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Adaptive Call Bot to Improve Operational Excellence for Pharma and MedTech Manufacturing

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Abstract:
Pharmaceutical and MedTech manufacturing environments are becoming more and more complicated, which requires smart digital solutions to be integrated into their regimes to improve their overall operational excellence. This investigation suggests an adaptive intelligent call bot framework that will have the ability to interact with digital twins (DTs) and Unified Namespace (UNS) structures, providing real-time communication, data access and referencing, and contextual decision-making assistance. A systematic literature review and architectural analysis of the research help determine the main enabling technologies such as MQTT, Sparkplug B, and large language models (LLMs) aiding in the application of scalable, compliant, and interoperable AI systems in regulated areas. The proposed solution would work well to align the call bot with the Industrial Internet of Things (IIoT) standards, the industry 4.0 principle, and the objectives of Pharma 4.0, which makes it evident in terms of efficiency in operations, human-machine interaction, and data-driven responsiveness in smart manufacturing environments. These results establish a basis on which conversational AI agents will be developed and deployed in the regulated industrial automation environment in future.

Section I: INTRODUCTION

The process of transformation of the pharmaceutical manufacturing industry, in general, and pharma and MedTech and biologics manufacturing industry, in particular, is being caused by the industry 4.0 and its industry-specific development, Pharma 4.0 (Graham, 2024). Such frameworks promote the adoption of the most recent digital technologies including the Industrial Internet of Things (IIoT), cloud computing, machine learning, and cyber-physical systems to facilitate smart, flexible manufacturing settings (Qiu et al., 2025). Even with such developments, the Pharma and MedTech industry is still struggling with unacceptable levels of inefficiency, such as batch failures, process deviations, and dependency on manual interventions because of disparate data environment and legacy systems (Kodumuru et al., 2025a). Conventional methods of quality management based on the compliance with SOPs, late root cause identification, offline auditing cannot satisfy the needs and requirements of dynamic production processes due to high throughput production lines (Toh and Chiu, 2013). Moreover, compliance and traceability of information and the ability to initiate corrective measures in real-time are also critical to complete digitalization of workflow in such a highly regulated context.

This study presents an integrative framework that can take advantage of three underlying paradigms to overcome such challenges. First, digital plant maturity model (DPMM), a diagnostics and transformation tool developed by the BioPhorum and ADMA TranS4MErs initiative is modified to suit the pharmaceutical manufacturing to evaluate digital readiness and implement an incremental digitalization process involving a sequence of successive transformations that will evolve processes within the five levels, including basic element of digitization to full-scale adaptive smart factories (BioPhorum, 2018, IMR, 2024). ADMA TranS4MErs (A European project assisting small and medium-sized enterprises (SMEs) in digital transformation) offers the DPMM as a systematic framework, although this suggests its use is adapted to pharma manufacturing as such and is independent of commercial interest (IMR, 2024). Second, Unified Namespace (UNS) is a contemporary data architecture applied to substitute its predecessor point-to-point integration with the single real-time source of data flow within plant systems (Péter, 2024), which includes manufacturing execution systems (MES), supervisory control and data acquisition (SCADA), enterprise resource planning (ERP), and computerized maintenance management systems (CMMS) platforms. Third, digital transformation (DT)—virtual replicas of physical processes, assets, or entire systems that simulate operational behavior using live and historical data—are enhanced with AI-driven conversational agents (Trivedi et al., 2024). These agents enable not only monitoring and prediction but also natural language interaction with human operators, providing contextual recommendations and reducing cognitive load.

This current research builds on but remains independent from the ADMA TranS4MErs framework, focusing on a doctoral-level extension that customizes DPMM specifically for Pharma and MedTech environments and integrates it with plug-and-play DT architectures and AI tools. This integration addresses real-world manufacturing problems unique to pharma and MedTech, such as the inability to retrieve non-owned or semi-structured data (e.g., from third-party SCADA systems), operator dependency on decision-making due to complex processes, and the lack of predictive quality control tools tailored to Good Manufacturing Practice (GMP) environments. This study aims to identify existing UNS solutions and explores the adoption of AI bot within Pharma and MedTech settings. By combining existing solutions concerning UNS, adopting AI call bot, and AI-human collaboration into one scalable, interoperable architecture, this research advances theoretical knowledge in pharmaceutical informatics, digital quality systems, and adaptive manufacturing, and practical capability for regulated manufacturing under Pharma 4.0.

Section II: LITERATURE REVIEW

2.1 Biomanufacturing Industry

Bioprocessing 4.0 refers to the increased application of cutting-edge digital technologies in the biomanufacturing industry. This concept is triggered by the Industrie 4.0, which originated in Germany in the vicinity of 2010 (Demesmaeker et al., 2020). That initiative was aimed at the modernization of manufacturing through linking production systems, supply chains (Arden et al., 2021), and business operations with the help of the Industrial Internet of Things (IIoT) (Isoko et al., 2024). The idea was to design intelligent, automated factories that could manufacture a large range of custom-made goods in a most effective way (Isoko et al., 2024). Nevertheless, biomanufacturing was not originally encompassed in these progresses and nowadays the industry is still passing through the third industrial revolution.

The digital maturity of biopharmaceutical manufacturing has been altered over the years as shown in figure 1. At the beginning, the main production was manual, and the main production control ran using paper-based systems to handle batch ones. Regulatory changes by the U.S. Food and Drug Administration (FDA) over the years, subsequently harmonized by the International Council of Harmonisation (ICH) propelled the sector slowly into automation and use of digital tools- heralding the entry of the industry into the industry 3.0 era. Whereas this industrial revolution led to mass production in some industries such as oil and gas where high production is of prime importance, biomanufacturing adopted a different path. The sector started to adopt smaller and leaner infrastructure, giving prominence to bioprocess intensification. The benefit of such an approach is creating smaller and modular production modules because they can produce a wide variety of pharmaceuticals, but with the reduced use of resources and thus with an increased output (Kumar et al., 2020).

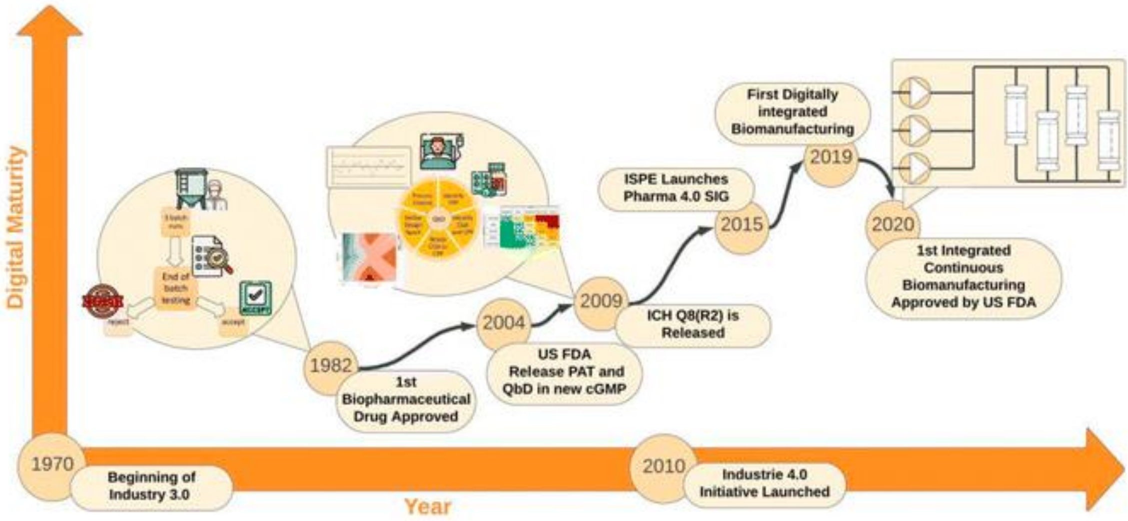

Figure 1: Digital integration progression within biomanufacturing sector from 1970 onwards (Isoko et al., 2024)

Advancements, especially in the last decades, in the form of a one-time use system, plug and play, and better cell-line technology, resulted in substantial productivity gains. As an example, due to these developments up to 5-gram per liter can now be achieved, using single-use bioreactors and optimized cell lines so that a 2000-liter bioreactor is as powerful as a 20 000-liter bioreactor a few decades ago (Subramanian, 2021). These low-volume upstreams also make downstream processing easier, a factor that adds to the attraction of current single-use systems.
This transition has also been facilitated with breakthroughs in integrated continuous based biomanufacturing (ICB) platforms. Such systems generally consist of such features as N-1 bioreactors, perfusion production, multicolumn and simulated/true moving bed chromatography, and single-pass tangential flow filtration. One of the major breakthroughs was also in 2019 when BiosanaPharma developed the first monoclonal antibody (mAb) using a fully integrated continuous process (Subramanian, 2021). This process was said to reduce manufacture schedules, fix yields and reduce costs as compared to the typical batch production (Isoko et al., 2024). Regulatory support has also been provided as continuous processing has seen the launch of guideline Q13 in 2023, which endorses the use of continuous processing in the pharmaceutical industry (Martagan et al., 2024). New technologies became widely adopted in the biomanufacturing industry at a remarkably quick pace bearing in mind the trends illustrated in Figure 1, even though it is a relatively young industry.

2.2 Need for Call Bots in Pharma Operations

The increasing complexity of operational environments in industries, particularly in the Pharma and MedTech manufacturing sector, has underscored the need for intelligent call bot systems to supplement or replace traditional human-operated help desks. Several organizational issues warrant the use of AI-driven call bot assistants in this regard (do Nascimento et al., 2023). The delicate nature of cleanroom operations means that human operators who work in Pharma and MedTech facilities may differ in terms of skills and training; they may lack situational expertise when compared to others in the same location (Kodumuru et al., 2025b). When it is essential to provide high pressure atmosphere with contamination risks of primary concern, the lack of skilled workers may have devastating effects on decision making procedures and timeline of resolving the issue. A study by (Lech, 2022) observes that knowledge asymmetry among human agents creates uneven service delivery and extends the resolution of problems particularly

situations where the new staff is not properly trained or when the experienced workforce changes the organization. This is essential, especially in Pharma and MedTech production where any delays may jeopardize the production, harming the safety of the products.
On the same note, companies tend to have massive databases of Standard Operating Procedures (SOPs) that lack an easy-to-use context, which is compounded by the fact that time is of the essence in a clean environment (Bauer, 2016). The challenge does not just consist in finding the right document, but also on how to interpret and work within the time allocated by the instructions, particularly within the limitations of GMP. According to (Bernhardt, 1995), the manual documentation systems are not efficient in supporting real time because of the search restrictions and cognitive overload on the users who must meet the deadline. A normal procedure of animation of human provision in such environments can take a few hours as caregivers require time to get acquainted with the problem, read various documents or consult different services to develop feasible approaches.

Although chatbot systems are becoming more and more widespread, most of them are non-interactive and appear to be static and users must read long text and understand what to do without any context relevant information (Biancofiore et al., 2025). Such systems are more of an FAQ retrieval system than intelligent assistants, and they are not enough to handle the dynamic requirements of Pharma and MedTech production (Yadav et al., 2024). In research conducted by (Izadi and Forouzanfar, 2024), traditional chatbots do not exhibit the capability to adapt cognitively and frequently disappoint the users with fixed conversation patterns and inadequate customization. Further, AI-based call bot with Natural Language Processing (NLP), speech recognition and conversational intelligence is providing a transformative change in call center-based real-time helpless system (Pothuri, 2024). Such models can understand the speech and place it in context, interpret user input, and give dynamic responses or even automate the implementation of the solution to the specifics of the Pharma and MedTech environment.

In comparison to the classic chatbots, intelligently developed AI call assistants, including GPT, BERT, or those trained with a segregated corporate approach, can converse meaningfully and ease the cognitive burden by engaging operators in interactive process optimization (Woodruff et al., 2024). Whereas conversational AI addresses this problem by learning on domain-specific data to deliver quick, accurate and personalized responses at a rate faster than human agents or traditional bots do (Kusal et al., 2022). These systems can also engage in real-timely learning as well as sustained adaption, something that is suitable in the dynamic operational environment of Pharma and MedTech manufacturing whose operational context demands process deviations and equipment failures which need urgent actions. As a result, the inefficiency of the operations due to the human factor, the delay in the retrieval of SOPs, the impossibility of chatbots due to the inactivity of the system make a strong argument in favor of AI-powered call bots (Durach and Gutierrez, 2024). The systems are scalable, intelligent and interactive, which improves real-time support and the decision-making process that fits the Pharma and MedTech manufacturing requirement.

