

## Transforming Quality and Compliance at Innovative Medical Equipment with Cloudtheapp



Revolutionizing Pain Relief with Targeted, Non-Opioid Solutions



## COMPANY OVERVIEW

**Innovative Medical Equipment, LLC (IME)**, founded by a world-renowned plastic surgeon and migraine research pioneer, specializes in the development, manufacturing, licensing, and distribution of medical equipment. Based in Cleveland, Ohio, IME is a dynamic and evolving company with a mission to leverage existing technologies and manufacturing techniques to deliver common-sense, non-opioid solutions to healthcare providers and consumers.

IME's flagship product, **ThermaZone**, is a cutting-edge pain management device that uses thermoelectric technology to deliver localized hot and cold therapy without the need for ice. This innovative device addresses an unmet clinical need for targeted, non-opioid therapy, providing consistent temperature management for patients in both clinical and at-home settings. For more information, please visit (<https://therma-zone.com/>)

## CHALLENGES

Before adopting Cloudtheapp, IME was operating with a manual, paper-based system that lacked digitalization. The company was searching for a Quality Management System (QMS) that could support their established, robust processes while allowing for modern, digital transformation. IME needed a solution that would enhance their workflows without forcing them to overhaul the way they conducted their business. The challenge was finding a system that provided flexibility, regulatory compliance, and seamless integration with their existing infrastructure.



## WHY IME SELECTED CLOUDTHEAPP

*"When selecting an electronic Quality Management System (eQMS), our priority was to find a solution that could not only meet current regulatory requirements but also scale with our evolving operational needs. We chose Cloudtheapp primarily for its high level of configurability, allowing us to tailor workflows and forms to match our internal processes without custom coding. This flexibility was key to ensuring a smooth and easy rollout across multiple teams. One of the standout features for us was Cloudtheapp's strong alignment with ISO 13485 regulatory compliance requirements, which gave us confidence in its ability to support our quality and audit readiness from day one. Additionally, the reporting and analytics capabilities have provided us with deeper visibility into our quality metrics, enabling more proactive decision-making. Another critical factor was the no-code environment, which empowers our quality team to make changes and manage configurations. Finally, the level of support we've received has been exceptional—from implementation through to ongoing maintenance—making Cloudtheapp not just a software vendor, but a valuable quality partner."*

**Emily Keen - Quality Manager**

IME chose Cloudtheapp as their QMS platform due to several key differentiators:

- **Extreme Configurability:** Cloudtheapp's ability to enable users to build and configure applications using natural language instructions and AI technology was a major selling point. This allowed IME to preserve their established processes while modernizing them without being bound by rigid software limitations.
- **Full Regulatory Compliance:** Cloudtheapp is a pre-validated platform according to FDA guidelines and GAMP standards. It supports electronic signatures, audit trails, role-based access, and data integrity, ensuring compliance with FDA, and global standards.

- **Modular & Scalable Architecture:** With over 50 pre-built applications available in the Cloudtheapp Store, IME could selectively deploy only the applications they needed. This made it easy to scale as the company grows, without unnecessary complexity.
- **Fast Deployment & Seamless Migration:** The implementation approach allowed for the rapid rollout of core applications in phases. Data migration was handled efficiently, minimizing customer effort.
- **Powerful Analytics & Reporting:** Cloudtheapp's built-in analytics and reporting features provided real-time visibility into compliance, risk, and quality metrics, eliminating the need for external tools.
- **Integration-Ready:** Cloudtheapp's embedded RESTful APIs and no-code logic enabled seamless integration with IME's existing systems, including their ERP system (NetSuite), ensuring that their QMS was fully connected and didn't operate in a silo.
- **Robust Support:** Cloudtheapp provided weekly working sessions, on-demand learning, and comprehensive training for super users to ensure smooth adoption and successful implementation.



## IMPLEMENTATION

*"Our implementation experience with Cloudtheapp was exceptionally smooth and efficient. From the outset, Cloudtheapp's intuitive interface and no-code configurability allowed us to quickly tailor the system to our existing processes without lengthy development cycles. This drastically reduced setup time and minimized disruption to day-to-day operations. One of the most impressive aspects of the implementation was how quickly we were able to achieve full deployment across all departments. Thanks to clear documentation, responsive support, and a user-friendly design, our teams were onboarded with minimal training time. The rollout plan was well-structured, allowing us to go live in phases while continuing to run daily operations. A major success factor was the integration with our ERP system, this ensured that quality data could flow freely between systems, supporting better traceability and operational efficiency. Overall, the speed and simplicity of the implementation process confirmed we had chosen the right platform—not only for its features, but for the strength of its deployment and support team."*

**Melanie Cumberledge – Supply Chain Manager**

- **Initial Rollout:** The first set of applications was rolled out in a span of **3 months**, from October to December, with a focus on rolling out key applications to production.
- **Full Implementation:** The entire suite of applications was rolled out over a period of **6 months**, from October to March. This included rolling out 26 applications to production.
- **ERP Integration:** A crucial aspect of the implementation was the **NetSuite integration**, which synchronized customers and contacts between NetSuite and Cloudtheapp on a daily basis. This enabled efficient customer lookups during key processes like Return Material Authorization (RMA) and Complaints handling.

