

# USER REQUIREMENT SPECIFICATION

## MAS-100 Libra® Settle Plate Changer



## DOCUMENT HISTORY

| VERSION | RELEASED   | HISTORY                |
|---------|------------|------------------------|
| 1.0     | 2025-04-25 | First released version |

## REVIEW AND APPROVAL OF URS

| NAME | DEPARTMENT | DATE | SIGNATURE |
|------|------------|------|-----------|
|      |            |      |           |
|      |            |      |           |

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# 1. GENERAL INFORMATION

## 1.1. INTRODUCTION

This document outlines the User Requirement Specification (URS) for the acquisition of an automated passive air sampler MAS-100 Libra®. The device will be deployed for automation of passive air sampling to ensure accurate measurements that comply with applicable regulations.

The purpose of this document is to define clear selection criteria by detailing the essential functional, technical, and regulatory requirements. It will serve as a reference throughout the procurement process, ensuring that the chosen equipment meets operational expectations and compliance standards.

The automated passive air sampling must:

- Comply with ISO 14644, and the EU Good Manufacturing Practices (GMP).
- Be designed for field use, meaning it should be easy to handle, and robust enough for various environments.

## 1.2. INSTRUMENT DESCRIPTION AND INTENDED USE

Monitoring air quality for microbiological contaminations is critical in pharmaceutical environments and cleanrooms to ensure compliance with cleanliness and safety standards. Passive air sampling with settle plates involves exposing an agar plate to ambient air for a defined period. This is the most commonly used method to continuously monitor air quality in cleanrooms, complying with the new EudraLex Annex 1 requirements (EudraLex 2022) Airborne microorganisms settle on the agar surface, where they can be incubated to form countable colonies. This straightforward and effective method is widely applied to assess microbial contamination in the air.

The MAS-100 Libra automates this process, enhancing precision and repeatability while minimizing manual intervention (see Figure 1). It is specifically designed for sensitive environments, such as pharmaceutical cleanrooms, where airflow control and the prevention of cross-contamination are paramount.

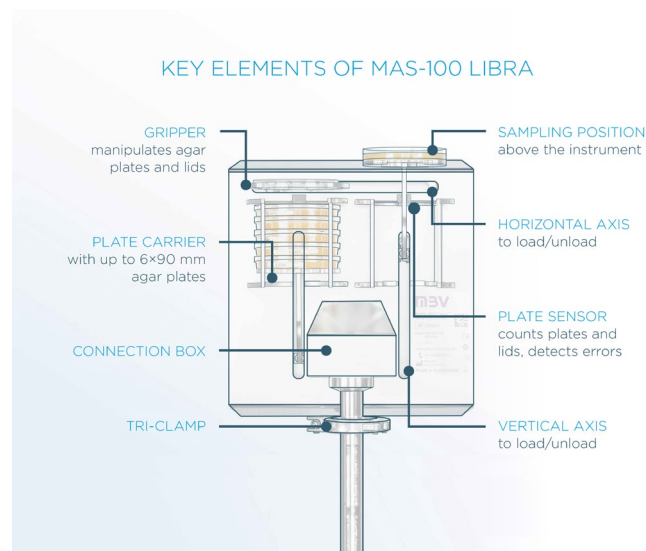


Figure 1: Schematic presentation of the MAS-100 Libra explaining its key components and their function.

### 1.3. REGULATORY STATUS AND REFERENCES

The requirements according to the following guidelines must be met:

- EU EUDRALEX Volume 4 – Medicinal Products for Human & Veterinary Use: Good Manufacturing Practice
- Part 1, Basic Requirements for Medicinal Products
- Annex 1, Manufacture of Sterile Medicinal Products
- Annex 13, Investigational Medicinal Products
- Annex 15, Qualification and Validation
- 21 Code of federal Regulations (21 CFR – FDA)
- Part 210, Current Good Manufacturing Practice in Manufacturing, Processing, Packaging or Holding of Drugs; General
- Part 211, Current Good Manufacturing Practice for Finished Pharmaceuticals
- Part 211, Subpart I – Laboratory Controls
- FDA Guide to Inspections of pharmaceutical quality control laboratories
- ICH Q9, Quality Risk Management
- WHO Laboratory biosafety manual, Third edition, 2004
- Internal SOPs to be added

