Challenge
A recent surge in regulation affecting all aspects of the drug industry – originating from global organizations such as the CDC, WHO, and FDA – has expanded the need for healthcare solution providers and integrators to leverage technologies to reliably collect and store data while maintaining regulatory compliance. At the same time, there are increasingly more drugs in the pipeline that have stringent temperature ranges that significantly affect efficacy. Regular, consistent temperature monitoring across the pharmaceutical supply chain (including while drugs are stored in dedicated pharmaceutical-grade refrigerators) is imperative in order to ensure product safety and regulatory compliance, as well as minimizing product loss.

Onset was already a leader in traditional temperature monitoring services for vaccines, biologics, traditional OTC drugs, and selective cell gene therapies. Their existing InTemp Monitoring solution – including both the hardware and Onset software application – offered standalone logger devices and probes for temperature measurement, that relied on one-to-one Bluetooth connections with mobile devices.

Onset saw an opportunity to extend and scale their solution to replace individual mobile devices with Bluetooth gateways, enabling centralized real-time device monitoring and control, while contributing to a better understanding of the risks of cold-chain management.

Solution
Prior to searching for a wireless technology infrastructure partner, Onset identified and evaluated four key solution requirements:

- **Existing solution interoperability.** Building a solution that could scale while working seamlessly with existing Onset InTemp sensors meant that new infrastructure hardware needed to be Bluetooth-based. Bluetooth provides the additional benefit of being a technology familiar to site staff – simplifying device
Why Rigado?

Ease of deployment
With a typical indoor range of 30-50m, even in supply chain environments, each Rigado high-performance Bluetooth gateway is able to manage connections and data collection for up to 50 Onset temperature loggers.

Bluetooth expertise
Rigado’s Bluetooth 5 solutions and experience allowed their team to partner with Onset’s design engineers to rapidly develop, test and deploy an enterprise-class Bluetooth wireless solution from pilot to production.

Edge processing capability
Edge processing on the Rigado gateway guarantees a securely encrypted data pipeline between Onset loggers and the InTempConnect cloud platform. It also enables centrally managed adjustments to temperature ranges and alarm limits on data loggers themselves, allowing sites to be more compliant to their individual boards of pharmacies.

Secure Management
The Rigado Cascade solution includes cloud-based services for gateway configuration, deployment, monitoring and updating. This not only saves development and deployment time and cost, but also keeps gateways secure in the field.

Cost-effectiveness. Designing a wireless solution removes the need for healthcare providers to engage with site facilities crews to run new wiring, saving significant costs. For their end customers Onset required a solution with a low Total Cost of Ownership that would enable a flexible cost structure.

Effect on operational efficiencies. Time is a precious resource for healthcare providers, and Onset needed a solution that could be easily installed, configured, and operated by staff at site level. For audit compliance the data logging digital chain would need to meet data integrity security standards and include a user-friendly data reporting capability.

Vendor knowledge and support. Onset wanted a technology partner with experience extending existing solutions with low power wireless infrastructure; one that would provide ongoing support to help ensure a successful rollout of their extended solution.

Meeting each of these requirements, Rigado’s edge infrastructure solution effectively allows Onset to focus on scaling their existing solution and cloud-based application without spending time and resources on custom-built wireless infrastructure.

The InTemp by Onset temperature monitoring solution works by sending individual logger temperature data via Bluetooth Low Energy to the Rigado gateway, where it is centrally processed and sent at scheduled intervals via Ethernet or Wi-Fi to the InTempConnect cloud-based data platform – where data excursions trigger automatic email and SMS notifications.

Results
By leveraging Rigado wireless edge infrastructure Onset has been able to successfully roll out their InTemp temperature monitoring solution to over 500 healthcare sites across the US. With their commercially-scalable solution Onset is now able to guarantee:

✓ Real-time device monitoring and management. Using gateways to feed data to a central platform gives IT teams the ability to remotely monitor multiple entire systems, and then push finely-tuned system adjustments to end devices as necessary. This means that the Onset InTemp solution is able to consistently run at peak performance – without technical support staff needing to be physically on site.

✓ Simplified regulatory compliance. Not only does edge processing improve the quality of data logged, automatic alerting and reporting makes it easier for supply chain providers to stay in compliance with regulations such as the FDA’s 21 CFR Part 11, which regulates electronic data collection and storage standards. Compliance benefits also extend to on-site staff, who no longer spend valuable time manually logging and processing cold-chain temperature data.

✓ Flexible solution deployments. Healthcare sites vary significantly in size, affecting the number of logger and gateway devices required. Onset InTemp loggers paired with white-label Onset CX gateways arrive to healthcare sites as simple plug-and-play kits – easily extended as deployment size increases. Further, the scalability of the solution supports successful regional rollouts for national chains and pharma companies, including quick process feedback integrations.

To learn more about Cascade edge infrastrucutre for commercial IoT visit www.rigado.com