Quality and project plan (QPP)

Type:	ZSE 12 HP-PH - 40D
Machine number:	06080
Order number:	N-40136146
Customer:	Next Pharma

Version History:

Date	Version	Change/Addition
01.08.2025	0.1	First draft
15.10.2025	1.0	Final

The document is project-dependent.
It may be neither copied nor reproduced nor used in any other way without the written permission of Leistritz Extrusionstechnik GmbH.

This document has been created, reviewed and approved by:

	Name	Signature	Date
Created:	Anne Retsch Qualification Engineer Leistritz Extrusionstechnik GmbH	retscha	Digital unterschrieben von retscha Datum: 2025.10.17 10:21:47 +02'00'
Reviewed / Approved:	Martin Witzl Project Engineering Leistritz Extrusionstechnik GmbH	Martin Witzl	Digital unterschrieben von Martin Witzl Datum: 2025.10.20 09:48:28 +02'00'

This document (plan) was reviewed and approved by the customer

☐ **Not applicable** _____ / _____ **(Date / Signum)**

	Name	Signature	Date
Reviewed:	Next Pharma		
Approved:	Next Pharma		

Table to Content

1. Introduction 4
2. Scope of Supply 4
2.1 Business travel activity 4
2.2 Realization of Project 5
2.3 List of Supplies 5
3. Quality Plan 5
3.1 Supplier QM Systems 5
3.2 V-Life-Cycle-Model 6
3.3 Computer System (SCADA) 6
3.4 Design-Specifications 6
3.5 Construction 6
3.6 Factory Acceptance Test (FAT) 6
3.7 Site Acceptance test (SAT) 6
4. Documentation Information 7
4.1 Leistritz Documents 8
4.2 Review 8
4.3 Change control of documents 8
4.4 Supplied Documentation 9
5. Project Organization 10
5.1 Roles and Responsibilities 11
5.2 Time schedule 11
6. Abbreviation 11
7. Further applicable documents 12
8. Attachments 12
9. Appendix 12

1. Introduction

A Leistritz Pharma Extruder will be designed, constructed and built according to customer requirements. The extrusion line consists of the components, which are shown in the following chapter.

The Quality-Plan defines the project organization, the tasks, the responsibilities and the approved results, which have to be fulfilled.

2. Project description

2.1 Scope of Supply

The Pharma Extruder ZSE 12 HP-PH - 40D is a co-rotating intermeshing twin screw extruder. The screws have an outer diameter of 12 mm and a process part length of 40D for a throughput range von 50-2000 g/h.

The assembling of the extruder itself is as follows:

- Motor and gear box
- Compact barrel with C-profile in 5D design (Zone 1-8)
- Cover/Contact protection
- Modularly designed screw for a process length of 40D
- Melt pressure and melt temperature device
- Software (in accordance with the requirements of 21 CFR part 11, EU GMP Annex 11)
- Material discharge in Zone 9 with die head LSK 12 (integrated material outlet) and die 1x0.8 mm/ 1x1.8 mm/ 1x3 mm

The following additional components and/or functions have been ordered:

- Injection die 1x0,3 mm and 1x0,5 mm

The following equipment is connected to the extruder:

- RX9100 Heating cooling unit zones BR-018-H1-K012-AE-FDA
- RX3000 Dosing unit MiniTwin MT-S-HD, Brabender
- RX4000 Liquid dosing Watson Marlow 120U/DV with pump head 114
- RX6000 Cooling belt MFB18-24VDC-BLE2-50.5-500, fedotec

The following services are ordered:

- Execution of a FAT with product run
- Calibration by Leistritz during FAT
- Installation and Training on site
- SAT
- Warranty extension to 24 months

Furthermore, a spare parts package is part of the order.

2.2 Realization of Project

Construction and manufacturing incl. electrical installation of the Extruder will be done by Leistritz according the actual GMP guidelines. This means, that the appropriated materials and the design are usable for the pharmaceutical environment.
Peripheral devices are designed and constructed by the respective manufacturer. Leistritz is responsible for the connection to the extruder. The realization of the visualization and programming will be done by Actemium in accordance with the actual GMP guidelines.

