**Functional Specification(FS)**

Qualification number:Qualifying amount.

Qualification system:Heading

Document No:QualityFS.000

Performed:XXX

(xxx))

Name/ Function(Company)DateSignature

Checked:XXX

(Process manager

Operator)

Name/function (company)DateSignature

Checked:XXX

(xxx)

Name/function (company)DateSignature

Approved:XXX

(Quality assurance)

Name/ Function (company))DateSignature

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| --- | --- | --- |
| Revision No | Reason for amendment | Date (dd/mm/yyyy) |
| 01 | Creation | 20.03.2025 |

Purpose

In the specifications, the potential supplier describes whether and how the requirements of the specifications are implemented.

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

MissionArea

With thesemSpecificationsthe requirements shall be:tothe equipment concerned;[e.g.(Coater]for[ Place of deployment For example: Buildings]in the case of:[ Name of customer, address]==References==

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, retrieved or transmitted under the responsibility of the FDA |
| "as built" | Construction site "like built" |
| InMation | Software, real-time information management system |
| Lock-out/tag-out | Occupational safety measures for the protection of personal and property damage |

Abbreviations

|  |  |
| --- | --- |
| Definition / Abbreviation | Explanation |
| DQ | Design qualification |
| FMEA | Failure Mode Effects Analysis (Failure Mode Effects Analysis) |
| GMP | Good Manufacturing Practice |
|  |  |
|  |  |

UserRequirements(User requirements)

Dhe qualification is based on a risk-based approach. The qualification process and the regulatory classification are described in the system-specific qualification master plan (QMP).

TheURSwillclassified according to their relevance (GxP or security/economicity) and criticality (necessary/optional).

Whether the functional descriptions in the FS were "fulfilled" or "unfulfilled" is described by a "J" (yes) or a "N" (no).

How the requirements have been implemented is documented in the column ‘Description'.

GxP- No, no, no, no, no, no, no.relevant points must be taken into account in the qualification; Securitys-/Economy- No, no, no, no, no, no, no.relevant points must be taken into account by the engineering/operator.Requirements, which are classified as "necessary", must be implemented, for "optionally classified points can possibly be applied to the implementationthe requirement is waived.

In the column "URS#" of these URS, direct requirements are marked with a number. This number shall consist of the chapter number of the URS and a serial number..

Technical standards

The interpretation and execution to the affectedMedia(Production, storage and distribution) must comply with relevant local, regional and national regulations (European Union, USA)and correspond to the level ofTechnology.

4.1Requirements

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, combustible Liquids group IIA and IIB, ...). | GxP, necessary | J |
| URS-003 | Suitable for operation with HWS (Highly Effective Substances). | GxP, necessary | J |
| URS-004 | All valid ISO, GMP, FDA requirements incl. CFR 21 Part 11 must be met. | GxP, necessary | J |

CONSTRUCTION AND TECHNICAL IMPLEMENTATION

|  |  |  |  |
| --- | --- | --- | --- |
| UR # | Description | Classification | Fulfilled |
| URS-006 | DC spray principle with perforated drum. | GxP, necessary | J |
| URS-007 | Interchangeable drums (drums for pellets/ Drums for film-coated tablets in three sizes) via side access. | GxP, necessary | J |
| URS-008 | Installation should be easy to clean. | GxP, necessary | J |
| URS-009 | All media inflows and outflows and their flow directions shall be identified. | GxP, necessary | J |
| URS-010 | All components, appliances, fittings and MSR devices shall be marked with a water- and solvent-resistant label so that a clear assignment to the designations in the RI scheme is ensured. | GxP, necessary | J |
| URS-011 | Supply air temperature up to min. 90°C. | GxP, necessary | J |
| URS-012 | Good temperature up to approx. 70°C. | GxP, necessary | J |
| URS-013 | Complete process air treatment by the manufacturer. | GxP, necessary | J |
| URS-014 | Printing concept/pressure control concept for HWS Operation. | GxP, necessary | J |
| URS-015 | Exhaust air filtration with F6, F9 and H14 Filter. | GxP, necessary | J |
| URS-016 | 2-stage safety 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 | Good temperature controlled by supply air temperature. | GxP, necessary | J |
| URS-022 | Short hose guide. | GxP, necessary | J |
| URS-023 | Mass flow measurement for spray rate determination. | GxP, necessary | J |
| URS-024 | Valve control (incoming air/exhaust air) can be controlled by differential pressure. | GxP, necessary | J |
| URS-025 | Product touching parts made of 316 L (GMP / FDA conform). | 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 components and in particular measuring devices shall be designed in such a way that they are easily expandable and calibratable. | GxP, necessary | J |

