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## Review Article

# Navigating Compliance: Key Insights from The Latest Amendments to Title 21 CFR Part 213 On Medical Gases

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### ABSTRACT

The article delves into Title 21 CFR Part 213, focusing on the current good manufacturing practices (cGMP) for medical gases, as regulated by the U.S. Food and Drug Administration (FDA)<sup>1,2</sup>. The primary aim of these regulations is to guarantee that medical gases, such as oxygen, nitrogen, and nitrous oxide, are produced, processed, packed, and held under conditions ensuring their safety, identity, strength, quality, and purity<sup>1,2</sup>. The most recent amendment enacted on June 18, 2024, introduces critical updates to the certification processes for designated medical gases, post marketing safety reporting, and labelling requirements to mitigate risks like fire hazards<sup>1,3</sup>. These updates underscore the FDA's commitment to patient safety and product integrity<sup>1,3</sup>. By examining the historical context, key components, recent amendments, and compliance enforcement, this article provides a comprehensive overview of the regulatory landscape for medical gases<sup>1,2</sup>. It highlights the importance of adherence to these standards for manufacturers and healthcare providers alike, ensuring the highest quality of medical gases for patient care<sup>1,2</sup>. The article concludes with a discussion on the future outlook of medical gas manufacturing practices, emphasizing the ongoing need for vigilance and compliance in this critical sector<sup>1,2</sup>.

## INTRODUCTION

The Current Good Manufacturing Practice (CGMP) regulations play a pivotal role in ensuring the quality and safety of medical gases, which are essential components in various healthcare settings<sup>1</sup>. Medical gases, including oxygen, nitrogen, carbon dioxide, helium, and nitrous oxide, are utilized for critical medical treatments

and must adhere to stringent standards to safeguard patient health<sup>1</sup>. Title 21 CFR Part 213 sets forth the specific CGMP requirements for medical gases, addressing their unique manufacturing, packaging, labelling, storing, and distribution needs<sup>2</sup>. The significance of these regulations cannot be overstated, as they provide a comprehensive framework that helps

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manufacturers maintain high-quality standards and regulatory compliance<sup>2</sup>. The recent amendments, published on **June 18, 2024**, mark a significant milestone in the evolution of CGMP regulations for medical gases<sup>3</sup>. These updates reflect advancements in industry practices, address emerging challenges, and aim to enhance the overall safety and efficacy of medical gases<sup>3</sup>. By incorporating more precise standards and streamlined processes, the amendments ensure that manufacturers can consistently meet the rigorous requirements necessary to protect public health<sup>3</sup>.

## Background

The regulation of medical gases under the Current Good Manufacturing Practice (CGMP) framework has a long history, reflecting the evolving understanding of safety and quality in the pharmaceutical industry<sup>1</sup>. Initially, medical gases were regulated under broader CGMP regulations applicable to all pharmaceuticals<sup>1</sup>. However, the unique properties and critical applications of medical gases highlighted the need for specific, tailored regulations<sup>3</sup>.

## Historical Context:

- **Early Regulations:** Medical gases have been a crucial part of healthcare for decades, with oxygen being one of the earliest and most widely used medical gases. The initial regulatory framework treated medical gases similarly to other pharmaceuticals, without specific provisions to address their unique characteristics<sup>4,5</sup>.
- **Emergence of Specific Standards:** Over time, it became evident that the general CGMP regulations were insufficient to address the complexities associated with the production, storage, and distribution of medical gases. This led to the development of dedicated regulations aimed at ensuring the safety, efficacy, and quality of these critical products<sup>6,7</sup>.

## Previous Versions:

- The CGMP regulations for medical gases have undergone several iterations. Earlier versions focused on basic quality control measures and manufacturing practices. However, advancements in technology, increased understanding of risks, and the growing diversity of medical gases necessitated more comprehensive and detailed regulations<sup>8,9</sup>.
- **Periodic Revisions:** Over the years, the regulations have been periodically revised to incorporate new scientific knowledge, address industry feedback, and respond to emerging challenges. Each revision aimed to enhance the clarity, applicability, and effectiveness of the regulations<sup>1,3</sup>.