## 2. USER REQUIREMENTS

### 2.1. FUNCTIONAL AND PERFORMANCE REQUIREMENTS

| URS ID <sup>1</sup> | REQUIREMENT DESCRIPTION                                                                                                                                                                                               | TYPE <sup>2</sup> | IMPORTANCE <sup>3</sup> | VENDOR CONFIRMATION |
|---------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|-------------------------|---------------------|
| URS-1-001           | The equipment is able to perform passive air sampling within a time window of 15 minutes up to 300 minutes (Annex 1 § 9.24).                                                                                          | G                 | Must                    |                     |
| URS-1-002           | The equipment must be able to perform continuous measurement for 1 hour to 24 hours (Annex 1 §9.24) without human intervention to exchange the plate.                                                                 | G                 | Must                    |                     |
| URS-1-003           | The time of plate change must be less than 2 minutes.                                                                                                                                                                 | B                 | Nice-to-have            |                     |
| URS-1-004           | The exposure time of a settle plate can be set on the equipment or via the digital interface, respectively.                                                                                                           | G                 | Must                    |                     |
| URS-1-005           | The plate exchange can be controlled remotely using Modbus, external button or digital interface.                                                                                                                     | B                 | Nice-to-have            |                     |
| URS-1-006           | The plate exchange can be controlled remotely using external button.                                                                                                                                                  | B                 | Nice-to-have            |                     |
| URS-1-007           | The plate exchange can be controlled remotely using digital interface.                                                                                                                                                | B                 | Nice-to-have            |                     |
| URS-1-008           | The equipment is compatible with cleanroom grade A, B, C or D environment, i.e., the equipment must be able to be disinfected or decontaminated and does not emit particles above limits specified in Annex 1 (§9.8). | G                 | Must                    |                     |

<sup>1</sup>URS-ID: Ongoing numbering for unique requirement identification starting with the abbreviation URS, containing the sub-chapter number and a consecutive number starting at 001.

<sup>2</sup>Following types are used for classifying the requirements:

B = requirement resulting from Business needs

G = requirement resulting from GMP and/or 21 CFR Part 11 regulation

S = requirement for Health, Safety, Security and Environment (HSSE) point of view

<sup>3</sup>The importance assignment served for the determination of the relevance of the requirements:

Must: Requirements that have to be fulfilled to deliver a system conform to the user expectations.

Important: Requirements that have to be fulfilled to deliver a system conform to the user expectations (workaround is nonetheless acceptable)

Nice-to-have: Requirements that improve the user acceptance and the efficacy of the system.

| URS ID <sup>1</sup>                                        | REQUIREMENT DESCRIPTION                                                                                                                                                  | TYPE <sup>2</sup> | IMPORTANCE <sup>3</sup> | VENDOR CONFIRMATION |
|------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|-------------------------|---------------------|
| URS-1-007                                                  | The equipment must be suitable for 88-92 mm agar plates from different suppliers.                                                                                        | G                 | Must                    |                     |
| URS-1-008                                                  | The equipment must be compatible with cleaning by manual wipe with disinfectant such as isopropanol (IPA) 70% and ethanol 70%. (Annex 1 §4.33, §4.7 and §9.8)            | G                 | Must                    |                     |
| URS-1-009                                                  | The equipment must ensure low flow resistance properties, minimizing turbulence and preventing backflow onto the exposed agar plate. (Annex 1 §9.22)                     | G                 | Must                    |                     |
| URS-1-010                                                  | The passive air sampler must be made of stainless steel 316/316L (1.4401 or better) (Annex 1 §4.7 and §9.8)                                                              | G                 | Must                    |                     |
| URS-1-011                                                  | All alarms are visual on the equipment or on the digital interface                                                                                                       | G                 | Must                    |                     |
| For user, planning to use MAS-100 Libra within an isolator |                                                                                                                                                                          |                   |                         |                     |
| URS-1-012                                                  | The equipment must be compatible to vaporised hydrogen peroxide (VHP) decontamination. (Annex 1 §4.33, §4.7 and §9.8)                                                    | G                 | Must                    |                     |
| URS-1-013                                                  | The VHP decontamination process must be qualified with the equipment in place. The supplier should demonstrate, if possible, that this has been tested. (Annex 1 § 8.42) | G                 | Nice-to-Have            |                     |
| URS-1-014                                                  | The equipment must be able to connect to the isolator HMI.                                                                                                               | G                 | Must                    |                     |
| URS-1-015                                                  | The equipment must be able to be started remotely (e.g. by connecting it to an HMI or using a remote button).                                                            | G                 | Must                    |                     |
| URS-1-016                                                  | All alarms must be displayed on the isolator's HMI.                                                                                                                      | G                 | Must                    |                     |
| URS-1-017                                                  | The communication with the equipment must be possible using RJ-45 ethernet cable.                                                                                        | G                 | Must                    |                     |
| URS-1-018                                                  | The installed equipment does not affect the integrity of the isolator. (Annex 1 §4.7 and §9.8)                                                                           | G                 | Must                    |                     |
| URS-1-019                                                  | The equipment can be transportable to be used in various environments.                                                                                                   | B                 | Nice-to-have            |                     |

