are delivered with the machine)
- Verification of calibration process instruments (the calibration certificates of the temperature probes supplied with the machine are delivered with the machine)
- Verification of Installation and Software Version of the HMI and PLC
- I/O Verification
- Start-up, shut down and communication failures
- Screens verification
- Access levels test (if required)
- Verification of safety systems
- Alarms and interlocks
- Parameter management
- Audit trail verification (if required)
- Data backup and retrieval (if required)
- Rejections
- Operation test for each format
- Dosing capacity/precision
- Verification of report generation (if required)

Pharma Factory Acceptance Test (FAT) Protocol

SAT (Site Acceptance Test) Protocol

SAT (Site Acceptance Test) Protocol

The purpose of the SAT protocol is to provide documentary evidence that the equipment has been delivered, installed and operates in compliance with its design specifications.

The following tests are included in the SAT protocol:

- Document verification (Final version)
- Operation test for each format
- Dosing capacity/precision

Each FAT and SAT test must include the following:

- Purpose of the test;
- Methodology for test performance;
- Acceptance criteria: minimum parameter values required to accept the test;
- Comments section to describe failures deviations or enter observations;
- Checkbox for the signature of the person responsible for performing the test;
- Approval checkbox to be signed when the test is accepted.

When the verifications performed during the Pharma FAT and SAT tests are satisfactory, properly documented and not affected by machine transport or any changes made to the machine, they can be referenced in subsequent qualification stages without having to repeat the tests.

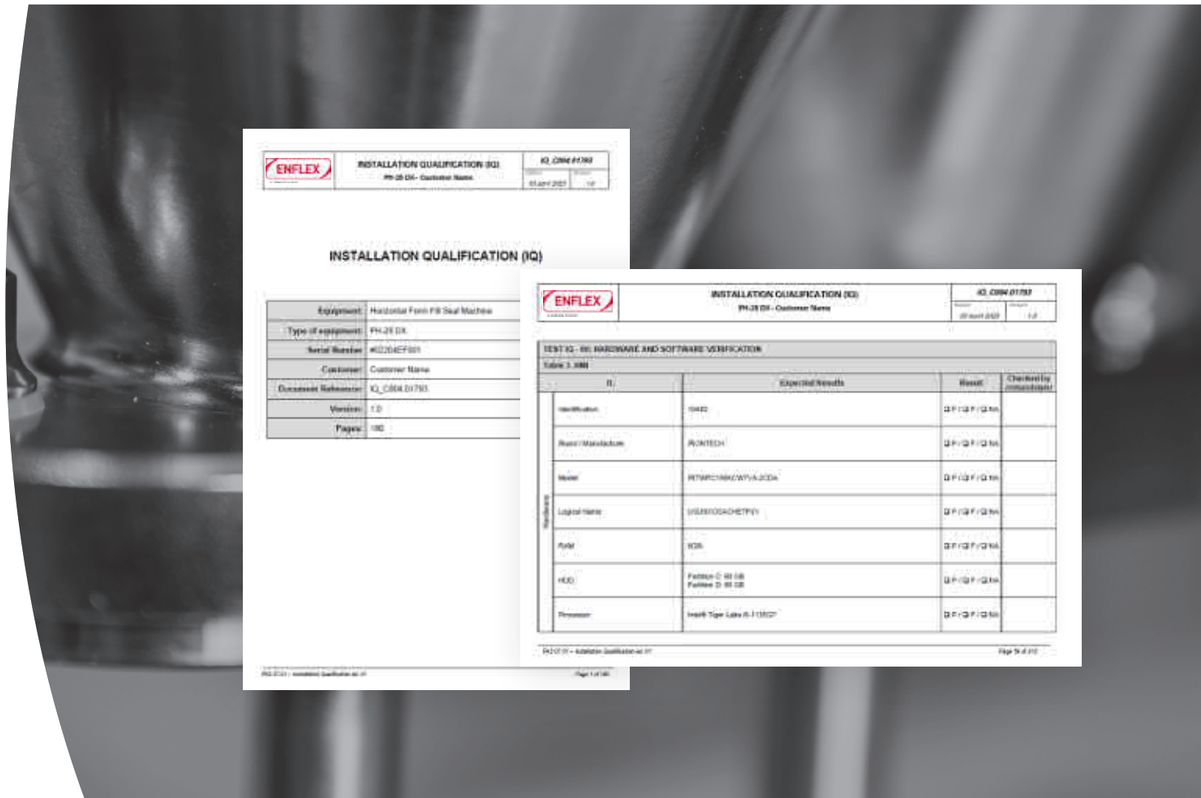
IQ (Installation Qualification) Protocol

