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Revolutionize Your Manufacturing Operations with Grantek's CloudEMS

ADVANCING MANUFACTURERS WORLDWIDE WITH DIGITAL SOLUTIONS

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WHITEPAPER

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What Are Environmental Monitoring Systems?

An EMS, or Environmental Monitoring System, automates the monitoring of the environmental conditions in secure manufacturing areas. They are designed to be secure and reliable, and they can report on a variety of environmental conditions, including temperature, humidity, differential pressure, and more.

EMS systems can also be configured to send alerts if conditions exceed certain thresholds. This ensures that product quality is maintained, and hence patient safety is ensured. EMS systems are typically used in cleanrooms, pharmaceutical warehouses, and other controlled environments, where they help to ensure that the environment in which products are made and stored is suitable for those products. EMS systems support compliance with the cGMPs.

In summary, an EMS automates the monitoring of environmental conditions and reports on these conditions.

1. It's a computerized system
2. It warns the manufacturer when the conditions deviate from allowable limits so that appropriate personnel can act accordingly
3. Some conditions or phenomena that are monitored are temperature, humidity, differential pressure, airborne particulates
4. It supports cGMP compliance

The Need for Environmental Monitoring Systems

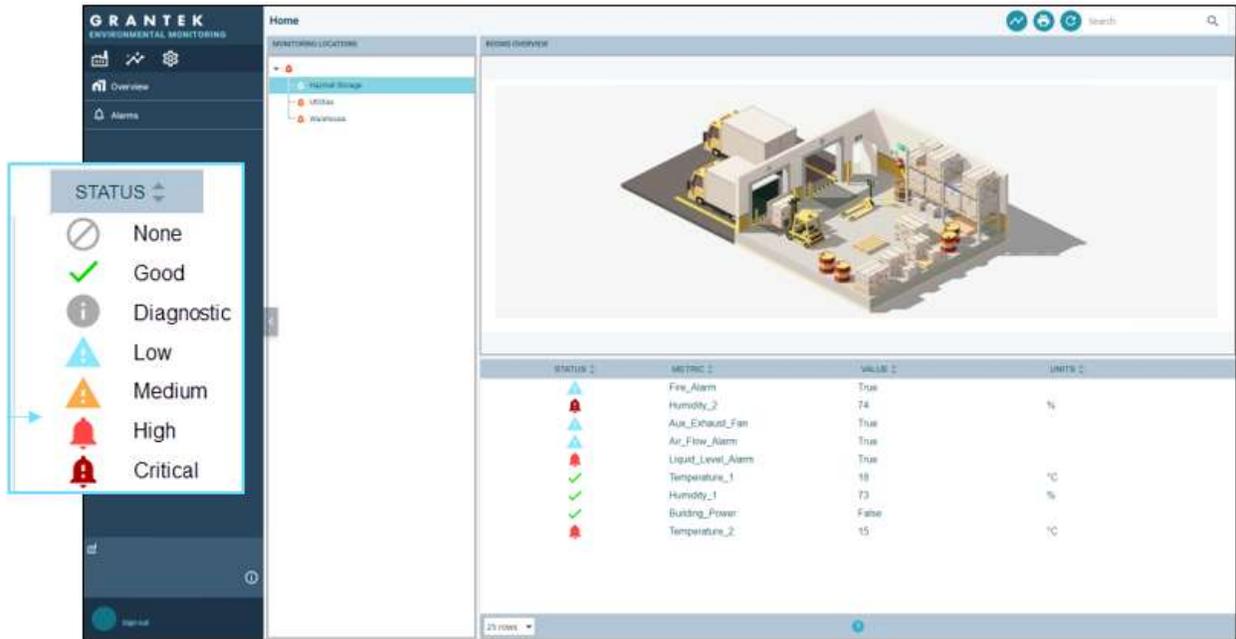
Product quality and patient safety are paramount to the pharma industry and its regulators. The conditions under which drug products are manufactured, stored, and distributed must be controlled to prevent contamination.

What is Grantek's CloudEMS?