2.3 List of Supplies

Leistritz is responsible for all suppliers of peripheral equipment or other contractually agreed additional components / services from subcontractors. This means that, unless otherwise agreed, contact with the subcontractors shall be exclusively through Leistritz.
The following suppliers are selected for the realization of the above-mentioned project.

Peripheral unit	Supplier
Volumetric Feeder	Kubota Brabender Technologie GmbH
Strand Conveyor Belt	Fedotec
Peristaltic Pump	Watson Marlow
PLC	Siemens
PLC-and Visualization Software	Actemium Controlmatic West GmbH
Heating / cooling unit	E-Braun

3. Quality Plan

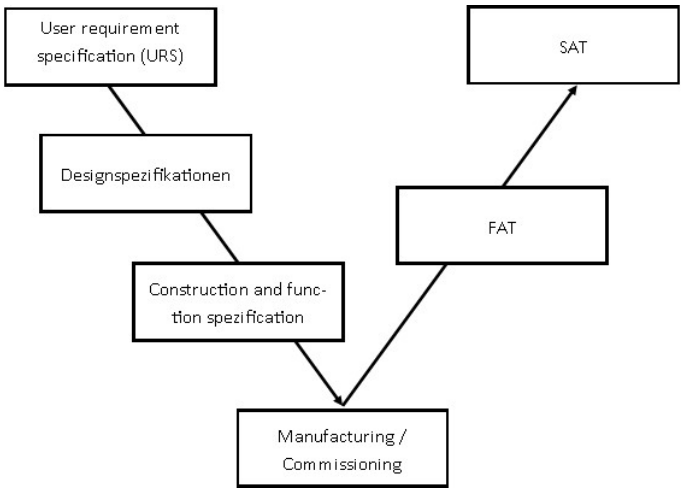
This chapter defines the responsibilities and the strategy of the verification activities. The development follows a so-called "V- model".

3.1 Supplier QM Systems

Company / supplier	QM-System
Kubota Brabender Technologie GmbH	ISO 9001:2015, Member of EHEDG
Siemens	ISO 9001:2015
Actemium Controlmatic West GmbH	ISO 9001:2015
E-Braun	ISO 9001:2015
Leistritz Extrusionstechnik	ISO 9001:2015
Watson Marlow	ISO 9001:2015
Fedotec	-

3.2 V-Life-Cycle-Model

The development of the equipment system/software is shown schematically below:



The requirements specified in the URS have been commentated and will be considered during the implementation of the project. The customer is responsible for monitoring compliance with the requirements.

3.3 Computer System (SCADA)

The software is based on a standard software / configuration from the manufacturer Actemium. The software complies with the actual GMP / GAMP guidelines.
The visualization is available in German and English.
The software is specified in the specification documents FDS, HDS, SDS as well as alarm and unit list resp. interlocking matrix.
The customer has purchased standard software. No further changes to the standard have been agreed.
The software was initially tested / qualified by Leistritz and is regularly maintained. From this status "a clone" is copied, which is then tested again for the customer's machine in those points that could have been influenced in their function (e.g. I/O check, software status, insertion of the required components etc.). See also point 3.5.

3.4 Design of the machine

Based on the URS, a piping and installation plan (P&I) is created by Leistritz. The customer must approve this document. Furthermore, the electrical documentation is prepared by Leistritz.
A design specification for the extruder is created, which can be understood as an appendix to the operating instructions with all technical details

3.5 Factory Acceptance Test (FAT)

As part of the FAT, Leistritz checks the documentation, installation and basic function of the entire system, including peripherals, in accordance with the actual GMP guidelines.

Two separate FAT documentations are created: One document for the verification of the computer system (FAT_C) and one document for the verification of the equipment (FAT_A). The acceptance criteria of the FAT tests are created based on the design documents.

The test results are documented in compliance with GMP in accordance with Leistritz's internal specifications (see "Leitfaden zur GMP-gerechten Dokumentation, LGD_PHE "). Deviations are defined as open issues and

their processing is documented in an open issue workflow protocol and evaluated in consultation with the customer.

All (technical) documents must be available for the FAT and approved by the customer, if applicable.
When the FAT has been successfully completed, the machine is released for delivery by the customer.

Leistritz does not create a separate IQ / OQ document. The two documents FAT_A and SAT comprehensively describe the necessary installation and function tests for the scope of delivery. The customer can refer to these documents in his own IQ / OQ documents (with document and version number).