Figure 1 shows this overview of the AI agents through a single conceptual framework with the ability to display intelligent behavior based on the features autonomy, reactivity, proactiveness, and social ability by being a computational entity (Deng et al., 2025). Such agents engage with their users and environments to pursue certain objectives through their perception of inputs, reasoning on objectives, planning and taking actions with the use of internal tools and external tools. The paradigm divides the workflow of the agent into two important aspects intra-execution and interaction. The three processes within intra-execution include perception, whereby the user inputs are re-formatted through prompt engineering to improve quality; brain where large language models are combined to reason and plan their way to determine information and develop strategies, and action whereby the external tools are called to execute the actions. The component of interaction, in its turn, deals with the relations of the agent to other agents, memories, and environments, involving external means of assistance with the performance of tasks. This framework, based on pioneering work on intelligent document retrieval and computer assistants, has been greatly enhanced with large language models, and can perform its tasks in a variety of domains, such as Pharma and MedTech production.

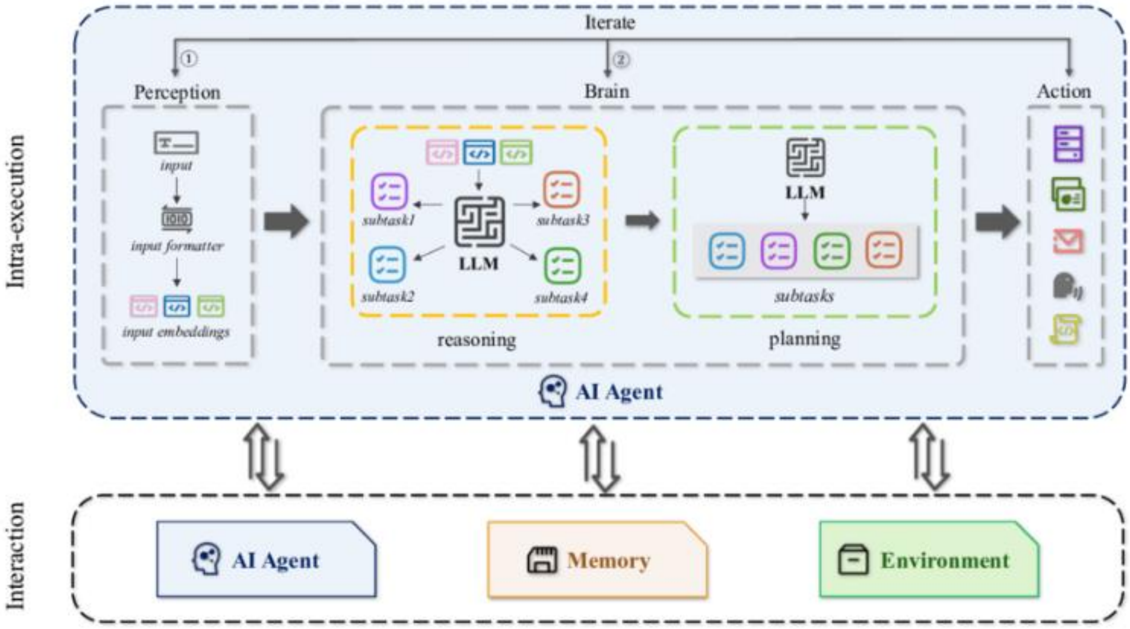

Figure 2: General workflow of AI agent
(Deng et al., 2025)

2.3 Requirements for AI Call Bot Systems

The creation and installation of an AI-based call bot manufacturing Pharma and MedTech are multifaceted tasks of interdisciplinary character that predominantly need not only modern AI models but also the fully developed, information-rich infrastructure. The availability, quality and integration of different types of data which depict the working environment, physical infrastructure, labour skills and past maintenance trends determine the performance and reliability of such systems (Austerjost et al., 2018). AI call bots and their variants, including those established to apply to industrial, manufacturing, tech support, and field service contexts such as the Pharma and MedTechs field, need to be capable of querying, interpreting, and responding to data which reflects the status of assets, including the accumulated knowledge of the institution (Tanzini et al., 2023). Without this, their responses are likely to be generic, inaccurate, or contextually irrelevant, leading to inefficiencies or even operational failures that could compromise product quality.

2.3.1 Real-Time Data from Field Devices and Sensors (Industrial IoT Integration)

The integration of real-time telemetry data from field devices is foundational to AI call bot functionality in Pharma and MedTech manufacturing (Okuyelu and Adaji, 2024). Modern operational technology environments rely heavily on Internet of Things (IoT) and edge devices that continuously monitor variables such as temperature, pressure, humidity, and particulate levels—critical factors in cleanroom operations (Dhone et al., 2023). These data streams form the dynamic context in which the AI call bot must operate to ensure compliance with GMP standards.

For instance, if a cleanroom raises a humidity alert, the AI call bot should be able to:

- Cross-reference the humidity level with historical fault patterns specific to Pharma and MedTech processes.

- Review the current environmental conditions and equipment status.
- Recommend predictive or corrective action in real time, such as adjusting HVAC settings (Kumar et al., 2024).

This requires seamless data pipelines from IoT platforms into the AI assistant's decision engine (Vani et al., 2024). (Bogdan and Pedram, 2018) emphasize that such integration creates "cognitive cyber-physical systems," enabling automated, intelligent decision-making that is contextualized to real-time conditions. Without such integration, the call bot is reactive rather than proactive, unable to offer insights beyond static documentation, which is inadequate for the Pharma and MedTech sector's stringent requirements.

2.3.2 Access to Comprehensive Asset Documentation and SOPs

AI call bots must be trained and connected to a centralized repository of machine and process documentation, including but not limited to:

- Equipment manuals and wiring diagrams for cleanroom machinery
- Troubleshooting guides specific to Pharma and MedTech production
- Standard Operating Procedures (SOPs) compliant with GMP
- Process flow diagrams for batch manufacturing
- Bill of Materials (BOMs) for raw materials and components (Hasan et al., 2017)

However, the mere availability of these documents is insufficient. The AI system must have semantic understanding capabilities to extract relevant procedural steps and technical constraints, particularly those related to contamination control and sterility assurance. For example, resolving an issue in a filling machine may involve retrieving a specific SOP, understanding the procedural dependencies (e.g., sterilization protocols), and adapting instructions to the equipment variant in use (Nimitwongsin, 2014). (Hasan et al., 2017) argue that document-aware AI diagnostic systems enhance human–machine collaboration, reduce the need for manual lookups, and dramatically cut downtime caused by information retrieval delays. Furthermore, documents must be structured, digitized, and enriched using metadata tagging to support rapid NLP-based querying. Legacy systems using PDF-based archives without structured tags severely limit AI assistant performance, a common issue in older Pharma and MedTech facilities.

2.3.3 Historical Maintenance Reports and Annotated Fault Logs

An effective AI call bot must also learn from the organization's historical problem-solving experiences, particularly those relevant to Pharma and MedTech manufacturing (Yadav et al., 2024). Maintenance reports, work orders, and annotated logs from past incidents offer valuable supervised learning datasets for training predictive models tailored to cleanroom operations.
These logs provide:

- Symptom–cause–solution patterns specific to Pharma and MedTech equipment failures.
- Frequently failing components, such as seals or valves in filling lines.
- Repair durations under GMP constraints.
- Technician recommendations for contamination prevention.

Moreover, (Landauer et al., 2023) showed that annotated historical logs can be used to improve fault recognition accuracy when incorporated into deep learning diagnostic models. Additionally, patterns from these logs support root cause analysis and anomaly detection, which are essential capabilities for intelligent support systems in sterile environments. Importantly, such data must be continuously updated to reflect evolving equipment and processes, a necessity given the rapid technological advancements in Pharma and MedTech production.

2.3.4 Skill Matrix and Human Resource Intelligence

One of the most significant parts of the AI call bot implementation in the production of Pharma and MedTech products is the information about the human workforce that represents real-time skill and availability matrix added by (Hadiyanto and Anggoro, 2024) and (Yin, 2024). In instances when an issue cannot be solved independently, either because of the regulatory nature or intricate departures, the AI call bot would need to push the problem over to the most appropriate encountered technician.

To do this effectively, it must understand:

- Technician certifications and competencies, like cleanroom experience or GMP training.
- Training history and experience level specific to Pharma and MedTech processes.
- Shift schedules and geographic location within the facility.
- Escalation protocols compliant and hierarchy role hierarchy with regulatory standards.

It will allow the bot to direct questions or alerts the appropriate human expert-a necessary step to any effort to minimize system outage and achieve accountability within a GMP-regulated context. The authors (David et al., 2024) and (Shamim, 2025) have showed how the integration of human resource data in predictive maintenance scheduling systems lowered Mean Time to Repair (MTTR) and improved overall equipment effectiveness (OEE). In very controlled industries such as Pharma and MedTechs, the ability to escalate to an unqualified technician can be in violation of compliance and hence this is necessary safety, and compliance must.

2.3.5 Training on Domain-Specific Conversational and Operational Data

Generic language models e.g. GPT or BERT should be adapted to work in the domain of Pharma and MedTech manufacturing, adopting corpora of the manufacturing domain. This includes:

- Historical conversation logs between operators and support staff in cleanrooms.
- Annotated chat transcripts from help desk tickets related to sterile processes.
- Maintenance call dialogues specific to GMP-compliant equipment.
- Troubleshooting Q&A knowledge bases tailored to Pharma and MedTech production (Gouveia et al., 2015).

Fine-tuning enables the AI call bot to use domain-specific language, understand unique problem descriptions (e.g., contamination events), and replicate the decision-making styles of experienced human experts in sterile settings (Souto et al., 2020). In the absence of personalization, AI bots can misunderstand, miss important signals (e.g. sterility compromise), suggest unsafe recommendations that do not conform to GMP (Huynh-Ba, 2022). Besides, the AI call bot-based Pharma and MedTech manufacturing is not a software engineering project, but an organizational transformation based on data. It needs centralization of field real-time data, high integration with data asset and maintenance, access to future history of problem-solving cases, and knowledge of human expertise availability. These data assets should be critically structured, accessible and kept up to date to comply with the requirements of the GMP (Chowdary and George, 2012). Organizations with plans of implementing AI call bots should therefore invest not only in AI infrastructure, but also in knowledge engineering, data governance and processes digitization. When approached in the right manner, it will lead to the creation of smart assistants that will change the reactive maintenance approach to predictive, responsive, context-sensitive support providers geared towards the sterile global injectables industry.

2.4 Key Data Collection and Interoperability Challenges

The process of gathering information on the security of AI agents in the production of Pharma and MedTechs involves several issues that can influence the manufacturing and implementation of secure and reliable AI programs (Machal, 2024). These are the challenges imposed by the complications of combining data between various sources, compatibility with the current technologies of AI, and security within different working conditions. Specifically, in the discussion below, each challenge is presented within the perspective of AI agent security, delving into the complexities of data collection in sterile environments.

2.4.1 Ageing Infrastructure

The problem of ageing infrastructure significantly impairs the proper collection of data that is used in the field of AI agent security in Pharma and MedTech facilities. The operation environments most of them use are legacy systems, which use older hardware and software, including older SCADA systems, many of which are not compatible with newer AI technologies (Babayigit and Abubaker, 2023). Such systems cannot offer timely and correct data efficiently and it is challenging to train AI representatives to safely process multistep user inputs or adversarial attacks, including prompt injections, in cleanroom services (Korodi et al., 2024). The unmentioned execution states in these legacy systems have further impeded audit and safeguarding of processes involved in AI agents which create partiality or unreliability of the data set that compromises the integrity of the AI programs in ensuring sterility.

2.4.2 Technology Migration

Technology migration, also known as migration of legacy systems, to new platforms poses major areas of data collection (Gholami et al., 2017). AI agents are often used in multiple development, deployment, and execution stages, which results in different data formats and protocols during migration. As an illustration, migration of the SCADA data in older systems to cloud-based systems in Pharma and MedTech facilities may create vulnerabilities, including prompt injection attack with indirect verification, unless external sources are adequately sanitized (Wali and Alshehry, 2024). These discrepancies cause issues when retaining data integrity and security which affects the reliability of the AI agent output and its capability to work within cleanroom environments.

2.4.3 Regulatory Compliance

In the collection of data to address AI agent security in Pharma and MedTech manufacturing, one of the vital obstacles is set on ensuring regulatory compliance. The access of external data, such as web plugins or third-party APIs, should be strictly regulated with the regards to data protection and user privacy relative to the requirement, such as the General Data Protection Regulation (GDPR) or the United States Food and Drug Administration (FDA) 21 CFR Part 11 to avoid any kind of penalty or ensure reliability (Narang, 2018). The inability to meet standards could deny the availability of essential files, particularly in a field as sensitive as Pharma and MedTechs, where the use of AI agents is gaining prominence as the new avenue of quality control. The efficacy of tool use audit is necessary to ensure that the compliances have been adhered to avoid incurring risks of data leaking out or being accessed by an wrong person but implementation is tricky without interfering with the performance of the systems (Jolly et al., 2013).