- **Applications Rolled Out:**

#	Application Name	Configuration Type
1	Advanced Inspections	Major Config
2	Bill of Materials	Minor Config
3	Change Management	Major Config
4	Corrective and Preventive Actions	Medium Config
5	Customers	Minor Config
6	Design Controls	Medium Config
7	Device Master Records	Minor Config
8	Documents	Minor Config
9	Equipment & Calibration	Minor Config
10	Failure Investigation Reports	New Application
11	Failure Mode and Effects Analysis	Medium Config
12	General Records	Minor Config
13	Items and Suppliers	Medium Config
14	Labeling & Packaging	New Application
15	Learning	Out-of-the-Box
16	Meetings	Minor Config
17	Nonconforming Material	Major Config
18	Preventive Maintenance	New Application
19	Product Release	New Application
20	Risk Assessments	Medium Config
21	RMA & Complaints	Major Config

22	Supplier Qualification	Major Config
23	Tasks	Out-of-the-Box
24	Test Protocols	New Application
25	Validation	Out-of-the-Box
26	Variance (Deviation)	Major Config



## REASONS FOR SUCCESS

*"Cloudtheapp played a pivotal role in our successful implementation by providing a flexible, scalable low-code platform that aligned seamlessly with our business goals. Their team collaborated closely with ours to ensure rapid configuration, tailored solutions, and a smooth rollout. With Cloudtheapp's intuitive design and responsive support, we empowered internal champions, streamlined workflows, and minimized reliance on custom code—resulting in strong user adoption and long-term value across the organization."*

**Glen Guyuron - Vice President / Operations**



1. **Established Processes:** IME had robust, well-defined processes in place even before implementing Cloudtheapp, which allowed for a smooth transition to a digital QMS. Their ability to articulate their user requirements clearly and professionally was key to a successful implementation.
2. **Extreme Configurability:** The platform's flexibility and configurability allowed IME to tailor the system to their unique needs. They were able to reconfigure existing applications and build new ones at a rapid pace, ensuring their QMS matched their exact requirements.
3. **Integration Capabilities:** Cloudtheapp's ability to integrate seamlessly with external systems, such as **NetSuite**, ensured that IME's QMS was fully connected to their broader ecosystem. This eliminated silos and provided real-time access to key data across all applications.
4. **Solid Internal Processes:** Cloudtheapp's team was impressed with IME's solid and efficient internal processes, such as:
  - ANSI standard sampling followed for inspections
  - Streamlined inspections and product release process
  - Robust RMA process
  - Thorough Design Controls and FMEA implementation

## KEY TAKEAWAYS:

IME's transition to Cloudtheapp was a success because of several factors:

- The **configurability** and **scalability** of Cloudtheapp allowed IME to maintain their established processes while modernizing their operations.
- The **integration with existing systems** and **robust compliance features** ensured that IME could meet all regulatory requirements and maintain data integrity.
- The **rapid implementation** and continuous support from Cloudtheapp's team ensured a smooth and effective transition, with all applications successfully rolled out within the timeline.



IME's experience demonstrates how companies in the medical device industry can benefit from Cloudtheapp's advanced, highly configurable QMS to enhance their quality, safety, and compliance processes while maintaining the flexibility to grow and adapt to new challenges.

## CONCLUSION:

With Cloudtheapp's versatile and scalable platform, IME has successfully digitized its operations without disrupting its established processes. The ability to integrate, configure, and rapidly deploy new applications has empowered IME to stay ahead in an increasingly competitive and regulated industry. Cloudtheapp's platform has not only streamlined operations but also paved the way for greater innovation and growth at IME.

## ABOUT CLOUDTHEAPP

Welcome to Cloudtheapp, where we set the standard in the industry with AI-Powered Extreme Configurability and leading-edge solutions for Digital Transformation. Specializing in Quality, Safety, and Compliance, Cloudtheapp offers a comprehensive suite of essential solutions tailored for diverse industries.

Our robust offerings include Enterprise Quality Management (EQMS), Food Safety Management (FSMS), Supplier Quality Management (SQM), Environmental Health and Safety (EHS), Regulatory Information Management (RIM), Enterprise Risk Management (ERM), Laboratory Management (LMS), Manufacturing Execution (MES), Product Lifecycle Management (PLM), and Data Analytics.

Cloudtheapp pioneers Innovative Enterprise Software Development, delivering scalable solutions on Enterprise Cloud-Native Software Platforms. Built by industry veterans with experience spanning over 3 decades, our AI-driven approach ensures unmatched configurability, facilitating seamless adaptation and optimization of processes across sectors such as pharmaceuticals, med-device, biotech, food & beverage, healthcare, manufacturing, and beyond.

Cloudtheapp supports Digital Transformation initiatives by optimizing workflows, enhancing productivity, and ensuring regulatory compliance effortlessly. Our platforms are validated according to FDA guidelines and include features necessary for organizations to comply with standards and regulations such as 21 CFR Part 11 and ISO 13485. This empowers companies in

the Life Sciences industry to use Cloudtheapp confidently, knowing they meet stringent regulatory requirements.

Harnessing the power of AI and unmatched No-Code drag/drop designer tools, Cloudtheapp enables organizations to rapidly build sophisticated applications in minutes by translating user requirements from natural language, thereby streamlining development processes and accelerating time-to-value.

Cloudtheapp also empowers collaboration both internally within the organization and with external parties such as suppliers, customers, product consumers, and more. This seamless connectivity enhances communication, improves feedback loops, and fosters a more integrated approach to quality and compliance management.

Explore Cloudtheapp and discover how our AI-Powered solutions redefine industry standards, driving efficiency, agility, and growth across your enterprise.