

Technological, Operational, Logistical, and Digital Integration in the Production and Distribution of Medical and Industrial Gases in Antioquia: An Approach Based on GMP, Digital Twins, and Intelligent Information Management.

Daniela María Marín Duque ¹*, León Daniel Restrepo Gaviria ², Lina Marcela Vélez Ruiz ³, David Alberto García Arango ⁴, Leidy Catalina Acosta Agudelo ⁵, Claudia Marcela Montoya Escobar⁶

¹*Bioxigen S.A.S., Cra 55, Cl. 79C Sur #16 #, La Estrella, Antioquia, Colombia.*

ORCID: <https://orcid.org/0009-0003-4692-0240>, email: direcciontecnica@bioxigen.com.co

²*Bioxigen S.A.S., Cra 55, Cl. 79C Sur #16 #, La Estrella, Antioquia, Colombia.*

ORCID: <https://orcid.org/0009-0004-0175-3642>, email: aplicaciones@bioxigen.com.co

³*Bioxigen S.A.S., Cra 55, Cl. 79C Sur #16 #, La Estrella, Antioquia, Colombia.*

ORCID: <https://orcid.org/0009-0006-4124-1734>, email: administracion@bioximad.com.co

⁴*Administrative Management Consultants S.A.S., Calle 5 Sur # 43C-80 Piso 9 Medellín – Colombia.*

ORCID: <https://orcid.org/0000-0002-0031-4275>, email: investigacion@amyc.com.co

⁵*Administrative Management Consultants S.A.S., Calle 5 Sur # 43C-80 Piso 9 Medellín – Colombia.*

ORCID: <https://orcid.org/0000-0003-1538-1881>, email: comercial@amyc.com.co

⁶*Administrative Management Consultants S.A.S., Calle 5 Sur # 43C-80 Piso 9 Medellín – Colombia.*

ORCID: <https://orcid.org/0000-0003-3566-1223>, email: talentohumano@amyc.com.co

ABSTRACT

Traditional management of medical gas production and distribution in the sector is characterized by high dependence on physical documentation, manual administrative processes, and limited real-time traceability, which increases operational risks, costs, and regulatory compliance gaps. This article presents a comprehensive model that combines the integration of medical and industrial gases with complete digitalization of production, logistical, and documentary processes. The model incorporates digital twins, custom software for order management, real-time delivery control, web platforms for customers, and the elimination of physical documents such as dispatch notes and loan contracts. Additionally, the modification and optimization of the production plant and its processes are addressed through the implementation of digital twins and 3D modeling, enabling technical and operational comparison with practices employed by multinational gas companies and the Colombian pharmaceutical industry. Likewise, the reconfiguration of distribution routes is analyzed based on Antioquia's geography, differentiating logistical strategies for the metropolitan area and areas outside it, in order to improve efficiency, service timeliness, and safety during transportation. Finally, the study demonstrates a significant change in the perception and trust of industrial gas customers, derived from the adoption of operational and quality protocols aligned with Good Manufacturing Practices (GMP) principles. The results demonstrate significant improvements in operational efficiency, reduction of administrative burden, increased customer reliability, and strengthened traceability, providing technical evidence for sector modernization and updating of the Colombian regulatory framework...

Keywords: digital twins, medical gas, industrial gas, gas production, 3D modelling

How to cite this article: Marín Duque DM, Restrepo Gaviria LD, Vélez Ruiz LM, García Arango DA, Acosta Agudelo LC, Montoya Escobar CM., Technological, Operational, Logistical, and Digital Integration in the Production and Distribution of Medical and Industrial Gases in Antioquia: An Approach Based on GMP, Digital Twins, and Intelligent Information Management...*Int J Drug Deliv Technol.* 2026;16(1s): 200-207; DOI: 10.25258/ijddt.16. 200-207

Source of support: Nil.

Conflict of interest: None

INTRODUCTION

Medical gases constitute an essential and critical input for the safe and continuous provision of healthcare services, being fundamental in areas such as intensive care, anesthesia, respiratory therapies, hospitalization, and home care. Their unavailability, contamination, or inadequate supply can result in serious adverse events for patients, which makes their production, storage, and distribution a process of high technical and sanitary criticality. In parallel, industrial gases play a strategic role in multiple productive sectors, sharing technologies, infrastructures, and logistical

chains with medical gases. This convergence has driven, both globally and in Colombia, productive integration models that seek to optimize resources, expand markets, and improve operational sustainability.