2.4.4 Workforce Limitation

The shortage of workforce that has specialized skills and capabilities in AI security and legacy system management is a key obstacle to productive data collection in Pharma and MedTech facilities (Santosh et al., 2025). The compound nature of the workflows in terms of intricate internal executions of AI agents cannot be executed without specialized personnel or expose the process to the threat of auditing and securing the system against a back door attack or misalignments of the LLMs. Another key obstacle to successful data collection in Pharma and MedTech manufacturing hubs is a shortage of knowledgeable personnel capable of competent expertise and skills in the realms of AI security and legacy systems management (Huynh-Ba, 2022). These intricate processes requiring complicated internal implementation of AI agents cannot be executed without technical expertise or subject to auditing and security of the process against a back door exploit or failure to align the LLMs.

2.4.5 Poor Data Integration

The main limitations of data integration which seriously complicate the data collection work in Pharma and MedTech manufacturing are poor data integration due to the point-to-point integration complexity and wide variety of different protocols (Alfred et al., 2021). This failure of identification of valid and invalid system instructions that are presented by external resources causes security vulnerabilities like those used in the indirect prompt injection attack, which may be an issue to sterility (Zürcher et al., 2022). Point-to-point connections can create data silos, even though the time differences between the sampling of data in SCADA and MES can further worsen data silos, thus making it impossible to view current state of operation of the AI agent with a centralized picture (Casian et al., 2022). These problems compromise the possibility of training AI agents to cope with real-time threats efficiently, which decreases their general security and performance in cleanrooms.

2.4.6 Improper Asset Lifecycle Management

Other barriers to data collection in Pharma and MedTech manufacturing plants include the lack of digital silos and inefficient methods to deal with legacy systems because of improper asset lifecycle management (Dhingra et al., 2020). Uncontrolled assets, including old cleanroom equipment or external tools that cannot be followed, could add behavioral variations in AI agents running in diverse operational settings (Sandle, 2024). Unless the data on these assets is well managed in terms of their lifecycle, this information might be inaccurate or incomplete and influence the way an agent treats this information when reasoning and planning securely, particularly when a GMP must be complied. This may be complemented by stringent audit tools used to test transparency, but inclusive adoption of comprehensive asset management must be implemented so that all sources of data can be secure and accounted during their lifecycle.

2.4.7 Adapting to Change

A particular issue in data collection around AI agent security is the resistance to change amid the stakeholders, such as users and developers of facilities involving Pharma and MedTechs (Sujan et al., 2022). Unpredictability of multi-step user interactions involving inadequately specified or malicious user inputs that might serve as the trigger point in creating a cascade of security concerns makes the scenario worse due to unwillingness to implement new information gathering patterns or security measures (Bianchini et al., 2019). The trend of shifting to newer frameworks to scale the older legacy frameworks is typically rebuffed because it becomes hard to implement safeguards like source recognition on the rise to secure external inputs (Pereira et al., 2021). To overcome such resistance, organizational commitment and training should therefore be inculcated to ensure alignment of data collection practices to modern security concerns within cleanroom operations.

2.5 Non-Owned Data: Availability and Value

The safety of AI agents in Pharma and MedTech manufacturing processes is tremendously profound in terms of non-owned data that are created and controlled by other systems, or third parties, and are supplied with the support of SCADA, MES, and asset management software (Ashok and Rama, 2020). They are data scattering, format deviation, and top-level logging, low accessibility, and hamper the establishment of security and reliable AI agents (Chen et al., 2024). Combining the non-owned data complicates the possibility of being exposed to vulnerability, e.g., to adversarial attack, data leak, and to adhere to regulatory standards. Below we show a critical review of the problems that each type of non-owned data might produce, highlighting their consequences as regards the implementation of AI agents in Pharma and MedTech contexts.

2.5.1 Electronic Batch Records

The SCADA or MES layers offer electronic batch records that are important in tracking Pharma and MedTech based production manufacturing processes yet they have widespread distribution within the systems (Marsh and Eyers, 2016). The records normally lack manual interactions like an operator operating a hand valve in cleanroom resulting in incomplete datasets (Alfred et al., 2020). Such incompleteness may lead to AI agents misunderstanding process states, and either making wrong decisions, or unsafe actions, which endanger sterility. As an example, an AI agent involved in optimizing a filling line would not have considered the unregistered manual interventions, which makes the process more likely to be affected (Ajmal et al., 2025). The SCADA systems and MES systems also do not support good data formats that can be utilized to integrate them, implying that high preprocessing methods are necessary to guarantee that the data quality is acceptable (Ashok and Rama, 2020). In the absence of strong data validation protocols, adversarial inputs (which may be as simple as prompt injections) can be used to target databases of batch records (Malik et al., 2024). Figure 2 demonstrates the data traffic within the hierarchy of a plant, which indicates a high (90%) reduction of the data level between sensors and ERP, which may pose concerns about implementing AI agents in Pharma and MedTech environments (Chen et al., 2020). Although the hierarchical system makes it convenient to manage on higher levels, it trades granularity to make management secure, which are risky and require complex solutions such as UNS and DT. It is important to consider these issues to build a strong MVP of an AI call bot agent that will allow the use of extensive data in predictive and adaptive capabilities.

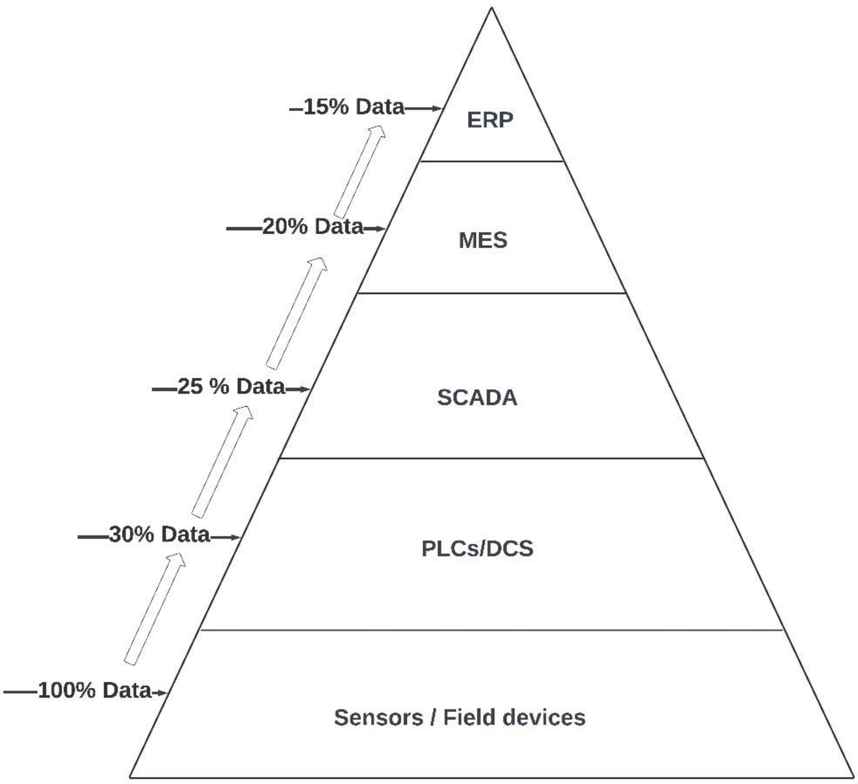

Figure 3: Data flow in the plant Hierarchy (Chen et al., 2020)

2.5.2 Machine and Equipment Performance Data

Transient operational modes, such as short bursts, brief pauses, and the micro-deviations in the performance of cleanroom equipment, are important machines and equipment performance data used to monitor equipment health during Pharma and MedTech manufacturing but are not trivial to measure as transient phenomena (Vaez et al., 2023). This is usually not recorded given the fine-grained sampling necessary to record these transient states which can often be missed due to standard SCADA and MES systems (Ashok and Rama, 2020). This constraint blocks the performance of real-time anomaly requisition by the AI agents, like equipment failures that may impact the sterility, thereby making the operation of AI hazardous. This problem is compounded by the inconsistency of data sampling practices in different systems, so developing coherent data sets to train strong AI is a challenge. As an example, an AI agent that aims at predictive maintenance might fail to notice crucial micro-deviations within a lyophilizer and make it less effective (Ucar et al., 2024). Although high frequency sensors and real time analytics proposed by (Jaime et al., 2023) are necessary, they should be balanced with computational and security measures to avoid vulnerabilities such as data tampering.

2.5.3 Process Execution Deviations

Process compliance repositories at MES level include process denied or varied execution, which is critical in determining Pharma and MedTech workflow anomalies (Manger, 2019). Nevertheless, these systems cannot provide fine-grained analysis due to high-level logging formats and sampling techniques. As an example, a deviation entered in a compliance repository might lack sufficient contextual information, like environmental conditions during the deviation, to identify the cause, which makes it more difficult to trace the event to insights that can be turned into action (Spindler et al., 2021). This complexity is further compounded by the unlimited formats attributed to repositories that can potentially lead to inconsistency in AI agents in their behaviour. In addition, insertion of data deviation in non-owned systems places it under great risk of malicious infiltration, such as the indirect prompt injection attack where non-confided information could be used to cause incorrect judgments in AI and cause sterility (Zephrani, 2019). The homogeneity of the logging mechanisms and the real-time sensitivity to anomaly is crucial in developing greater security and trust in the safe AI agents where deviation data is processed.

2.5.4 Environmental Micro-Fluctuations

Micro-variations of the environment such as fluctuation in temperature or moisture as measured in the Asset management software e.g. Blue Mountain are a significant aspect of ensuring the best conditions in cleanrooms of Pharma and MedTech (Ahmed et al., 2024). Nonetheless, the nontrivial logging formats at higher levels of these systems offer a limited use of analysis (Miranskyy et al., 2016). In another instance, an AI agent trying to optimize environmental controls can misinterpret micro-fluctuations on the absence of complete data and can cause unsafe decisions such as temperature control errors that violate sterility levels. The fact that the availability of this data depends on systems that do not belong to us creates security issues, including the leakage of the data or hostile input, especially in cases where the ability to properly clean up external resources is not available (Vaez et al., 2023). The lack of digital silos is also a problematic factor in integration because environmental data are generally present in disjointed repositories which make achievable access to information in real time impossible. To address challenging dynamic cleanroom operating environments, secure data retrieval machinery and fine-grained logging are needed so that AI agents can perform reliably.

2.5.5 Visual Inspection Results

Visual inspection outcomes, which are usually provided by human operators or third-party systems in Pharma and MedTech production, pose a major issue as they are qualitative and non-standardized (Jambon et al., 2024). Such findings are not usually coded into digital processes and hence, it becomes cumbersome to integrate them into the workflow of an AI agent, without rigorous preprocessing (Melchore, 2011). An example would be when an AI agent dealing with quality assurance would miss out on defects in pre-filled syringes due to vague or incomplete inspection databases resulting in a greater likelihood of unsafe results impacting product quality. The fact that this data should be obtained with the help of outside sources also increases the security risks, including immediate leaking attacks, where crucial inspection information may be disclosed (van den Born-Bondt et al., 2025). Such proposals of automated visual inspection systems with a standard data format would alleviate these challenges provided measures are put in place to ensure security in the framework of such inspection systems.

2.5.6 Material Handling and Inventory

Pharma and MedTech manufacturing and logistics require that AI agents have real-time information on handling and inventory data information such as material type, frequency of use, movement, small uses, spill up, and conditions during transportation or storage (Ahmadi et al., 2019). These data are usually distributed to non-owned systems, such as MES or a warehouse management system, at different rates and with different protocols (Pethappachetty et al., 2025) . Such as, an AI agent that optimizes inventory would not consider small spills or in real time material status (e.g. temperature excursions in transportation), so would not plan correctly or do things dangerously to affect sterility.

2.5.7 Reserve Availability and Engagement

The availability of reserve assets and participation, especially, human assets and skill-mapping matrix in an AI call bots, which aims to solve problems and prioritize the tasks in the Pharma and MedTech facility, are of paramount importance (Parlikad and Jafari, 2016). Such bots will need access to data outside their ownership like the skill matrices and engagement status of the employee, typically present in the human resource systems. Nonetheless, the decentralized distribution of such data, as well as privacy and regulations compliance (e.g., GDPR, FDA 21 CFR Part 11), is problematic (Narang, 2018). As an example, an AI bot recommending ways to resolve a problem in a cleanroom would have to combine skill matrix data as a way of identifying the appropriate persons to use but there is the possibility of these data being leaked out in case of prompt leaking attacks unless it is fully secured. The main importance of data integration frameworks that are secure and preserve privacy, and a uniform blank text of skill matrices is to make the AI agents perform their functionality responsibly in workforce management.

