
Understanding Compounding Pharmacy: Processes and Regulations

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Abstract:

Compounding pharmacy involves the customized preparation of medications tailored to the specific needs of individual patients. Unlike mass-produced pharmaceuticals, compounding pharmacists create unique formulations that may include altering the dosage forms, combining ingredients, or removing allergens. The processes in compounding pharmacy are governed by strict guidelines to ensure safety and efficacy. Compounding typically involves several steps: assessing patient needs, preparing the medication in a controlled environment, and conducting quality control tests to verify the final product. Regulations by the United States Pharmacopeia (USP), the Food and Drug Administration (FDA), and state licensing boards help ensure that compounded medications meet stringent safety standards and are free from contaminants. Regulatory oversight of compounding pharmacies is critical for patient safety, given the potential risks associated with improperly prepared medications. The Drug Quality and Security Act (DQSA) was enacted in 2013 to enhance the regulation of compounding pharmacies. It established a framework for distinguishing between traditional compounding for individual patients and larger-scale operations that may function more like drug manufacturers. Compliance with these regulations includes maintaining proper records, undergoing regular inspections, and adhering to good compounding practices (GCP). By ensuring rigorous adherence to these standards, compounding pharmacies can provide effective and safe personalized medications while minimizing risks to patients.

Keywords: Compounding Pharmacy, Customized Medications, Patient-Specific Formulations, Preparation Processes, Safety and Efficacy, Quality Control, Regulatory Oversight, United States Pharmacopeia (USP), Food and Drug Administration (FDA), Drug Quality and Security Act (DQSA), Good Compounding Practices (GCP), Risk Minimization.

Introduction:

In the realm of pharmaceutical care, the intersection of personalized medicine and regulatory frameworks gives rise to a critical area known as compounding pharmacy. This specialized practice involves the tailored preparation of medications by pharmacists to meet the unique needs of patients. Compounding pharmacies play an essential role in

ensuring that patients receive medications that are often unavailable in standard formulations, whether due to allergies, specific dosages, or the need for alternative delivery methods. In recent years, the significance of compounding pharmacy has been amplified, prompting a closer examination of its underlying processes and the regulations imposed to govern its practice [1].

Compounding pharmacy differs fundamentally from conventional pharmacy, where medications are manufactured in bulk by pharmaceutical companies and dispensed directly to patients. Compounding pharmacists utilize their expertise in chemistry, pharmacology, and therapeutic decision-making to create customized medications based on a licensed healthcare provider's prescription. This process involves various practical activities, including the selection of raw ingredients, accurate measurement and mixing, and the formulation of dosage forms tailored to individual patient profiles. Compounding can address a variety of patient needs, from flavoring medications for children to formulating hormone replacement therapies and preparing sterile products for immediate use in hospitals [2].

However, the appeal and necessity of compounding pharmacy do not come without challenges. Due to the individualized nature of compounded medications, there is an increased risk of variability in quality, potency, and sterility when compared to mass-produced pharmaceuticals. This concern has underscored the need for stringent oversight and regulation of compounding practices to ensure patient safety and uphold the integrity of the pharmaceutical supply chain. Over the years, various legislative and regulatory measures have been introduced in response to high-profile incidents involving contaminated or improperly compounded medications, further emphasizing the necessity for robust compliance protocols [3].

Regulatory frameworks governing compounding pharmacy operate at both state and federal levels, each with its unique set of guidelines and requirements. In the United States, the Food and Drug Administration (FDA) and state pharmacy boards are primarily responsible for overseeing compounding practices. The Drug Quality and Security Act (DQSA) of 2013 established critical distinctions between traditional compounding—performed by pharmacists based on individual prescriptions—and large-scale compounding operations, referred to as outsourcing facilities. This legislation aimed to bolster the safety and effectiveness of compounded medications by implementing stringent reporting and compliance mechanisms for outsourcing facilities [4].

