



FL-EMS flex

Plug-and-monitor GMP monitoring system

With the 'FL-EMS flex' GMP monitoring system, RETEL is able to provide a next-generation, scalable system, which can be perfectly aligned to the customer's needs.

With 'FL-EMS flex', you can implement the following business cases in precise accordance with your needs:

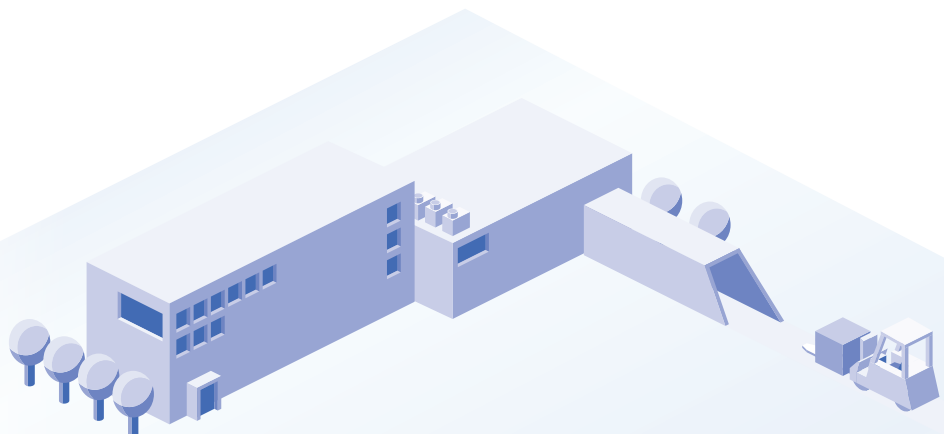
- GMP-compliant data acquisition for rooms / processes / facilities
- Compliant with FDA 21 CFR Part 11 / EU Annex 11 and data integrity
- Simple and intuitive user handling
- Complete integration of the solution into the customer's system landscape
- Data exchange with higher-level systems (ERP, MES, data historian, etc.)
- Enables advanced analyses of data captured
- Lower investment costs (hardware, engineering, installation costs)
- Faster project deployment
- Investment security due to standard hardware components and the latest technology
- Easily expandable to 'FL-EMS high feature'

