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A Design Methodology for an IoT-Enabled Warehouse Monitoring System in Pharmaceutical Storage Environments

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منهجية تصميم لنظام متابعة المخازن مدعوم بتقنية إنترنت الأشياء في بيئات مخازن الأدوية

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Abstract:

In modern logistics, the Internet of Things (IoT) plays a vital role in enforcing Good Manufacturing Practices (GMP) by enabling precise environmental monitoring. Maintaining good storage conditions is essential for product safety. This research introduces a practical design and implementation of an IoT monitoring system in a pharmaceutical warehouse. The system uses sensors connected through Wi-Fi and Ethernet to monitor cold and ambient areas. It enables real-time tracking, automatic logging, and timely alarm notifications. The pilot system is designed, validated and testing confirms accurate sensor readings, reliable alarm delivery, and uninterrupted system performance during power and Wi-Fi outages. The system also supports remote access and interactive staff training. Results show that IoT integration offers a scalable, cost-effective approach to environmental monitoring, particularly for resource-limited sectors

Keywords: Internet of Things; Good Manufacturing Practices; Real-Time.

الملخص:

في قطاع النقل و التوزيع الحديثان، تلعب تقنيات إنترنت الأشياء (IoT) دورًا حيويًا في تطبيق ممارسات التصنيع الجيدة (GMP) من خلال تمكين المراقبة البيئية الدقيقة. حيث يُعد الحفاظ على ظروف تخزين جيدة أمرًا أساسيًا لسلامة المنتجات. يُقدم هذا البحث تصميمًا وتطبيقًا عمليًا لنظام متابعة يعتمد على تقنية إنترنت الأشياء في مخزن خم للأدوية. يستخدم النظام أجهزة استشعار متصلة عبر شبكات لاسلكية و سلكية لمتابعة مناطق التخزين الباردة المجمدة والاعتيادية . يُتيح النظام التتبع الفوري والتسجيل التلقائي مع اصدار إشعارات الإنذار في الوقت المناسب. تم تصميم النظام التجريبي والتحقق من صحته واختباره، مما يؤكد دقة قراءات أجهزة الاستشعار ، وتوصيل الإنذارات بشكل موثوق، وأداء النظام المتواصل أثناء انقطاع

التيار الكهربائي وشبكات البيانات. كما يدعم النظام الوصول عن بُعد والتدريب التفاعلي للموظفين. تُظهر النتائج أن تكامل إنترنت الأشياء يوفر نهجًا قابلًا للتطوير وفعالًا من حيث التكلفة للمراقبة البيئية، وخاصةً للقطاعات محدودة الموارد.
الكلمات المفتاحية: انترنت الاشياء, ممارسات التصنيع الجيد, الوقت الحقيقي.

1. Introduction

Pharmaceutical products are sensitive to environmental conditions, particularly temperature and humidity, during storage and distribution. The maintenance of optimal storage conditions is critical to ensure drug efficacy, safety, and regulatory compliance. Inappropriate environmental conditions can lead to the degradation of active pharmaceutical ingredients, reduced shelf life, and compromised patient safety. Therefore, the implementation of reliable monitoring systems is a fundamental requirement of GMP [1][2][3].

The World Health Organization (WHO) and various national and regional regulatory authorities, including the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA), emphasize that pharmaceutical storage must maintain controlled environmental conditions. WHO's guidelines on Good Storage Practices (GSP) for pharmaceuticals require continuous monitoring of temperature and humidity in all critical storage areas [4]. These guidelines demand the use of validated systems with traceable records, alarm functionalities, and documented corrective actions. As such, the role of modern monitoring technologies is becoming increasingly vital in complying with these expectations [5]. The IoT has emerged as a powerful enabler of real-time environmental monitoring. By integrating sensors, wireless communication and centralized software platforms, IoT-based solutions offer continuous data logging, automated alerts, and historical recordkeeping. These capabilities support traceability, risk-based monitoring, and audit-readiness that shape core pillars of the GMP and Good Automated Manufacturing Practices (GAMP) frameworks [6]. In pharmaceutical warehousing, IoT systems not only enhance operational efficiency but also contribute directly to quality assurance and regulatory compliance [7]. In many developing countries, the pharmaceutical sector faces challenges in adopting modern compliance-oriented technologies. Limited infrastructure, lack of local expertise, and high costs of validated solutions contribute to gaps in regulatory adherence [8][9]. This context highlights the need for locally adapted and cost-effective systems that meet international standards.