Furthermore, individual state pharmacy boards maintain their guidelines, which can vary

significantly across jurisdictions. This decentralized regulatory approach has led to a patchwork of standards and practices, creating potential compliance challenges for pharmacists operating in multiple states or serving patients in border communities. As a result, the conversation around compounding pharmacy continues to evolve, highlighting the need for increased education and communication among stakeholders, including healthcare providers, pharmacists, and regulatory agencies [5].

Gaining a comprehensive understanding of the processes and regulations surrounding compounding pharmacy is crucial for promoting patient safety and efficacy in pharmaceutical care. This involves not only examining the technical aspects of compounding such as formulation techniques, quality control measures, and product stability but also exploring the ethical and legal implications of personalized medicine. Addressing these complexities requires an ongoing commitment to research, best practices, and policy development, ensuring that compounding pharmacy can safely and effectively fulfill its vital role in healthcare [6].

History and Evolution of Compounding Practices:

Compounding practices in pharmacy represent a crucial yet often underappreciated aspect of the healthcare landscape. The art and science of compounding involve the preparation of personalized medications tailored to the individual needs of patients [7].

The roots of compounding can be traced back to ancient civilizations, where the art of medicine was intertwined with that of pharmacy. In Mesopotamia, around 3000 BCE, practitioners formulated medicines using a range of local plants and minerals, experimenting with various dosages and combinations. The Ebers Papyrus, an ancient Egyptian medical text dating back to 1550 BCE, documents numerous recipes for various ailments, demonstrating an early understanding of medicinal properties [8].

Greek physician Hippocrates (460-370 BCE) is often regarded as the "Father of Medicine." He emphasized the importance of observation and the use of natural substances in treatment, setting the stage for future advancements. In the first century

AD, Dioscorides wrote "De Materia Medica," a five-volume pharmacopoeia that provided instructions on compounding drugs from plants, animals, and minerals, emphasizing the necessity of individualized treatment [9].

The Middle Ages marked a significant phase in the development of compounding practices. Islamic scholars preserved Greek medical texts and expanded upon them, developing a sophisticated understanding of pharmacology. Avicenna, a Persian scholar, wrote "The Canon of Medicine," which included principles for the preparation of medications. This era saw the emergence of apothecaries who began to play a pivotal role in compounding, moving beyond merely collecting herbs to preparing and dispensing tailored medicines [10].

The Renaissance further advanced compounding practices as curiosity about human anatomy and physiology ignited a scientific exploration of health and illness. The introduction of the printing press allowed for the dissemination of knowledge, leading to the establishment of more structured educational environments for aspiring pharmacists and physicians. The formulation of various tinctures, elixirs, and powders became more precise as innovations in chemistry emerged, laying the groundwork for modern pharmacological principles [11].

The 19th century was a transformative period for compounding practices. The rise of industrialization and advances in chemistry heralded a new era of drug manufacturing. The isolation of active pharmaceutical ingredients (APIs) from natural sources began to take precedence; morphine, quinine, and aspirin emerged as significant products of this era. However, despite these developments, the role of the pharmacist as a compounding expert remained relevant. Many pharmacists worked in their own apothecaries, compounding medications to suit individual patients, particularly before the mass production of drugs became commonplace [12].

The founding of the American Pharmaceutical Association in 1852 and the establishment of pharmacy schools aimed to standardize pharmaceutical education and practice, underscoring the importance of compounding in the pharmacy profession. By the latter half of the

century, innovations such as the introduction of the metric system further refined compounding practices by enhancing measurement precision [13].

The 20th century witnessed a paradigm shift in compounding practices. The advent of commercial pharmaceuticals in the early decades, particularly with the introduction of antibiotics and other life-saving medications like insulin, led to a decline in personalized compounding as patients began to rely more on standardized medications. Mass production offered convenience and efficiency, and pharmaceutical companies rapidly expanded their operations to meet the growing demand [14].

