Application note: N°F076

November 2016

Mapping & Monitoring in the pharmaceutical industry

Facts & figures:

The FDA regulates foods, drugs, vaccines, blood products, medical devices, electronic products, cosmetics, veterinary products, and tobacco products.

For the first time in history global pharmaceutical spending crossed the $1 trillion plateau in 2014. Think about that for a moment: $1 trillion equates to 1.3% of global GDP, and is higher than the cumulative annual GDP of all but 15 countries around the world.

The concept of validation was first proposed by two FDA officials, Ted Byers and Bud Loftus, in the mid 1970s in order to improve the quality of pharmaceuticals. It was proposed in direct response to several problems in the sterility of large volume parenteral market.

Discussed in this edition:

Humidity and temperature mapping

Mapping is a process often conducted in production and storage areas to determine all possible humidity and temperature gradients.

To obtain an accurate room mapping, data loggers are placed strategically in order to find hot and cold spots and to monitor the different parameters over a certain period of time. Factors such as direct sunlight, heating, air conditioning and windows have to be also taken into consideration.

Using the measured data, it is possible to define the optimal storage positions for products or optimize the room climate by, for example, improving thermal isolation or by changing the way the air conditioning system works so the room temperature is homogeneous.

Based on this data, pharmaceutical companies are then able to place sensors and measuring devices in the proper locations and connect them to a monitoring system that complies with regulations.

Monitoring in the pharmaceutical industry

Uncontrolled temperature and humidity conditions can result in expensive and dangerous damage to ingredients and final products during production and storage.

In this regard, the pharmaceutical industry is strictly subjected to obligatory international regulations. Guidelines set by regulatory authority such as the FDA in the United States provide minimum requirements to meet by any pharmaceutical to prove the quality of its products.

These regulatory demands also apply to data logging systems and software. To be used in the pharmaceutical industry , this equipment is asked to be compliant with the so-called Good Automated Manufacturing Practices (GAMP) and FDA CFR Part 11, which “applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted under any records requirements set forth in Agency regulations”.

In order to validate processes and equipment, provision of documented evidence is needed showing that a system is qualified to ensure safe and reproducible results. The system must meet previously specified demands in the course of practical use and be operated in a qualified manner since it was introduced.

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What solution can Rotronic offer?

Mapping:

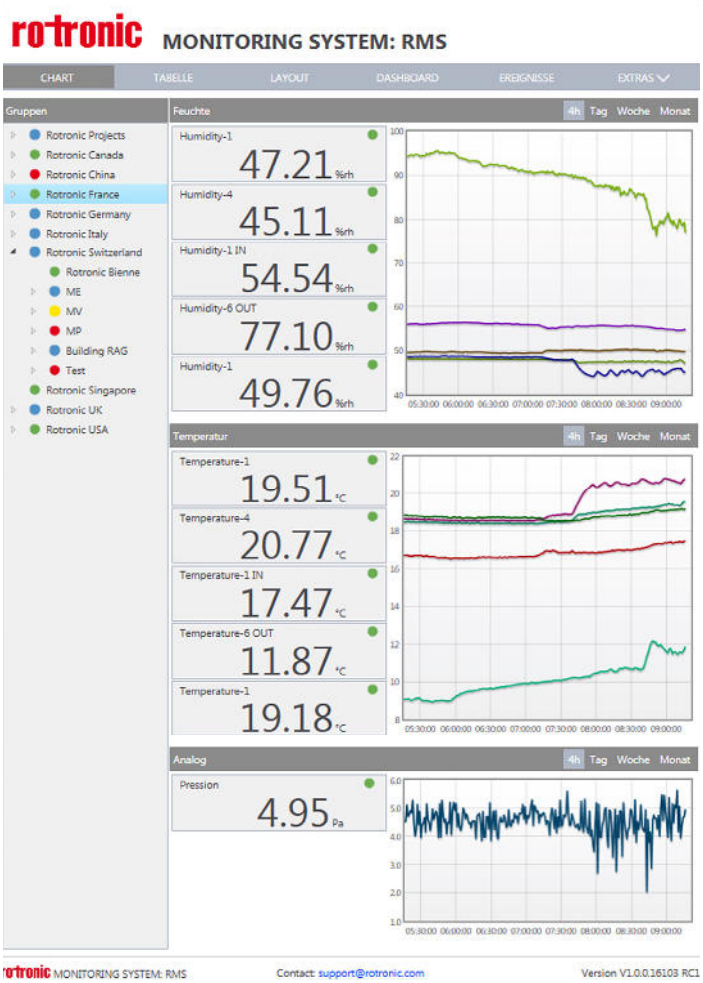
HygroLog HL-1D

The HL1D is a compact, low cost data logger capable of ±3.0 % RH and ±0.3°C accuracy. The internal memory can store up to 16,000 data points and includes the HW4-Lite software. Together with the HW4-P the logger is FDA 21 CFR Part 11/GAMP 4 compliant.

HL-1D Humidity & Temperature Logger

Environmental Monitoring System:

So now that we understand why there is a requirement to carry out a heat mapping for certain areas, Rotronic also offer an FDA compliant monitoring system. This Rotronic Monitoring System (RMS) will allow for a global monitoring of the environment (covering all of the cold and hot spots). The RMS will allow for real time monitoring and will set off alarms should any of the measurement reach a critical status.

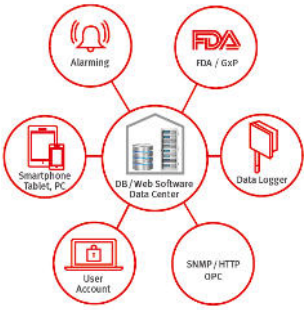


Main Features

- GMP/GLP/GDP compliance
- FDA 21 CFR Part 11
- EN 12830
- PDF report with chart and statistics
- Alarm notification by voice call, SMS or email
- Server or cloud based software
- Suitable for smartphones and tablets

Validation

When requested, the system checks the data integrity automatically by self-test, it switches all input modules into their various states and check the alarms that are meant to be triggered and generates a validation report on the complete system.



Data logger
RMS-LOG

Temperature data logger
RMS-LOG-T

Temperature mini data logger
RMS-MLOG

Analog input module
RMS-ADC

Digital input module
RMS-DI

Digital input mini module
RMS-MDI

Analog output module
RMS-DAC

Relay module
RMS-DO

Display module
RMS-D

Find out about RMS in: www.rotronic.com/rms