However, the integration of medical and industrial gases poses significant challenges when managed under traditional schemes, characterized by high dependence on physical documentation, manual administrative processes, and limited real-time traceability. In the Colombian context, this situation is aggravated by regulatory fragmentation and the absence of clear guidelines that coherently articulate the

*Author for Correspondence: Daniela María Marín Duque.

technical, sanitary, and logistical aspects of the medical gas supply system. As a result, gaps persist in operational safety, process control, administrative efficiency, and regulatory compliance.

From a regulatory perspective, medical gases in Colombia are in a normative gray zone. Although the National Institute for Food and Drug Surveillance (INVIMA) is the competent authority for sanitary surveillance of medical gases, the current regulatory framework does not comprehensively address their production, storage, and distribution, generating ambiguities in the interpretation and application of quality, safety, and traceability requirements. Colombian Technical Standard NTC 5318 establishes general guidelines for medical gas systems in healthcare institutions, but it does not cover in sufficient depth aspects related to the supply chain, distribution logistics, or the integration of digital technologies for real-time control.

At the international level, standards such as NFPA 99 (National Fire Protection Association, 2024) and ISO 7396-1 (International Organization for Standardization, 2018) provide detailed technical frameworks for the design, installation, and operation of medical gas systems, including specific requirements for distribution, storage, and quality control. These standards have been widely adopted in developed countries and serve as reference for best practices in the sector. However, their implementation in Colombia faces barriers related to lack of harmonization with the national regulatory framework, limited technical capacity in some organizations, and insufficient dissemination of their content.

In this context, the present study arises from the need to develop and validate an integrated model that addresses the technical, operational, logistical, and digital challenges associated with the production and distribution of medical and industrial gases in the department of Antioquia. The model is based on the implementation of Good Manufacturing Practices (GMP), the incorporation of digital twins and 3D modeling for process optimization, the development of custom software for order management and real-time traceability, the modernization and specialization of the vehicle fleet, and the complete digitalization of administrative and contractual documentation.

The general objective of this research is to design, implement, and evaluate a comprehensive model of technological, operational, logistical, and digital integration in the production and distribution of medical and industrial gases, based on GMP principles, digital twins, and intelligent information management, in order to improve operational efficiency, regulatory compliance, and customer satisfaction in the context of Antioquia.

The specific objectives are: (1) to implement Good Manufacturing Practices in the production and distribution of medical and industrial gases, aligning processes with international standards such as NFPA 99 and ISO 7396-1; (2) to develop and implement custom software for order management, delivery control, and digitalization of administrative and contractual processes; (3) to design and execute a strategy for modernization and specialization of the vehicle fleet adapted to the geographical characteristics

of Antioquia; (4) to optimize the production plant and its processes through the use of digital twins and 3D modeling, comparing the configuration obtained with standards used by multinational gas companies and the Colombian pharmaceutical industry; (5) to evaluate the impact of the model on operational efficiency, traceability, administrative burden reduction, and customer perception.

The relevance of this study lies in its contribution to the modernization of the medical and industrial gas sector in Colombia, providing technical evidence on the feasibility and benefits of integrating advanced technologies and standardized processes in a context characterized by regulatory fragmentation and limited adoption of digital tools. Additionally, the research offers a replicable reference model that can guide both companies in the sector and sanitary authorities in updating the regulatory framework and improving safety and quality of medical gas supply.

METHODOLOGY

This research was developed under a mixed methodological approach, combining qualitative and quantitative elements to address the design, implementation, and evaluation of the integrated model. The study was structured in five main phases: (1) diagnosis and planning; (2) design and development; (3) implementation; (4) evaluation and monitoring; (5) analysis and documentation. Each phase was executed sequentially, although some activities were carried out in parallel to optimize time and resources.

Phase 1: Diagnosis and Planning

The first phase consisted of a detailed diagnosis of the current state of production and distribution processes of medical and industrial gases at Bioxigen S.A.S. For this purpose, direct observation techniques, semi-structured interviews with operational and administrative personnel, and documentary review of internal procedures, regulatory records, and customer complaints were used. Likewise, a gap analysis was conducted comparing current practices with the requirements established in Colombian Technical Standard NTC 5318, NFPA 99, and ISO 7396-1. This analysis allowed identifying critical points in the supply chain, regulatory compliance deficiencies, and improvement opportunities in operational, logistical, and administrative aspects.

Based on the diagnosis, a strategic plan was designed that defined the objectives, scope, resources, and timeline for implementing the integrated model. This plan included the formation of a multidisciplinary work team composed of production, logistics, systems, quality, and administrative personnel, as well as the definition of key performance indicators (KPIs) to monitor progress and evaluate results.