The FAT includes at least the following tests:

- Installation Verification:
  - Verification of the correct labeling of the extruder incl. CE
  - Verification of delivery incl. documentation
  - Verification of the machine installation incl. peripheral devices
  - Verification of the main components of the extruder and the peripheral devices
  - Verification of data connection and media supply
  - Verification of the labeling of safety and hazard warnings
  - Verification of emergency stop and main switch
  - Verification of the wiring and I/O
  - Verification of surfaces / materials with product contact
  - Verification of oil and lubricants
  - Calibration

- Operational Verification
  - Verification of the functions of the main components of the extruder and the peripheral devices
  - Verification of the emergency stop functionality
  - Verification of the heating zones (heating current, heating tests)
  - Dosing tests
  - Product run
  - Disaster recovery

3.6 Site Acceptance test (SAT)

The SAT is carried out by Leistritz after delivery and installation at the customer's site. For this purpose, a SAT document is created by Leistritz and approved by the customer.
In the SAT, only the FAT points that could have been influenced by the deinstallation / transportation of the machine to the customer are repeatedly checked. Furthermore, a product run is to be carried out.
The SAT also includes the processing/closure of any open issues that may have occurred during the FAT.

The documentation of the test results is GMP-compliant in accordance with Leistritz's internal specifications (see "Leitfaden zur GMP-gerechten Dokumentation, LGD_PHE "). Open issues and their processing are documented in an open issue protocol and evaluated in consultation with the customer.
The SAT includes at least the following tests:

- Installation Verification:
  - Verification of the processing status of deviations from FAT
  - Verification of delivery incl. documentation
  - Verification of the machine installation incl. main components of the extruder and peripheral devices
  - Verification of data connection and media supply

- Operational Verification:
  - Verification of the start-up of the machine
  - Verification of the functions of the main components of the extruder and the peripheral devices
  - Verification of the emergency stop functionality
  - Verification of the heating zones (heating tests)
  - Dosing tests
  - Product run
  - Verification of disaster recovery

4. Documentation Information

All documents requiring approval are sent by e-mail as a “draft version”. These versions are used for review and comments.

4.1 Leistritz Documents

The documentation created by Leistritz will be identified with a clear document number:
PPP_XXXX

“PPP” is a placeholder for the short name of the document
“XXXX” is a placeholder for the machine number

Example: DEV_6080

Code	Description
DEV	Description document type of document (DEV (device or measuring point list), UNL (unit list), ARL (alarm list), LMX (interlock matrix), CBL (calibration list), PCM (list of surfaces in contact with the product), DS (design specification), OM (operating manual), DR (disaster recovery manual))
6080	Machine Number

4.2 Review

All documents which have to be reviewed by the customer should not exceed a review time of max. 5 working days and starts with the delivery of the documents. All draft documents will be sent in digital form (Office or PDF documents) via E-Mail. For each document only one review phase is specified. Leistritz is responsible for sending the documents to the customer. The customer must send feedback to Leistritz.
The documents will be sent in a protected manner so the review points will be labeled automatically. Or in case of PDF format, please use the comment function. After the review phase, the documents will be fixed as version 1.0 and sent to the customer for approval.

4.3 Change control of documents

Changes during the review phase of a document will be documented in the version history of the respective documents. The draft version number is increased when changes are made (e.g. from 0.1 to 0.2). After the review phase, the documents are finalized, set to version e.g. 1.0 and sent for signature.
Changes to approved documents are documented in the version history of the respective documents. The version of these documents is increased (e.g. from 1.0 to 1.1.). The new version must be reviewed and approved again by the responsible persons or authorized representatives.