Grantek's CloudEMS is a cloud-based Environmental Monitoring System (EMS) that provides the life sciences industry with a compliant, cyber-resilient solution that leverages the capabilities of the cloud to safeguard the safety and efficacy of their products via round-the-clock monitoring of the environmental conditions under which they make and store those products.

It is an efficient and secure way to monitor environmental conditions in your laboratory, warehouse, or production area. It allows you to collect data from sensors installed in your facility and store it in the cloud for later retrieval and analysis. It alerts your users to environmental conditions that may affect product quality.

It also provides an intuitive user interface for viewing real-time data and historical data, setting notifications, and generating reports. This new product is designed to help life sciences companies meet compliance requirements for environmental monitoring, such as the cGMPs. It also complies with the technical requirements of 21 CFR Part 11 and Annex 11. The cloud-based architecture of CloudEMS ensures that data is always accessible and secure, while the intuitive user interface makes it easy to use.



What Problems Does CloudEMS Solve?

Reduced Cost of Quality

1. Risk-based approach
2. Leveraging supplier activities

Enhanced Data Integrity & Security

1. Modern software development practices
2. Cybersecurity best practices

Reduction in IT Infrastructure Cost

1. Minimal on-site footprint
2. Reduced maintenance

What does it do?

CloudEMS will handle data collection, processing, alarming, and notifications, while also leveraging industry-standard communication protocols (OPC-UA, MQTT).

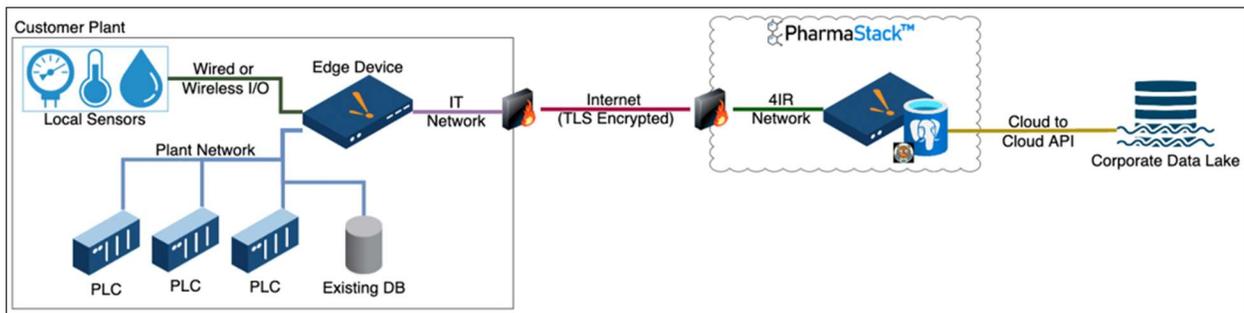
This will be a 21 CFR Part 11 ready solution, which meets the technical requirements for regulatory compliance and uses encryption to satisfy the requirements of an “open system”.

CloudEMS will feature a lightweight deployment on-site, allowing for better accessibility. Notifications will be sent via SMS, email or (future) push. 24 hours a day, 7 days a week and 365 days a year.

How is it different?

CloudEMS is hosted on the PharmaStack™ cloud platform from 4IR Solutions. 4IR Solutions is the leading provider of cloud-based platform solutions for manufacturing to enable digitalization and embrace the 4th Industrial Revolution. In 2021, Grantek named 4IR Solutions a Strategic Partner focused on Cloud technologies.

PharmaStack™ is a secured cloud Platform-as-a-Service (PaaS) designed for Life Science companies. PharmaStack™ uses best-in-class applications and a DevSecOps framework to provide manufacturers with a secure and scalable solution platform for Industry 4.0.