2.5.8 Operator Action and Efficiency Matrix

The matrices of operator action and efficiency that monitor the performance of operators and their interactions with the industrial systems of the Pharma and MedTech plants are usually kept in non-owned systems such as MES or human-machine interfaces (Lee and Ahmed, 2021) (Oliveira and Lopes, 2020). These systems have unstandardized sampling rates and logging formats that are high-level making them unreliable for analytical purposes. When incomplete information is used to plan workflows by an AI agent, it could not assume that fulfilling sterility and less sterility actions by the operators could generate suboptimal operators. Indirect prompt injection attacks represent a potential threat of malicious data injection by the means of external interfaces because of the utilization of non-owned systems.

2.6 DPMM Concept as a Potential Solution

DPMM provides a systematic approach to solving the problem of non-owned data integration and AI agent security in Pharma and MedTech production, especially on designing a predictive and adaptive AI call bot agent (Xia et al., 2021). DPMM achieves these qualities by advancing through the five-maturity level pre-digital, digital silos, connected plant, predictive plant, and adaptive plant (Alzoubi et al., 2022). The model can use the UNS and high-end DT concepts to address data ownership challenges, difficult integration and security challenges inherent within the Pharma and MedTech environments. The following critical discussion of the main elements of the DPMM solution as well as the necessity of UNS and DT is presented below and a Minimum Viable Product (MVP) structure of implementing an AI call bot agent is proposed.

a. Need for Unified Namespace (UNS)

UNS serves as a centralized, real-time data architecture that integrates disparate data sources, including non-owned data from SCADA, MES, and asset management systems, into a single, accessible framework for Pharma and MedTech manufacturing (Péter, 2024). UNS addresses critical challenges in industrial data management, enabling AI agents to operate securely and efficiently (Péter, 2024). Industry 4.0 is a

centralized storage that can disseminate and link different networks, machines, and devices in the industrial processes. UNS acts as the centralized hub that consolidates the stream of the real-time data about systems and processes, including statuses, metrics, and control signals, and will enable this data to be available to every part of the organization and provided to the staff operating it, and made available to enterprise-wide analytics systems (Chen, 2018). UNS integrates the various data sources and eradicates the traditional silos whereby various departments or systems have a different communication protocol hence allowing effective and synchronous data sharing of the entire operation (Mäule et al., 2024).
This functionality supports sophisticated applications, such as predictive maintenance, prescriptive maintenance, digital twins and Overall Equipment Effectiveness (OEE) monitoring (Salcher et al., 2024). Under predictive maintenance, UNS offers specific and properly timed data now when it is requested, unlike prescriptive maintenance that furthermore simulates maintenance events and gives data-based guidelines on what should be done in terms of corrective measures (Freitas et al., 2025). Nevertheless, data standardization efforts, interfacing with legacy systems, and cybersecurity issues can be described as the challenges that hamper the adoption of UNS. These issues, and knowledge gaps, including insufficient research concerning edge analytics computation, scalability, and the use of UNS towards achieving sustainability, are the areas that ought to be solved to realize the potential of UNS (Keskin et al., 2025). The elimination of these obstacles can next go a long way towards industrial maintenance being improved in UNS and the general Industry 4.0 perspective, metaphorically speaking, there is more to industrial maintenance and optimization as it pertains to its operational efficiency as well as system reliability.

b. Need for Digital Twin

DT concept, a virtual representation of physical resources and forms, is necessary to translating and joining information inside the DPMM system for Pharma and MedTech fabricating. Advanced DT upgrades information analytics, recreation, and automation, empowering AI operators to provide prescient and versatile capabilities (Haber and Carmeli, 2023). Unlike UNS, which centers on information accumulation, DT gives relevant experience by modeling complex intelligent between hardware, procedures, and operators in cleanroom settings.
Advanced DT coordinating real-time information from UNS to recreate transitory operational states, natural micro-fluctuations, and handle deviations, tending to the restrictions of high-level logging in MES frameworks (O'Connell et al., 2023). For occasion, a DT can model equipment execution to foresee failures in a sterile filling line, empowering an AI call bot to proactively alarm operators. In any case, making precise DT requires high-fidelity information and computational assets, which may be compelled in bequest Pharma and MedTech situations (Haber and Carmeli, 2023). Moreover, DT must consolidate security measures to anticipate ill-disposed control of reenactment yields, such as untrue forecasts that might deceive AI operators and influence sterility. Additionally, the Advanced DT concept also bolsters automation and reviewing by producing reports and compliance logs, decreasing manual overhead and improving transparency in GMP-compliant operations (Sinha and Jha, 2021). However, the complexity of modeling multi-vendor systems and ensuring interoperability across DT poses challenges, particularly in connected plant scenarios where data sources are diverse (Liu et al., 2024). Continuous validation and updating DT are essential to maintain their accuracy and reliability in Pharma and MedTech contexts.

Section III: REFINEMENT OF RESEARCH-PRACTICE GAPS

The Pharma and MedTech sector reveal critical gaps between AI agent research and practice. Unpredictable multi-step inputs from operators, often due to complex cleanroom procedures, lead to process deviations. Complex internal executions obscure security risks, such as undetected prompt injections, in GMP-compliant systems. Environmental variability in cleanrooms, including micro-fluctuations, affects AI reliability. Untrusted external data (e.g., batch records from third-party SCADA) increases vulnerability to adversarial attacks. Current DPMM applications lack sterile-specific adaptations, and the 90% data reduction from sensors to ERP, as shown in Figure 2, hinders predictive control. These gaps necessitate targeted research to bridge security, data integrity, and adaptability in Pharma and MedTech manufacturing. Below, we analyze the specific issues which are identified.

i. Data Ownership/Collection Issue

In Pharma and MedTech plants, non-owned data, whether the electronic batch record or visual inspection outcomes of third-party systems, tends to be distributed over several external systems, so ownership and collection are made more difficult. The absence of data governance may contribute to future missing sets, which cannot offer an informed decision to the AI agents regarding sterility (Babu et al., 2024). UNS solves this by offering a common data tier which pools together non-owned data, which is accessible but traceable at the same time. Nonetheless, the application of UNS introduces a further aspect of data governance policies to resolve ownership conflicts, and in a multi-vendor environment often seen within pharmaceutical supply chains, this may become expensive (Xia et al., 2021).

ii. Complexity of P2P Integration

The traditional point-to-point (P2P) integration where multiple connections are made tends to lead to a fragmentation of data flows, format variability at risk of encountering errors or security breaches, e.g. PD-induced prompt tool injection attacks that may imply a violation of cleanroom integrity (Federico et al., 2021). UNS also removes the complexities between P2P by being a central broker that can standardize the data exchange mechanism between different systems. This lowers the integration overhead and requires a large upfront investment in middleware and standardization of protocols, which is a challenge to resource-squeezed Pharma and MedTech facilities.

iii. Lack of Comprehensive Digital Strategy

A significant portion of Pharma and MedTech plants has a disjointed digital strategy, causing ad-hoc data management policies that further compound silos and inefficient data management (Hanelt et al., 2021). UNS offers a long-term perspective on digital transformation, because it allows sharing real-time data, as well as interoperability of cleanroom functions. But still UNS adaptation may be stalled by the lack of organizational fit and change management since stakeholders can be averse to changing to new work processes that replace the legacy work practices (O'Connell et al., 2023).

iv. Legacy Plant Structures and Outdated Equipment

Obsolete equipment in older Pharma and MedTech factories, which might also have legacy plant structures, is not well-suited to the requirements of current data collection, leading to incomplete or unreputable records (Chen et al., 2020). UNS has incorporated legacy systems into a new data structure by pulling data out of legacy equipment, including aging autoclaves, via edge gateways. Such a strategy reduces the compatibility problems, but security is a concern that needs to be keenly guarded to avoid weaknesses in data, including data manipulation, when retrieving data (Xia et al., 2021).

v. Workforce Consent and Cooperation

The resistance from workforce to implement new technologies, like UNS, can obstruct data collection exertions, predominantly when integrating skill matrix data or operator action within Pharma and MedTech settings (Haber and Carmeli, 2023). UNS execution entails workforce consent and training to guarantee cooperation, as operators must network with new data interfaces under GMP constraints. Moreover, resistance can be moderated by change management agendas, nonetheless these add intricacy and cost to the disposition process (Hanelt et al., 2021).

vi. Data Security and Privacy Concerns

Non-owned data integration over UNS raises noteworthy privacy and security concerns in Pharma and MedTech manufacturing, comprising risks of adversarial attacks like prompt leaking or data leaks that could affect patient safety (Lee and Ahmed, 2021). UNS discourses these by uniting secure access controls and data transmission protocols; nevertheless, ensuring compliance with regulations remains challenging, chiefly for process or sensitive personnel data (Lee and Ahmed, 2021). In the UNS architecture, auditing and robust encryption mechanisms are critical for maintaining security and trust. Furthermore, UNS serves as a common platform that enables seamless integration of adaptive and predictive systems, facilitating real-time decision-making and continuous optimization by harmonizing data flows from diverse sources within a secure and unified namespace.

Section IV: INITIAL RESEARCH METHODOLOGIES / CONSTRUCTS / CONCEPTS IDENTIFIED

4.1 Study Design

To assess the current setting/solutions of UNS solutions and determine the possibility of introducing predictive and adaptive AI on-call bots in sterile pharmaceutical contexts, the present study adopts a Systematic Literature Review (SLR). The reporting and the planning of the SLR are carried out in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA 2020) guidelines (Ortiz et al., 2021). This technique ensures that all the academic and technical literature available to the study is well integrated, transparent, and replicable, based on its core objectives and research questions (Islam et al., 2025). The primary research question (RQ1) centers on the design and integration of AI bots into DT platforms supported by UNS architecture, whereas the sub-questions (RQ1a and RQ1b) dive into the components of data integration, framework interoperability, compliance, and human-system interaction. The systematic review encourages the comprehensive identification of pertinent studies over numerous domains—namely industrial automation, AI in manufacturing, pharmaceutical compliance, and frameworks interoperability—making it the most suitable methodology for this exploratory however organized investigation.

The basis for utilizing a SLR over other research strategies (e.g., experimental experimentation, survey-based examination, or case studies) is threefold:

- The intersection of UNS structures, AI-driven operator assistance, and pharmaceutical manufacturing presents a novel and generally underexplored area. SLR empowers the collation of divided information over different sources and disciplines (Lame, 2019).
- The research ranges technical (e.g., MQTT, OPC-UA, edge computing), organizational (e.g., GMP compliance), and human-centered (e.g., user interaction, situational awareness) components. An SLR permits multidisciplinary exploration that other strategies might not proficiently support.
- The results of this study point to illuminate a conceptual framework for integrating AI call bots within a UNS-guided digital twin framework. SLR gives evidence-based establishment for such theoretical advancement.

Moreover, the study followed PRISMA guidelines to path this study involving inclusion, exclusion, extraction, data quality, search terms, and related. In addition, the study aims to conduct thematic analysis to identify existing UNS solutions and implementation of AI call bot within Pharma and MedTech settings. As this study is constrained to secondary data obtained from published literature, there are no direct moral concerns concerning human or animal subjects. Nevertheless, care is taken to accurately cite and credit all sources, maintain intellectual integrity, and avoid plagiarism in understanding with institutional and publisher guidelines.

4.2 Search Strategy

A structured search was performed using a combination of keywords and Boolean operators to capture relevant peer-reviewed literature. The strategy was designed to identify research on the application and integration of UNS architectures and AI call/chat bots within Pharma and MedTech manufacturing environments. Databases Searched including IEEE Xplore, Scopus, PubMed, SpringerLink, and

ScienceDirect. Moreover, search strings included combinations of the following: "Unified Namespace" OR "semantic middleware" OR "MQTT integration" AND "AI chatbot" OR "adaptive conversational agent" OR "AI call bot" OR "AI co-pilot" AND "Pharma manufacturing" OR "MedTech" OR "regulated manufacturing" OR "Pharma 4.0". The study period was between 2011–2025.

4.3 Study Selection

All records retrieved were first screened for relevance based on titles and abstracts. Duplicates were removed using reference management software. Full-text articles were then reviewed independently by two reviewers based on the inclusion and exclusion criteria as indicated in Table 1. The selection process followed the PRISMA guidelines and was recorded in a PRISMA flow diagram.

Table 1. Inclusion and Exclusion Criteria

Inclusion	Exclusion
Peer-reviewed journal articles or conference proceedings	Editorials, opinion pieces, marketing blogs, or non-peer-reviewed literature
Studies published in English	Studies not related to Pharma/MedTech or manufacturing
UNS architectures or integration frameworks in Pharma/MedTech manufacturing	Chatbot studies focused solely on patient-facing or customer service use without industrial context
AI-based chatbots/call bots integrated in regulated or industrial environments	Literature not mentioning AI integration or data architecture
Concepts combining real-time data systems and intelligent agents	
Studies focusing on Industry 4.0 or Pharma 4.0 applications	

4.4 Data Extraction

A data extraction form was designed to capture the following key elements from each included study: authors and year of publication, title and source, study objectives, type of AI bot or UNS architecture used, application domain (e.g., Pharma/MedTech, Industry 4.0), deployment details (e.g., cloud-based, edge, hybrid), AI-human collaboration features, and outcome measures or observed impact. All data were reviewed and validated independently by two reviewers to ensure accuracy and minimize bias.

