

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.

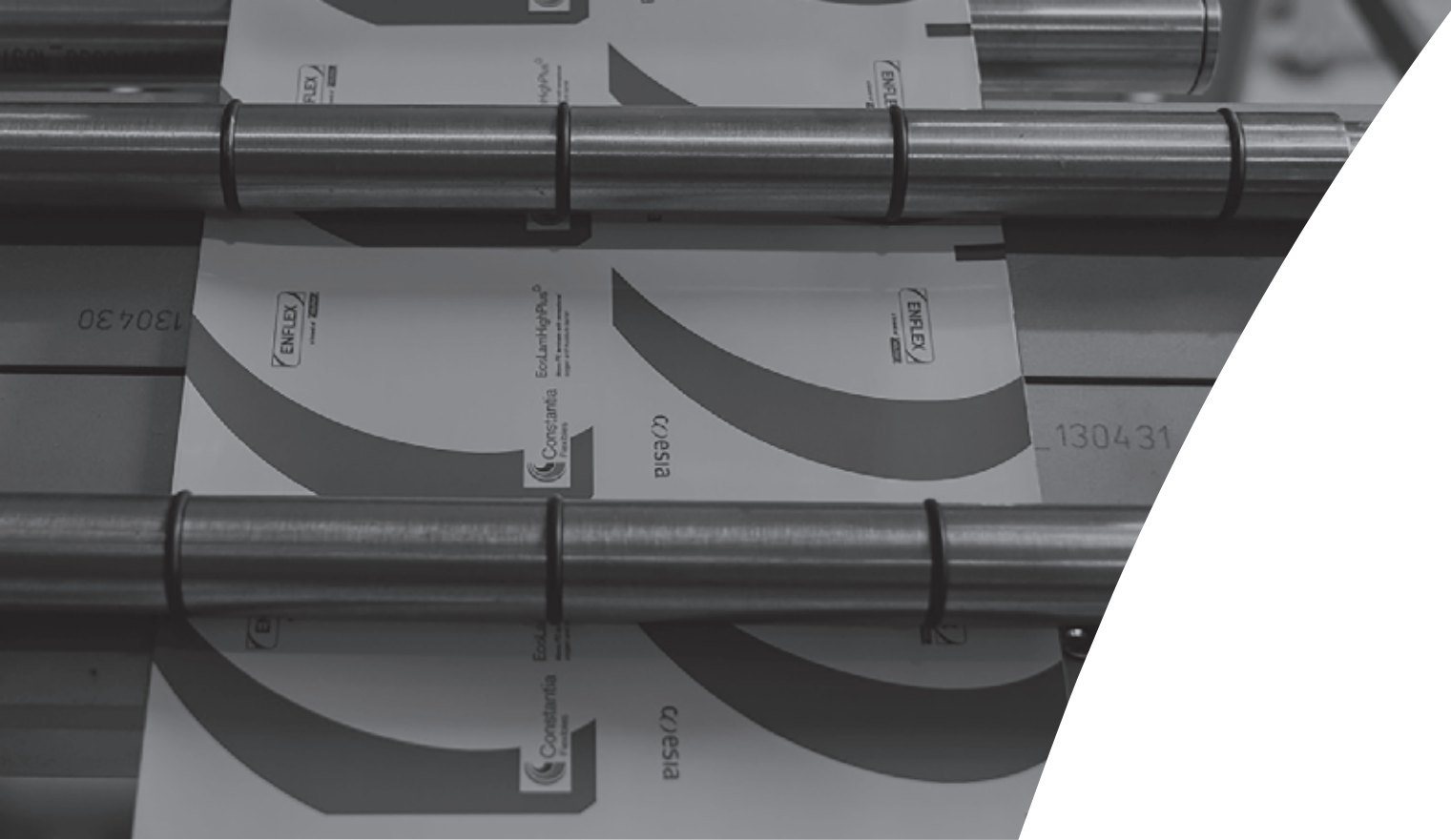
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Validation & qualification packages



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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)

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.

Pharma Risk Analysis (RA)

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.