## Need for Updates:

- **Technological Advancements:** With rapid technological advancements in the production and distribution of medical gases, the regulations needed to be updated to reflect current industry practices and technological capabilities<sup>12</sup>.
- **Safety Concerns:** Incidents related to the improper use, storage, or labeling of medical gases underscored the need for stricter regulations to ensure patient safety and mitigate risks<sup>13</sup>.
- **Industry Growth:** The expansion of the medical gas industry, including the introduction of new gases and novel applications, called for regulations that could accommodate these developments while maintaining high safety and quality standards<sup>14</sup>.
- **Global Harmonization:** The need to align with international standards and practices also drove the updates, ensuring that U.S. regulations are consistent with those in other major markets, facilitating global trade and compliance<sup>13</sup>.



The most recent amendments, published on **June 18, 2024**, are a culmination of these needs, providing a robust and comprehensive regulatory framework specifically tailored to the unique challenges and requirements of the medical gas industry<sup>16</sup>.

### Key Amendments

- **Updates to CGMP Standards:** The amendments introduce more stringent standards for production facilities and equipment used in the manufacturing of medical gases. These standards are designed to ensure that medical gases meet the highest quality criteria and are free from contaminants<sup>3</sup>.
- **Certification Process:** A streamlined certification process for designated medical gases (DMGs) has been established. This process includes clear guidelines for manufacturers to follow when seeking certification, reducing administrative burdens and ensuring consistency in the evaluation of medical gases<sup>3</sup>.
- **Postmarketing Safety Reporting:** New requirements for postmarketing safety reporting have been introduced to enhance monitoring and ensure swift action in case of adverse events. These changes address both human and animal use of medical gases and reflect the development, manufacturing, and distribution processes<sup>3</sup>.
- **Labeling Requirements:** The amendments include updated labeling requirements, such as mandatory "no smoking" and "no vaping" statements, as well as graphic warning symbols on oxygen containers to mitigate fire risks. These changes aim to improve consumer awareness and safety<sup>3</sup>.

### Impact on Industry

The amendments to **Title 21 CFR Part 213** have a profound impact on the medical gas industry,

introducing both challenges and benefits for manufacturers.

### Challenges

1. **Increased Compliance Requirements:** Manufacturers must upgrade their facilities and equipment to meet the new, more stringent CGMP standards. This can involve significant investment in new technology and infrastructure<sup>1</sup>.
2. **Certification Process:** While the streamlined certification process aims to reduce administrative burdens, manufacturers must still navigate this new system. Ensuring that all required documentation and quality assurance measures are in place can be time-consuming and resource-intensive<sup>3</sup>.
3. **Labeling Updates:** The updated labeling requirements necessitate changes in packaging and labeling processes. Manufacturers must ensure that their products meet the new standards, which may involve redesigning labels and updating printing equipment<sup>3</sup>.
4. **Postmarketing Safety Reporting:** The new requirements for postmarketing safety reporting add another layer of responsibility for manufacturers. They must establish robust systems for monitoring, reporting, and addressing adverse events, which could require additional personnel and resources<sup>3</sup>.

### Benefits

1. **Enhanced Product Quality:** The updated CGMP standards ensure that medical gases are produced under the highest quality conditions, leading to improved product consistency and reliability. This can enhance the reputation of manufacturers and increase consumer trust<sup>1</sup>.
2. **Clearer Regulatory Framework:** The amendments provide a clearer and more specific regulatory framework tailored to the unique characteristics of medical gases. This



helps manufacturers better understand and comply with the regulations, reducing the risk of non-compliance and associated penalties<sup>3</sup>.