However, compounding did not fade entirely from the landscape. It remained an integral part of patient care, especially for individuals requiring unique formulations due to allergies, specific dosages, or administration routes. During this time, regulatory bodies, notably the U.S. Food and Drug Administration (FDA), began to take notice of compounding practices, advocating for increased oversight to ensure safety and efficacy due to concerns surrounding quality control, particularly in unregulated compounding practices [15].

Entering the 21st century, the practice of compounding experienced renewed interest, fueled by an increasing recognition of the need for personalized medicine. Patients with complex medical conditions such as cancer, hormonal imbalances, or chronic pain often require tailored therapies that cannot be satisfied by commercially available products. In response to this, advancements in technology, including computer-assisted compounding and sophisticated sterile compounding practices, have transformed how pharmacists prepare individualized medications. This raises the standard of care and ensures higher efficacy and safety for patients [16].

However, the surge in compounding practices has also ushered in significant challenges and scrutiny. The tragic outbreak of fungal meningitis in 2012, linked to contaminated compounded steroids from a compounding pharmacy, highlighted the urgent need for stricter regulatory measures. In its aftermath, the Drug Quality and Security Act (DQSA) was enacted in 2013, which established a new regulatory framework for compounding pharmacies and emphasized the need for compliance with stringent quality assurance practices. This

represented a pivotal moment in the history of compounding, underscoring the delicate balance between the necessity of individualized patient care and the due diligence required to safeguard public health [17].

Key Processes in Compounding Pharmacy:

Compounding pharmacy refers to the tailored preparation of medications by licensed pharmacists to meet unique patient needs. Unlike commercial medications, which are manufactured in bulk and include standardized dosages and formulations, compounded medications are made to order. This personalized approach is crucial for patients who may have specific health conditions, allergies, or preferences that preclude the use of available commercial products [17].

Compounding pharmacy serves a vital role in healthcare by addressing specific therapeutic requirements. Conditions such as chronic pain management, hormone replacement therapy, pediatric medicine, and palliative care often necessitate individualized treatments. For instance, pediatric patients may require medications in flavors and forms that make them easier to administer, while patients with allergies may need formulations free of particular excipients. Furthermore, compounded medications can be essential for patients who require discontinued drugs or those who need a specific dosage that isn't available in commercially manufactured options [17].

Key Processes in Compounding

The processes involved in compounding pharmacy can be broken down into several key stages, each requiring meticulous attention to detail and adherence to safety guidelines.

1. **Assessment of Patient Needs:** The compounding process begins with a thorough assessment of the patient's medical history and current medication regimen. Pharmacists engage in consultations with patients and healthcare providers to gather essential information regarding allergies, other medications, and therapeutic goals. This dialogue is paramount, as it lays the groundwork for

understanding the tailored medication requirements [18].

2. **Formulation Development:** Once the patient's needs have been assessed, the pharmacist develops a formulation that aligns with those needs. This involves choosing suitable active pharmaceutical ingredients (APIs) and excipients. Depending on the patient's requirements, different dosage forms might be considered—such as creams, gels, oral solutions, capsules, or suppositories. The pharmacist must also consider the stability, solubility, and compatibility of the chosen ingredients [18].
3. **Preparation and Compounding Techniques:** Compounding medications require a high level of precision and adherence to established protocols. There are various methods for compounding, including:
 - **Mixing and Blending:** This is the simplest form of compounding, where the pharmacist mixes the necessary ingredients to achieve the desired final product. It is essential that the pharmacist achieves homogeneity to ensure consistency in dosing [18].
 - **Levigation:** In this process, a solid substance is reduced in particle size using a liquid to facilitate uniform distribution in a cream or ointment.
 - **Emulsification:** This technique combines oil and water phases to create emulsions, which may be necessary for certain topical applications.
 - **Molding or Compression:** For solid dosage forms like tablets, molding or compression techniques are used to achieve the desired shape and hardness.
 - **Sterile Compounding:** Certain medications, particularly those administered via injection, require

sterile preparation techniques to minimize the risk of contamination. This process involves using aseptic techniques in a controlled environment, often necessitating the use of laminar flow hoods and the preparation of specialized sterile products [19].