Phase 2: Design and Development

The second phase focused on the design and development of the technological, operational, and logistical components of the model. The main activities carried out in this phase were:

Operational procedures were reviewed and updated to align them with GMP principles, establishing quality controls, traceability protocols, and sanitary safety measures throughout the production and distribution chain. Specific

procedures were designed for equipment calibration, cleaning and disinfection, handling of medical gases, storage, and transportation.

A web-based information system was designed and developed to integrate order management, route programming, real-time delivery tracking, and digitalization of administrative and contractual processes. The software was developed using agile methodologies, with active participation of end users in the definition of functional requirements and validation of prototypes.

A logistical analysis of distribution routes was conducted, considering the geographical characteristics of Antioquia, population density, road infrastructure, and specific needs of customers. Based on this analysis, a strategy was designed to modernize and specialize the fleet, incorporating vehicles adapted to different operational contexts: motorcars for the metropolitan area, vans for intermediate routes, cargo trucks for high-volume deliveries, and tanker trucks for liquid gas supply.

3D modeling tools were used to redesign the layout of equipment, operational areas, and workflows in the production plant. The design was based on principles of digital twins, allowing simulation of different configurations and comparison with standards used by multinational gas companies and the Colombian pharmaceutical industry. The model incorporated aspects such as material flow, physical separation of areas, ventilation, access control, and operational safety.

A web platform was developed that allows customers to place orders, consult their purchase history, access technical documentation, and receive real-time notifications on the status of their deliveries. Additionally, training materials were designed for customer training on the use of the platform and on safety and quality aspects in the handling of medical and industrial gases.

Phase 3: Implementation

The third phase consisted of the gradual implementation of the model components in the company's operational environment. Implementation was carried out in stages, starting with pilot tests in controlled areas and progressively expanding to the entire operation. The main activities carried out in this phase were:

Training sessions were conducted for operational, administrative, and logistics personnel on the new procedures, use of software, handling of vehicles, and GMP principles. Training included theoretical and practical components, as well as competency evaluations to ensure adequate understanding and application of knowledge.

The AIR-Bioxigen software and the web platform for customers were deployed in the production environment, integrating them with existing systems for inventory management, billing, and accounting. Functionality tests, stress tests, and information security tests were conducted to ensure system stability and reliability.

New vehicles were acquired and existing vehicles were adapted according to the specialization strategy defined in the design phase. Vehicles were equipped with real-time tracking systems, temperature and pressure sensors for medical gases, and communication devices to facilitate coordination with the operations center.

The modifications designed in the 3D model were implemented in the production plant, including redistribution of equipment, installation of new quality control systems, improvement of ventilation and lighting, and implementation of access control and traceability measures.

Physical documents such as dispatch notes, loan contracts, and quality certificates were eliminated, replacing them with digital records generated and managed through the AIR-Bioxigen software. Procedures were implemented to ensure authenticity, integrity, and availability of digital documents, in compliance with legal and regulatory requirements.

Phase 4: Evaluation and Monitoring

The fourth phase focused on evaluating the impact of the implemented model and continuously monitoring key performance indicators. For this purpose, data were collected on operational efficiency, traceability, administrative burden reduction, and customer satisfaction.

The main indicators evaluated were:

Delivery times, route compliance rate, vehicle utilization rate, production downtime, and product quality.

Percentage of deliveries with complete digital record, response time to traceability queries, and number of traceability incidents.

Time spent on administrative tasks, consumption of physical resources (paper, ink, storage), and number of administrative errors.

Satisfaction surveys, Net Promoter Score (NPS), number of complaints and claims, and platform adoption rate.

Data were collected through the AIR-Bioxigen software, satisfaction surveys, direct observation, and interviews with operational and administrative personnel. Data were analyzed using descriptive statistical techniques and comparative analysis before and after implementation.

Phase 5: Analysis and Documentation

The fifth phase consisted of analyzing the results obtained, interpreting their significance in the context of the study objectives, and documenting the findings. A comparative analysis was conducted with international standards and practices used by multinational gas companies and the Colombian pharmaceutical industry. Likewise, the implications of the results for the modernization of the sector and updating of the Colombian regulatory framework were discussed.

Figure 1 presents the methodological process applied in the research and the relationship between the different phases.