3. **Improved Consumer Safety:** The focus on consumer safety, including stricter labeling requirements and enhanced postmarketing surveillance, helps protect end-users from potential risks. This can reduce the incidence of adverse events and improve overall patient outcomes<sup>1</sup>.
4. **Market Opportunities:** The streamlined certification process can facilitate the introduction of new medical gas products into the market. By reducing administrative burdens and providing clearer guidelines, manufacturers can innovate and bring new products to market more efficiently<sup>3</sup>.
5. **Global Competitiveness:** Aligning with international standards and practices enhances the global competitiveness of U.S. manufacturers. By adhering to rigorous CGMP standards, manufacturers can more easily enter and compete in international markets<sup>13</sup>.

In summary, while the amendments to Title 21 CFR Part 213 present certain challenges for manufacturers, the long-term benefits of enhanced product quality, clearer regulatory frameworks, improved consumer safety, and increased market opportunities outweigh these challenges. These changes ultimately contribute to a more robust and reliable medical gas industry.

## Regulatory Compliance

Compliance with the new regulations under **Title 21 CFR Part 213 - Current Good Manufacturing Practice for Medical Gases** requires manufacturers to adhere to a comprehensive set of standards and procedures designed to ensure the safety, quality, and efficacy of medical gases. Here are the key requirements for compliance and the steps manufacturers need to take:

## Key Compliance Requirements

1. **Upgraded Facilities and Equipment:** Manufacturers must ensure that their facilities and equipment meet the updated CGMP standards. This involves regular inspections, maintenance, and upgrades to prevent contamination and ensure consistent product quality<sup>1</sup>.
2. **Quality Control and Assurance:** Implement robust quality control and assurance processes to monitor and verify that all manufacturing activities comply with the regulatory standards. This includes regular testing and validation of the gases produced<sup>1</sup>.
3. **Proper Documentation:** Maintain accurate and detailed records of all manufacturing processes, including raw materials, production batches, equipment maintenance, and quality control tests. Proper documentation is crucial for demonstrating compliance during inspections<sup>1</sup>.
4. **Employee Training:** Ensure that all personnel involved in the manufacturing process are adequately trained on the updated CGMP regulations and procedures. Continuous training programs should be in place to keep employees informed about any changes or updates<sup>1</sup>.
5. **Certification:** Follow the streamlined certification process for designated medical gases (DMGs). This includes preparing and submitting the necessary documentation and ensuring that the products meet all certification requirements<sup>1</sup>.
6. **Labeling and Packaging:** Comply with the updated labeling and packaging requirements, including mandatory "no smoking" and "no vaping" statements, as well as graphic warning symbols on oxygen containers. Labels must be clear, accurate, and compliant with the regulatory standards<sup>1</sup>.
7. **Postmarketing Safety Reporting:** Establish a robust system for monitoring and reporting adverse events related to the use of medical



gases. This includes timely reporting to the regulatory authorities and taking appropriate corrective actions<sup>1</sup>.

### Steps to Ensure Compliance

1. **Conduct a Gap Analysis:** Perform a thorough gap analysis to identify areas where current practices may fall short of the updated regulations. This helps in understanding the specific changes needed to achieve compliance<sup>1</sup>.
2. **Develop a Compliance Plan:** Create a detailed compliance plan outlining the steps required to meet the new regulations. This plan should include timelines, responsibilities, and resources needed for implementation<sup>1</sup>.
3. **Upgrade Facilities and Equipment:** Invest in upgrading facilities and equipment to meet the new CGMP standards. This may involve purchasing new machinery, retrofitting existing equipment, or enhancing cleanroom environments<sup>1</sup>.
4. **Implement Quality Management Systems:** Establish or enhance quality management systems to ensure consistent application of CGMP standards. This includes procedures for quality control, risk management, and continuous improvement<sup>1</sup>.
5. **Train Employees:** Develop comprehensive training programs for all employees involved in the manufacturing process. Ensure that they understand the new regulations and are capable of implementing the required procedures<sup>1</sup>.
6. **Maintain Documentation:** Establish robust documentation practices to record all aspects of the manufacturing process. Ensure that records are complete, accurate, and readily accessible for inspections<sup>1</sup>.
7. **Engage with Regulatory Authorities:** Maintain open communication with regulatory authorities to stay informed about

any updates or changes to the regulations. Seek guidance or clarification when needed<sup>1</sup>.