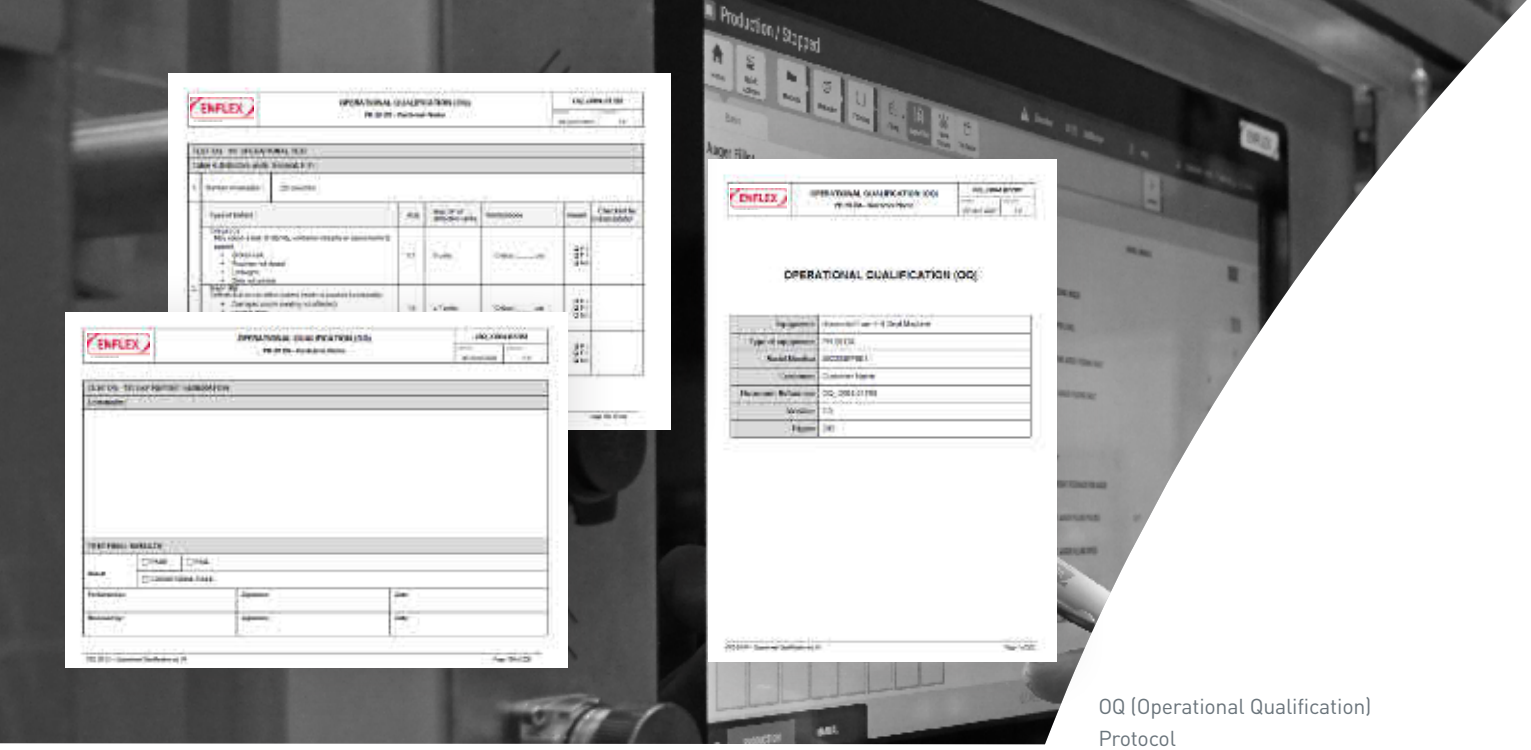
The purpose of the IQ protocol is to verify that the machine has been installed according to the customer's requirements (URS) and/or the design parameters set out in the offer or order. These checks are carried out without starting up the machine. The documentation includes an explanatory summary of each significant part of the machine and highlighting its function within the machine as a whole.

The following tests are included in the IQ protocol:

- Preliminary verification (FAT Approval)
- Document verification (Final version)
- Conformity of the plans (Final version)
- Conformity of the components
- Verification of the parts in contact with the product (the material certificates of the components that are in contact with the product are delivered with the machine)
- Verification of calibration process instruments (the calibration certificates of the temperature probes supplied with the machine are delivered with the machine)
- Verification of Installation and Software Version of the HMI and PLC
- I/O Verification
- Verification of services (equipment supplies and connections)

IQ (Installation Qualification) Protocol





OQ (Operational Qualification) Protocol

OQ (Operational Qualification) Protocol

The purpose of this protocol is to verify that the machine operates according to the customer's requirements (URS) and/or the design parameters set out in the offer or order. The documentation includes an explanatory summary of each significant part of the machine and highlighting its function within the machine as a whole.

The following tests are included in the OQ protocol:

- Preliminary verification
- Start-up, shut down and communication failures
- Screens verification
- Access levels test (if required)
- Verification of Safety Systems
- Alarms and interlocks
- Parameter Management
- Audit Trail Verification (if required)
- Data backup and retrieval (if required)
- Rejections
- Operation test for each format
- Dosing capacity/precision
- Verification of report generation (if required)

Each IQ and OQ test must include the following:

- Purpose of the test;
- Methodology for test performance;
- Acceptance criteria: minimum parameter values required to accept the test;
- Comments section to describe failures deviations or enter observations;
- Checkbox for the signature of the person responsible for performing the test;
- Approval checkbox to be signed when the test is accepted.