## 2.2. SUPPLIER REQUIREMENTS

| URS ID <sup>1</sup> | REQUIREMENT DESCRIPTION                                                                                                                                                                                                                                                                                                                                                                               | TYPE <sup>2</sup> | IMPORTANCE <sup>3</sup> | VENDOR CONFIRMATION |
|---------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|-------------------------|---------------------|
| URS-2-001           | The supplier must supply according to this URS.                                                                                                                                                                                                                                                                                                                                                       | G                 | Must                    |                     |
| URS-2-002           | <p>The supplier will provide at the minimum the following documentation electronically in English:</p> <ul style="list-style-type: none"> <li>- Material specifications</li> <li>- Instrument test</li> <li>- User instructions (operation, cleaning, instrument test, maintenance and safety)</li> <li>- Validation summary</li> <li>- CE certificates</li> <li>- Complete list of alarms</li> </ul> | G                 | Must                    |                     |
| URS-2-003           | The supplier is responsible for the transport of the system. The instrument must be appropriately protected against environmental influences and damage during transport.                                                                                                                                                                                                                             | B                 | Must                    |                     |
| URS-2-004           | <p>The following qualification activities must be performed for the sampler:</p> <ul style="list-style-type: none"> <li>- Installation qualification</li> <li>- Operational qualification</li> </ul>                                                                                                                                                                                                  | G                 | Must                    |                     |

## 2.3. ENVIRONMENTAL REQUIREMENTS

| URS ID <sup>1</sup> | REQUIREMENT DESCRIPTION                                                                                                             | TYPE <sup>2</sup> | IMPORTANCE <sup>3</sup> | VENDOR CONFIRMATION |
|---------------------|-------------------------------------------------------------------------------------------------------------------------------------|-------------------|-------------------------|---------------------|
| URS-3-001           | The sampler must be capable of operating in ambient temperature of 15 to 30°C.                                                      | B                 | Must                    |                     |
| URS-3-002           | The equipment must be capable to be connected to a 24 Volts of Direct Current (VDC).                                                | B                 | Must                    |                     |
| URS-3-003           | The equipment should be capable to work with a 24VDC powerbank.                                                                     | B                 | Nice to have            |                     |
| URS-3-004           | The footprint of equipment should not be more than 400cm <sup>2</sup> .                                                             | B                 | Nice to have            |                     |
| URS-3-005           | The weight must be not more than 6kg, to fit to the isolator. The place for the Libra will be prepared by _____ (concerned company) | B                 | Nice to have            |                     |

