rotronic
MEASUREMENT SOLUTIONS

REAL-TIME MONITORING SYSTEM – DEVELOPED **WITH** THE PHARMACEUTICAL INDUSTRY **FOR** THE PHARMACEUTICAL INDUSTRY

When customers and developers engage in a lively exchange, third parties also benefit. As was the case with Novartis and the Rotronic Monitoring System.

Discussion in the Rotronic Development Department: (from right to left) Romano Berni, Michel Legio, James Pickering, Fredi Hagenbucher

"We appreciated the good and close cooperation and continue to do so, because the after-sales service is excellent."

Michel Legio, Novartis

Launched in 2015, the Rotronic Monitoring System (RMS) is now one of the leading real-time and data monitoring systems with countless installations worldwide. The Novartis division NIBR (Novartis Institute for BioMedical Research) has been a customer from the very beginning and with its requirements and feedback has contributed significantly to making the RMS one of the most flexible monitoring systems on the market. The system was originally developed by the pharmaceutical industry for the pharmaceutical industry. Various other industries have long since benefited from the advantages of the modular monitoring system; from small applications to comprehensive solutions with several thousand measuring points and parameters.

We shine a light on the success story with background information on the Novartis project and its concrete applications as well as the somewhat unconventional way in which Rotronic came to RMS.

We interviewed:

- Romano Berni, Head of After Sales at Rotronic
- Michel Legio, Project Manager at Novartis
- James Pickering, Head of Monitoring Systems at Rotronic
- Fredi Hagenbucher, Head of Development at Rotronic

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1. THE NEMO PROJECT AT NOVARTIS

What is it about?

NEMO is the **N**ovartis **E**nvironmental **Mo**nitoring System of the Novartis division NIBR.

What were the requirements?

NIBR (Novartis Institute for BioMedical Research) is Novartis's innovation engine. The division wanted to replace its outdated environmental monitoring system, but it also wanted to integrate and continue to use the many NTC probes it had used to date.

What regulations are in place?

When working within the innovation field, the NIBR team has to comply with the GLP requirements of the US FDA. The Good Laboratory Practice (GLP) requirements describe good practices for non-clinical lab studies that support research or marketing approvals for FDA-regulated products.

Research is carried out to ensure uniformity, consistency, reliability, repeatability, quality and integrity of chemical non-clinical safety tests. GLP applies to non-clinical studies conducted to assess the safety or efficacy of chemicals for humans, animals and the environment.

The equipment requirements are the following: appropriately designed, adequately housed, routinely maintained and calibrated.

2. THE ROTRONIC MONITORING SYSTEM (RMS)

(Interview with Fredi Hagenbucher)

What was the idea behind the RMS?

Rotronic invests in forward-looking digital technology. We already used the slogan "Rotronic goes digital" for the Hygroclip. So before the Internet of Things (IoT) even caused a stir, Rotronic had realized the potential of digitization. Today, the hype of IoT has now reached industry, in the form of the so-called Industrial Internet of Things (IIoT).

The RMS is a modular system comprising hardware and software. The RMS combines IoT, M2M (Machine-to-Machine) and Industry 4.0. The most important elements in IoT are the sensors, which provide the necessary information for new business models. RMS devices can interact autonomously. This means they transmit information to the Internet or another device, either locally or globally. The RMS software collects and analyzes data, and independently monitors, informs, alerts and documents.

Rotronic sees the business model of the future as a symbiosis of sensors and service. In the case of RMS, the device, or rather the individual component, takes a back seat. The focus is on the system as a whole, and the customer's requirements.

I am convinced that the benefits of digitization will set new standards in creativity. With RMS, Rotronic offers the possibility of user integration. This is an important factor in favour of IoT models. User integration is the integration of the customer into the processes he desires.

I am proud that with RMS we can offer solutions for IoT and M2M and that our team has mastered the new digitization at the highest level.

When was the foundation stone for the RMS concept laid and how did the project get going?

The RMS concept was developed in 2013 based on my personal interest in Industry 4.0. The idea was presented to the Rotronic management team and, thanks to Novartis's NEMO, the actual project took shape.

How did the first RMS project with Novartis go?

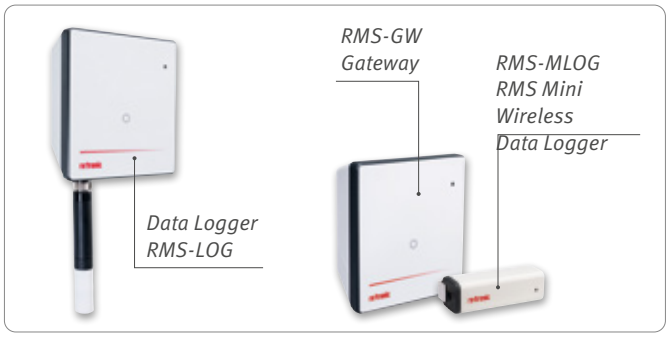
Rotronic adopted the Novartis NEMO User Requirement Specifications (URS) and adapted the system accordingly. Against this background, the system was then designed with a pharmaceutical company for a pharmaceutical company.