8. **Monitor Compliance:** Regularly review and audit compliance with the new regulations. Conduct internal audits and inspections to identify and address any non-compliance issues promptly<sup>1</sup>.

By following these steps, manufacturers can ensure that they meet the updated regulatory requirements for medical gases, thereby enhancing product quality, safety, and regulatory compliance.

### Consumer Safety

The updated regulations under **Title 21 CFR Part 213 - Current Good Manufacturing Practice for Medical Gases** play a crucial role in enhancing consumer safety and ensuring the quality of medical gases. Here are some of the key ways these regulations achieve this:

#### Stringent Quality Control

The updated CGMP standards introduce more stringent quality control measures, ensuring that medical gases are produced under highly controlled conditions. This includes regular testing for contaminants and impurities, which helps in preventing compromised products from reaching consumers<sup>1</sup>.

#### Improved Manufacturing Practices

The regulations require manufacturers to adhere to updated best practices in manufacturing, which include the use of state-of-the-art equipment and facilities. By maintaining high standards of cleanliness and precision in the manufacturing process, the risk of contamination is significantly reduced, leading to safer end products<sup>1</sup>.

#### Enhanced Labeling Requirements

One of the critical updates in the regulations is the enhanced labeling requirements. These include



mandatory "no smoking" and "no vaping" statements, as well as graphic warning symbols on oxygen containers. These labels serve as clear warnings to consumers about the potential hazards associated with improper use of medical gases, thereby reducing the risk of accidents and misuse<sup>1</sup>.

### **Robust Postmarketing Surveillance**

The updated regulations also strengthen postmarketing safety reporting requirements. Manufacturers are now required to implement more robust systems for monitoring and reporting adverse events related to the use of medical gases. This ensures that any potential safety issues are quickly identified and addressed, protecting consumers from harm<sup>1</sup>.

### **Certification Process**

The streamlined certification process ensures that only medical gases that meet the highest safety and quality standards are allowed in the market. By providing clear guidelines for certification, the regulations help manufacturers produce consistent and reliable products, ultimately benefiting consumers<sup>1</sup>.

### **Consistent Standards**

The updated CGMP regulations provide a clear and consistent framework for manufacturers to follow. This consistency helps in maintaining high standards across the industry, ensuring that all medical gases meet the necessary safety and quality requirements. As a result, consumers can trust that the medical gases they use are safe and effective<sup>1</sup>.

### **Focus on Consumer Awareness**

The emphasis on clear and informative labeling, combined with robust postmarketing surveillance, enhances consumer awareness and safety. By providing consumers with the information they need to use medical gases safely, the regulations

help prevent accidents and ensure proper usage<sup>1</sup>. In summary, the updated regulations under Title 21 CFR Part 213 significantly enhance consumer safety and the quality of medical gases. By implementing stringent quality control measures, improving manufacturing practices, enhancing labeling requirements, and strengthening postmarketing surveillance, the regulations ensure that medical gases are safe, effective, and reliable for all users<sup>1</sup>.