Recent research has extensively explored the integration of Internet of Things (IoT) technologies into GMP environments to enhance environmental monitoring and compliance management. Studies have emphasized IoT's capacity to automate tracking of temperature and humidity across pharmaceutical storage facilities, improving data integrity, traceability, and regulatory adherence [10], [11]. Several implementations have focused on modular, wireless sensor networks for cold chain logistics, validating the reliability of real-time alerting and long-term data archiving [12]. However, existing systems are often limited by high deployment costs, proprietary software, and dependence on advanced IT infrastructure [13]. This study differentiates itself by presenting a practical and cost-effective IoT-based monitoring framework developed and validated within a resource-limited context. Unlike prior models that rely heavily on cloud infrastructures, the proposed system emphasizes local control, scalability, and offline reliability—key attributes for developing regions [14]. Thus, this work contributes to the literature by demonstrating a compliant, validated, and adaptable system architecture aligned with GMP and GAMP 5 principles.

In this study, an IoT-based Humidity and Temperature Monitoring System (HTMS) was designed, pre-installed, and validated in a pharmaceutical warehouse. The aim was to create a scalable system that supports GMP compliance, ensures continuous environmental monitoring, and provides audit-ready documentation. The implemented system includes digital and analog sensors, network integration, centralized alerting, and staff training components. This work presents the technical design, validation strategy, and performance results of the pre-implemented HTMS. It aims to serve as a practical reference for small and medium pharmaceutical enterprises, especially in limited-resource settings, seeking to implement cost-effective solutions for environmental monitoring in alignment with global regulatory expectations.

2. Motivations

To ensure reliable storage of pharmaceutical and medical products, regulatory frameworks play a critical role in establishing systems that maintain controlled environmental conditions. Core standards, such as GMP and GAMP shape the foundation for ensuring product safety and quality. These technical and procedural frameworks are issued and enforced by major regulatory authorities including the WHO. Furthermore, these standards aim to reduce human error by promoting standardized procedures and automation, thereby decreasing reliance on manual processes. Notably, they advocate risk-based methodologies in the design and validation of monitoring systems, focusing attention on high-risk processes. Practically, adherence to internationally harmonized standards facilitate regulatory approval, encourages mutual recognition across jurisdictions, and expands global market access for pharmaceutical manufacturers. Despite the global importance of GMP, GAMP, and other frameworks in ensuring pharmaceutical quality and patient safety, their implementation in developing countries presents a set of significant administrative and technical challenges. Addressing these challenges requires a multi-faceted approach, including the review of national regulatory constraints, inspecting existing infrastructure and human capital, and the adoption of digital and automated technologies. Within the scope of this research, we adopt internationally recognized standards and guidelines as the foundation for developing a technical monitoring system. The contributions focus on three core objectives as follows:

i. Ensuring alignment with global compliance requirements,
ii. Implementing a GMP-compliant temperature and humidity monitoring system,
iii. Promoting awareness and capacity building through training.

3. The system design methodology

To comply with regulatory requirements, the proposed IoT-based monitoring system was fully designed and implemented according to GMP & GAMP constraints. The system shall perform continuous monitoring of warehouse temperature and humidity, to generate time-stamped data logs, and automatically to trigger audible alarms and email alerts in response to deviations from predefined thresholds. The system architecture includes wireless connectivity (via Wi-Fi) that links sensor nodes to a central computer, which runs dedicated monitoring software responsible for data visualization, alarm notification, and report generation, ensuring compliance, traceability, and proactive environmental control. The scope is obviously to monitor identified zones that have an ambient environment except one cold room that requires special temperature and humidity ranges. For this purpose, the site design map is reviewed to determine each area. The methodology adopted in this study follows a structured design, development, and validation approach consistent with GMP and GAMP frameworks. The process included system architecture design, sensor calibration, network configuration, data acquisition, and efficiency validation.