## 2.4. DATA REQUIREMENTS

| URS ID <sup>1</sup>                                        | REQUIREMENT DESCRIPTION                                                                                                                                                                                                                                                                                                                                   | TYPE <sup>2</sup> | IMPORTANCE <sup>3</sup> | VENDOR CONFIRMATION |
|------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|-------------------------|---------------------|
| URS-4-001                                                  | <p>The equipment can be connected to a computer and the instrument log can be displayed on the computer including at least following information:</p> <ul style="list-style-type: none"> <li>- date of sampling</li> <li>- start time and end time of sampling</li> <li>- presence of warnings and errors</li> </ul>                                      | B                 | Nice-to-have            |                     |
| URS-4-002                                                  | Instrument log files must be generated and stored in non-modifiable format.                                                                                                                                                                                                                                                                               | G                 | Must                    |                     |
| URS-4-003                                                  | Instrument log files can be saved in PDF format.                                                                                                                                                                                                                                                                                                          | B                 | Important               |                     |
| URS-4-004                                                  | No data must be created, deleted or modified outside of the system.                                                                                                                                                                                                                                                                                       | G                 | Must                    |                     |
| URS-4-005                                                  | All alarms are displayed on the instrument log file.                                                                                                                                                                                                                                                                                                      | G                 | Must                    |                     |
| URS-4-006                                                  | The system must include an instrument logs, which records all relevant events with a date and timestamp.                                                                                                                                                                                                                                                  | G                 | Must                    |                     |
| For user, planning to use MAS-100 Libra within an isolator |                                                                                                                                                                                                                                                                                                                                                           |                   |                         |                     |
| URS-4-007                                                  | <p>Sampling data is recorded in the equipment and can be shown on the isolator HMI including at least following information:</p> <ul style="list-style-type: none"> <li>- Date of sampling</li> <li>- Start time and end time of sampling</li> <li>- Current status and ongoing step of the process</li> <li>- presence of warnings and errors</li> </ul> | G                 | Must                    |                     |

## 2.5. OTHER REQUIREMENTS

| URS ID <sup>1</sup> | REQUIREMENT DESCRIPTION                                                                                                                                                                                                                                                          | TYPE <sup>2</sup> | IMPORTANCE <sup>3</sup> | VENDOR CONFIRMATION |
|---------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|-------------------------|---------------------|
| URS-5-001           | <p>The installation must comply to applicable national laws and regulations, e.g.:</p> <ul style="list-style-type: none"> <li>- Provide declaration of conformity (CE) (in English or German)</li> <li>- Provide user manual with safety hints (in English or German)</li> </ul> | G                 | Must                    |                     |
| URS-5-002           | <p>The following documentation must be prepared for the sampler:</p> <ul style="list-style-type: none"> <li>- SOPs for operation, cleaning, maintenance and instrument testing procedures</li> <li>- Logbook</li> </ul>                                                          | G                 | Must                    | N/A                 |
| URS-5-003           | Supplier must provide maintenance services (Annex 1 § 4.32).                                                                                                                                                                                                                     | G                 | Must                    |                     |

### 3. GLOSSARY

| ABBREVIATION                  | MEANING                                                                                             |
|-------------------------------|-----------------------------------------------------------------------------------------------------|
| °C                            | Temperature in degrees Celsius                                                                      |
| CE                            | European Conformity                                                                                 |
| CFR                           | Code of Federal Regulations                                                                         |
| FDA                           | Food and Drug Administration                                                                        |
| GMP                           | Good Manufacturing Practice                                                                         |
| H <sub>2</sub> O <sub>2</sub> | Hydrogen peroxide                                                                                   |
| HMI                           | Human-Machine Interface                                                                             |
| HSSE                          | Health, Safety, Security and Environment                                                            |
| ICH                           | International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use |
| IPA                           | Iso Propyl Alcohol                                                                                  |
| ISO®                          | International Organization for Standardization                                                      |
| LPM                           | Liter per minute                                                                                    |
| min                           | Minute                                                                                              |
| N/A                           | Not Applicable                                                                                      |
| SOP                           | Standard Operating Procedure                                                                        |
| TSA                           | Trypticase Soy Agar                                                                                 |
| URS                           | User Requirement Specification                                                                      |
| VDC                           | Volts of Direct Current                                                                             |
| VHP                           | Vaporized hydrogen peroxide                                                                         |
| WHO                           | World Health Organisation                                                                           |