



MKL-GmbH  
Cleanroom Software Solutions  
Munich  
Germany



## WHITEPAPER MOQLERO GENERATION 10

### STANDARDS

**ISO 14644**  
**GMP (INCL. GMP ANNEX 1)**  
**ALCOA++**  
**21 CFR PART 11**

### SYSTEM ENVIRONMENT

**SERVER**  
Cloud-based solution  
  
Microsoft SQL Server  
  
Python report generation  
  
PHP 8.4  
  
**NOTEBOOKS**  
**WINDOWS 11**

### SECURITY

**LOGIN OPTIONS WEB PORTAL**  
LDAPS  
  
Single-Sign-On  
  
**ROLE-BASED ACCESS TO WEB PORTAL**  
Permissions checked via group memberships for each action/page  
  
**ENCRYPTION**  
End-to-end communication via SSL/TLS  
  
**SAP INTERFACE**  
Authentication and Authorization via x509 certificate and secret

### SAP INTERFACE

**AUTOMATIC DATA TRANSFER**  
Automatic order reception and creation from SAP  
  
Automatic transfer of completed orders and results to SAP  
  
**SECURITY**  
Fully SSL/TLS-encrypted communication  
  
Authentication and authorization via x509 certificate and secret



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### WEB PORTAL

#### GENERAL

Measurement protocols/reports

Workorder management

Master data management \*)

Maintenance breaks

Trend analysis

Audit trail

#### DEVIATION MANAGEMENT

Automatic notifications

Digital workflows for issue resolution

Electronic signature required for non-conformities

Repeat measurements can be triggered after repairs

Integrated, automatic, and complete documentation

#### CHANGE MANAGEMENT

Automatic notifications

Changes must go through a digital workflow

Electronic release of changes only by authorized personnel

Integrated, automatic, and complete documentation

### NOTIFICATIONS / ALARMS

#### NOTIFICATIONS / ALARMS

Deviations/Discrepancies, Maintenance Breaks

Pending/started/completed/deleted Workflows or Management Procedures,

Required/pending Signatures

### INTERNATIONAL FEATURES

#### MULTILINGUAGE

English, German, Mandarin

#### TIME ZONES

All supported, time format local datetimeoffset



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### NOTEBOOKS

#### **14 SUPPORTED MEASUREMENT METHODS**

##### **AUTOMATED CONTROL OF PARTICLE COUNTERS <sup>\*\*1)</sup>**

Automatic configuration of measurement parameters (e.g., duration)

Automatic start and stop of measurements

Simultaneous control of up to 6 devices

##### **AUTOMATIC READING AND EVALUATION**

Measurement results automatically and error-free transferred to notebook

Automatic evaluation of the results against configured limits

##### **SPONTANEOUS / AD-HOC MEASUREMENTS**

Measurements can be performed without a work order

Also fully automated (configuration, control, evaluation, etc.)

##### **OVERVIEW, ACTIVITIES, AND N-FINDINGS**

Complete overview of open and measured orders

Guidance, execution, and confirmation of typical activities

N-Findings can be set

### PARTICLE MEASUREMENTS

#### **MEASUREMENT METHODS**

Classification/Monitoring in Operation

Classification/Monitoring at Rest

Zero measurements

Particle measurement in gases

Recovery test (2 options available)

Clean-up Test (EU GMP Annex 1 2022)

#### **ADDITIONAL OPTIONS**

Parallel measurements: Conducting multiple measurements simultaneously

Block measurements: Multiple samples of a measuring point are measured in a block and jointly evaluated as valid/invalid



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### FILTER TESTS

#### TYPES

- Integral filter test
- Filter scan test (sequential)
- Filter scan test per ISO 14644
- Filter scan test per customer SOP
- Filter scan test by separation efficiency criteria

#### STATIC RETESTING / LEAK TESTING

- Following leak detection in the measurement results
- Following failed visual inspection

### LAMINAR FLOW BOXES, EQUIPMENTS

#### MEASUREMENT METHODS

- Qualification and maintenance measurements
- Air velocity measurements

### PHYSICAL ENVIRONMENT MONITORING

#### PHYSICAL PARAMETERS OPTION

- Pressure, humidity, temperature

### ACTIVITIES

#### DOCUMENTED MANUAL INTERVENTIONS

- Covers typical tasks during monitoring or classification  
(e.g., CG-distributor change)

### AIR MEASUREMENTS

#### MEASUREMENT METHODS

- Air exchange rate
- Airflow volume

#### MASTER DATA IMPORT VIA CSV



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## APPENDIX

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### SUPPORTED PARTICLE COUNTERS

Abakus (Markus Klotz GmbH)  
Apex R5p (Lighthouse Worldwide Solutions)  
CAS CI-1053 (Climet Instruments Company)  
CAS CI500 (Climet Instruments Company)  
Lasair II (Particle Measuring Systems)  
Lasair III 5100 (Particle Measuring Systems)  
Lasair III 310B (Particle Measuring Systems)  
Met One 2400 (Beckman Coulter)  
Met One 3400 (Beckman Coulter)  
PZG 31 (RR Reinraum Elektronik)  
Solair 3100 (Lighthouse Worldwide Solutions)  
*... Any particle counter you use*

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### MASTER DATA MANAGEMENT

#### SAP ORDERS

##### DEVICES

Particle counters	Probes
Pressure sensors	Diffusers
Differential pressure sensors	Dilution stages
Temperature sensors	Vane anemometers
Humidity sensors	Hot-wire anemometers
Airflow sensors	Balometers
Measurement notebooks	Flow measuring devices

##### MEASUREMENT POINTS

Particle	Activities
Filter	Air exchange rate
Physical environment	Airflow volume
LF Maintenance	

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**LOCATIONS**

Buildings

Facilities / Equipment

Rooms

Room parts

**ORGANIZATION**

Departments

Standard comments

Users

(Maintenance breaks)

**ACCEPTANCE CRITERIA**

Hygiene zones / Cleanliness classes

Physical environment limits

Warning limits

Clean-up

Filter classes

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