



MKL-GmbH
Cleanroom Software Solutions
Munich
Germany



WHITEPAPER MOQLERO GENERATION 9

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

MULTILANGUAGE

- 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 **)

- 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

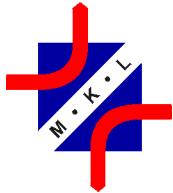
MEASUREMENT METHODS

- 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

**)

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

*)

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	

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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