Our geographical proximity and the fact that all participants speak the same language helped the project to develop on the basis of real customer requirements. The entire R&D team responded very flexibly to the requirements of Novartis and encouraged regular communication between the two companies.

3. THE RMS HARDWARE PRODUCTS

(Interview with James Pickering)

What is so special about the hardware?



Selection of RMS products

The RMS LAN and wireless devices are designed to ensure perfect data integrity. Thanks to various features, data integrity is of the highest level and can cover any risk:

- High measurement accuracy
- Digital communication between probe and logger (information such as serial number and calibration characteristics are recognized by the system).
- On board memory
- 24 VDC, PoE (only for LAN devices) and battery power supply (except for the MLOG, which only have battery power supply).
- Encrypted communication in the network.
- All information is stored in an SQL database (IT security is guaranteed by our certified hosting partner or by the customer).
- HTTPS access to the RMS software.

The RMS system offers flexibility to every user:

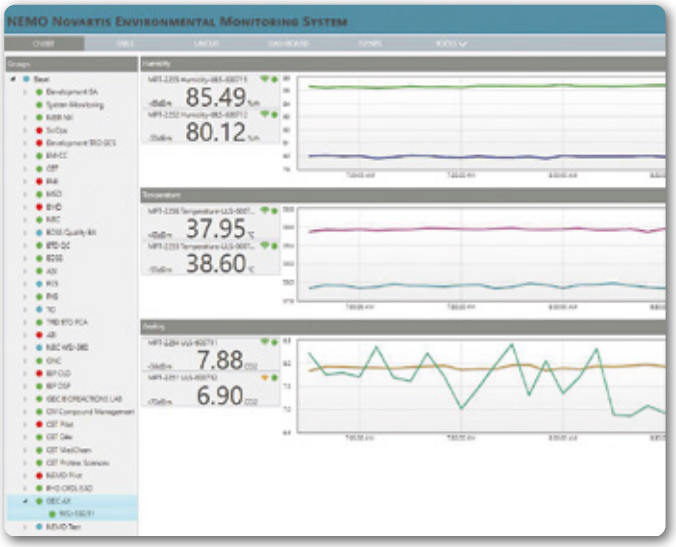
- Integration of any analog device with analog-to-digital converter.
- Integration of any MODBUS TCP device (if the protocol is available).
- Integration of JSON files.

4. THE RMS SOFTWARE*

The RMS is a [1] GAMP©5 category 4 software [2] in combination with category 1 hardware [3]. It helps users to monitor their GxP-regulated applications [4], to check critical quality attributes and to monitor critical process parameters.

In this way, the RMS enables customers to focus on patient safety, product quality and data integrity, and ensures compatibility with EudraLex Annex 11 [5] and FDA 21 CFR Part 11 [6].

We offer our customers both cloud and on-site solutions. The cloud solution is hosted by an external security-certified Swiss IT partner. The on-site solution is integrated into the customer's IT environment. The RMS architecture can thus be designed extremely flexibly for every conceivable application, far beyond the requirements of the pharmaceutical industry.



NEMO Chart View

5. THE NOVARTIS RMS APPLICATION

(Interview with Romano Berni)

Which after-sales services were used?

Installation

In cooperation between Novartis, ISS and Rotronic, around 1,000 RMS loggers have now been mounted on the refrigerators and the existing probes connected to them. During placement, care was taken to ensure that the devices can be removed quickly and easily for annual calibration.

RMS Mini temperature logger with cable probe

Initial calibration after startup of the RMS devices

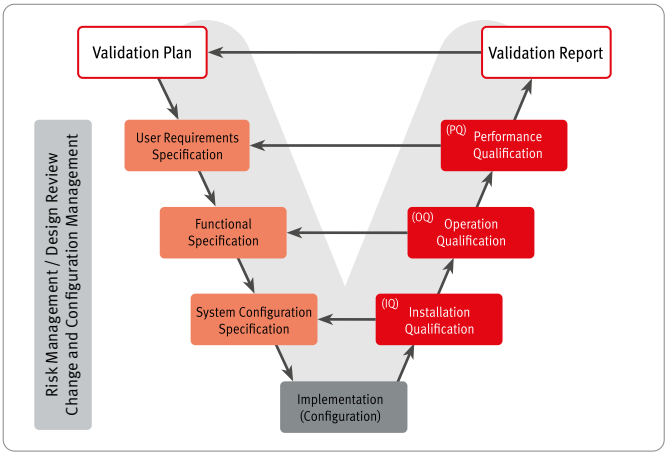
After the loggers had been installed and connected to the existing probes, a functional check and initial calibration were carried out –if the sensors were in specification, an alarm test was carried out according to the Novartis test instructions and documented in compliance with GMP.