4. **Quality Control and Testing:** After compounding, the medication undergoes rigorous testing for quality assurance. This includes checking the physical properties of the compound, such as appearance, texture, and consistency. Pharmacists may perform identity and potency tests on each batch to ensure that the medication meets the established specifications. Stability testing is also critical, especially for compounds with shorter shelf lives or those exposed to various environmental factors [20].
5. **Dispensing and Labeling:** Once the compounded medication has passed all quality control checks, it is dispensed to the patient along with appropriate labeling. Labels must contain vital information, including dosage instructions, storage requirements, and any potential side effects. Patient counseling is also a crucial aspect, wherein pharmacists engage in discussions to ensure patients are aware of how to correctly use their medications [20].
6. **Record Keeping and Documentation:** Maintaining meticulous records of each compounded medication is essential for regulatory compliance and patient safety. Pharmacists must document the formulation process, including ingredient sources, lot numbers, and expiration dates. This record-keeping helps in tracking and tracing the medications if any issues arise and also supports ongoing quality assurance [20].

Regulatory Framework

Compounding pharmacies operate within a comprehensive regulatory environment that ensures patient safety and product integrity. In the United States, the U.S. Food and Drug Administration

(FDA) regulates compounded medications, but the extent of regulation may vary between state and federal jurisdictions. State pharmacy boards also impose specific regulations governing compounding practices, including licensing requirements, facility inspections, and staff training standards [21].

In 2013, the Drug Quality and Security Act (DQSA) was enacted to enhance the safety of compounded medications following several high-profile incidents of contamination. The DQSA established clear guidelines for outsourcing facilities that prepare compounded medications for larger distribution, requiring them to adhere to Current Good Manufacturing Practices (cGMP) [22].

Regulatory Framework Governing Compounding Pharmacies:

Compounding pharmacies play a critical role in the healthcare landscape, addressing unique medication needs for patients by creating customized pharmaceutical products. These establishments prepare personalized medications tailored to the specific requirements of individual patients, thus providing essential services that conventional retail pharmacies may not offer. However, due to the inherent risks associated with compounding—such as contamination, dosing errors, and the potential for drug interactions—compounding pharmacies operate under a rigorous regulatory framework designed to ensure patient safety and product efficacy [22].

Compounding refers to the process of combining, mixing, or altering ingredients to create a medication that meets unique patient needs. The compounding process may involve altering the dosage form, flavoring agents, or excipients to suit the patient's age, allergies, or specific medical conditions. Compounding pharmacies can generally be classified into two categories: non-sterile compounding and sterile compounding. Non-sterile compounding includes creating solid, semi-solid, or liquid forms of medications, while sterile compounding involves the preparation of medications that are free from viable microorganisms, typically required for intravenous (IV) medications and parenteral therapies [23].

Regulatory Bodies and Framework

In the United States, the regulatory framework governing compounding pharmacies is multifaceted, involving both federal and state oversight. The two main federal regulatory bodies include the Food and Drug Administration (FDA) and the Drug Enforcement Administration (DEA). At the same time, individual state boards of pharmacy play a crucial role in enforcing laws and regulations that apply to compounding practices [24].

1. Food and Drug Administration (FDA):

The FDA oversees the safety and effectiveness of all pharmaceutical products, including compounded medications. Under the Federal Food, Drug, and Cosmetic Act (FDCA), the FDA has the authority to regulate the manufacture and distribution of all drugs, including those that are compounded. However, the FDA's jurisdiction over compounding has specific exceptions. In 2013, the Drug Quality and Security Act (DQSA) amended the FDCA, distinguishing between traditional compounding pharmacies and larger compounding entities that often manufacture compounded drugs in bulk for distribution across state lines. The latter must register as "outsourcing facilities" and adhere to current Good Manufacturing Practices (cGMP) [25].