Sensor Technology: The system employs hybrid architecture combining digital and analog sensors. Digital sensors (precision ±0.2°C, humidity ±2%) were used in critical zones such as cold rooms, while analog probes were deployed in ambient areas. Each sensor was pre-calibrated and validated by an accredited national laboratory [15]. All sensors were connected via Wi-Fi and Ethernet to ensure redundant data communication.

Data Collection and Processing: The monitoring software automatically logged readings every 30 seconds, generating timestamped data stored locally and retrievable in both tabular and graphical formats. A data integrity verification function checked for packet loss or communication errors in real-time.

Validation Procedures: Validation followed GAMP 5's V-model structure, including Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ). Efficiency was assessed by comparing recorded readings with calibrated reference instruments under controlled conditions. Alarm tests simulated deviation events (e.g., 8°C in cold room) to verify alert speed and system recovery time.

The system architecture is built to ensure seamless data communication between sensor units and the central monitoring computer. At the core of the system are connected sensors from the Plug & Track [16]. These smart devices are designed for industrial environmental monitoring. Each unit supports up to three input channels

for connecting temperature, humidity, or other environmental probes. The devices send real-time data to the monitoring centralized workstation, where all packets are collected. For cold storage units, high-accuracy digital temperature sensors are deployed, capable of measuring extreme ranges from –200°C to +250°C, suitable for plasma storage and other thermally sensitive products. These probes are designed with IP65-rated waterproof casings and rugged industrial-grade cables to ensure durability and reliability in harsh conditions. In contrast, analog temperature and humidity sensors are used in the general storage zones, where environmental conditions are less variable, and the monitoring requirements are less stringent. This hardware setup ensures robust and scalable environmental monitoring across the facility, while supporting the core GMP requirement for precise, traceable, and secure environmental control.

The monitoring system is integrated with a developed software platform designed for the real-time supervision of environmental conditions. This application provides features for real-time visualization, graphical plotting, and report generation in various formats, including Excel and PDF data formats. The system supports adjustable alarm thresholds with configurable delay intervals and can trigger visual pop-up alerts and email notifications in the event of threshold violations. The ability to export data and alarm logs ensures traceability, audit readiness, and effective quality control management. The system allows the scalable integration of an unlimited number of sensor devices, making it suitable for comprehensive monitoring across large storage facilities. Table 1, Table 2 and Fig.1 illustrates design process with integrated IoT Wi-Fi system, i.e. design topology, the network includes a Power over Ethernet (PoE) switch that provide power to access points, three Wi-Fi access points (AP1, AP2, AP3), and six Sensor Net Connect data loggers—each equipped with digital or analog probes depending on the environmental at the deployment zones.

Table. 1: Wi-Fi access points seamless coverage.

Access points names	Wi-Fi AP location	IP address	SSID*
AP1	Near Dispatch area	192.168.0.254	HTM
AP2	At Staging area	192.168.0.253	HTM
AP3	Near Quarantine area	192.168.0.252	HTM

*SSID: Service Set Identifier

Table .2: full coverage integration of Connected Sensors.

Name	IP address	Type	Position description
Cool room (CR)	192.168.0.10	Digital	Digital temperature probe at Fridge
Dispatch (Disp)	192.168.0.20	A H/T	At the Receiving zone
Returned (Ret)	192.168.0.30	A H/T	At the Returned products zone
Staged (Stg)	192.168.0.40	A H/T	After products sorting (before placement)
Medicine (Med)	192.168.0.50	A H/T	At the Main medical warehouse storage
Quarantine (Qur)	192.168.0.60	A H/T*	Next to returned products area