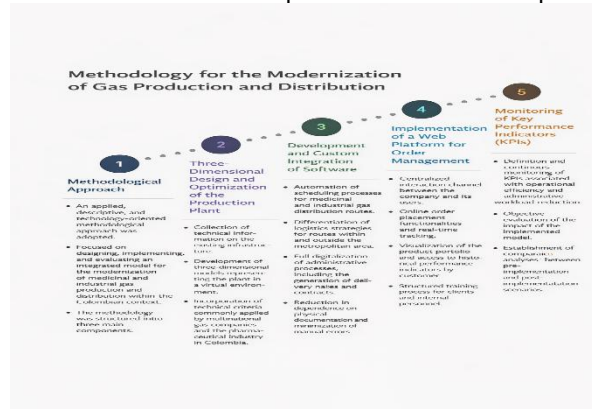


Figure 1. Methodological process applied in the research and relationship between phases.

RESULTS

The results of this research are presented according to the specific components of the implemented model, addressing operational, technological, logistical, and customer perception aspects. Each section includes a detailed description of the actions carried out, the results obtained, and their implications for operational efficiency and regulatory compliance.

Implementation of Good Manufacturing Practices (GMP) in the production and distribution of medical and industrial gases represented a fundamental change in the company's operational culture. The main actions carried out included: (1) review and updating of operational procedures, aligning them with the requirements of NFPA 99 and ISO 7396-1; (2) implementation of quality controls at all stages of the production and distribution chain; (3) establishment of traceability protocols for raw materials, intermediate products, and finished products; (4) implementation of sanitary safety measures in handling, storage, and transportation; (5) training of personnel in GMP principles and their practical application.

The results evidenced a significant improvement in product quality, reflected in a reduction in non-conformities detected in internal and external audits. Likewise, an increase in regulatory compliance was observed, facilitating inspections by sanitary authorities and certification processes. Implementation of GMP also generated a positive impact on customer perception, especially in the industrial gas segment, where the adoption of quality protocols traditionally associated with the health sector was valued as a differentiating element.

From a technical perspective, GMP implementation allowed standardizing processes, reducing variability in production, and establishing clear criteria for decision-making in critical situations. This is consistent with what is reported in the international literature on quality management in regulated sectors, where standardization and traceability are identified as key factors to ensure safety and efficacy of products (United States Food and Drug Administration, 2022).

Modernization and Specialization of Vehicle Fleet

Modernization and specialization of the vehicle fleet constituted one of the most visible and operationally impactful components of the model. The strategy was based on differentiating vehicle types according to the geographical, volumetric, and temporal characteristics of each delivery route. Four main vehicle categories were incorporated:

Motorcarts: Used for deliveries in the metropolitan area, especially in areas with difficult vehicular access, heavy traffic, or restricted parking. Motorcarts allow greater maneuverability, lower operating costs, and shorter delivery times in urban contexts.

Vans: Used for intermediate routes, both in the metropolitan area and in nearby municipalities. Vans offer

an adequate balance between load capacity, fuel efficiency, and versatility to adapt to different types of roads.

Cargo trucks: Used for high-volume deliveries to institutional customers, such as hospitals, clinics, and industries. Cargo trucks allow transporting large quantities of cylinders and medical gas equipment, optimizing costs per unit transported.

Tanker trucks: Used for supply of liquid medical gases (oxygen, nitrogen, argon) to customers with cryogenic storage tanks. Tanker trucks are equipped with specialized transfer systems and safety controls to ensure product integrity during transportation.

Figure 2 presents the modernization of the vehicle fleet.



Figure 2. Modernization of vehicle fleet.

As can be observed in Figure 2, motorcarts were incorporated for agile deliveries in the metropolitan area, vans for intermediate routes, cargo trucks for high-volume deliveries, and tanker trucks for liquid gas supply. This specialization allowed optimizing delivery times, reducing operating costs, and improving service quality.

The results evidenced a significant reduction in average delivery times, especially in the metropolitan area, where the use of motorcarts reduced times by approximately 30% compared to conventional vehicles. Likewise, an increase in route compliance rate and a reduction in delivery incidents related to transportation were observed.

From a logistical perspective, fleet specialization allowed adapting the distribution system to the specific characteristics of Antioquia's geography, which presents significant challenges due to its topographic diversity, dispersion of population centers, and variability in road infrastructure quality. This result is consistent with what is reported in the literature on distribution logistics in complex geographical contexts, where fleet adaptation and route optimization are identified as critical factors to improve operational efficiency (Toth & Vigo, 2014; Rodriguez et al., 2020).

Design and Implementation of Custom Software AIR-Bioxigen

Development and implementation of custom software AIR-Bioxigen constituted the technological backbone of the integrated model. The software was designed to integrate

all stages of the supply chain, from order reception to delivery confirmation and generation of digital documentation. The main functionalities implemented were:

Order management: Reception, validation, and processing of customer orders, with automatic verification of product availability, credit conditions, and delivery capacity.