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



RISK ASSESSMENT (RA)	RA_CRM-01780
#11-28 03 - Customer Name	#11-28-0303 - 1/2



RISK ASSESSMENT (RA)	RA_CRM-01780
#11-28 03 - Customer Name	#11-28-0303 - 1/2

RISK ASSESSMENT (RA)

Equipment:	Horizontal Press Fill Seal Machine
Type of equipment:	PH-200X
Serial Number:	#0230427001
Customer:	Customer Name
Equipment Reference:	RA_CRM-01780
Version:	1.0
Page:	25

3.3 - Risk Expansion

Considering the probability of failure with severity and detectability in the following table, OMP initially is determined:

Probability	Severity	OMP Criticality		
		Detectability		
		Low	Medium	High
High	High	High	High	Medium
	Medium	High	High	Medium
	Low	High	Medium	Low
Medium	High	High	High	Medium
	Medium	High	Medium	Low
	Low	Medium	Low	Low
Low	High	High	Medium	Low
	Medium	Medium	Low	Low
	Low	Medium	Low	Low

The value of OMP Criticality assigned serves as risk measure to assist where the company is most exposed to risk. There should be comparison relative to the risk tolerance. Its classification will determine:



RISK ASSESSMENT (RA)	RA_CRM-01780
#11-28 04 - Customer Name	#11-28-0303 - 1/2

7 - RISK ASSESSMENT TABLE

No.	Item	Risk	Exposure				Measure	Risk Consequence considering defined measures			
			Frequency	Severity	Detectability	OMP Criticality		Frequency	Severity	Detectability	OMP Criticality
1.	Description	Control failure:									
		System component is not available, or the description available does not represent the actual situation									
		Block of input:									
		The description corresponding to the system has been generated	M	H	M	H		L	M	M	L
		Block of consequence:									
		The system is not properly dimensioned									
		Regulatory limits									
		Even after operation and quality, and does not in coordination table									

RA_CRM-01780 - Risk Assessment (RA)

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Hardware Design Specifications (HDS) & Software Design Specifications (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:

- Architecture
- 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

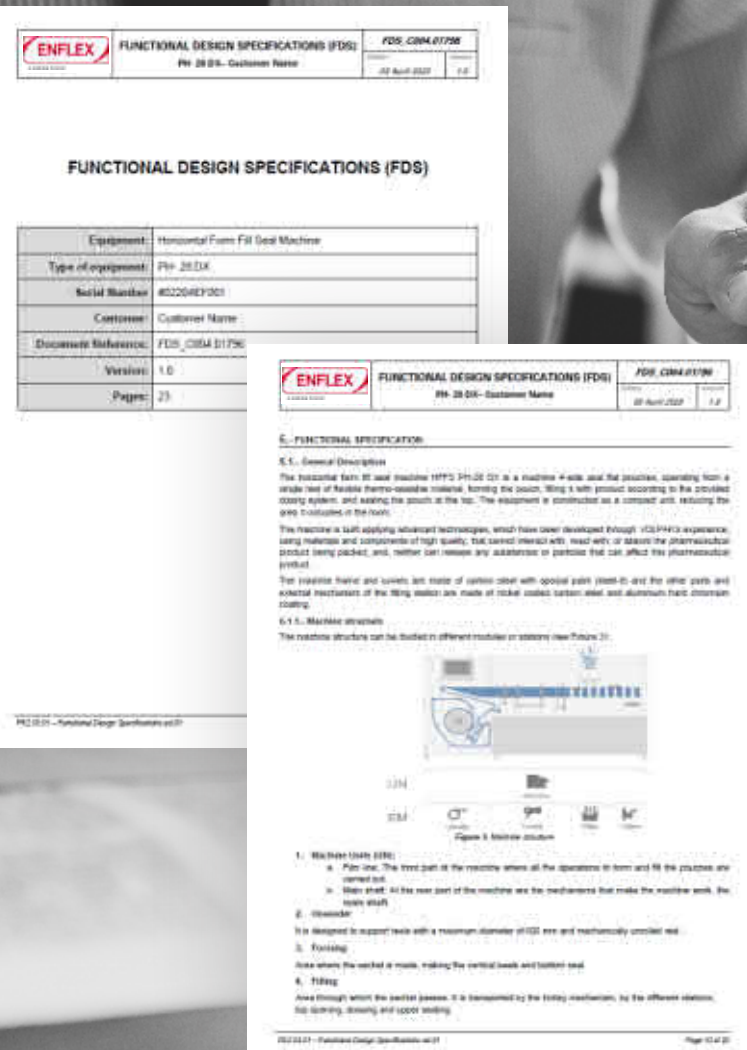
Hardware Design Specifications (HDS) &
Software Design Specifications (SDS)

Functional and Design Specifications (FDS)