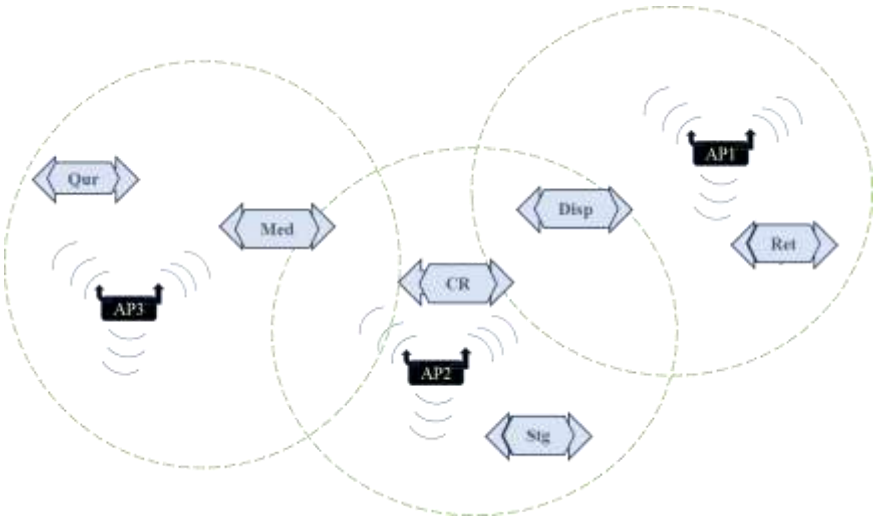

Figure. 1: Wi-Fi design with integrated IoT connected Sensors

Although the system is functional, it is noted that power instability poses a risk to Wi-Fi availability, computer operational storage and connected sensors. This issue potentially disrupts real-time communication and sensor connectivity. This limitation highlights the need for power conditioning or backup systems to ensure continuous operation in critical environments. Hereafter, we installed a backup battery and an uninterruptible power supply (UPS) which has a direct power source and other power from a backup reliable generator. Fig.2 shows a block diagram of the designed reliable electrical availability where the Automated Transfer Switch (ATS) enables the available power source automatically to ensure continuous electrical service either from the main AC power source or Diesel Generator (DG) connected. The load nodes are UPS, Digital Video Reorder (DVR), and both POE switches that connect IOT sensors and Wi-Fi access points.

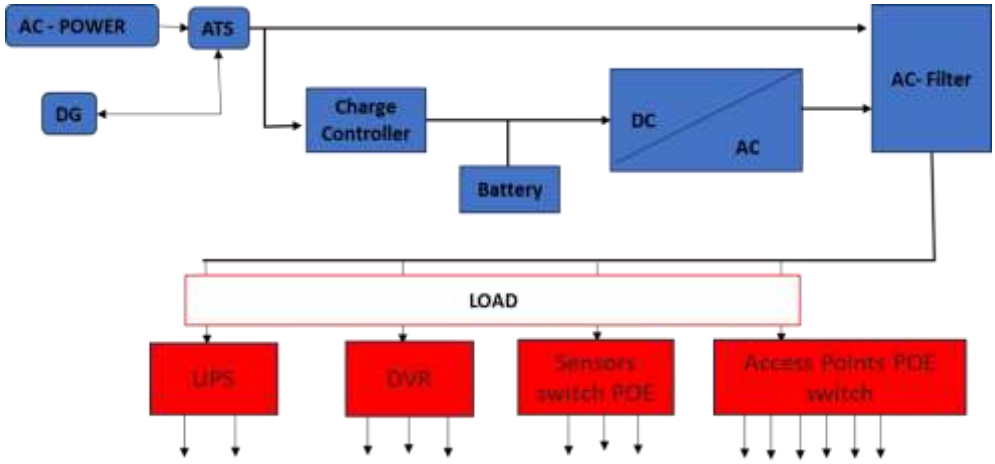

Figure.2: The block diagram of the designed reliable electrical

4. Results

5. Firstly, the focus was on the Cold Room due to its critical importance. Data revealed a critical deviation after February 2025, i.e. about 4 weeks after preliminary implementations, where the temperature spiked to 15.5°C for an extended period, well beyond the expected 3–7°C range for cold storage. The event was successfully detected, and alarms were triggered via email and on-screen notifications, demonstrating the effectiveness of the alerting system. During all other periods (from Feb to June), the temperature stabilized within the designated range, averaging between 1.3°C and 4.5°C. Second critical area is the main medicine storage, i.e. the main warehouse of stocked medicine, where temperature values remained consistently between 17.3°C and 18.3°C, and humidity levels were maintained from 47% to 75%, matching the acceptable ambient pharmaceutical storage conditions. For preliminary design we inspected the system performance, the reader can recognize, from Fig.3, early results of test (period for 10 days).