Route programming: Automatic generation of delivery routes based on geographical, volumetric, temporal, and priority criteria, optimizing vehicle use and minimizing travel times.

Real-time tracking: Monitoring of vehicle location, delivery status, and incidents during transportation, with automatic notifications to customers and operations center.

Digitalization of administrative processes: Generation and management of digital documents such as dispatch notes, loan contracts, quality certificates, and invoices, eliminating the need for physical documents.

Traceability and reporting: Recording of all operations in a centralized database, allowing queries, audits, and generation of management reports in real time.

Figure 3 presents the operation of the software.

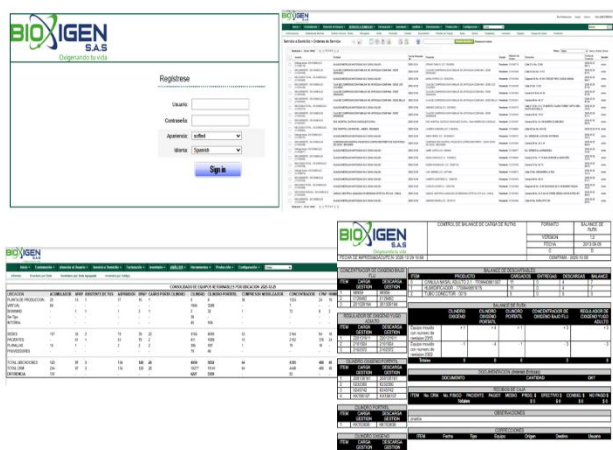


Figure 3. Screenshot of AIR-Bioxigen software operation.

The results evidenced a significant reduction in administrative burden, reflected in a decrease in time spent on manual tasks, a reduction in administrative errors, and an improvement in information availability for decision-making. Likewise, a substantial decrease in consumption of physical resources (paper, ink, storage) was observed, contributing to environmental sustainability and cost reduction.

From a traceability perspective, the software allowed recording all operations in a structured and accessible manner, facilitating audits, incident investigations, and regulatory compliance demonstrations. This is consistent with what is reported in the literature on information systems in regulated supply chains, where digitalization and integration are identified as key factors to improve transparency, efficiency, and regulatory compliance (Kane et al., 2015; OECD, 2021).

Web Platform for Orders and User Training

The web platform for orders constituted a key element in transforming the relationship with customers, offering them direct, transparent, and continuous access to the supply system. The platform was designed with a user-friendly and accessible interface, allowing customers to:

Place orders: Select products, specify quantities, delivery dates, and special conditions, with real-time validation of availability and automatic confirmation.

Consult purchase history: Access complete records of previous orders, including dates, products, quantities, and invoices.

Access technical documentation: Download safety data sheets, certificates of analysis, user manuals, and regulatory documents.

Receive real-time notifications: Obtain automatic alerts on order status, estimated delivery times, and any incidents or changes in programming.

Participate in training: Access training materials, tutorial videos, and online courses on safety and quality in handling medical and industrial gases.

Figure 4 shows the web platform for orders.

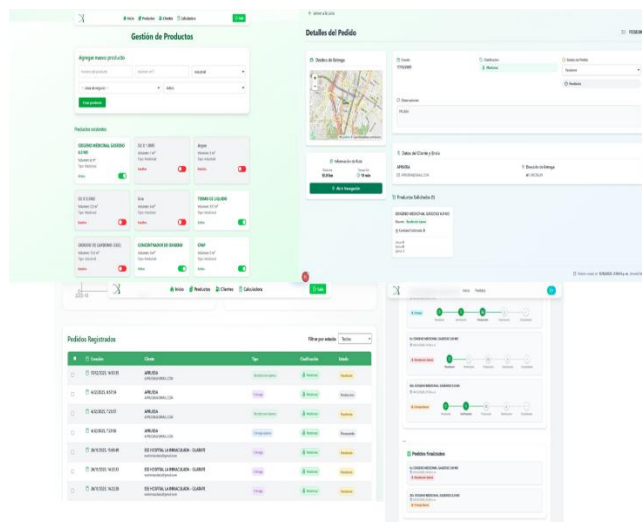


Figure 4. Web platform for orders of Bioxigen S.A.S.

The results evidenced a high adoption rate of the platform by customers, especially in the industrial gas segment, where ease of use and access to information were valued as significant improvements compared to the previous system. Likewise, an increase in customer satisfaction was observed, reflected in satisfaction surveys and Net Promoter Score (NPS).