4.5 Quality Assessment

The methodological quality of each included study was assessed using a customized version of the CASP (Critical Appraisal Skills Programme) checklist by considering relevance to the research question, clarity of system design and architecture, evidence of deployment or testing in Pharma/MedTech, compliance with regulatory frameworks (e.g., GAMP, CFR 21 Part 11), and transparency of AI models and explainability features. Each study was scored as High, Moderate, or Low quality based on these criteria. Discrepancies between reviewers were resolved by discussion.

4.6 Data Synthesis and Analysis

A narrative synthesis approach was employed, categorizing studies according to their relevance to the following themes: UNS Integration Techniques: E.g., MQTT, semantic web, OPC-UA, AI Call Bot Frameworks: NLP-based, Transformer-based, or multi-agent systems, Human-AI Collaboration Models, Regulatory and Operational Considerations. Patterns and gaps were identified by cross comparing the architecture, technological maturity, and applicability of each solution. Where applicable, architectural frameworks and components were tabulated or visualized to highlight convergence or divergence across studies.

Section V: CHALLENGES AND CONSIDERATIONS

The integration of big data in pharmaceutical and MedTech manufacturing, particularly within the framework of Pharma 4.0, presents multifaceted challenges that must be addressed to enable the adoption of adaptive AI call bots within a UNS architecture Table 2.

Table 2. Challenges and considerations

Notion	Challenges	Considerations
Data Heterogeneity and Variety	Pharmaceutical and MedTech environments generate diverse data types, including structured data (e.g., Electronic Health Records (EHRs), batch records) and unstructured data (e.g., sensor logs, imaging, and operator notes). Tthe variety of data sources, such as clinical, genomic, and social media data, complicates integration due to differing schemas and formats. This heterogeneity poses a significant barrier to creating a unified data access layer required for a UNS.	Implementing a UNS requires robust mechanisms to handle data variety, such as data lakes or semantic web technologies (e.g., RDF, OWL), which can harmonize disparate data formats. The AI call bot must be designed to interpret and process these diverse data types, potentially leveraging standards like SNOMED CT or FHIR for semantic consistency.
Real-Time Data Processing and Velocity	The high velocity of data in manufacturing settings, such as real-time sensor data from production lines or quality control systems, demands rapid processing capabilities. The speed of data flow, exemplified by 6,000 tweets per second on Twitter, underscores the need for technologies that can handle high-velocity data streams. Traditional batch-oriented ETL processes are inadequate	Data propagation and virtualization techniques, such as those implemented in SparkMed or SAP HANA, can support near-real-time data integration. The AI call bot must integrate with these technologies to process data streams dynamically, ensuring timely responses for operational decisions like predictive maintenance or quality assurance.

	for real-time requirements in adaptive manufacturing.	
Interoperability and Standards Compliance	Interoperability remains a significant hurdle due to overlapping and inconsistent healthcare standards (e.g., HL7, ASC X12). In Pharma 4.0, manufacturing systems must comply with regulatory standards (e.g., GMP, FDA guidelines) while integrating with clinical and quality data systems, which often use different terminologies and protocols.	Adopting standards like FHIR, which supports web-based RESTful protocols, or SNOMED CT for clinical terminology can enhance interoperability within a UNS. The AI call bot must be designed to interface with these standards, ensuring seamless data exchange across manufacturing and regulatory systems.
Data Veracity and Quality	The uncertainty (veracity) of healthcare data, due to incomplete, incorrect, or outdated information, affects the reliability of integrated datasets. In manufacturing, poor data quality can lead to erroneous decisions by AI systems, compromising product quality and regulatory compliance.	Data fusion techniques, as discussed in the traditional data integration process, can resolve inconsistencies by merging duplicate records and ensuring data accuracy. The AI call bot should incorporate machine learning algorithms to validate and clean data in real-time, enhancing the trustworthiness of insights generated within the UNS.
Scalability and Performance	The scalability of integration solutions is critical in Pharma 4.0, where data volumes grow exponentially due to IoT devices and advanced analytics. Pairwise schema matching is not scalable for large, heterogeneous datasets, and performance issues arise in data virtualization due to query load dependencies.	Leveraging scalable technologies like Apache Hadoop, HDFS, or cloud-based data lakes can address volume and performance challenges. The AI call bot must operate within a scalable UNS architecture, utilizing distributed computing frameworks to handle large-scale data processing efficiently.
Security and Privacy	The presence of sensitive data (e.g., patient data, proprietary manufacturing data) would access security and compliance with such laws as HIPAA or GDPR. Security aspects of the cross-cutting	The model of the UNS and AI call bot should contain strong security measures like encryption and access control to preserve data integrity and data privacy. It is also possible to use semantic web technologies, such as OWL, to

	components of data integration scheme.	enable secure exchange of data by standardizing access procedures.
AI-Human Collaboration	Integrating AI call bots into human-centric manufacturing processes requires seamless collaboration to ensure operator trust and effective decision-making. The document does not explicitly address AI-human collaboration but notes the complexity of integrating human-generated data (e.g., recorded conversations) with automated systems.	The AI call bot should be designed with explainable AI principles, providing transparent insights to human operators. Workflow components in the data integration framework can be adapted to include human-in-the-loop processes, ensuring that the bot augments rather than replaces human expertise.

These issues indicate the sophistication in the implementation of an AI call bot in a UNS in the framework of Pharma 4.0. The solution is a multifactor treatment involving high technologies, established protocols, and effective data governance to provide operational perfection.

Section VI: DISCUSSION

6.1 Preliminary Findings

Table 3 demonstrates the conceptual path of research development in the field of medical and pharmaceutical AI, chatbot, and data integration in 2011-2025. The foundational phase began with (Salathé and Khandelwal, 2011), who explored NLP-based public sentiment modeling, setting the stage for contextual AI inputs. In 2013, (Bahga and Madisetti, 2013) introduced a cloud-based, interoperable EHR platform essential for regulated AI systems, while (Mudunuri et al., 2013) advanced distributed data integration across large biological datasets. Likewise, (Fang et al., 2014) extended this work to big data applications in clinical settings, paving the way for targeted AI use cases such as call bots. Semantic applications and big data applications gained major strides between 2015 and 2016. Further (Bellazzi et al., 2015) focused on chronic disease management through big data, and (Mezghani et al., 2015) emphasized semantic integration of wearable health data. The authors (Poulymenopoulou et al., 2015) contributed to health surveillance using semantic ETL techniques. In 2016, (Ceri et al., 2016) proposed genomic data architectures to support AI analytics, while (Bhuvaneshwar et al., 2016) developed the G-DOC Plus platform for integrative bioinformatics.

The focus began shifting toward AI-driven patient interaction, as shown by (Kondylakis et al., 2017) who developed an AI-enhanced patient empowerment architecture. Likewise, (Nadarzynski et al., 2019) conducted a mixed-methods study on the acceptability of AI chatbots in healthcare, and (Holmes et al., 2019) evaluated the usability of conversational UIs in health-related applications.
The period from 2021 to 2022 saw increasing attention to Industry 4.0 and regulatory considerations. The study (Li and Yang, 2021) introduced Bot-X, an AI assistant for intelligent manufacturing with relevance to Pharma 4.0. Additionally, (McDermott et al., 2022) examined how Industry 4.0 affects regulatory aspects of the medical product lifecycle. In addition, (Kühler et al., 2022) attempted the regulatory and technical challenges of connected MedTech products, and (Hsu and Yu, 2022) proposed a medical chatbot architecture based on machine learning and natural language understanding. Moreover, (Ajagbe et al., 2022) integrated AI chatbots into IoMT platforms for real-time diagnostics and data-driven healthcare.

The most recent advancements (2024–2025) reflect a shift toward domain-specific large language models and smart infrastructure. The authors (Babu and Boddu, 2024) introduced a BERT-based medical chatbot aimed at improving communication , while Azam et al. presented PharmaLLM, a prescription-support chatbot leveraging open-source LLMs (Azam et al., 2024). Pintilie et al. contributed an UNS architecture using MQTT and Sparkplug B protocols for pharmaceutical control systems (Pintilie, 2025). Fan et al. reviewed vision-language models for enhancing human-AI collaboration in manufacturing (Fan et al., 2025), and (Kodumuru et al., 2025a) focused on AI-IoT synergy in Pharma, emphasizing regulatory alignment and smart infrastructure.

Table 3. Key Contributions from Included Studies

Year	Author(s)	Key Contribution
2011	Salathé and Khandelwal	NLP-based public sentiment modeling, supporting AI-bot contextual input.
2013	Bahga and Madisetti	Cloud-based, interoperable EHR platform—core to regulated AI systems.
2013	Mudunuri et al.	Distributed data integration across large biological datasets.
2014	Fang et al.	Big data clinical applications—supports focused call bot use cases.
2015	Bellazzi et al.	Big data applications in chronic disease management.
2015	Mezghani et al.	Semantic integration of wearable health data.
2015	P.M. et al.	Health surveillance using semantic ETL.
2016	Ceri et al.	Genomic data architecture supporting AI analytics.
2016	Bhuvaneshwar et al.	G-DOC Plus platform enabling integrative bioinformatics.
2017	Kondylakis et al.	AI-enhanced patient empowerment architecture.
2019	Nadarzynski et al.	Mixed-methods study on AI chatbot acceptability in healthcare.
2019	Holmes et al.	Usability testing of conversational UIs in healthcare bots.
2021	Li and Yang	Bot-X AI assistant for intelligent manufacturing—direct relevance to Pharma 4.0 bots.
2022	McDermott et al.	Industry 4.0's regulatory impact on medical product lifecycle.
2022	Kühler et al.	Regulatory and technical challenges of connected MedTech products.
2022	Hsu and De Yu	ML and NLU-based chatbot architecture for medical communication.
2022	Ajagbe et al.	IoMT platforms—real-time analytics, data-driven diagnostics, AI chatbot integration.
2024	Babu and Boddu	BERT-based medical chatbot for improved communication.
2024	Azam et al.	*PharmaLLM*: Chatbot using LLMs for prescription and patient communication.
2024	Pintilie et al.	UNS architecture using MQTT + Sparkplug B in Pharma control systems.
2025	Fan et al.	Vision-language model survey for human-AI collaboration in manufacturing.
2025	Kodumuru et al.	AI-IoT synergy in Pharma—smart infrastructure with regulatory alignment.

Moreover, Table 4 categorizes the reviewed studies into thematic clusters, highlighting their key contributions to AI, healthcare, and pharmaceutical domains. The largest cluster, AI Chatbots in Healthcare/Pharma (25%), includes six studies focused on natural language processing (NLP), large language models (LLMs), chatbot architecture, and user interaction in regulated healthcare settings. Notable examples include Azam et al. (2024), who developed the PharmaLLM chatbot, and studies by Babu and Boddu (2024), Holmes et al. (2019), Nadarzynski et al. (2019), Hsu and De Yu (2022), and Li and Yang (2021), all exploring aspects such as usability and intelligent assistant design.

The Regulation and Compliance cluster (17%) comprises four studies addressing the regulatory challenges in Pharma and MedTech domains. Kühler et al. (2022), McDermott et al. (2022), Kodumuru et al. (2025), and Pintilie et al. (2024) examined frameworks for digital compliance and the lifecycle of connected medical products. Two studies (8%) fall under the IoMT & Infrastructure cluster, focusing on connected health technologies and smart IoT infrastructures for real-time diagnostics, represented by Ajagbe et al. (2022) and Fang et al. (2014). Under the cluster the Big Data and Interoperability Platforms (17%), are the works of Bellazzi et al. (2015), Bahga and Madisetti (2013), Mudunuri et al. (2013), and Mezghani et al. (2015) that focused on scalable analyses and structural and unstructured health data integration into an interoperable intelligence platform.

Similarly, approximately 13 percent of research titles in the Semantic AI Pipelines & ETL cluster (13%), which deal with the evolution of semantic data transformation and an extract, transform, and load (ETL) architecture crucial to the readiness of AI, were done by P.M. et al. (2015), Ceri et al. (2016), and Bhuvaneshwar et al. (2016). Human-AI collaboration Models (13%): The cluster identifies how the human expertise can be combined with AI and includes works by Fan et al. (2025), Li and Yang (2021), and Kondylakis et al. (2017), who discuss patient empowerment and workflow-accelerating LLMs. Another, smaller cluster, Public Sentiment / Social Health NLP (4%), is represented by the study of Salath and Khandelwal (2011): they used NLP to model the behavior of the population health and the attitude of the population.