5.1. Results discussion

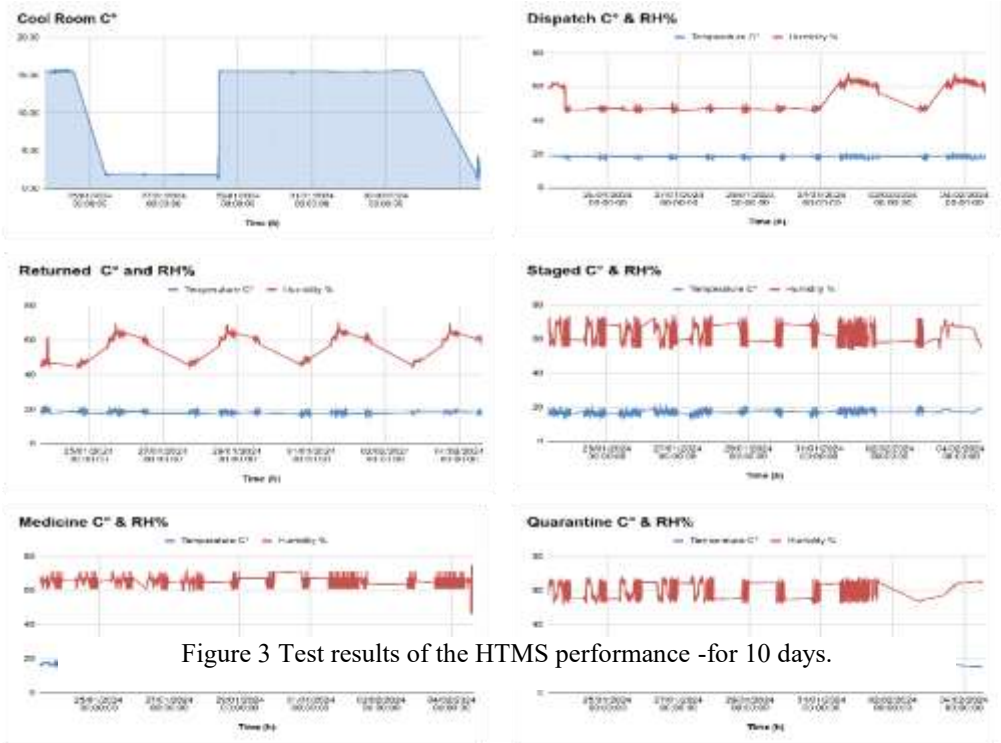

Figure 3 Test results of the HTMS performance -for 10 days.

No significant deviations were recorded, and the data confirmed both environmental stability and accurate sensor tracking. Fig. 3 shows that the third critical zone is the dispatch area, where medicine sorting might take a full day. Readings showed minimal fluctuation, with temperature fixed around 18.3°C and humidity held between 56% and 61%. This highlights the system's capacity to monitor smaller temperature shifts with high resolution and stability, even in frequently accessed zones. Another important area is the returned goods area, where many products are in good condition and might be reoriented to the main medicine storage area. The return zone also demonstrated excellent consistency, with temperature between 18.13°C and 18.25°C, and humidity ranging from 58% to 61%. These results indicate the successful integration of sensor nodes and accurate calibration in a lower-priority but regulatory-relevant area.

For the staging area, i.e. receiving zone, warehouse employees keep moving to receive and sort many products every week. The staging area experienced wider but acceptable variation in both temperature (16.9°C to 19.7°C) and humidity (54% to 71%), likely due to regular movement of products and recurrent opening of the main entrance. Despite this, the system detected all inside environment trends and retained precise logs, confirming

its suitability for dynamic warehouse environments. Finally, the quarantine area, i.e. a closed area with restricted access, was consistently maintained within safe thresholds, with temperature values between 15.3°C and 16.5°C and humidity between 53% and 66%. The controlled environment for this critical inspection zone supports GMP principles of secure and traceable handling of unverified products. The observed system performance, for 6 months, aligns with GMP and GAMP expectations by enabling environmental control through real-time monitoring and threshold-based alerts, data integrity with automated, tamper-proof archiving, audit readiness via exportable logs and system traceability and risk-based thinking, especially evident in the critical cold storage zone. The successful detection of a real temperature deviation in the cold room demonstrates the system's essential role in maintaining product quality and preventing potential risks to patient safety. These preliminary implementations achieve fundamental goals of the regulatory compliant system.

