**Functional Specification (FS)**

Qualification number : QualiNr .

Qualification system: designation

Document No.: QualiNr- FS.000

Carried out: XXX

(xxx)

Name/ Position (Company) Date Signature

Checked: XXX

(Process owner

Operator)

Name/ Position (Company) Date Signature

Checked: XXX

(xxx)

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Approved: XXX

(Quality assurance)

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# Purpose

# In the specifications, the potential supplier describes whether and how the requirements of the specifications will be implemented.

# Detailed requirements for individual rooms (room conditions) are defined in the room book and attached to this document (see Appendix 1).

# Area of application

This specification sets out the requirements for the affected equipment [e.g. ( coater )] for [location, e.g. building] is described at [customer name, address] .

# Terms and abbreviations

## Definitions

**Water qualities**

|  |  |
| --- | --- |
| **Name / Abbreviation** | **use** |
| 21 CFR Part 11 | CFR Part 11 applies to all electronic records and signatures created, modified, maintained, archived, accessed, or transmitted under FDA jurisdiction |
| " as built “ | Structural facility “as built” |
| InMation | Software, real-time information management system |
| Lock-out/Tag-out | Occupational safety measures to protect against personal injury and property damage |

## 

## Abbreviations

|  |  |
| --- | --- |
| **Expression /** **abbreviation** | **Explanation** |
| DQ | Design qualification |
| FMEA | Failure Mode Effects Analysis​ |
| GMP | Good Manufacturing Practice |
|  |  |
|  |  |

# User Requirements​

Qualification is conducted using a risk-based approach. The qualification procedure and regulatory classification are ultimately described in the system-specific Qualification Master Plan (QMP) .

The URS is classified according to its relevance (GxP or safety/economic efficiency) and criticality (necessary/optional).

Whether the functional descriptions in the FS were “fulfilled” or “not fulfilled” is described with a “Y” (Yes) or an “N” (No).

How the requirements were implemented is documented in the “Description” column.

GxP-relevant points must be considered in the qualification process; safety/economically relevant points must be considered by the engineering/operator. Requirements classified as "necessary" must be implemented; for points classified as "optional," implementation may be waived.

In the "URS#" column of this URS, direct requirements are assigned a number. This number consists of the chapter number of the URS and a sequential number.

## Technical standards

The design and implementation of the affected media (generation, storage and distribution) must comply with the relevant local, regional and national regulations (European Union, USA) and correspond to the state of the art.

## 4.1 Requirements

### General requirements

| **URS#** | **Description** | **Classification** | **Fulfilled** |
| --- | --- | --- | --- |
| URS -001 | Batch size up to approx. 30 kg. | GxP, necessary | J |
| URS -002 | Ex version (ST-1 / ST-2, flammable liquids group IIA and IIB, ...). | GxP, necessary | J |
| URS -003 | for use with HWS ( highly effective substances). | GxP, necessary | J |
| URS -004 | All valid ISO, GMP, FDA requirements including CFR 21 Part 11 must be met. | GxP, necessary | J |

### DESIGN AND TECHNICAL EXECUTION

| **UR #** | **Description** | **Classification** | **Fulfilled** |
| --- | --- | --- | --- |
| URS -006 | Direct current spray principle with perforated drum. | GxP, necessary | J |
| URS -007 | Interchangeable drums (drum for pellets/drum for film-coated tablets in three sizes) via side access. | GxP, necessary | J |
| URS -008 | The system should be easy to clean. | GxP, necessary | J |
| URS -009 | All media inflows and outflows and their flow directions must be marked. | GxP, necessary | J |
| URS -010 | All components, apparatus, fittings and MSR equipment must be marked with a plate with water- and solvent-resistant inscription so that a clear assignment to the designations in the RI scheme is guaranteed. | GxP, necessary | J |
| URS -011 | Supply air temperature up to min. 90°C. | GxP, necessary | J |
| URS -012 | Material temperature up to approx. 70°C. | GxP, necessary | J |
| URS -013 | Complete process air treatment by the manufacturer. | GxP, necessary | J |
| URS -014 | Pressure concept/pressure control concept for HWS operation . | GxP, necessary | J |
| URS -015 | Exhaust air filtration with F6, F9 and H14 filters. | GxP, necessary | J |
| URS -016 | 2-stage security filter (police filter) with F9 and H13 and crack monitoring. | GxP, necessary | J |
| URS -017 | Drum speed continuously adjustable. | GxP, necessary | J |
| URS -018 | Minimum drum speed: 3 rpm . | GxP, necessary | J |
| URS -019 | Maximum drum speed: between 15 and 20 rpm . | GxP, necessary | J |
| URS -020 | Night or interval operation possible. | GxP, necessary | J |
| URS -021 | Material temperature regulated via supply air temperature. | GxP, necessary | J |
| URS -022 | Short hose routing. | GxP, necessary | J |
| *URS -023* | *Mass flow measurement for spray rate determination.* | GxP, necessary | J |
| *URS -024* | Damper control (supply air/exhaust air) can be controlled via differential pressure. | GxP, necessary | J |
| *URS -025* | *Product contact parts made of 316 L (GMP / FDA compliant).* | GxP, necessary | J |
| *URS -026* | *All other machine parts made of stainless steel AISI 304 or AISI 316.* | GxP, necessary | J |
| *URS -027* | *All seals must be made of silicone, Teflon and PTFE.* | GxP, necessary | J |
| *URS -028* | *Cable connections of the sensors to be calibrated with reserve length for easy recalibration handling.* | GxP, necessary | J |
| *URS -029* | *All system components and in particular measuring devices must be designed so that they can be easily removed and calibrated.* | GxP, necessary | J |