Table 4. Thematic Clustering of Literature

Cluster	**Studies**	**% of studies**	**Key Focus**	**Sample Studies**
AI Chatbots in Healthcare/Pharma	6	25%	NLP, LLM, chatbot architecture, usability, acceptability in regulated domains	Azam et al. (2024), Babu and Boddu (2024), Holmes et al. (2019), Nadarzynski et al. (2019), Hsu and De Yu (2022), Li and Yang (2021)
Regulation & Compliance (Pharma/MedTech)	4	17%	MedTech product lifecycle, digital compliance frameworks	Kühler et al. (2022), McDermott et al. (2022), Kodumuru et al. (2025), Pintilie et al. (2024)
IoMT & Infrastructure	2	8%	Connected health tech, smart sensing, IoT pipelines	Ajagbe et al. (2022), Fang et al. (2014)
Big Data & Interoperability Platforms	4	17%	Integrated analytics, unstructured/structured EHR platforms	Bellazzi et al. (2015), Bahga and Madisetti (2013), Mudunuri et al. (2013), Mezghani et al. (2015)
Semantic AI Pipelines & ETL	3	13%	Semantic pipelines and data transformation layers	P.M. et al. (2015), Ceri et al. (2016), Bhuvaneshwar et al. (2016)
Human–AI Collaboration Models	3	13%	Human-AI teaming, LLM + robot integration	Fan et al. (2025), Li and Yang (2021), Kondylakis et al. (2017)
Public Sentiment / Social Health NLP	1	4%	Population behavior modeling with NLP	Salathé and Khandelwal (2011)

6.1.1 AI Chatbots in Pharma

Research papers included in this thematic strand focus on the progress, usefulness and effectiveness of AI-based conversational agents meant to be used in the healthcare and pharmaceutical fields. PharmaLLM chatbot is an open-source large language model (LLM)-based chatbot-based chatbot introduced by Azam et al. (2024), illustrated in Figure 5, that can offer prescription advice and holds the ability to participate in contextually aware conversations in a multitude of languages. Although the study established a successful proof in usability and intent recognition, the study failed to investigate integrating it in regulated DT environments or consider compliance protocols that are necessary to implement the solution in an enterprise setting. Likewise, Babu and Boddu (2024) proposed a BERT-based chatbot trained on clinical corpora (e.g., MIMIC-III, PubMed) and reported exceptionally good performance in the medical domain when it comes to understanding and response generation in Figure 6 of their work. The task-specific model is fine-tuned by optimizing the loss with the help of the Adam optimizer, and gradients are calculated in respect to the parameters of BERT. This process fine-tunes the layers of BERT, but maintains prior knowledge training, until some convergence, or achieved after a fixed number of iterations and it is then used to answer queries in a medical chat bot. The study was technically solid but unnoticed regulatory compliance issues, scalability and integration into the bigger platform architectures.

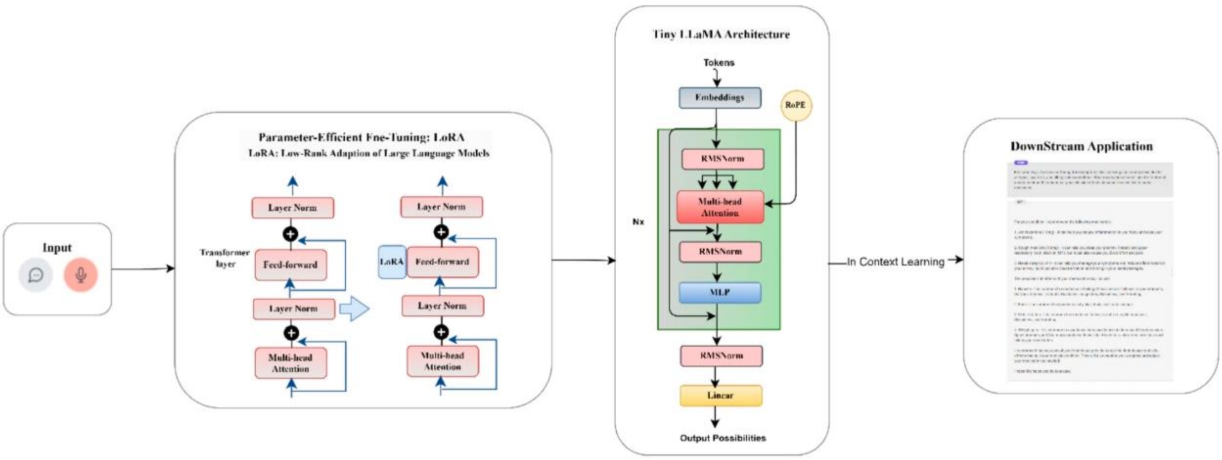

Figure 4. PharmaLLM Architecture Proposed
(Azam et al., 2024)

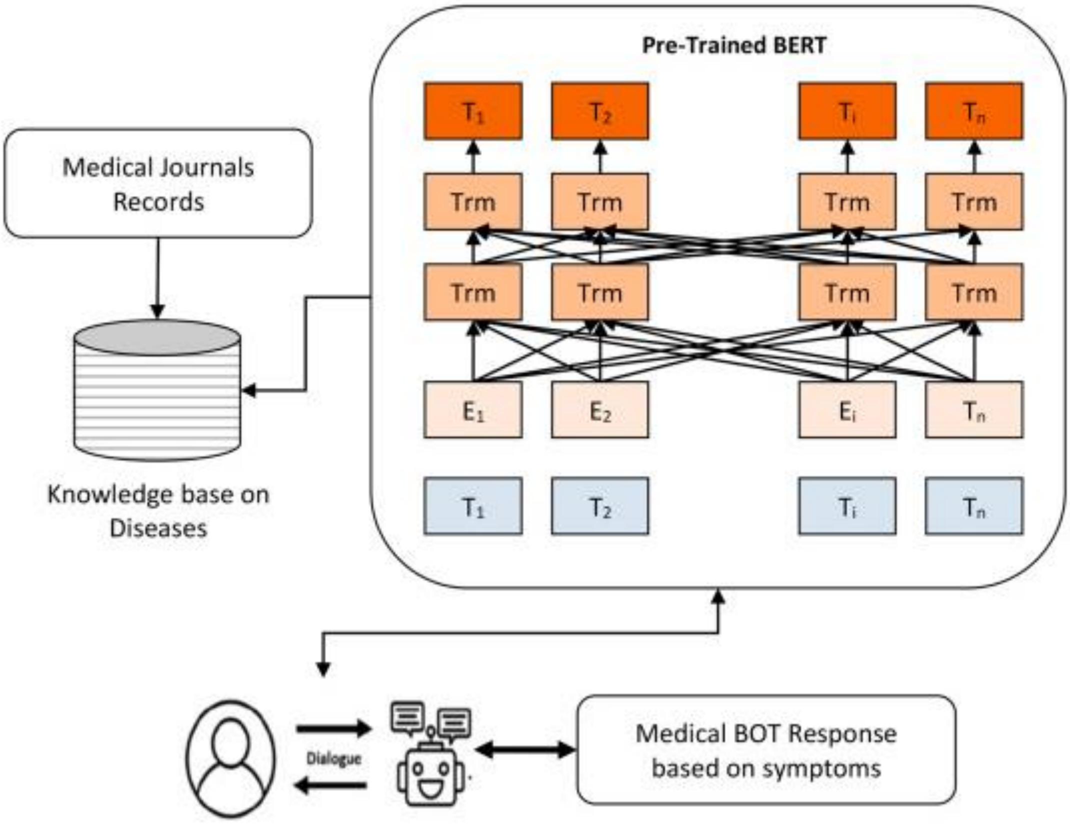

Figure 5. Proposed design for BERT base medical BOT
(Babu and Boddu, 2024)

In a usability, image, and societal context, Nadarzynski et al. (2019) did combined research that studied acceptability of AI-driven chatbots in health care. Among the findings, it was noted that trust, data privacy and empathy are the main issues that affect the receptivity of the users. Hence the issue of designing bots that do not lack ethical and contextual intelligence needs to be stressed especially in sensitive areas like health. To supplement this, Holmes et al. (2019) also performed a cognitive ergonomics assessment of conversations user interfaces, and key areas of weakness were found to be conversational breakdowns and user fatigue--two issues that could severely challenge the usefulness of chatbots in long-term monitoring equipment, or intricate decision-making contexts. Moreover, a model of chatbots with a combination of machine learning (ML) and natural language understanding (NLU) provided by Hsu and De Yu (2022) was characterized by high intent classification accuracy in isolated cases but proved insufficiently contextually coherent after extended dialogues, raising doubt over a high long-term reliability of persistent digital twin interactions. Finally, Bot-X is an intelligent manufacturing assistant that was suggested by Li and Yang (2021) using artificial intelligence. Even though this system had developed the progression of multi-task orchestration in agents, it had no considerations towards interoperability with formalized architectures or controlled infrastructures.

6.1.2 Regulation and Compliance (Pharma/MedTech)

This cluster includes works that discuss regulatory frameworks and compliance issues that should be incorporated when adopting AI-driven solutions in the pharmaceutical and medical technology industries. The study by McDermott et al. (2022) identified implications of the industry 4.0 technology on the lifecycle compliance of medical products that require traceability, validation, and the need to hold the entire system accountable. These observations demonstrate the legal limitations that need to be implanted in such type of AI- or digital-twin-empowered infrastructure. On the same note, Kuhler et al. (2022)

investigated the development and regulation of connected combined products in the MedTech and pharma industry and revealed the inconsistency in regulatory standards and the importance of establishing general compliance frameworks compatible with connected systems and smart agents.

To investigate the possible integration of AI and IoT technologies in pharmaceutical manufacturing, the study developed by Kodumuru et al. (2025) showed how smart infrastructures might lead to advancements in real-time analytics, predictive maintenance, and decision support. While technically robust, the proposed integration requires further elaboration on governance mechanisms, especially for data privacy, lifecycle management, and compliance assurance. Pintilie et al. (2024) provided a highly relevant contribution by presenting a UNS architecture using MQTT and Sparkplug B protocols in alignment with ISA-88 standards. The shift from purely PLC-based architecture to a hybrid system integrating PLCs with .NET control modules highlighted both the complexities and advantages of IIoT-driven automation as shown in Figure 7. This configuration preserved the real-time reliability of PLCs while enhancing adaptability through .NET's flexibility, aligning with the growing industry preference for scalable and modular control systems (Xia et al., 2022). Additionally, standardized communication protocols, particularly MQTT, were instrumental in enabling efficient and scalable device integration. The literature affirms that protocols like MQTT and Sparkplug B streamline the coordination of heterogeneous systems and reduce both development and maintenance burdens (Khan et al., 2022). The study addressed data harmonization across automation systems and serves as a foundational model for incorporating AI bots into compliant, real-time digital twin environments.

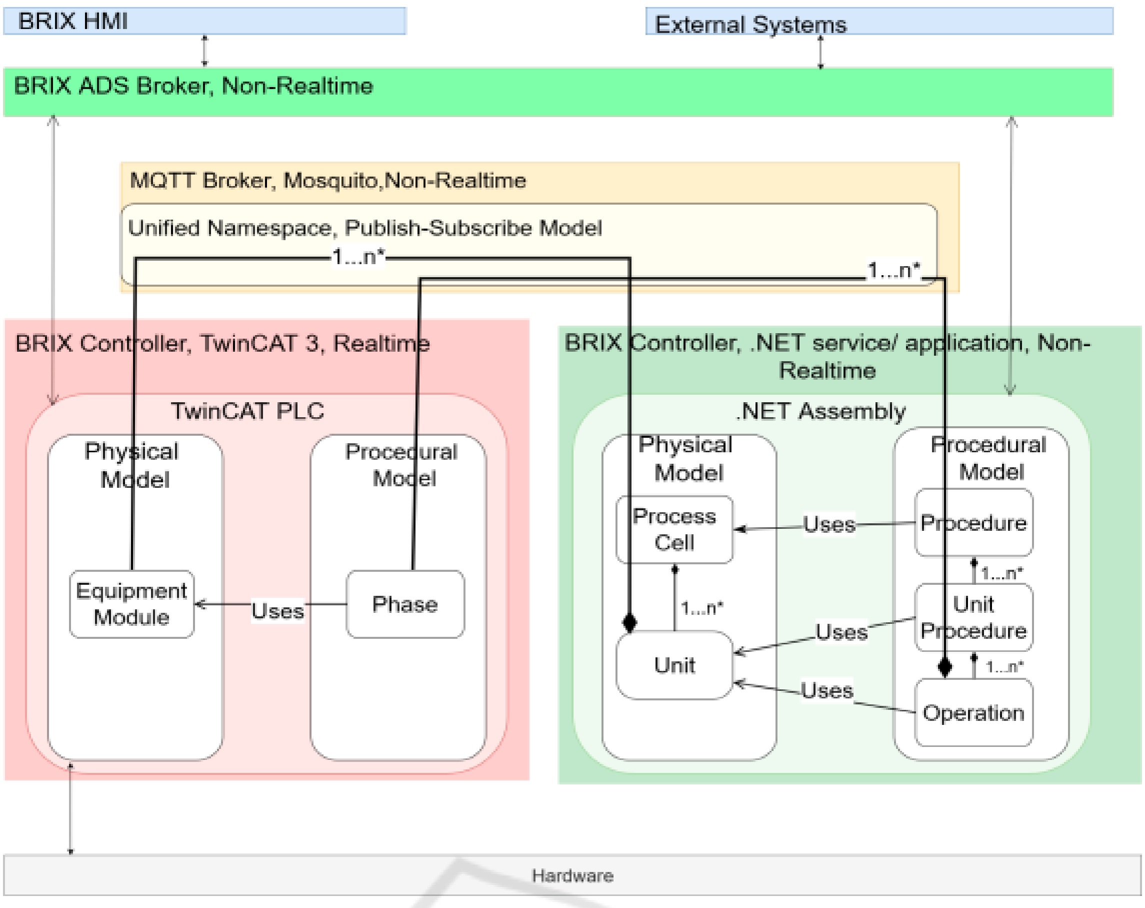

Figure 6. Enhanced communication in BRIX controllers enabled by MQTT and a unified namespace. Red lines represent new communication channels; black lines depict improved existing connections, derived from legacy architecture
(Pintilie, 2025)