Benefits of CloudEMS

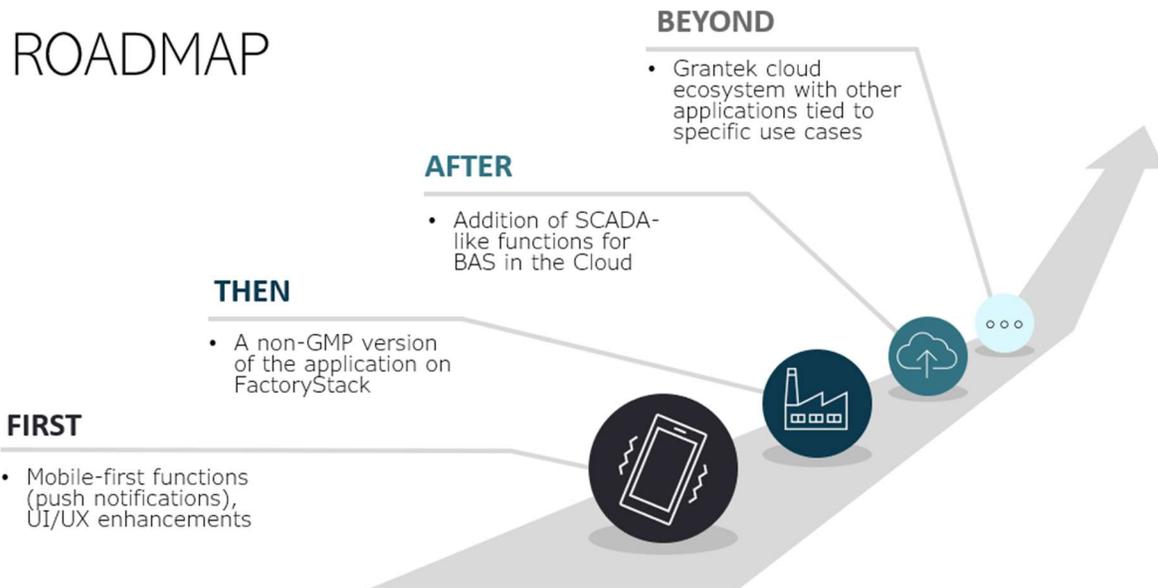
1. Regulatory Compliance – CloudEMS leverages current regulatory and industry guidance to ensure it meets today’s data integrity & cybersecurity requirements
2. Enhanced Support – Grantek’s Service & Support infrastructure ensures that CloudEMS is always working behind the scenes
3. Peace of Mind – Grantek’s CloudEMS is built on a modern cloud technology stack using our current web design technologies created with Pharma 4.0 in mind
4. Look-and-Feel – CloudEMS has a similar look-and-feel to earlier Grantek EMS offerings, but with a refreshed user experience, ensuring a seamless transition
5. Mobility – CloudEMS is built on a mobile-responsive platform allowing access from tablets and other mobile devices

Cybersecurity & Cyber-resilience

Cybersecurity is a major concern in the pharmaceutical industry, CloudEMS helps you protect your sensitive data throughout its life cycle.

We address the risks of operating in the cloud by:

1. Our application is built on a secure platform that's trusted by the industry
2. DevOps processes are used to protect the live system from uncontrolled changes
3. Data encryption in transfer to the cloud
4. Assessment of cloud service provider to ensure proper controls are in place for data protection



Conclusion

While manufacturers become increasingly digitalized and regulators demand higher compliance, businesses will need to adjust to satisfy both these needs through industry 4.0 technologies. Our CloudEMS solution helps manufacturers achieve this with security and cyber-resiliency.

Providing manufacturing facilities with a solution that elevates and futureproofs their facilities, CloudEMS is the next logical step for businesses that require their needs to be met.

For over 40 years, top manufacturers in Food & Beverage, CPG and Life Sciences/Pharmaceuticals have called upon Grantek to solve their most complex business and manufacturing challenges. Grantek automates Pharmaceutical and Food & Beverage manufacturing operations, including integration with business systems for seamless solutions. Grantek helps customers meet the stringent requirements and challenges of the 4th Industrial Revolution. Grantek is a system integrator and solution provider with a specialization in Smart Manufacturing solutions, Manufacturing Automation solutions, Industrial IT/Cybersecurity solutions and Manufacturing Consulting services. Call 1.866.936.9509 or email info@grantek.com to learn more.