2. Drug Enforcement Administration (DEA):

The DEA regulates controlled substances and, consequently, has a direct influence on compounding pharmacies that deal with medications classified as controlled substances. Pharmacies engaging in the compounding of controlled substances must comply with the registrational, record-keeping, and security precautions mandated by the Controlled Substances Act (CSA) [25].

3. State Boards of Pharmacy:

Each state has its own board of pharmacy, which regulates pharmacy practice, including compounding. These boards establish specific guidelines and requirements for compounding practices,

which can vary significantly from one state to another. State regulations often include standards for compounding procedures, facility requirements, personnel qualifications, and record-keeping mandates [25].

Standards and Guidelines

Several organizations contribute to the establishment of best practices and standards within compounding, emphasizing quality control and patient safety.

1. United States Pharmacopeia (USP):

The USP provides compounding pharmacies with a set of standards related to the quality and consistency of compounded formulations. USP General Chapter <797> explicitly addresses sterile compounding practices and outlines requirements for facilities, personnel, equipment, and procedures to minimize risk and ensure patient safety. Similarly, USP General Chapter <795> deals with non-sterile compounding [26].

2. American Pharmacists Association (APhA) & Other Professional Organizations:

Various professional organizations contribute to the conversation surrounding compounding, offering development resources, continuing education, and practice guidance. These organizations often produce practice parameters and educational programs that help compounding pharmacists stay informed about best practices, developments in regulatory science, and advances in technology relevant to compounding [27].

Challenges in Regulation

While the regulatory framework serves a critical purpose, it also presents numerous challenges for compounding pharmacies. One major challenge is the balance between regulation and innovation. As pharmacies strive to customize medications for patients, they face pressure to innovate while remaining compliant with often complex and evolving regulations. The variability in state regulations further complicates compliance,

particularly for pharmacies that operate in multiple states [27].

Another significant issue is the perception of compounding pharmacies versus large pharmaceutical manufacturers. Following incidents of contamination and product recalls—most notably the 2012 fungal meningitis outbreak linked to compounded steroids from a non-sterile compounding facility—public and regulatory scrutiny on compounding practices has intensified. Such events have prompted calls for stricter oversight, particularly concerning sterile compounding, causing some compounding pharmacies to struggle with the increased costs and burdens associated with compliance [28].

Quality Assurance and Control in Compounding:

Quality assurance (QA) and quality control (QC) are two indispensable components in the field of compounding, a practice that involves the customization and preparation of medications to meet the unique needs of patients. Compounding pharmacies play a vital role in healthcare by providing tailored medication solutions when commercially available drugs do not suffice. However, given the complexities and risks associated with drug compounding, the implementation of effective quality assurance and quality control practices is essential to ensure patient safety and therapeutic efficacy [28].

Quality assurance is a systematic approach that involves the establishment of processes and protocols aimed at ensuring that products meet defined quality standards throughout the lifecycle of compounding. It encompasses the planning, implementation, and monitoring of quality-related activities, ultimately fostering a culture of continuous improvement. On the other hand, quality control refers to the operational techniques and activities specifically focused on fulfilling quality requirements. This includes testing and inspection processes to ensure that compounded products are safe, effective, and of the highest quality [29].

Together, QA and QC work synergistically to minimize errors, prevent medication-related harm, and enhance patient outcomes. While QA lays the

groundwork by establishing the framework and standards for consistency, QC serves as the guardrails that catch deviations from these established norms.

In the United States, the compounding pharmacy sector is primarily regulated by state pharmacy boards and the federal Drug Enforcement Administration (DEA). Additionally, the Food and Drug Administration (FDA) plays a significant role, particularly in the oversight of drugs that are compounded in large quantities. The Drug Quality and Security Act (DQSA) of 2013 introduced provisions that distinguish between traditional compounding and the compounding of large volumes for distribution [29].