From a customer relationship perspective, the platform allowed strengthening trust and transparency, offering customers greater control and visibility over their orders. This is consistent with what is reported in the literature on digital transformation in customer relationship management, where accessibility, transparency, and personalization are identified as critical factors to improve customer experience and loyalty (Kane et al., 2015).

Process Optimization through Design and 3D Modeling
The use of design and 3D modeling tools, based on digital twin principles, allowed optimizing the configuration of the production plant and its processes. The methodology

consisted of creating a detailed virtual representation of the plant, including equipment, operational areas, material flows, and workflows. This representation was used to:

Simulate different configurations: Evaluate alternatives for equipment distribution, physical separation of areas, and workflow optimization, identifying the most efficient and safe configuration.

Compare with international standards: Contrast the obtained configuration with standards used by multinational gas companies and the Colombian pharmaceutical industry, identifying best practices and improvement opportunities.

Support decision-making: Provide visual and quantitative information to support decisions on modifications, investments, and operational changes, reducing risks and costs associated with physical implementation.

Facilitate training and communication: Use the 3D model as a training and technical communication tool for operational personnel, supervisors, and external auditors.

Figure 5 presents the 3D modeling for optimization of plant layout, including operational, administrative areas, and workflows.

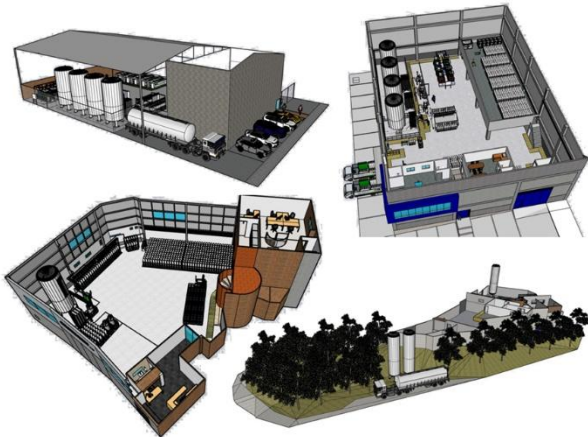


Figure 5. 3D modeling for optimization of plant layout.

The results evidenced a significant improvement in operational efficiency, reflected in a reduction in production times, an increase in equipment utilization rate, and an improvement in product quality. Likewise, an improvement in operational safety was observed, due to better physical separation of areas, optimization of material flows, and reduction of risks associated with interference between processes.

From a technological perspective, the use of digital twins and 3D modeling allowed anticipating impacts of modifications before their physical implementation, reducing costs and risks associated with trial and error. This is consistent with what is reported in the literature on digital twins in manufacturing and logistics, where simulation and virtual representation are identified as key tools to improve operational efficiency and reduce risks (Grieves & Vickers, 2017; Boschert & Rosen, 2016).

Impact on Customer Perception in Industrial Gas Segment
One of the most relevant and unexpected results of the study was the positive impact on the perception and trust of industrial gas customers, derived from the adoption of operational and quality protocols aligned with GMP

principles. Traditionally, industrial gas customers do not expect the same level of formality, traceability, and quality control as medical gas customers. However, implementation of the integrated model generated a significant change in this perception.

Industrial gas customers valued positively the adoption of standardized procedures, complete traceability, access to technical documentation, and transparency in the supply process. This change in perception was reflected in satisfaction surveys, where industrial gas customers expressed greater confidence in product quality and reliability of service. Likewise, an increase in loyalty and a reduction in customer turnover rate were observed.

From a commercial perspective, this result suggests that the adoption of quality and safety standards traditionally associated with the health sector can constitute a competitive differentiator in the industrial gas market, especially in segments where quality, reliability, and regulatory compliance are valued.

Discussion

The results obtained in this study demonstrate that technological, operational, logistical, and digital integration in the production and distribution of medical and industrial gases constitutes an effective strategy to improve operational efficiency, regulatory compliance, and customer satisfaction. The implemented model, based on GMP principles, digital twins, and intelligent information management, allowed overcoming the limitations associated with traditional management schemes, characterized by manual processes, high dependence on physical documentation, and limited real-time traceability. From a technical perspective, GMP implementation in the production and distribution of medical and industrial gases represented a fundamental change in operational culture, aligning processes with international standards such as NFPA 99 and ISO 7396-1. This alignment not only improved product quality and regulatory compliance but also strengthened customer perception, especially in the industrial gas segment, where the adoption of quality protocols traditionally associated with the health sector was valued as a differentiating element. This finding is consistent with what is reported in the international literature on quality management in regulated sectors, where standardization and traceability are identified as key factors to ensure safety and efficacy of products (United States Food and Drug Administration, 2022; World Health Organization, 2023).