4.4 Supplied Documentation

The following documents are created within the framework of this project:

Documentation description	Document number	Approval by customer	Language
Layout plan	BZ_40136146AU010	Yes	English
Alarm list	ARL_6080	No	English
User manual SCADA system	OM_ 6080	No	English
User manual extruder	N/A	No	English
CE certificate	N/A	No	English
Disaster Recovery manual	DR_ 6080	No	English
Design specification	DS_6080	No	English
Unit list	UNL_6080	No	English
Spare part list	N/A	No	English
FAT extruder	FAT_A_ 6080	Yes	English
FAT Computer system	FAT_C_ 6080	No	English
Functional specification	FDS_6080	No	English
Hardware design specification	HDS_6080	No	English
Calibration	TSA_ 6080	No	English
Calibration list	CBL_6080	No	English
List parts with product contact	PCM_6080	No	English
Device list	DEV_ 6080	No	English
QPP (quality and project plan)	QPP_6080	Yes	English
PID	BZ_40136146PI010N/A	Yes	English
Risk assessment using Actemium standard software for a follow-up project	RA_ 6080	No	English

Documentation description	Document number	Approval by customer	Language
SAT (site acceptance test)	SAT_6080	Yes	English
Screw drawing	N/A	No	English
SDS (software design specification)	SDS_ 6080	No	English
Wiring diagram	6080	No	English
Technical documentation dosing unit Brabender	N/A	No	English
Technical documentation EBraun (heating / cooling unit)	N/A	No	English
Technical documentation cooling belt fedotec	N/A	No	English
Technical documentation FC cooling belt	N/A	No	English
Technical documentation Watson Marlow peristaltic pump	N/A	No	English
Documentation motor	N/A	No	English
Technical documentation FC, CPU and UPS	N/A	No	English
Technical documentation drive	N/A	No	English
Technical documentation melt pressure	N/A	No	English
Technical documentation melt temperature	N/A	No	English
Technical documentation temperature sensor zones	N/A	No	English
Technical documentation valves	N/A	No	English
Interlockmatrix	LMX_ 6080	No	English
Confirmation lubricant conformity	N/A	No	English

A 2.2 documentation is agreed for the parts of the extruder with product contact. The dosing units as well as the cooling belt are supplied with 2.2 material certificates or better.

5. Project Organization

5.1 Roles and Responsibilities

The following register gives an overview of the project team:

Name	Phone	E-Mail	Company
Key Account			
Albrecht Huber	+49 911 4306-788	ahuber@leistritz.com	Leistritz
Project Management			
Martin Witzl	+49 911 4306-519	mwitzl@leistritz.com	Leistritz
Anne Barann	+49 151 70004599	abarann@leistritz.com	Leistritz
Matthias Schmidt	+49 911 4306 170	matschmidt@leistritz.com	Leistritz
Software			
Marlene Robles	+49 1520 3112946	marlene.robles@actemium.de	Actemium
Electrical Department			
Markus Loeffler	+49 911 4306-562	mloeffler@leistritz.com	Leistritz
Mechanical Department			
Robert Rein	+49 911 4306-604	rrein@leistritz.com	Leistritz
Documentation / Qualification			
Anne Barann	+49 151 70004599	abarann@leistritz.com	Leistritz
Anne Retsch	+49 176 10399292	aretsch@leistritz.com	Leistritz

5.2 Time schedule

The most important milestones of the project are listed below:

To do	Calendar week
Construction, Layout, PID	Completed
Production	In progress
Software	In progress
Preparation of documentation	In progress
FAT	CW46/47
Delivery	05.12.2025
Commissioning / SAT	CW3/4 2026

6. Abbreviation

Abbreviation	Description
ARL	Alarm List
CBL	Calibration List
CE	Conformité Européenne
DEV	Device List
DR	Disaster Recovery

DS	Design Specification
FAT_A	Factory Acceptance Test Machine
FAT_C	Factory Acceptance Test Computer system
FDS	Functional Design Specification
GAMP	Good Automated Manufacturing Practice
GMP	Good Manufacturing Practice
HDS	Hardware Design Specification
I/O	Input/Output
IQ	Installation Qualification
LMX	Interlock Matrix
N/A	Not applicable
OM	Operating Manual
OQ	Operational Qualification
PCM	List of parts in contact with material
PDF	Portable document format
PID	Piping and Installation Diagram
PLC	Programmable Logic Controller
QM	Quality Management
QPP	Quality and Project-Plan
SAT	Site Acceptance Test
SCADA	Supervisory Control and Data Acquisition
SDS	Software design specification
UNL	Unit list
URS	User Requirement Specification

7. Further applicable documents

Document Number	Version	Title
N-40136146-02	02	Order confirmation
LGD_PHE	2.0	Leitfaden zur GMP-gerechten Dokumentation

8. Attachments

none

9. Appendix

none