The DQSA's creation of outsourcing facilities has also brought forth a new layer of regulation, requiring these facilities to adhere to Current Good Manufacturing Practices (CGMPs). Compliance with CGMPs assures that compounded products are consistently produced and controlled per quality standards [30].

Quality assurance in compounding also aligns with the United States Pharmacopeia (USP) guidelines. USP chapters such as USP <795> for non-sterile compounding and USP <797> for sterile compounding set forth standards emphasizing risk assessment, proper facility design, and the implementation of quality management systems, underscoring the necessity for comprehensive quality assurance protocols at every stage [30].

QA and QC Methodologies in Compounding

Implementing QA and QC methodologies is fundamental to achieving high-quality compounded medications. Some of the critical strategies include:

1. **Standard Operating Procedures (SOPs):** Establishing SOPs is a crucial part of QA. These written instructions are designed to guide compounding processes, ensuring consistency and compliance with established quality norms. SOPs cover everything from raw material handling to equipment maintenance and documentation practices [31].
2. **Employee Training and Competency Assessments:** High-quality outcomes rely heavily on the competencies of pharmacy

personnel. Regular training programs and competency assessments are vital to ensure that staff are knowledgeable about compounding techniques, safety protocols, and quality standards [31].

3. **Environmental Monitoring:** In the case of sterile compounding, maintaining a clean and controlled environment is paramount. Environmental monitoring programs help track the cleanliness of compounding areas, air quality, and microbial contamination, enabling proactive measures to mitigate risks [31].
4. **Batch Record Review:** QA necessitates rigorous documentation practices whereby each compounded batch is recorded, detailing materials used, processes followed, and results obtained. These records should be reviewed routinely to ensure compliance and establish accountability [32].
5. **Quality Control Testing:** QC entails systematic testing of compounded formulations, including physical inspection, potency analysis, sterility testing, and stability assessments. This proactive testing helps identify discrepancies before products reach patients [32].
6. **Error Reporting and Feedback Loops:** Establishing a non-punitive error reporting system encourages staff to disclose mistakes or near misses. Analyzing these incidents can inform process improvements and promote a culture of safety within the pharmacy [32].

Challenges in Implementing QA and QC

Despite the clear importance of QA and QC in compounding, several challenges impede their effective implementation. First and foremost, resource limitations, including financial constraints and staff shortages, can hinder the establishment of robust quality systems. Smaller compounding pharmacies, in particular, may struggle to ensure compliance with all regulatory requirements and best practices due to resource limitations [33].

Another notable challenge is the rapidly evolving nature of compounding practices, influenced by emerging therapies and technologies. Keeping abreast of current guidelines, methodologies, and regulatory changes can be overwhelming for pharmacy personnel. Moreover, ensuring consistent application of QA and QC practices across different compounds and formulations can pose a significant challenge [33].

Lastly, the potential for complacency can undermine quality assurance efforts. As compounding becomes routine, there may be a tendency to overlook established protocols, leading to a degradation of quality and an increase in errors. Cultivating a culture of vigilance and commitment to quality is essential for mitigating these risks [34].

Challenges and Risks in Compounding Pharmacy:

Compounding pharmacy plays a critical role in the healthcare system by providing personalized medications tailored to meet the unique needs of patients. Unlike mass-produced pharmaceuticals, compounded medications are crafted by pharmacists who manipulate and combine active ingredients to create formulations that address specific health conditions, allergies, or patient preferences. While compounding pharmacies serve an essential function, they face numerous challenges and risks that can impact patient safety, regulatory compliance, and the overall effectiveness of the medications they provide [35].