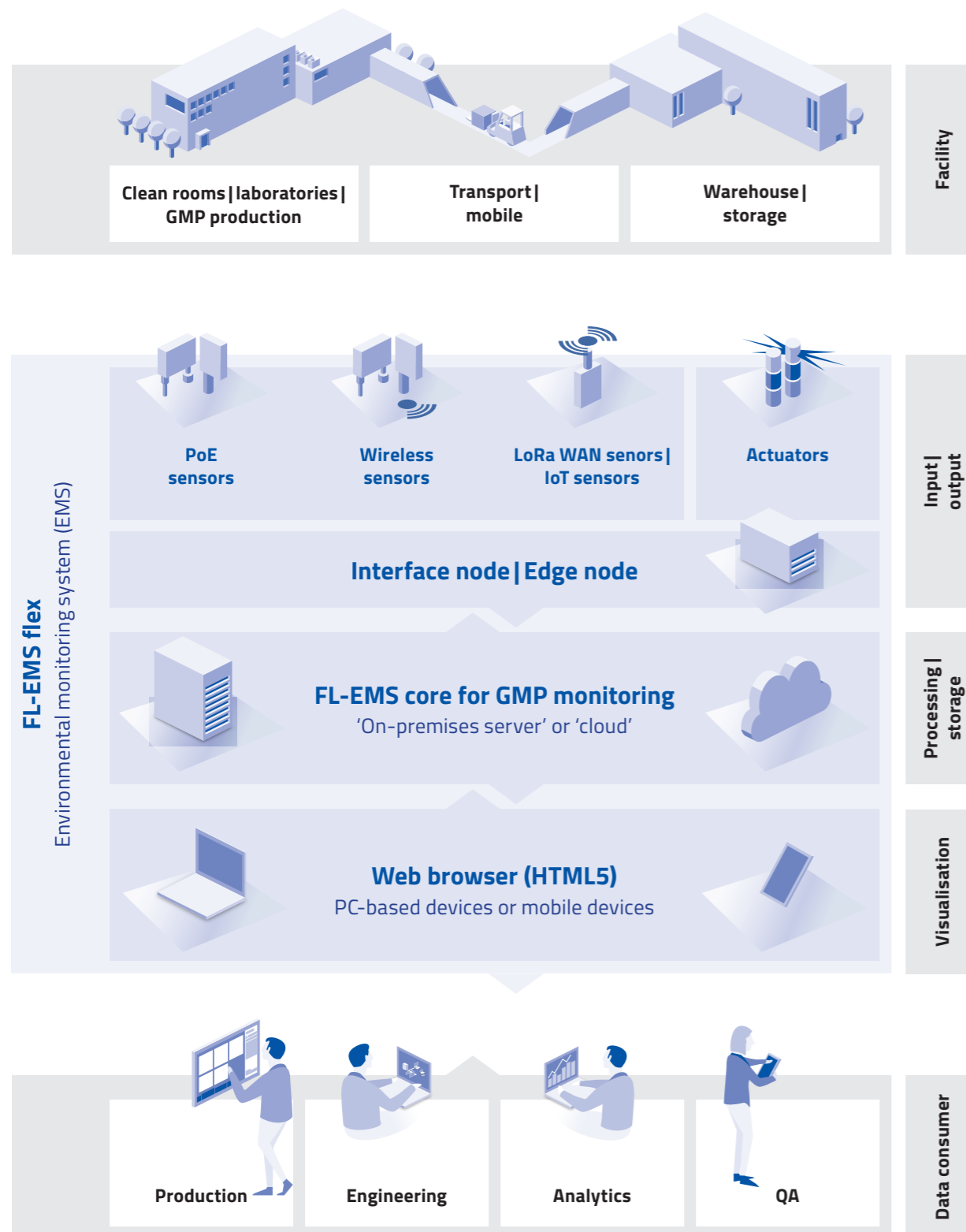
'FL-EMS flex' areas of application

- Clean rooms / laboratories
- GMP production
- Temperature Control Units (TCUs)
- Warehouses

Abbreviations

EMS	Environmental Monitoring System
FL	FactoryLayer (RETEL SW Framework)
GMP	Good Manufacturing Practice
MES	Manufacturing Execution System
ERP	Enterprise Resource Planning





The 'FL-EMS flex' GMP monitoring system is used to guarantee compliance with the legal / regulatory requirements for seamless documentation of the critical environment, process and production parameters.

The GMP 'FL-EMS flex' monitoring system at a glance

Input | output layer

Recording of critical environment, process and production parameters as well as control of visual / acoustic signal units.

Concept	Scope of functions	Architecture
<ul style="list-style-type: none"> Use of PoE Ethernet or wireless sensors Minimal electrical installation No electrical switch cabinets Data stored as close to the source as possible Automatic data synchronisation after disconnection 	<ul style="list-style-type: none"> Real-time recording of physical parameters such as temperature, humidity, differential pressure, air velocity, airborne particles, etc. Signalling of limit exceedance by means of signal units 	<ul style="list-style-type: none"> Vendor-neutral HW components No data loggers / no PLCs PoE / wireless / IoT / IIoT sensors Visual / acoustic signal units

Processing | storage layer

Provision of GMP monitoring functionality and data storage for storing configuration data and raw data in an MS SQL database.

Concept	Scope of functions	Architecture
<ul style="list-style-type: none"> Data points are parameterised, not programmed Sensor administration by the customer or RETEL Sophisticated design and CSV templates 	<ul style="list-style-type: none"> Long-term data storage Operating mode switching (production, reduced, etc.) Alarm forwarding Automatically generated reports Data export to Excel Interface for vertical integration 	<ul style="list-style-type: none"> Client-server architecture (modular and scalable) Configuration data and raw data storage in MS-SQL database Integration into customer IT / OT system landscape Servers: on-premises, virtualised or cloud

Visualisation layer

Allows the monitoring system to interact with the appropriate users, e.g. alarm acknowledgement, simple report generation.

Concept	Scope of functions	Architecture
<ul style="list-style-type: none"> Simple and intuitive to use Limit violations are clearly signalled Operating via HTML5 web browser (no software client installation required) 	<ul style="list-style-type: none"> Graphical data visualisation (floor plan / table / interactive trend) Limit monitoring incl. acknowledgement and alarm forwarding Multi-stage alarm evaluation workflow (eSig) Extensive reporting (raw data, alarms, audit trail, statistics, configuration, system status, etc.) 	<ul style="list-style-type: none"> Support for various client end devices / responsive design (laptops, PCs, tablets, smartphones, etc.) Accessible from IT / OT network

Graphical data visualisation

Measurements are updated and stored in real time. Data that has been recorded can be accessed by means of a graphical floor plan or tabular representation. Where limits are exceeded, this is highlighted in colour for the corresponding measuring points.

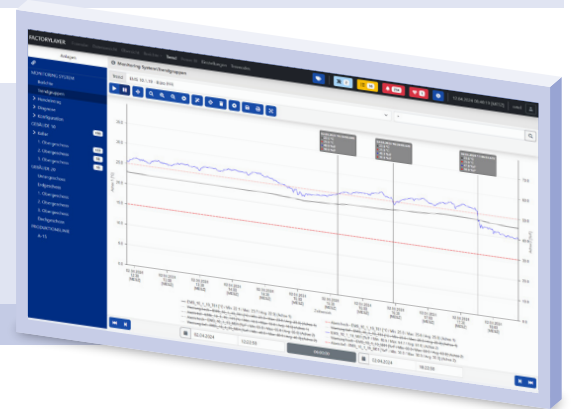


Limit monitoring incl. acknowledgement

For each value measured, parameters can be set for any number of limit controls (alarms and warnings). The system has an alarm list detailing all active exceeded limits to be acknowledged, along with historical alarms.

Graphical illustration of trends

The measurements can be displayed individually or as predefined groups in the interactive trend module. The user can access various functions such as zoom, marker, free text caption, export, etc. to facilitate an optimal evaluation outcome.



Detailed information on each measuring point

The following details are displayed for each measuring point:

- Measuring point information
- Event settings (alarms / warnings)
- Limits about to be exceeded
- Graphical trend progression



'FL-EMS flex' ... the plug-and-monitor GMP monitoring system – compliant, simple, scalable and cost-effective.

RETEL offers you ...

- Intelligent, GMP data acquisition solutions
- Consulting, concept development and support in selecting the right system
- Execution planning, implementation and qualification
- After-sales services throughout the entire system life cycle