### Operation, control and data acquisition

| **UR #** | **Description** | **Classification** | **Fulfilled** |
| --- | --- | --- | --- |
| URS -030 | Data recording of: supply air temperature, supply air volume , exhaust air temperature, exhaust air volume, spray rate, spray air pressure, spray liquid pressure, spray liquid temperature, product temperature, boiler speed, process duration (date and time), operator, printout date + time, batch name (21 CFR 11). | GxP, necessary | J |
| URS -031 | Color protocol printer for the batch report.  Note for URS (2.0):  Process files as PDF files. | GxP, necessary | J |
| URS -032 | Control panel near the system.  Note for URS (2.0):  New control element. | GxP, necessary | J |
| URS -033 | Pre-equipment of the control system for transferring process data to a higher-level IT system.  Note for URS (2.0):  Use of InMation for data analysis and Dahlia for data backup. | GxP, necessary | J |
| URS -034 | Control (PLC) from Siemens (desired: Simatic S7).  Note for URS (2.0):  A current Simatic S7 PLC is planned. | GxP, necessary | J |
| URS -035 | Audit trail functionality. | GxP, necessary | J |
| URS -036 | Backup function. | GxP, necessary | J |
| URS -037 | Operating system MS Windows XP (if necessary: WIN 2000).  New description URS (2.0):  Operating system Microsoft Windows 10. | GxP, necessary | J |
| URS -038 | User interface with display of current parameters. | GxP, necessary | J |
| URS -039 | User interface with various password-protected user levels. At least standard user, user with recipe creation permissions, and all rights. | GxP, necessary | J |
| URS -040 | User is uniquely identified by name and password | GxP, necessary | J |

### OCCUPATIONAL SAFETY

|  |  |  |  |
| --- | --- | --- | --- |
| **UR #** | **Description** | **Classification** | **Fulfilled** |
| URS -041 | Safety switches (emergency stop) and other protective devices | Security, necessary | J |

### documentation

|  |  |  |  |
| --- | --- | --- | --- |
| **UR #** | **Description** | **Classification** | **Fulfilled** |
| URS -042 | CE certificate. | GxP, necessary | J |
| URS -043 | Hazard analysis by the manufacturer (according to CE guidelines). | GxP, necessary | J |
| URS -044 | German-language operating instructions in duplicate | GxP, necessary | J |
| URS -045 | German-language maintenance instructions. | GxP, necessary | J |
| URS -046 | Spare/wear parts list. | GxP, necessary | J |
| URS -047 | Specifications/System specification. | GxP, necessary | J |
| URS -048 | Circuit diagrams. | GxP, necessary | J |
| URS -049 | Technical data of the machine. | GxP, necessary | J |
| URS -050 | Layout plan. | GxP, necessary | J |