Modernization and specialization of the vehicle fleet, adapted to the geographical characteristics of Antioquia, constituted one of the most visible and operationally impactful components of the model. Differentiated incorporation of motorcarts, vans, cargo trucks, and tanker trucks allowed optimizing delivery times, improving service coverage, and strengthening supply continuity in urban, rural, and institutional scenarios. This result is consistent with what is reported in the literature on distribution logistics in complex geographical contexts, where fleet adaptation and route optimization are identified as critical factors to improve operational efficiency (Toth & Vigo, 2014; Rodriguez et al., 2020). In the context of

Antioquia, characterized by its topographic and urban heterogeneity, this strategy acquires special technical relevance.

The developed information system integrates orders, route programming, delivery tracking, and document management, configuring itself as a cyber-physical decision support system. From a systems engineering perspective, this integration reduces informational fragmentation and allows continuous feedback between planning and execution. Recent literature on healthcare supply chains highlights that real-time visibility and data interoperability are critical factors to improve performance and resilience, especially in essential inputs such as medical gases (World Health Organization, 2024; OECD, 2024). The study results empirically support these approaches in a real operational context.

The use of digital twins and three-dimensional modeling provides an additional component of technological maturity to the system. The digital twin functions as a functional representation of the production and logistical process, allowing simulation of scenarios, evaluation of alternative configurations, and anticipation of impacts before their physical implementation. Recent studies show that digital twins in logistics and supply chains increase the analytical capacity of the system, improve decision-making, and reduce operational risks when integrated with real process data (Boschert & Rosen, 2016; Liu et al., 2024; Román et al., 2025). In this project, 3D modeling not only fulfills a design function but also supports training, technical communication, and continuous improvement.

From a regulatory and risk management perspective, end-to-end digital traceability strengthens the system's capacity to demonstrate compliance and respond to audits, incidents, or critical events. Recent evidence indicates that digital traceability systems reduce errors, improve transparency, and increase resilience in regulated supply chains, especially when directly integrated into operational processes and not limited to reporting functions (Sim et al., 2022). In this sense, replacement of physical documentation with structured digital records represents a substantial improvement in terms of system control and governance.

On the other hand, despite the results obtained, this study presents some limitations that should be considered when interpreting its findings. First, it is an applied case study, focused on a company and a specific geographical context, which may limit direct generalization of results to other territories or organizational configurations. Second, although operational and administrative improvements are reported, the analysis is mainly based on internal system indicators and does not incorporate, at this stage, experimental methods or comparisons with control groups. Likewise, impact evaluation focuses on operational and logistical variables, without delving into long-term clinical or environmental metrics. Finally, the level of technological maturity and organizational disposition to change can significantly influence results, suggesting that model replicability requires considering contextual and change management factors.

With the above, it can be concluded that the integration of GMP, comprehensive digitalization, logistical optimization,

and digital twins constitutes a technically sound approach to improve the performance of medical and industrial gas production and distribution systems. The results support the research objective and suggest that this type of integrated architecture can serve as a reference for modernization processes in regulated sectors, provided they are adapted to the technical, organizational, and regulatory conditions of each context.

CONCLUSIONS

The present study demonstrated that technological, logistical, and digital integration in the production and distribution of medical and industrial gases constitutes an effective strategy to improve safety, operational efficiency, and traceability in the Colombian context. Based on the implementation of a comprehensive model based on Good Manufacturing Practices, international standards, and advanced digital tools, it was evidenced that it is possible to overcome the limitations associated with traditional management schemes, characterized by manual processes, high dependence on physical documentation, and operational fragmentation.

One of the main contributions of the study was the validation of a vehicle fleet specialization approach adapted to the complex geography of the department of Antioquia. The differentiated incorporation of motorcarts, vans, cargo trucks, and tanker trucks allowed optimizing delivery times, improving service coverage, and strengthening supply continuity in urban, rural, and institutional scenarios. This result confirms that medical gas logistics must be conceived as a dynamic system, sensitive to territorial context and aligned with risk management principles, even when national regulations do not establish specific guidelines in this regard.

The implementation of custom software AIR-Bioxigen was consolidated as a structural element of the model, by integrating route programming, real-time delivery control, and digitalization of administrative and contractual processes. The results evidenced a significant reduction in administrative burden, a decrease in paper use, and a substantial improvement in information traceability, strengthening response capacity to audits and critical events. This finding highlights that digitalization not only optimizes costs but becomes an essential component of supply system safety.