6.1.3 IoMT and Infrastructure

This area considers research involving the Internet of Medical Things (IoMT) and infrastructure supporting intelligent and connected healthcare systems. Ajagbe et al., (2022) provided an ample review on the technologies involved in IoMT including applicable scenarios, issues of integration, and future perspectives in data-driven healthcare. The study noted the significance of strong communication structures and normalization-features that are important in the facilitation of the AI bots to communicate with the real-time sensing system across distributed DT systems as shown in Figure 8, which highlights IoMT real-time applications. The study by Fang et al. (2014) on the creation of specialist clinics based on big data analytics of enhancing the workflow of treatments related to patient outcomes and improved centralization of clinical data. The study did not extend to distributed infrastructure or AI-facilitated user interface, however, thereby restricting its user's application in general digital twin implementations.

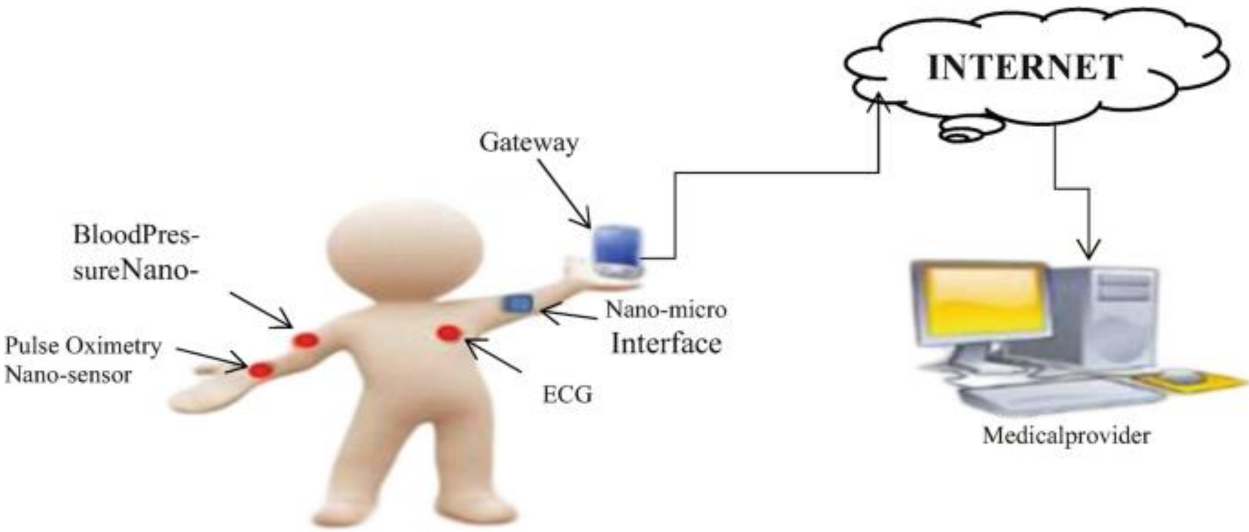

Figure 7. IoMT applications in real time
(Ajagbe et al., 2022)

6.1.4 Big Data and Interoperability Platforms

This theme dwells on scalable integration and data interoperability which are the basis of digital twin systems and the functions of AI bots. The work of Bellazzi et al. (2015) is devoted to the use of big data technologies in chronic disease treatment, in this case, diabetes. The implications of the study embraced the benefits of predictive analytics and integrative data models, yet issues emphasized by the study concerned semantic interoperability and data harmonization. Bahga and Madisetti (2013) developed a framework of interoperable electronic health records (EHRs) and made it cloud-based that is based on the standardized data exchange specifications like HL7 and CCD. Although the model enabled data cross-platform integration, it was not interactive in terms of AI functionality and not compliant in terms of governance features.

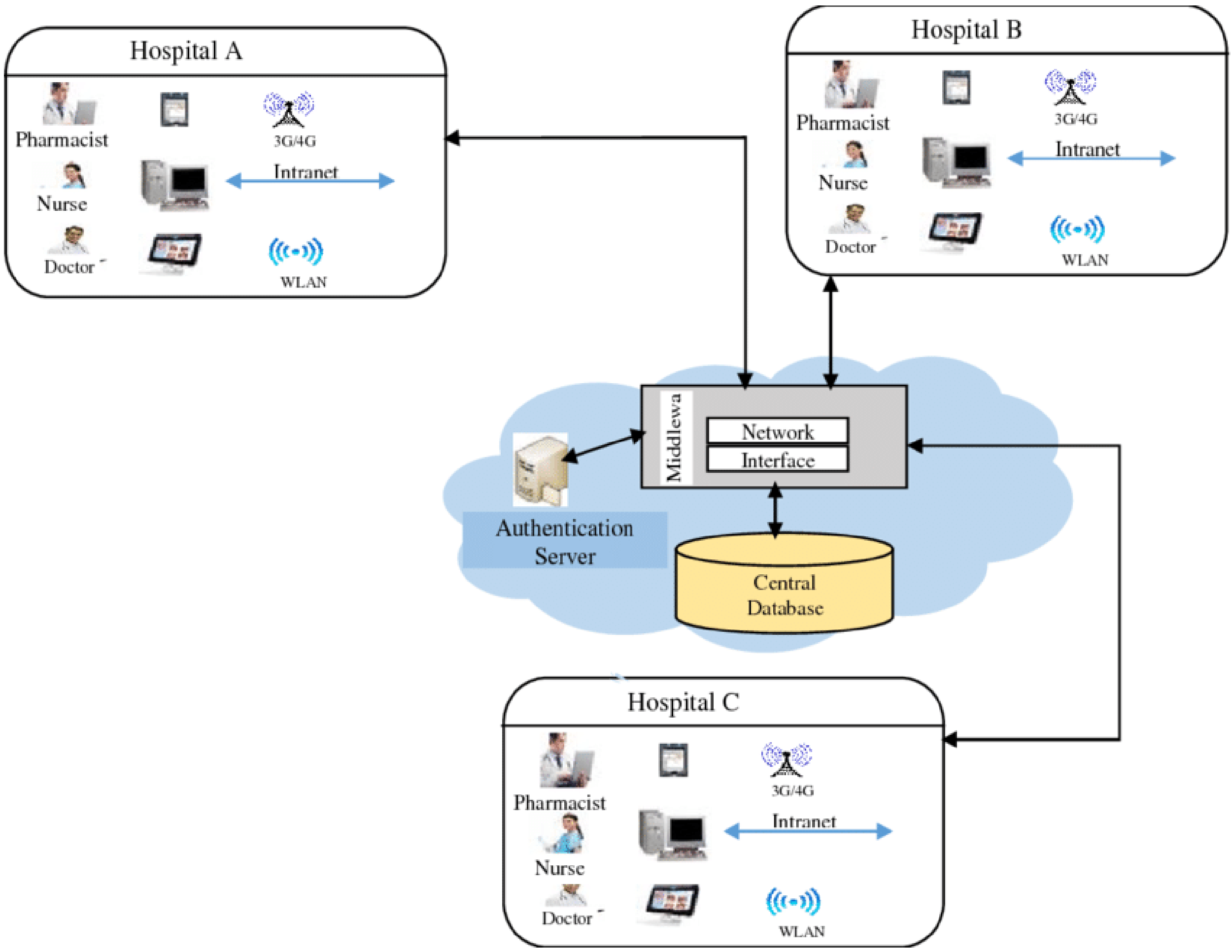

Figure 8. A Cloud-Based Enterprise Electronic Health Records System (Abayomi-Alli et al., 2014)

In a similar fashion, Mudunuri et al. (2013) created an example based on distributed queries by integrating structured and unstructured data in biological research, which demonstrates the capabilities of integrated analytics on big biomedical data. Despite its value, the technique could only be restricted to certain stationary environments lacking real time processing ability, which is imperative in dynamic DT platforms. In providing an integrated system of heterogeneous wearable data in healthcare, Mezghani et al. (2015) introduced a semantic big data platform. The platform enhanced data access and contextual richness but not AI-based interaction with the user and did not respond to the issue of compliance with the operation, thus its relevance in industrial settings regulated by respective regulations.

6.1.5 Semantic AI Pipelines and ETL

This group comprises works being related to semantic data processing and transformation which is of the essence in the adoption of harmonized UNS-based architectures. Different data sources can be harmonized by using ontologies to achieve a semantic extracttransform-load (ETL) service to obesity surveillance proposed by P.M. et al. (2015). This practice is a prime specimen of scalability of integrations that can be applied in digital twin systems (where consistency and lineage are required). Ceri et al. (2016) discussed the issue of genomic data management placing their emphasis on metadata modeling and traceable analytics. Despite being genomic biased, architectural concepts could be applied in a broad way across other compliance-driven environments like pharmaceutical automation. Bhuvaneshwar et al. (2016) created the G-DOC Plus platform that unites clinical data, genomic data, as well as imaging data. Their study was a good illustration that integrative bioinformatics platforms can facilitate as part of personalized medicine. Nonetheless, there is a lack of real time conversational AI agents and regulatory constraints, which makes it less immediately applicable to AI-enhanced digital twins.

6.1.6 Models of Human–AI Collaboration

Within this thematic area, the interaction of AI systems with human users is the important facet of system reliability and adoption in the regulated context. Fan et al. (2025) presented a survey of the state-to-the-art vision-language models (VLMs) on human-robot interaction and addressed the issue of how smart manufacturing processes can be improved with support of contextual multimodal understanding. Although technologically sophisticated, limited use of real-world is restricted due to the unavailability of operational compliance and interoperability features and the architectural constraints. According to Li and Yang (2021) Bot-X system is a feasible approach to multi-agent collaboration between people and artificial intelligence in the manufacturing domain, where real-time task planning and contextual interaction are introduced. Nonetheless, it lacked integration of data lineage, regulatory traceability and UNS protocols. Kondylakis et al. (2017) created a self-management platform in cancer patients, iManageCancer. The platform facilitated customer-specific guidance and information available only at the personal level without prioritizing interoperability and integration of systems on a higher level and the combination with automation-related DT platforms.

6.1.7 Public Sentiment / Social Health NLP

Salath and Khandelwal (2011) examined the sentiments of people towards vaccination through the NLP of social media sites. This experiment showed the value of unstructured data of the population as inputs to behavioral models with relevance to disease surveillance efforts and policy. Though the work did not rely on frameworks of compliance and interoperability, it suggested effective approaches to accommodating the public sentiment in AI-powered systems, which may be further applied to feedback-conscious DT implementations.

6.2 Conclusion of Thematic Synthesis

Collectively, these clusters highlight a fragmented but rich research landscape. While numerous studies have advanced components of the digital twin ecosystems such as semantic integration, AI-human interaction, and regulatory frameworks—very few integrate these components holistically. Particularly underrepresented are studies that bring together AI chatbot design, UNS-based data architecture, and regulatory compliance within a unified platform. Your research is thus uniquely positioned to address this intersection, offering a comprehensive framework for embedding intelligent, compliant, and interoperable AI bots within digital twin platforms in healthcare and pharmaceutical manufacturing. Furthermore, Table 5 summarizes the findings of this review.