### Requirements for computerized systems

| **UR #** | **Description** | **Classification** | **Fulfilled** |
| --- | --- | --- | --- |
|  | Login to the application/software should be possible via Active Directory groups ( sLDAP or similar encrypted communication) (per user group). | GxP, necessary | J |
|  | The application/software should have its own/integrated user management. | GxP, necessary | J |
|  | A written role-based authorization concept must be in place. | GxP, necessary | J |
|  | User accounts within the software/application with at least three user levels/user classes must be available (e.g. user/operator, supervisor, maintenance, technician, software/ application user administrator).  The access authorization must ensure that the personnel employed in the company are only assigned the rights (e.g. to the data and recipes/configurations/functions, etc.) that they need to perform their tasks. | GxP, necessary | J |
|  | The manufacturer can create specific user levels/user classes. | GxP, necessary | J |
|  | An authorization matrix must be available.  The manufacturer can provide a current user matrix, which will be adapted. | GxP, necessary | J |
|  | The authorizations of the individual user levels/user classes should be editable by authorized persons and not fixed by the manufacturer. | GxP, optional | J |
|  | Separation of administration rights (optional)  For traceability, the system should distinguish between "user administrator" and "system administrator." Separation of duties as described below.  User Administrator - at application level  (PTC qualification):   * + Abnormalities in user logins   + Changes within user management (user management, authorization levels, authorization matrix, connection to Active Directory, etc.)   + View, configure and administer user data   System Administrator - at operating system level (DTDS):   * + Install/uninstall programs (if necessary with manufacturer)   + administer the operating system   + Operating system migration and patches   + Make system configuration settings (IT tools such as Secure Desktop)   Initial creation of AD groups | GxP, optional | J |
|  | There should be no single user level that is authorized to perform all functions. A hierarchical distribution of rights should be avoided (e.g., the highest authorization level may not perform all functions, with the exception of the Glatt administrator). | GxP, optional | J |
|  | Access to the Windows interface must be blocked by the application/software.  Not every user should be able to access the Windows interface (even keyboard shortcuts like Ctrl+Alt+Delete won't allow the user to access Windows). With certain permissions, such as Admin, it's possible to exit the software and access the Windows interface. | GxP, necessary | J |
|  | Access to the system must be via personalized access with a unique user ID and password. | GxP, necessary | J |
|  | The date and time settings, as well as the time zone, must be protected from unauthorized access. | GxP, necessary | J |
|  | Login to the software should be possible via local accounts (per user group). | GxP, necessary | J |
|  | If an incorrect password is entered, access to the system must be denied. | GxP, necessary | J |
|  | Passwords must be allowed to be at least 12 characters long. Passwords must also contain at least one character from at least three of the following four categories:   * + Capital letters (A - Z)   + Lowercase letters (a - z)   + Arabic numerals (0 - 9)   + Special characters (e.g. @ $ %! \*) | GxP, necessary | J |
|  | The system requires that passwords expire after 365 days and must then be changed. The system must prevent the new password from being inconsistent with previously used passwords. | operation, necessary | J |
|  | Any passwords will not be stored in plain text in the registry or anywhere else (e.g. in the software) on the PC. | operation, necessary | J |
|  | An automatic logout must occur after a defined period of 30 minutes during which the system is not used. This time should be editable by authorized personnel. | GxP, necessary | J |
|  | The application/software must have an automatic, electronic audit trail. | GxP, necessary | J |
|  | The application/software audit trail must contain at least the following information:   * + User ID (who?)   + Timestamp (date/time; when?)   + activities performed (What?)   + Difference between new and old data   a field to indicate the reason for the change. | GxP, necessary | J |
|  | The audit trail must contain at least the following process data:   * + Recipe parameters   + Changes to local users   Creating new and changing/deleting existing recipes | GxP, necessary | J |
|  | The audit trail cannot be deleted, deactivated or changed (without authorization). | GxP, necessary | J |
|  | Granting, modification and revocation (including log on/off activities) of access authorizations must be recorded. | GxP, necessary | J |
|  | All changes made by an application/software administrator must be visible in the audit trail. | GxP, necessary | J |
|  | Changes to GMP data must be logged in the application's audit trail. GMP data includes all data defined as relevant, such as process and method parameters. | GxP, necessary | J |
|  | The information in the application/software audit trail must be stored and accessible in a human-readable format for review.  Optionally possible:   * + Search, filter and sort the audit trail   + Printout of the audit trail | GxP, necessary | J |
|  | The software can store data locally on the PC. | GxP, necessary | J |
|  | A data storage/backup concept must be in place. This includes, for example:   * + What data is stored?   + Where is the data stored?   + who has access to the data?   + How is external data backup carried out?   + When is the data backup carried out?   + Where does the data backup go?   + Which data is the original data/raw data?   + Is the data permanently available?   + Is the data safe from misuse?   + What type of data is stored (data formats)?   + the criticality of the data was assessed * CQAs ( critical quality attributes )   CPPs ( critical process parameters )? | GxP, necessary | J |