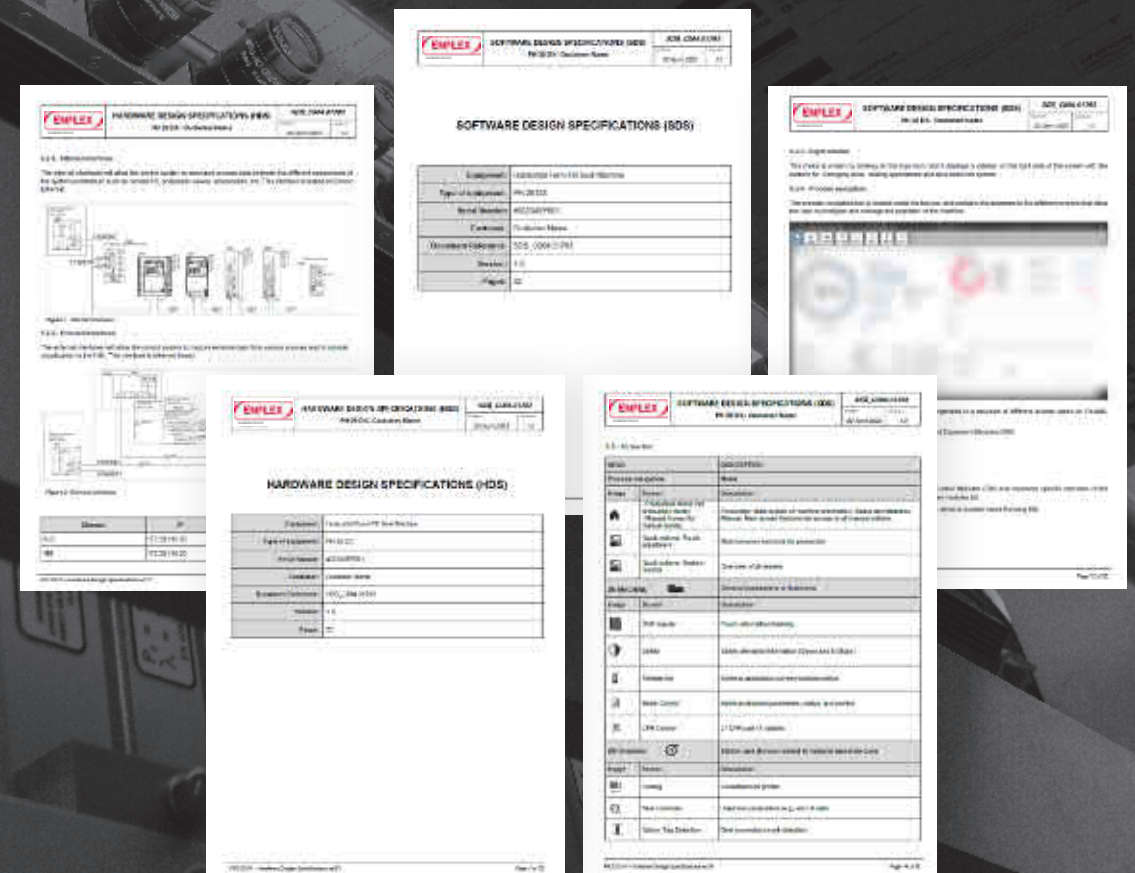
This document is prepared during the design phase and approved by the customer once the phase has been completed.

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.



Functional and Design Specifications (FDS)



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)

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

	FACTORY ACCEPTANCE TEST (FAT)		FAT 0001701	
	FAT 0001 - Customer Name		ENFLEX	
1.1. TEST FAT - 01 (See IMMEDIATELY VERIFICATION)				
Equipment:				
Verify the suitability of equipment (construction, specifications, and material) at the supplier and material receipt, and to compare:				
Measurement:				
All the measurements (for specifications, construction and to compare) are within the tolerance and within the tolerance.				
All the equipment are within the tolerance.				
For each FAT (Customer, FAT 0001, FAT 0002, FAT 0003, FAT 0004, FAT 0005, FAT 0006, FAT 0007, FAT 0008, FAT 0009, FAT 0010, FAT 0011, FAT 0012, FAT 0013, FAT 0014, FAT 0015, FAT 0016, FAT 0017, FAT 0018, FAT 0019, FAT 0020, FAT 0021, FAT 0022, FAT 0023, FAT 0024, FAT 0025, FAT 0026, FAT 0027, FAT 0028, FAT 0029, FAT 0030, FAT 0031, FAT 0032, FAT 0033, FAT 0034, FAT 0035, FAT 0036, FAT 0037, FAT 0038, FAT 0039, FAT 0040, FAT 0041, FAT 0042, FAT 0043, FAT 0044, FAT 0045, FAT 0046, FAT 0047, FAT 0048, FAT 0049, FAT 0050, FAT 0051, FAT 0052, FAT 0053, FAT 0054, FAT 0055, FAT 0056, FAT 0057, FAT 0058, FAT 0059, FAT 0060, FAT 0061, FAT 0062, FAT 0063, FAT 0064, FAT 0065, FAT 0066, FAT 0067, FAT 0068, FAT 0069, FAT 0070, FAT 0071, FAT 0072, FAT 0073, FAT 0074, FAT 0075, FAT 0076, FAT 0077, FAT 0078, FAT 0079, FAT 0080, FAT 0081, FAT 0082, FAT 0083, FAT 0084, FAT 0085, FAT 0086, FAT 0087, FAT 0088, FAT 0089, FAT 0090, FAT 0091, FAT 0092, FAT 0093, FAT 0094, FAT 0095, FAT 0096, FAT 0097, FAT 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0498, FAT 0499, FAT 0500, FAT 0501, FAT 0502, FAT 0503, FAT 0504, FAT 0505, FAT 0506, FAT 0507, FAT 0508, FAT 0509, FAT 0510, FAT 0511, FAT 0512, FAT 0513, FAT 0514, FAT 0515, FAT 0516, FAT 0517, FAT 0518, FAT 0519, FAT 0520, FAT 0521, FAT 0522, FAT 0523, FAT 0524, FAT 0525, FAT 0526, FAT 0527, FAT 0528, FAT 0529, FAT 0530, FAT 0531, FAT 053				

