



SUCCESS STORY

How has the Eupry system optimized work and minimized temperature compliance procedures for the manufacturer of OSTEOGROW cure for bone regeneration?

About Genera Research Ltd

Genera Research is a small privately owned company located in the Zagreb area of the Republic of Croatia. The company's activity is mainly based on the production of **high quality therapeutic proteins** using recombinant DNA technology.

The company operates in Kalinovica near Sveta Nedjelja, where a GMP production plant is located and produces **bone-morphogenic protein BMP6** - the active substance of the cure OSTEOGROW, which is being tested in clinical studies in orthopedic surgery.

This drug is given to patients in the form of an **autologous blood coagulum of the patient** and phase II of the clinical development of the drug has been completed.





Find out more about OSTEOGROW



The main challenges in temperature monitoring

"In our area, the main challenge every day is to monitor the temperature conditions in the chambers outside the working hours of the laboratory. The temperature is visually read by laboratory staff and the readings are manually entered into the temperature list, which is a very time-consuming process."

Dora Adanić, Chief Operating Officer, Genera Research Ltd

The temperature monitoring methods used so far are **digital thermometers** that need to be read visually, while laboratory staff has to enter a certain value in the predicted temperature list twice during the working hours of the laboratory. The whole procedure is very time-consuming and there is no possibility of monitoring the temperature **between the reading interval and without the presence of laboratory staff.** Genera Research is looking for a solution that will have the following features:

automatic and continuous temperature monitoring



alarms in case of temperature deviations regardless of the presence of laboratory staff



easy data and temperature reports export for regulatory controls.



The solution for Genera Research facility

Wide temperature range for the most sensitive substances

Genera Research uses a total of 5 Eupry data loggers placed in incubators, freezers and refigerators, where sensitive substances for the production of OSTEOGROW cure are stored. The Eupry systems used, operate in the temperature range from -50° C to 50° C and from -196° C to 150° C.

Real-time data availability

Temperature data is always available to laboratory staff in the online application. Reporting deviations via free SMS messages and e-mail notifications was extremely important to the staff in case of physical absence or accidental failures - such as left open doors of cooling device, sudden breakdowns or power outages.



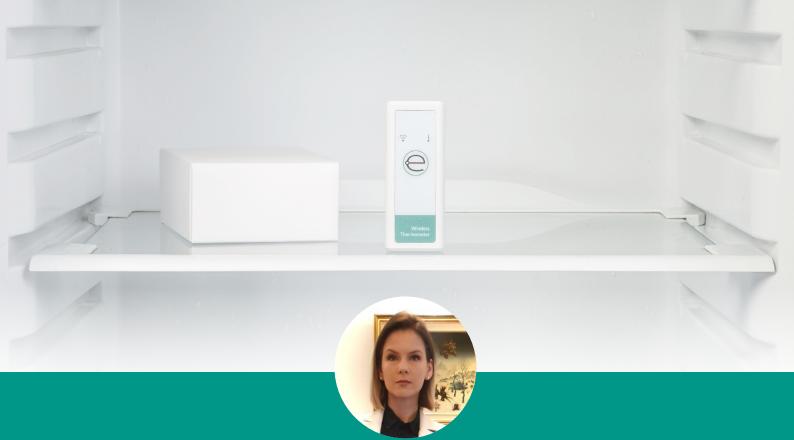
Carefree work of laboratory staff

Eupry data loggers are installed on site and connected to the existing Wi-Fi network, which allows the staff of Genera Research to easily move the device in case of need. An additional advantage is that there is no interruption of work, because when recalibrating the device, it is not physically taken to the laboratory, but you only change the sensor, which is previously calibrated.

Minimized data compliance procedures

OSTEOGROW is manufactured in accordance with GMP guidelines, which require a prescribed temperature monitoring procedure, accompanied by written record of the temperature deviations. The Eupry system enables the generation of temperature reports and fast data export in accordance with regulatory requirements and 21 CFR, part 11 guidelines. The whole process is fully automated, which reduces the need for physical handling and minimizes the risk of human error.





Dora Adanić, Chief Operating Officer, Genera Research Ltd

"Eupry is a real refreshment in the Croatian market. We are delighted with its ease of use and alarm functions. All data is traceable and easy to follow and we are especially pleased with the fast calibration service that is also a part of the service."

The process of temperature monitoring with the Eupry system is significantly simplified, since all data is stored in the online application that displays temperature fluctuations and allows the data, charts and reports export based on data stored for up to 5 years.

Eupry has proven to be a safe solution for maintaining the optimum temperature in cooling devices with valuable substances for the production of a new innovative cure for the regeneration of bone defects.







Want to know more about Eupry? Get in touch with us!

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