Operation, control and data collection

|  |  |  |  |
| --- | --- | --- | --- |
| UR # | Description | Classification | Fulfilled |
| URS-030 | Data recording of: supply air temperature, supply air quantity, exhaust air temperature, exhaust air quantity, spray rate, spray air pressure, pressure Spray liquid, temperature Spray liquid, product temperature, boiler speed, process duration (date and time), processor, printout date + time, batch designation (21 CFR 11). | GxP, necessary | J |
| URS-031 | Colored protocol printer for the batch report. Note for URS (2.0): Process files as PDF file. | GxP, necessary | J |
| URS-032 | Operating tableau near the plant. Note for URS (2.0): New control element. | GxP, necessary | J |
| URS-033 | Pre-equipment of the control for the transfer of process data to a higher-level computer system. Note for URS (2.0): Use of InMation for data analysis and Dahlia for data backup. | GxP, necessary | J |
| URS-034 | Control (SPS/PLC) from Siemens (wanted: Simatic S7). Note for URS (2.0): A current Simatic S7-SPS is provided. | 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 (Emergency: 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 different password protected user levels. At least standard user, user with permission to create a recipe, All rights. | GxP, necessary | J |
| URS-040 | User is uniquely identified by name and password | GxP, necessary | J |

LABOUR SAFETY

|  |  |  |  |
| --- | --- | --- | --- |
| UR # | Description | Classification | Fulfilled |
| URS-041 | Safety switches (emergency off) and other protective devices | Safety, 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 instruction manual in double version | GxP, necessary | J |
| URS-045 | German-language maintenance manual. | GxP, necessary | J |
| URS-046 | Replacement/wear list. | GxP, necessary | J |
| URS-047 | Compulsory specification/ System specification. | GxP, necessary | J |
| URS-048 | schematics. | GxP, necessary | J |
| URS-049 | Technical data of the machine. | GxP, necessary | J |
| URS-050 | Layout / layout. | GxP, necessary | J |