One of the primary challenges in compounding pharmacy is navigating the intricate regulatory landscape that governs its practice. In the United States, compounding pharmacies are regulated by both federal and state authorities. The Food and Drug Administration (FDA) sets forth guidelines for outsourcing facilities and bulk drug substances, while individual state boards of pharmacy establish their own regulations concerning the practice of compounding within state lines. These varying regulations can create ambiguity, particularly regarding what qualifies as a compounded medication versus a manufactured drug [35].

This regulatory complexity can lead to compliance issues. Pharmacists must ensure they are not crossing the line into drug manufacturing, which requires stringent testing, quality control, and

approval processes that most compounding pharmacies lack the resources to fulfill. Failure to adhere to these regulations can result in severe consequences, including substantial fines, license revocation, and legal liability, thereby compromising the viability of the pharmacy and endangering patient safety [35].

Unlike commercially manufactured medications, which undergo rigorous quality control measures, compounded medications often lack standardized protocols for ingredient sourcing, preparation processes, and final formulations. This lack of standardization presents significant challenges related to the quality and efficacy of compounded products. Compounding pharmacies must implement their own quality assurance systems to minimize the risks associated with ingredient variability, contamination, and inaccuracies in formulation [36].

Compounded medications often utilize bulk drug substances that may not be subject to the same stringent testing as commercially available drugs. Fluctuations in the quality of raw materials can thus affect the potency and safety of the final product. For instance, the tragic outbreak linked to contaminated compounded steroids in 2012, which led to numerous cases of fungal meningitis, highlighted the dire consequences of inadequate quality control in compounding pharmacies. Such events underscore the importance of robust safety and quality measures and the potential for harm when these are lacking [37].

The personalized nature of compounding pharmacy has its advantages, particularly for patients who require specialized formulations due to allergies, sensitivities, or unique medical needs. However, this personalization can also lead to safety risks if not managed properly. Patients may not always be fully aware of the differences between compounded medications and their commercially available counterparts, leading to misunderstandings regarding efficacy and safety [37].

Additionally, the risks of medication errors are heightened in compounding practices. The complexity involved in formulating bespoke medications increases the likelihood of human error, whether in dosing, common ingredient interactions, or the omission of critical information during patient consultations. Education and clear communication

between pharmacists and patients are essential to mitigate these risks and ensure optimal therapeutic outcomes, yet gaps in understanding persist in many cases [37].

Economic challenges also confront compounding pharmacies, particularly in an era of escalating healthcare costs and changing reimbursement models. Compounding, by its nature, often involves small batch production, which can be cost-prohibitive compared to mass manufacturing. The expense associated with acquiring quality raw ingredients, maintaining pharmacy certifications, and investing in training and quality assurance personnel can strain resources, particularly for smaller compounding pharmacies [38].

Moreover, reimbursement policies from insurance providers for compounded medications can vary significantly, complicating the financial landscape. Patients may face higher out-of-pocket costs for compounded medications, particularly when they are not widely covered by insurance plans. This financial burden can limit access to essential compounded treatments, potentially leading patients to seek alternative (and, in some cases, less effective) therapies that do not meet their unique needs [38].

As technology continues to evolve, compounding pharmacies face both opportunities and challenges regarding the integration of new tech into their operations. Innovations such as automation in the compounding process hold the potential to enhance precision and efficiency, potentially reducing human error and improving product quality. However, the initial investment costs associated with upgrading technology and staff training can be daunting, especially for independently owned pharmacies [39].

Moreover, reliance on technology introduces its own set of challenges, particularly concerning cyber security and data privacy. With increasing instances of data breaches and cyberattacks in the healthcare sector, compounding pharmacies must prioritize the protection of sensitive patient information while still navigating the complexities of integrating advanced technologies into their operations [39].

Comparative Analysis: Compounding vs. Commercial Manufacturing:

The healthcare and pharmaceutical sectors are vital to public health and welfare, serving a critical role in disease prevention, treatment, and management. Within this domain, two distinctive approaches to producing medications have emerged: compounding and commercial manufacturing. Both methods are instrumental in ensuring patient access to medications, though they operate under different frameworks, regulations, goals, and practices [40].