The web platform for order management proved to be a key factor in strengthening customer relationships, by offering transparency, access to historical information, and real-time tracking. Adoption of this tool generated an increase in user trust and satisfaction, including industrial gas customers, who evidenced a positive change in their perception when interacting with processes aligned with quality standards and GMP traditionally associated with the health sector.

The use of design and 3D modeling, supported by digital twin principles, allowed optimizing the arrangement of equipment, operational areas, and workflows in the production plant, comparing them with standards of multinational gas companies and the national pharmaceutical industry. This approach facilitated informed decision-making, reduced risks associated with physical

modifications, and contributed to raising the level of productivity and process quality.

Finally, the study provides relevant evidence for the regulatory debate in Colombia, evidencing the need to update NTC 5318 and harmonize the regulatory framework with international standards such as NFPA 99 and ISO 7396-1. The proposed model is positioned as a replicable technical reference, capable of guiding both companies in the sector and sanitary authorities in the modernization of the medical gas supply system.

Future Research Lines

Based on the results obtained, several future research lines are identified that can expand and deepen knowledge in this field. First, it is pertinent to develop studies oriented to quantitative evaluation of the clinical impact of improvement in continuity and traceability of medical gas supply, analyzing its relationship with patient safety indicators and care quality in healthcare institutions.

Second, it is proposed to investigate the integration of artificial intelligence and predictive analytics in logistics management software, in order to anticipate supply failures, optimize demand, and improve vehicle fleet planning in high variability scenarios. This line would allow evolving from reactive models to proactive risk management systems.

Another relevant line corresponds to regulatory harmonization analysis, comparatively evaluating the applicability of NFPA 99 and ISO 7396-1 in the Colombian context and proposing adaptive regulatory models that can be incorporated in future updates of NTC 5318. This approach would contribute to reducing heterogeneity in inspection and surveillance processes by sanitary authorities.

Likewise, it is recommended to deepen the study of environmental impact and sustainability, evaluating the reduction of carbon footprint associated with route optimization, fleet modernization, and decrease in paper use through document digitalization.

Finally, future research could explore the replicability of the model in other regions of Colombia and in Latin American countries with similar regulatory and geographical contexts, validating its scalability and adaptability to different operational realities.

REFERENCE

1. National Fire Protection Association. (2024). NFPA 99: Health Care Facilities Code. NFPA.
2. International Organization for Standardization. (2018). ISO 7396-1: Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum. ISO.
3. World Health Organization. (2023). Oxygen sources and distribution for COVID-19 treatment centres. WHO.
4. Ministerio de Salud y Protección Social. (2022). Lineamientos para la gestión de tecnologías en salud. Colombia.
5. United States Food and Drug Administration. (2022). Current Good Manufacturing Practice (CGMP) regulations. FDA.
6. Grieves, M., & Vickers, J. (2017). Digital twin: Mitigating unpredictable, undesirable emergent behavior in complex systems. In *Transdisciplinary perspectives on complex systems* (pp. 85–113). Springer. https://doi.org/10.1007/978-3-319-38756-7_4
7. Boschert, S., & Rosen, R. (2016). Digital twin—The simulation aspect. In *Mechatronic futures* (pp. 59–74). Springer.
8. Toth, P., & Vigo, D. (2014). *Vehicle routing: Problems, methods, and applications*. SIAM.
9. Rodríguez, J. P., Comtois, C., & Slack, B. (2020). *The geography of transport systems* (5th ed.). Routledge.
10. Kane, G. C., Palmer, D., Phillips, A. N., Kiron, D., & Buckley, N. (2015). Strategy, not technology, drives digital transformation. *MIT Sloan Management Review*, 14(1), 1–25.
11. OECD. (2021). *Digital security risk management*. OECD Publishing.
12. World Health Organization. (2024). *Strengthening health supply chains: A global perspective*. WHO.
13. OECD. (2024). *Health system resilience and supply chain management*. OECD Publishing.
14. Liu, M., Fang, S., Dong, H., & Xu, C. (2024). Review of digital twin about concepts, technologies, and industrial applications. *Journal of Manufacturing Systems*, 73, 536–549.
15. Román, M., Rodríguez, J., & García, A. (2025). Digital twins in supply chain optimization: A systematic review. *International Journal of Production Research*, 63(2), 412–431.
16. Sim, J., Kim, S., & Park, J. (2022). Digital traceability systems in pharmaceutical supply chains: Impact on quality and compliance. *Journal of Pharmaceutical Innovation*, 17(3), 678–692.