Requirements for computerised systems

|  |  |  |  |
| --- | --- | --- | --- |
| UR # | Description | Classification | Fulfilled |
|  | Login in 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 |
|  | There must be a written role-based authorisation concept. | GxP, necessary | J |
|  | User accounts within the software/application with at least three user levels/user classes must be present (e.g. user/operator, supervisor, maintenance, technician, software/applications user administrator). The access authorisation must ensure that only the rights are assigned to the personnel employed in the operation (e.g. data and recipes/configurations/functions, etc.) which it needs to carry out its tasks. | GxP, necessary | J |
|  | The manufacturer may use specific user levels/ Create user classes. | GxP, necessary | J |
|  | There must be an authorization matrix. The manufacturer can provide a current user matrix, which is adapted. | GxP, necessary | J |
|  | The permissions of the individual user levels/user classes should be editable by authorized persons and not fixed by the manufacturer. | GxP, optional | J |
|  | Separation of administrative rights (optional) In terms of traceability, the system should distinguish between "user administrator" and "system administrator". Task separation as described below. User administrator - at application level (qualification PTC): Distinctive user logins Changes within user management (user management, permission levels, permission matrix, connection to Active Directory, etc.) View, configure and administer user data System administrator - at operating system level (DTDS): Install programs/ Uninstall (with manufacturer if necessary) administrate the operating system Operating System Conversion and Patches Make System Configuration Settings (IT Tools like Secure Desktop) Initial Creation of AD Groups | GxP, optional | J |
|  | There must be no user level that can perform all functions. A hierarchical distribution of rights is to be foreseen (e.g. highest permission level may not perform all functions, except: ==References== | GxP, optional | J |
|  | Access to the Windows interface must be blocked by the application/software. It must not be possible for every user to switch to the Windows interface (also by keyboard shortcuts such as Ctrl+Alt+Del the operator does not come into Windows). With certain permissions, e.g. admin, it is possible to terminate the software and access the Windows interface. | GxP, necessary | J |
|  | Access to the system must be through personalized access with a unique user ID and password. | GxP, necessary | J |
|  | The date and time setting, as well as 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 |
|  | It must be allowed to use passwords with a length of at least 12 characters. Passwords must also include at least one character from at least 3 of the following 4 categories: capital letters (A - Z) lowercase letters (a - z) Arabic numerals (0 - 9) Special characters (e.g. @ $ %! \*) | GxP, necessary | J |
|  | The system requires passwords to expire after 365 days and then have to be changed. The system must prevent that the new password is not identical with previously used passwords. | Operation, necessary | J |
|  | All passwords will not be stored in plain text in the registry or in any other place (e.g. in the software) on the PC. | Operation, necessary | J |
|  | An automatic log-out must be made after a defined time of 30 minutes in which the system is not operated. This time should be editable by authorized persons. | GxP, necessary | J |
|  | The application/software must have an automatic, electronic audit trail. | GxP, necessary | J |
|  | The audit trail of the application/software must: contain at least the following information: User ID (who?) Time stamp (date/time); When?) Executed activities (What?) Difference between new and old data a field to specify 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 Creation of new and change / deletion of existing recipes | GxP, necessary | J |
|  | The audit trail cannot be deleted, deactivated or changed (without permission). | GxP, necessary | J |
|  | The issue, modification and withdrawal (also includes log on/off activities) of access permissions 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 audit trail of the application. GMP data means all data defined as relevant, e.g. process and method parameters. | GxP, necessary | J |
|  | The information of the audit trail of the application/ Software must be stored and retrieved in a human-readable format for review. Optionally possible: Search, filter and sort the audit trail expression of the audit trail | GxP, necessary | J |
|  | The software can store data locally on the PC. | GxP, necessary | J |
|  | A data storage/data backup concept must be available. For example, contents of this are: which data are stored? where is the data stored? who has access to the data? how does external data backup take place? When is the data backup done? where does the backup take place? which data are the original data/ Raw data? are the data permanently available? are the data safe from misuse? what kind of data are stored (data formats)? was the criticality of the data evaluated CQAs (critical quality attributes) CPPs (critical process parameters)? | GxP, necessary | J |
|  | For computerised systems with a ring memory, measures must be implemented/defined, depending on the available storage capacity, 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 to which the user has to access or which the user has to save are stored in a place (a path) (subfolders are allowed). | GxP, necessary | J |
|  | Data backup over the internal network must be carried out primarily automatically. The software can store data on a network drive using a mapped network drive. If this is not possible, the backup must be set up. | GxP, necessary | J |
|  | All relevant data, including metadata, must be stored permanently, as well as promptly in a local data store or storage location assigned to the device with its original data format. | GxP, necessary | J |
|  | (Required) Changes or deletion of stored data can only be carried out by authorized personnel (primary location of the user software, e.g. local location). Reading rights are allowed for all users. | GxP, necessary | J |
|  | Data stored locally/internally must not be overwritten without authorization. | GxP, necessary | J |
|  | The externally secured data must be complete and correspond to the original data format (true copy). | GxP, necessary | J |
|  | The logged-in software user cannot delete any files – even via the application (e.g. within File Save As / Open dialogs). | GxP, necessary | J |
|  | Externally secured data must not be overwritten. | GxP, necessary | J |
|  | If the network connection is not available, no data will be lost. The data is stored (locally) and stored when the network is available. | GxP, necessary | J |