Training

Every user and administrator was trained and accompanied according to their task. Rotronic and Novartis were thus able to ensure that no user had to perform the first RMS steps without appropriate instruction. The training for the users comprised a total of about 600 people and was held efficiently and directly in small groups.

Validation of the soft- & hardware

The validation was carried out hand in hand with Novartis. Once the URS was fulfilled, a team set out to test the various products and applications. The system still proves to be very stable today and passed validation according to the V-model.



Where are which parameters measured?

In refrigerators

Typically, products that may not exceed or fall below a temperature of 2°-8°C are stored here. The RMS monitors whether this temperature range is maintained permanently.

In the laboratory (room air)

Room air is measured in working laboratories where products are tested, checks conducted and product trials carried out. It is not only the optimal climate for products that is controlled, but also that for laboratory staff.

In incubators

For incubation of live cultures, a temperature of 37°C is set in incubators. Rotronic loggers are used to monitor the temperature constantly and, if necessary, to send an alarm via mobile phone or e-mail.

In cryotanks (-196°C)

A wide variety of products are stored in these cabinets, and the RMS checks that the very low temperature of -196°C is strictly kept.

In the laboratory

- Water detectors
  Documents are stored in numerous laboratories. The RMS ensures that no water damage occurs during the air-conditioning of laboratory rooms, for example in the event of a burst pipe.
- Light measurements (day/night simulation)
  The devices monitor whether the light is switched on and/or off in the different test laboratories.

6. CUSTOMER SATISFACTION

(Interview with Michel Legio)

What was the decisive factor that led you and Novartis to choose Rotronic and the RMS?

Several factors were decisive. Firstly, Rotronic has a very good image in the pharmaceutical industry as a reliable manufacturer of measurement and control products. Also decisive were the simplicity/intuitive use of the system and Rotronic's willingness to respond in detail to Novartis's customer requirements.

For example, existing, already mounted NTC probes could be integrated into the RMS hardware and software and used further. And last but not least, the very good value for money and the customer service convinced us.

What was the cooperation with Rotronic like?

Rotronic accompanied us very competently during the entire project phase. We appreciated the good and close cooperation and continue to do so, because the after-sales service is excellent.

RMS PRODUCTS DEPLOYED

- **Gateway:** RMS-GW-868
- **Data loggers:** RMS-LOG-868, RMS-LOG-L
- **Differential pressure probe:** PCD-S-MZZ
- **Temperature sensors:** T10-0002, T10-0005
- **Humidity and temperature probe:** RMS-HCD-S
- **Mini wireless data loggers:** RMS-MLOG-LGT-868, RMS-MLOG-T-868, RMS-MLOG-T10-868, RMS-MADC-868-A
- **Analog probe:** CCA-S-20X

ABOUT NOVARTIS

The Novartis Institutes for BioMedical Research (NIBR) is the innovation engine of Novartis. We collaborate across scientific and organizational boundaries, with a focus on powerful new technologies that have the potential to help produce therapeutic breakthroughs for patients. Basel is one of NIBR's most important research locations worldwide: more than 2200 scientific, medical and commercial employees –more than a third of the entire NIBR workforce –work here.

Using pioneering methods and state-of-the-art technology, they conduct research every day into potential breakthroughs in areas such as the treatment of musculoskeletal diseases, cancer, skin diseases and immune disorders. NIBR has more than 300 partnerships with universities and private research institutes around the world.

(Source: www.novartis.com)

* **The RMS Software**

[1] GAMP©5 guidelines for a risk-based approach to compliant GxP computerized systems.

[2] Category 4 software: Configurable software package.

[3] Category 1 hardware: Standard hardware components.

[4] GxP guidelines are designed to ensure that products are safe, meet their intended purpose and in regulated industries such as drugs, foods, medical devices and cosmetics, adhere to quality processes during manufacturing, control, storage and distribution.

[5] EudraLex is the collection of rules and regulations governing medicinal products in Europe. Annex 11 is part of the European GMP guidelines and defines the terms of reference for computerized systems used by organizations in the pharmaceutical industry. Amongst other things, Annex 11 defines the criteria under which electronic records and electronic signatures are to be managed.

[6] FDA is the US Food and Drug Administration that is responsible for protecting public health by ensuring the safety, efficacy and security of human and veterinary drugs, biological products and medical devices; and by ensuring the safety of the USA's food supply, cosmetics and products that emit radiation. CFR 21 Part 11 stipulates the FDA regulations for electronic records and electronic signatures (ERES).

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