5.2. Results Validation and compliance

System performance was validated through a six-month operational period. Quantitative metrics confirmed system stability, accuracy, and responsiveness. Table 1 summarizes validation metrics benchmarked against GMP expectations.

Table 3. System Validation Metrics

Parameter	Measured Value	Acceptance Criterion	Status
Temperature accuracy	±0.2°C	≤ ±0.5°C	Passed
Humidity accuracy	±2% RH	≤ ±5% RH	Passed
Wi-Fi uptime	99.3%	≥ 95%	Passed
Alert response time	8 seconds	≤ 15 seconds	Passed
Data integrity (missing packets)	< 0.05%	≤ 1%	Passed

To avoid human errors that may lead to noncompliance. Personnel training was conducted to ensure system adoption and regulatory compliance. Training sessions covered GMP principles, sensor operation, data interpretation, alarm response, and documentation practices. Interactive workshops were held for warehouse staff and quality assurance teams, emphasizing proactive alarm management and corrective actions. Post-training evaluations indicated improved awareness of GMP-compliant monitoring and reduced human error in environmental documentation [17].

To ensure the validation, GMP/GAMP Compliance Mapping is summarized, where table 4 shows how the system's features align with GMP and GAMP 5 principles.

Table 4. Alignment with GMP and GAMP 5 Principles

System Feature	Compliance Aspect	GMP/GAMP Principle	Description
Automated data logging	Data integrity	GAMP 5, Part 11	Ensure secure, time-stamped records
Alarm notifications	Risk management	GMP 1.5, GAMP 5	Enables prompt corrective actions
Calibration and validation	Quality assurance	GMP 6.2	Confirms measurement reliability
Audit trail	Traceability	GAMP 5 Annex 11	Supports audit readiness

User training	Personnel competence	GMP 2.9	Strengthens procedural compliance

6. Conclusion

The implemented system is built in adherence to internationally recognized GMP, GAMP guidelines and was tailored to address the operational and regulatory needs of medicine storage environments. The system demonstrated high reliability in continuously monitoring six distinct warehouse zones, including the cold room, medicine storage, dispatch, returned goods, staging, and quarantine areas. Across all the warehouse zones, the implemented system provided: a) Accurate real-time logging with timestamps, b) Reliable alert delivery via email to warehouse staff, quality control director, and IT management, c) Continuous operation during Wi-Fi and power outages due to UPS and generator backup, d) High-resolution sensing, particularly in the cold room and staging areas. In addition, calibration was externally validated by a national company, which issued a compliance certificate after testing sensor accuracy under controlled conditions. By integrating IoT technologies, the system not only enhances environmental monitoring but also supports traceability, risk-based thinking, and automated compliance key elements of GMP and GAMP frameworks. It further offers a practical and scalable model for warehouse storage operators in developing regions seeking to achieve international quality standards through accessible, and validated technologies. The system was designed to optimize performance while minimizing cost. The total implementation cost per monitoring node was estimated to be below USD 800, significantly lower than commercial systems that exceed USD 1,000 per node [18]. Scalability was verified by simulating network expansion to twelve sensors without latency or data loss. The system's modular architecture allows incremental growth by adding access points and sensor nodes without reconfiguration.

This system could be extended to include predictive analytics, mobile access dashboards, and integration with Warehouse Management Systems (WMS) to further automate compliance reporting, improve decision-making and enable broader scalability across multi-site pharmaceutical operations. Future research will focus on enhancing the system's intelligence and integration capabilities. Key directions include the implementation of machine learning to forecast deviations before they occur, integration with WMS for automated compliance reporting, and the development of mobile dashboards for real-time supervisory control. Additionally, cybersecurity hardening will be explored to ensure data protection and regulatory alignment with 21 CFR Part 11 and ISO/IEC 27001 standards [19].

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