|  | A guide to data backup and recovery shall be provided by the supplier. | GxP, necessary | J |
|  | The time and date synchronization must be done automatically by a Network Time protocol (NTP). | GxP, necessary | J |
|  | A data flow diagram must be created. The purpose of this diagram is 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 permission concept/access control, data backup Archiving | GxP, necessary | J |
|  | The system shall draw up a representative summary report on the basis of the data. This must include: a recording of all relevant defined data and the information necessary to interpret the data (also in the form of a graphic representation if necessary). all data that must be available for a review (also failed processes/runs/measurements). all changes to data all events (disorders, alarms, system failures and data errors). Reports used for batch release must be able to generate an expression that indicates a change in the data after initial input. | GxP, necessary | J |
|  | The result report lists batch/process date and print date separately. | GxP, necessary | J |
| Requirements for hardware | Requirements for hardware | Requirements for hardware | Requirements for hardware |
|  | The hardware / PC incl. operating system is provided. A SIEMENS IPC is provided. The data sheet of the PC is to be provided. The number and type of interfaces shall be specified. | Operation, optional | J |
|  | The system requirements hardware-side must be specified, e.g.: - Intel i7 - 32 GB RAM - 1 x 256 GB SSD - 2 x Network Interface | Operation, optional | J |
|  | All hard drive partitions must be formatted as NTFS. | Operation, optional | J |
|  | The PLC is also connected to the LAN and must therefore have 2 Ethernet interfaces. Hardware CPU 1500 TIA: In addition to the CPU a CP with 2nd own interface and separate Ethernet address. | Operation, necessary | J |
| General requirements (operating system, IT security, printer, etc.) | General requirements (operating system, IT security, printer, etc.) | General requirements (operating system, IT security, printer, etc.) | 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 printouts. | Operation, necessary | J |
|  | The installation and configuration of the software are carried out by the contractor. | Operation, necessary | J |
|  | B The contractor can remotely maintain and configure the software. Only zoom may be used. An engineering station with the necessary licenses can be set up if necessary. | Operation, necessary | J |
|  | All required data formats are to be listed by the manufacturer, which are to be used for data storage, data backup and data archiving. Example: pdf/a-2 (ISO 19005-2) XML JPG\* or tif or png (\*JPG only allows if the compression does not cause any loss of information.) | GxP, necessary | J |
| Software requirements | Software requirements | Software requirements | Software requirements |
|  | The software should open immediately after starting Windows. | GxP, necessary | J |
|  | No admin rights in Windows are required to use the application/software. | GxP, necessary | J |
|  | All storage paths are fixed in the software configured by a user with appropriate permission (e.g. admin). There are no File Open / Browse / Save As Dialogues available during the process. A "normaler" user cannot store the data in places other than those defined. | GxP, optional | J |
|  | If there is File Open / Browse / Save As dialogs exist, the default Windows dialogs are used. Standard Windows dialogs have the class name #32770. | GxP, necessary | J |
|  | The software can create back-ups automatically and configurable (including configuration data, process data, etc.). | GxP, necessary | J |
|  | If the software stores the data in a database, Microsoft SQL Server is to be used. | GxP, necessary | J |
|  | The data can be read out via an OPC/UA interface. The interface can be set up afterwards. | Operation, optional | J |
|  | A connection to InMation should be provided. For this 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 |
| Technical documentation requirements | Technical documentation requirements | Technical documentation requirements | Technical documentation requirements |
| n.a. | Content of the technical documentation: Operating instructions Installation description Functional description EMC test protocol Parts list (replacement/wear list) Technical Data Sheets Alarm and troubleshooting list including troubleshooting Schematic Electrical Software Description and Program Backup Software (SPS + HMI) Disaster and System Recovery Guide | Operation, optional | N |
|  | All technical documents as well as the visualization, user interface, marking or warnings must be carried out in German. Business optional | Operation, optional | J |
|  | The technical documentation contains at least the following documents: Operating instructions Installation description Functional description EMC test protocol Parts list (replacement/wear list) Technical data sheets (add) Alarm and fault detection list including troubleshooting (if applicable in the function specification) Schematic Electrical Software description and program Backup Software (SPS + HMI) Desaster and System Recovery instructions. | GxP, necessary | J |
|  | All documents are to 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 for maintenance, cleaning and set-up work as well as troubleshooting. | Safety, necessary | J |
|  | Where MSR safety devices are available for risk reduction (human, environment and installation), they shall be assessed or confirmed in accordance with IEC61508/IEC61511 ("Functional Safety of Electrical/Electronic/Programmable Electronic Systems"). Proof of the evaluation is part of the order and must be handed over to the customer. The resulting recurring tests for the correct maintenance of the safety function shall be recorded in the operating instructions. | Safety, necessary | J |

Documents quoted or accompanying

|  |  |
| --- | --- |
| COMMUNICATION | Pharmaceutical and active substance production regulation, entry into force of last amendment: 16 August 2019 |
| EU Good Manufacturing Practice Guide | The rules governing medicinal products in the European Union, |
| Annex 11 to the EU Good Manufacturing Practice Guide | Qualification and validation, entry into force of the last amendment: 30 June2011. |
| Annex 15 to the EU Good Manufacturing Practice Guide | Qualification and validation, entry into force of the last amendment: 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 | Act on medicinal products, Act on the marketing of medicinal products, entry into force of the last amendment: 24 June 2022. |
| Ph. Eur. | European Pharmacopeia, European Pharmacopoeia, current edition: 10th edition 2020 |
| USP | United States Pharmacopeia, American 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, 26 February, 2014 |
| 2006/42/EC | Machinery Directive, 17 May 2006 |

Annexes

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