Table 5. Summary of findings

Technology	Description	Applications in Pharma	Relevance to UNS and AI Call Bot	Pros	Cons
Data Lake (Apache Hadoop/HDFS) (Bellazzi et al., 2015)	A repository for storing vast amounts of raw data in its native format, supporting schema-on-read access.	Used in EHR integration, cost analysis, and biomedical data processing.	Provides a scalable UNS backbone for centralizing manufacturing and quality data, enabling AI call bot to	Flexible schema, supports large-scale data, multi-workload processing.	Requires significant infrastructure, batch-oriented processing may limit real-time use.

			access diverse datasets.		
Data Virtualization (SAP HANA, HDFS Federation) (Ceri et al., 2016)	Federates disparate data sources into a single access layer without moving data, using real-time querying.	Applied in e-Health services, genomic computing, and EHR interoperability (Page 8).	Enables real-time data access within a UNS for AI call bot to query production and quality data dynamically.	Real-time access, no data copying, supports heterogeneous sources.	Performance depends on query load, schema changes require updates.
Data Propagation (SparkMed) (Constantinescu et al., 2011)	Active, event-driven integration for near-real-time data updates across systems.	Integrates multimedia data in mobile healthcare and hospital systems.	Supports real-time updates in UNS, allowing AI call bot to respond to manufacturing events (e.g., equipment failures).	Near-real-time updates supports dynamic environment.	Requires advanced synchronization technologies, high performance demands.
Semantic Web (RDF, OWL, SPARQL) (Mezghani et al., 2015)	Uses standardized data models to link and integrate heterogeneous data with semantic context.	Integrates genomic, drug, and clinical data (e.g., Big Linked Cancer Data, SNOMED CT in OWL) (Page 9).	Enhances UNS interoperability by standardizing data relationships, enabling AI call bot to interpret complex manufacturing data.	Robust for linking diverse data, supports cloud-based integration.	Complex to implement requires expertise in ontology design.
Machine Learning (Hosseini et al., 2017)	Analyzes and interprets complex, heterogeneous data for predictive analytics and context-aware processing.	Improves prognostic predictions (e.g., glioblastoma) by integrating clinical and genomic data.	Powers AI call bot to process UNS data, predict quality issues, and optimize manufacturing processes.	Enhances data understanding, supports predictive analytics.	Requires high-quality data, computationally intensive.
Cloud Computing (Bahga and Madisetti, 2013)	Provides scalable infrastructure for data storage and processing, supporting	Used in cloud-based EHRs and biomedical data integration.	Scales UNS for large-scale data processing, enabling AI call bot to operate across distributed	Scalable, supports distributed access, and is cost-effective for large datasets.	Security and compliance challenges for sensitive data.

	interoperable systems.		manufacturing systems.		

6.3 The Technological Gap in Current Market Solutions
Despite the advancements in big data integration, several technological gaps limit the adoption of AI call bots in Pharma and MedTech manufacturing:

- Lack of Unified Namespace Integration: While data lakes and virtualization provide unified access to data, they are not explicitly designed as UNS architectures that centralize all manufacturing and quality data into a single, real-time accessible namespace. traditional data warehouses are rigid and struggle with the dynamic, schema-less nature of big data, indicating a gap in solutions tailored for UNS in manufacturing (Dhayne et al., 2019).
- Limited Real-Time Capabilities: Current solutions like Apache Hive operate in batch mode, which is insufficient for the real-time requirements of adaptive manufacturing. AI call bots require near-real-time data propagation to respond to manufacturing anomalies or quality issues promptly.
- Insufficient AI-Human Collaboration: The literature lacks frameworks for integrating AI call bots with human operators in manufacturing settings. While Dhayne et al. (2019) discuss data integration frameworks, they do not address AI-human interaction models, which are critical for operator trust and effective decision-making in Pharma 4.0.
- Interoperability Challenges: Overlaps and inconsistencies among standards (e.g., HL7 vs. ASC X12) complicate data integration across manufacturing and regulatory systems. Current solutions often fail to provide a standardized, interoperable framework for integrating diverse data sources in a UNS.
- Scalability and Security Trade-offs: While technologies like Hadoop and cloud computing offer scalability, they introduce security and performance challenges, particularly for sensitive manufacturing data. Current solutions lack integrated security frameworks tailored for UNS architectures in regulated environments.

These gaps highlight the need for a tailored solution that integrates UNS principles, real-time AI processing, and standardized interoperability to support Pharma 4.0.

6.4 Required Solution
As discussed in section IV, considering the technological gaps observed in the above section, the system must provide high-frequency real-time data streaming to support pharmaceutical and MedTech manufacturing operations, ensuring that advanced machine learning analytics deliver predictive maintenance insights and prescriptive guidance. It should offer robust digital twin support, creating virtual representations of assets for real-time monitoring and defect identification (Pintilie, 2025). Utilizing modern cloud-edge architecture, the solution must ensure quick adaptability and cost-effective scaling to accommodate both small-scale facilities and large, multi-site organizations. Integration services are essential for specialized deployments, including compliance with pharmaceutical regulations and quality tracking (Kodumuru et al., 2025a). Granular visibility should include the health and performance of equipment through integration with. IoT and sensors. To enable real-time data interchange and remove silos and aid interoperability, a common namespace (UNS) will be needed (Pintilie, 2025). Conversational interfaces and AI agents are required to make interaction of users with very large or remote manufacturing settings easier to ensure better levels of operator confidence and decision-making (Azam et al., 2024).
In addition to this, asset management should integrate sensor data into digital twin models to create accurate equipment replacements, which is essential in the high-risk industries (Ajagbe et al., 2022). Advanced scheduling and optimization should be implemented in predictive and prescriptive maintenance functions to ensure reduced downtime and organisational breakdowns (Fan et al., 2025). Dynamic anomaly detection and real-time live KPI dashboards necessitate real-time monitoring and the study of sensor data (Holmes et al., 2019). The enterprise integration capabilities should provide the same synchronization between the current ERP, SCADA and MES systems to manage the consolidated work

orders and inventory handling. Moreover, two-way communicational opportunities must allow real-time harmonization between machine conditions and outside scheduling functionality.

6.4.1 MVP Framework for Predictive and Adaptive AI Call Bot Agent

The proposed MVP for a predictive and adaptive AI call bot agent aligns with the DPMM's five maturity levels, progressively addressing data integration and security challenges to deliver advanced AI capabilities in Pharma and MedTech manufacturing (Ilin et al., 2022). Figure 8 shows the proposed MVP solution and their levels.

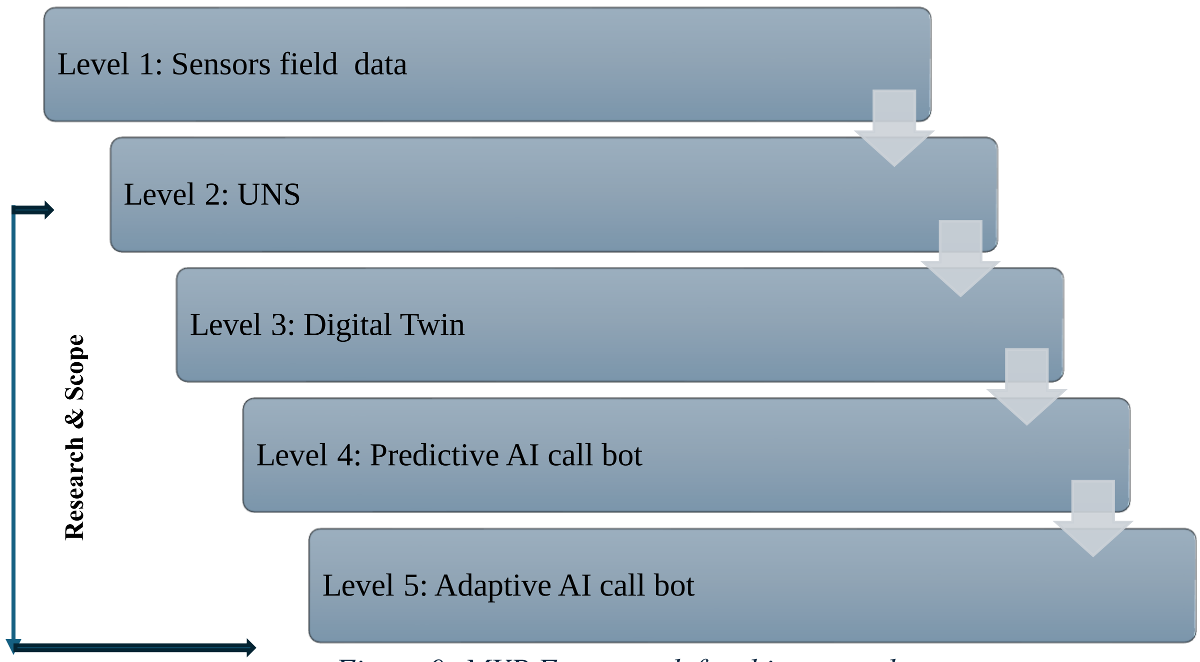

Figure 9: MVP Framework for this research

Level 1: Pre-Digital

Pre-digital plants rely on manual processes and legacy systems with minimal digital integration, a state already existing in many Pharma and MedTech facilities. This level requires no development but limits AI agent deployment due to inaccessible or unreliable data (De Carolis et al., 2017).

Level 2: Digital Silos (UNS)

Digital silos, enabled by UNS, address the first challenge of non-owned data and legacy equipment integration into Pharma and MedTech plants. UNS summations data from SCADA, MES, and undercover operation systems into a centralized namespace, naming P2P complications and data power effects (Blatz et al., 2018). The AI bot at this position can pierce consolidated data but is limited to introductory query responses due to the absence of improved analytics. screen measures, similar as data encryption and access controls, are overcritical to help susceptibility during data aggregation (Gajsek et al., 2019).

Level 3: Connected Plant (Digital Twin)

The connected manufactory position leverages DT to integrate and dissect UNS data, enabling analytics, simulation, report generation, checkups, and automation in Pharma and MedTech environments (Pfenning et al., 2021). The AI call- bot evolves into a contextual aide, furnishing perceptivity grounded on DT simulations, similar as outfit failure prognostications or process optimization recommendations for cleanroom operations. Still, the complexity of modeling different data sources and securing real- time synchronization poses challenges, taking robust computational structure and security protocols to help adversary attacks (Colli et al., 2019).

Level 4: Predictive Plant (Advanced Digital Twin)

In the predictive factory, advanced DT enhances the AI call bot's capabilities to serve as an on- call adjunct, interacting with human drivers and answering queries grounded on predictive analytics and training data (Leyh et al., 2016). For illustration, the bot can foretell outfit time-out in a lyophilizer and suggest conservation schedules, drawing on skill matrix data to recommend suitable drivers with GMP credentials. Non-owned data dependency enhances security vulnerabilities making sophisticated protection to mitigate timely injection attacks such as data marking and anomaly detection difficult (Sjödin et al., 2018).

Level 5: Adaptive Plant (Adaptive Digital Twin)

The adaptive plant depicts the pinnacle of DPMM as adaptive DT functions in a plug- and-play system, which allows the AI call bot to form sole opinions and notify drivers in the availability of evidence in Pharma and MedTech installations(Mittal et al., 2018). For example, the bot is capable of self-adjusting process parameters based on micro-changes in the environment and seeking driver approval, increasing efficiency and safety. However, to reach such a status, flawless interoperability, real-time inflexibility and tight security textures are demanded to prevent illegal decision-making or crypto-hacking actions.

The DPMM concept, through UNS and advanced DT, offers a transformative result for addressing non-owned data challenges and enabling a predictive and adaptive AI call bot agent in Pharma and MedTech manufacturing. UNS resolves data integration and power issues, while DT provides analytics and robotization capabilities essential for connected, predictive, and adaptive. However, implementing this framework requires overcoming significant barriers, including legacy system constraints, security vulnerabilities, and workforce resistance. Strategic investments in infrastructure, security, and change management are critical to realizing the full potential of DPMM in this regulated industrial application. Finally, the solution must adapt to the evolving demands of Pharma 4.0, addressing the obsolescence of traditional systems.

Section VII: CONCLUSION

The study reveals that the integrated approach is essential to manage quality challenges and operational inefficiency in pharmaceutical and MedTech manufacturing. Using the latest technologies like real-time data streams, digital twins, and AI agents, companies can boost their production stability, reduce waste, and primarily meet the requirements of strict regulations. With the help of predictive analytics and real-time monitoring, manufacturers will be able to detect possible problems in advance, minimize the cutting of operations and economic losses, and optimize maintenance processes. A decent digital transformation plan, which is enhanced by UNS architecture, simplifies the data collection, analysis, and decision-making process, enhancing better process control and traceability. By instilling a culture of constant improvement and training operators to accept AI-driven innovations, long-term flexibility to changes that occur in the industry is guaranteed. These steps will help manufacturing firms to make optimum use of their resources and retain their competitive advantage as well as ensure standard product quality in the high-tech world of Pharma 4.0.

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