|  | For computerized systems with a ring buffer, depending on the available storage capacity, measures must be implemented/defined so that data loss can be excluded. | GxP, necessary | J |
|  | An interface for data backup must be available. | GxP, necessary | J |
|  | The software can store data on a network drive in UNC notation. | GxP, necessary | J |
|  | All files that the user needs to access or save are stored in one location (one path) (subfolders are allowed). | GxP, necessary | J |
|  | Data backup over the internal network must primarily be automated. The software can store data on a network drive using a mapped network drive.  If this is not possible, data backup must be set up. | GxP, necessary | J |
|  | All relevant defined data, including metadata, must be able to be stored permanently and promptly in their original data format in a local data storage or storage location assigned to the device (data storage). | GxP, necessary | J |
|  | (Necessary) changes or deletion of stored data can only be performed by authorized personnel (primary storage location of the application software, e.g., local storage location). Read permissions are permitted for all users. | GxP, necessary | J |
|  | Locally/internally stored data may not be overwritten without authorization. | GxP, necessary | J |
|  | The externally backed up data must be complete and correspond to the original form (original data format) ( true copy ). | GxP, necessary | J |
|  | The logged in software user cannot delete files – not even via the application (e.g. within File Save As / Open dialogs). | GxP, necessary | J |
|  | Externally backed up data must not be overwritten. | GxP, necessary | J |
|  | If the network connection is unavailable, no data is lost. The data is cached (locally) and saved when the network becomes available. | GxP, necessary | J |
|  | The supplier must provide instructions for data backup and recovery. | GxP, necessary | J |
|  | Time and date synchronization must be done automatically using a Network Time Protocol (NTP). | GxP, necessary | J |
|  | A data flow diagram ( data flow ). This diagram is intended to provide an overview and control of the data.  The following points must be taken into account:   * + Data Input + Output   + Critical data (e.g. CQAs and CPPs)   + User and authorization concept/access control,   + Data backup   Archiving | GxP, necessary | J |
|  | The system must generate a representative, summary report based on the data. This report must include:   * + a record of all relevant defined data and the information necessary to interpret the data (possibly also in the form of a graphical representation).   + all data that must be available for a review (including failed processes/runs/measurements).   + all changes to data   + all events (faults, alarms, system failures and data errors).   For reports used for batch release, it must be possible to generate a printout that shows any changes to the data after it was first entered. | GxP, necessary | J |
|  | The results report lists the batch/process date and the print date separately. | GxP, necessary | J |
| **Hardware requirements** | | | |
|  | The hardware/PC including operating system is provided.  A SIEMENS IPC is planned.  The PC data sheet must be made available.  The number and type of interfaces must be specified. | Operation, optional | J |
|  | The system hardware requirements must be specified, e.g.:   * + - Intel i7   + - 32 GB RAM   + - 1 x 256 GB SSD   - 2 x Network Interface | Operation, optional | J |
|  | All hard disk partitions must be formatted as NTFS. | Operation, optional | J |
|  | The PLC is also connected to the LAN and therefore must have 2 Ethernet interfaces.  Hardware CPU 1500 TIA:  In addition to the CPU, a CP with a second dedicated interface and separate Ethernet address. | operation, necessary | J |
| **General requirements (operating system, IT security, printer, etc.)** | | | |
|  | An autologon in Windows can be set up. | GxP, necessary | J |
|  | Update operating system:  Windows 10 LTSC 2019, 64-bit | operation, necessary | J |
|  | The Windows standard printer should be used for printing. | operation, necessary | J |
|  | The installation and configuration of the software is carried out by the contractor. | operation, necessary | J |
|  | B The contractor can maintain and configure the software remotely. Only Zoom may be used for this purpose. An engineering station with the necessary licenses can be set up additionally if necessary. | operation, necessary | J |
|  | The manufacturer should list all required data formats to be used for data storage, backup, and archiving. Example:   * + pdf /a-2 (ISO 19005-2)   + XML   + JPG\* or tif or png (\*JPG only allowed if compression does not result in any loss of information.)   Inclusion of additional formats if required | GxP, necessary | J |
| **Software requirements** | | | |
|  | The software should open immediately after Windows starts. | GxP, necessary | J |
|  | No admin rights in Windows should be required to use the application/software. | GxP, necessary | J |
|  | All storage paths are permanently configured in the software by a user with appropriate permissions (e.g., admin). No File Open/Browse/Save As dialogs are available during the process.  A “normal” user cannot save the data anywhere other than the defined locations. | GxP, optional | J |
|  | If there are File Open / Browse / Save As dialogs, the standard Windows dialogs are used. Standard Windows dialogs have the class name #32770. | GxP, necessary | J |
|  | The software can create automatic and configurable backups (including configuration data, process data, etc.). | GxP, necessary | J |
|  | If the software stores the data in a database, Microsoft SQL Server must be used. | GxP, necessary | J |
|  | The data can be read via an OPC/UA interface. The interface can be configured later. | Operation, optional | J |
|  | A connection to InMation must be provided. For this purpose, the customer-defined interface must be implemented accordingly (reference project: GPCG Modcos - PN 18528). | Operation, optional | J |