### **Future Implications**

The regulation of medical gases is likely to continue evolving in response to technological advancements, emerging safety concerns, and global harmonization efforts. Here are some potential future developments and how manufacturers can prepare for these changes<sup>1</sup>:

### **Potential Future Developments**

1. **Technological Integration:** The integration of advanced technologies such as sensors, IoT (Internet of Things) connectivity, and data analytics is expected to play a significant role in the future of medical gas regulation. These technologies can enhance real-time monitoring of gas levels, pressure, and flow rates, improving safety and efficiency<sup>15</sup>.
2. **Global Harmonization:** As the medical gas industry becomes increasingly global, there will be a greater emphasis on harmonizing regulations across different countries. This will facilitate international trade and ensure that manufacturers meet consistent standards worldwide<sup>13</sup>.
3. **Sustainability Focus:** Future regulations may place a stronger emphasis on sustainability, encouraging manufacturers to adopt eco-friendly practices in the production and distribution of medical gases<sup>16</sup>.
4. **Enhanced Safety Measures:** With the growing demand for medical gases, especially in critical care settings, future regulations may introduce more stringent safety measures to



prevent accidents and ensure the safe handling and use of these gases<sup>17</sup>.

5. **Postmarketing Surveillance:** Enhanced postmarketing surveillance systems will likely be implemented to monitor the long-term safety and efficacy of medical gases. This will help identify and address any potential issues more quickly<sup>3</sup>.

### How Manufacturers Can Prepare

1. **Stay Informed:** Manufacturers should stay updated on regulatory changes and industry trends by participating in relevant conferences, workshops, and industry associations. This will help them anticipate and adapt to upcoming changes<sup>18</sup>.
2. **Invest in Technology:** Investing in advanced technologies such as IoT and data analytics can help manufacturers improve their monitoring and compliance processes. These technologies can provide valuable insights into production processes and help identify areas for improvement<sup>15</sup>.
3. **Enhance Quality Management Systems:** Strengthening quality management systems to align with future regulatory requirements will be crucial. This includes implementing robust documentation practices, risk management protocols, and continuous improvement processes<sup>8</sup>.
4. **Engage with Regulatory Authorities:** Building strong relationships with regulatory authorities can provide manufacturers with valuable guidance and support. Regular communication with these authorities can help manufacturers understand upcoming changes and prepare accordingly<sup>8</sup>.
5. **Focus on Sustainability:** Adopting sustainable practices in the production and distribution of medical gases can help manufacturers stay ahead of future regulatory requirements. This includes reducing waste, optimizing energy use, and exploring eco-friendly alternatives<sup>16</sup>.

6. **Prepare for Global Markets:** Manufacturers should prepare to meet international standards and regulations to facilitate global trade. This may involve obtaining certifications and ensuring compliance with the regulatory requirements of different countries<sup>13</sup>.

By proactively addressing these potential future developments, manufacturers can ensure that they remain compliant with regulations, enhance consumer safety, and maintain a competitive edge in the industry.

### Dates:

This rule is effective December 18, 2025, except for the amendments to §§ 4.2 (amendatory instruction 2), 4.3 (amendatory instruction 3), and 4.4 (amendatory instruction 4) (21 CFR 4.2, 4.3, and 4.4), which are effective February 2, 2026. The incorporation by reference of certain material listed in this rule has been approved by the Director of the Federal Register as of February 2, 2026<sup>3</sup>.

### CONCLUSION

The updated Title 21 CFR Part 213 represents a significant step forward in ensuring the safety, quality, and efficacy of medical gases. By adhering to these regulations, manufacturers can assure healthcare providers and patients that the medical gases they rely on are produced under stringent and consistent standards<sup>1</sup>. The latest amendments, which came on June 18, 2024, underscore the ongoing commitment to patient safety and product reliability<sup>3</sup>. In summary, the 2024 amendments to Title 21 CFR Part 213 reflect an evolving landscape of medical gas manufacturing, where quality and safety are paramount. As the industry continues to innovate and develop, these regulations will play a crucial role in safeguarding public health<sup>3</sup>. Moving forward, manufacturers must remain diligent in their efforts to comply with these standards, thereby contributing to the overall integrity and



trustworthiness of medical gas products<sup>3</sup>. This continued vigilance will ensure that the medical gases used in hospitals, clinics, and homecare settings are of the highest quality, ultimately supporting the well-being of patients worldwide<sup>3</sup>.

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