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

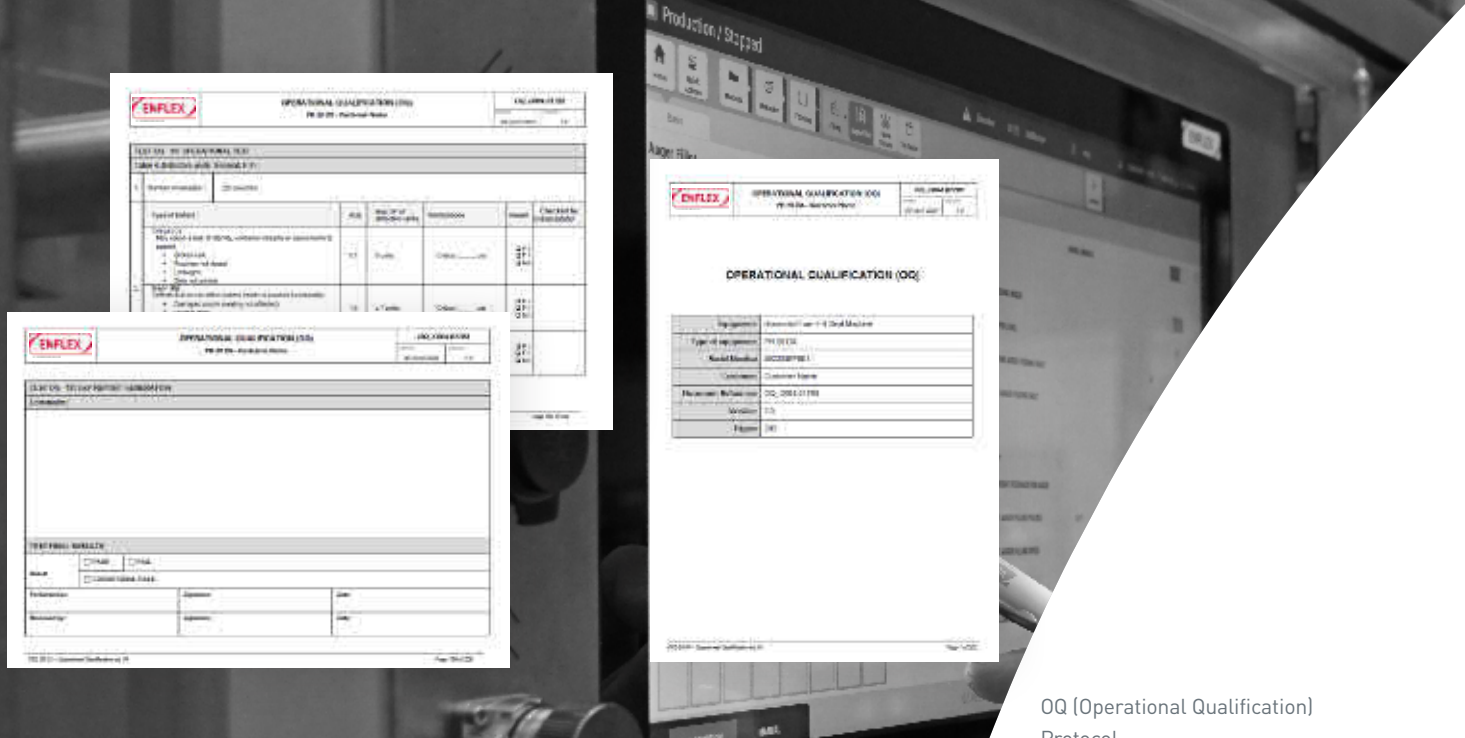
The purpose of the IQ protocol is to verify that the machine has been installed according to the customer's requirements (URS) and/or the design parameters set out in the offer or order. These checks are carried out without starting up the machine. The documentation includes an explanatory summary of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

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.