### Requirements for technical documents

| **UR #** | **Description** | **Classification** | **Fulfilled** |
| --- | --- | --- | --- |
| **Requirements for technical documentation** | | | |
| n/a . | Contents of the technical documentation:   * + Operating instructions   + Plant description   + Functional description   + EMC test report   + Parts list (spare/wear parts list)   + Technical data sheets   + Alarm and fault report list including fault rectification   + Electrical circuit diagram   + Software description and program   + Backup software (PLC + HMI)   + Disaster and System Recovery Guide | Operation, optional | N |
|  | All technical documents as well as the visualization, user interface, labeling, and warnings must be in German. Business  optional | Operation, optional | J |
|  | The technical documentation contains at least the following documents:   * + Operating instructions   + Plant description   + Functional description   + EMC test report   + Parts list (spare/wear parts list)   + Technical data sheets (supplement)   + Alarm and fault report list including fault rectification (if applicable in the functional specification)   + Electrical circuit diagram   + Software description and program   + Backup software (PLC + HMI)   + Disaster and system recovery guide. | GxP, necessary | J |
|  | All documents must be created in one of the following formats:   * + Microsoft Office   + E-Plan   + Auto CAD as DWG or DXF   + PDF | GxP, optional | J |
|  | The operating instructions include a written concept for lock-out/tag-out protection during maintenance, cleaning and setup work as well as during troubleshooting. | Security, necessary | J |
|  | If MSR safety devices are present to reduce risks (to people, the environment and the system), they must be assessed or their suitability confirmed in accordance with IEC61508/IEC61511 (“Functional safety of safety-related electrical/electronic/programmable electronic systems”).  Proof of the assessment is part of the order and must be handed over to the customer.  The resulting recurring tests to ensure correct maintenance of the safety function must be recorded in the operating instructions. | Security, necessary | J |

# Cited or relevant documents

|  |  |
| --- | --- |
| AMWHV | Medicinal Products and Active Substances Manufacturing Ordinance, entry into force of the last amendment: 16 August 2019 |
| EU Guide to Good Manufacturing Practice | The regulation of medicinal products in the European Union, |
| Annex 11 to the EU Guide to Good Manufacturing Practice | Qualification and validation, last amendment entered into force on 30 June 2011. |
| Annex 15 to the EU Guide to Good Manufacturing Practice | Qualification and validation, last amendment entered into force: October 2015. |
| ISPE | Current guidelines of the International Society for Pharmaceutical Engineering |
| GAMP 5 | Good Automated Manufacturing Practice for Validation of Automated Systems in Pharmaceutical Manufacture ( current version 2nd Edition - August 2022) |
| AMG | Medicines Act, Act on the Trade in Medicinal Products, entry into force of the last amendment: June 24, 2022. |
| Ph . Eur. | European Pharmacopeia , current edition: 10th edition 2020 |
| USP | United States Pharmacopeia , May 2022 |
| PIC/S | Pharmaceutical Inspection Co-operation / Scheme, Guide to Good Manufacturing Practice for Pharmaceutical Products, February 2022. |
| 2014/30/EU | EMC Directive, Electromagnetic Compatibility of Electrical and Electronic Products, February 26, 2014 |
| 2006/42/EC | Machinery Directive , 17 May 2006 |

# Attachments

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