Definitions and Distinctions

At its core, **compounding** refers to the custom formulation of medications tailored to the specific needs of individual patients. Pharmacists create compounded medications when commercially available drugs are unsuitable due to a variety of reasons such as allergies, dosage requirements, or specialty formulations. Compounding can involve combining, mixing, or altering ingredients to create a medication that meets a patient's unique medical conditions or needs [41].

In contrast, **commercial manufacturing** entails the mass production of pharmaceuticals by large-scale companies that conform to strict regulatory standards. These companies produce standardized medications in bulk, which are then distributed to pharmacies, hospitals, and healthcare providers. The process emphasizes consistency, quality control, and broad accessibility of medications to meet the population's general health needs [42].

Processes Involved

Compounding typically involves the following processes:

1. **Assessment of Patient Needs:** This involves gathering detailed health information from patients to understand their specific medication requirements [43].
2. **Formulation Design:** Creating a unique formulation based on the patient's characteristics, such as allergies or dosage form preferences.
3. **Ingredient Sourcing:** Obtaining individual active pharmaceutical ingredients (APIs) and excipients that meet quality standards.

4. **Preparation:** Compounding pharmacists prepare the medication in a controlled environment, adhering to guidelines to ensure safety and efficacy.
5. **Quality Testing:** The compounded medication may undergo some level of quality assurance, although this varies based on local regulations [43].

Commercial manufacturing, on the other hand, follows a more structured process that includes:

1. **Research and Development (R&D):** Extensive studies are conducted to develop a drug, including clinical trials to determine safety and efficacy.
2. **Scale-Up Production:** After a drug is approved, the manufacturing scale is increased to produce large quantities consistent with market demand.
3. **Quality Control:** This stage involves rigorous testing of the drugs for purity, potency, and consistency, often following Good Manufacturing Practices (GMP).
4. **Packaging and Distribution:** Once finalized, medications are packaged for distribution to various healthcare facilities and pharmacies [44].

Regulatory Frameworks

The regulatory landscape governing compounding and commercial manufacturing significantly differs. In the United States, the **Food and Drug Administration (FDA)** oversees commercial manufacturing, imposing stringent requirements to protect public health. Companies must adhere to GMP regulations, conduct extensive preclinical and clinical trials, and submit New Drug Applications (NDAs) to secure FDA approval [45].

Conversely, compounding is generally regulated at the state level. While pharmacists are required to follow specific compounding guidelines as outlined by organizations such as the **Pharmacy Compounding Accreditation Board (PCAB)** and the **National Association of Boards of Pharmacy (NABP)**, the criteria can vary significantly from one state to another. The FDA has stepped in to address concerns, particularly around large-scale compounding operations, but these regulations are

not as comprehensive as those for commercial manufacturing [46].

Advantages and Challenges

Both compounding and commercial manufacturing have unique advantages and challenges.

Advantages of Compounding:

- **Personalization:** Compounded medications can be tailored to individual patient needs, accommodating allergies, adverse effects, or specific dosage forms (liquids, creams).
- **Accessibility:** Compounding pharmacies can provide medications that are discontinued or unavailable in commercial forms.
- **Innovation:** Pharmacists can create novel formulations that address specific health issues or conditions not covered by existing commercial products [47].

Challenges in Compounding:

- **Quality Assurance:** Variability in compounding practices can lead to inconsistencies in potency and quality.
- **Regulatory Scrutiny:** Compounding pharmacies may face increased regulatory pressures, especially following cases of contamination and adverse events.
- **Limited Resources:** Many compounding pharmacies operate on a smaller scale, which can limit their resources for quality control and technology [48].

Advantages of Commercial Manufacturing:

- **Standardization:** Mass-production ensures uniformity and reliability of medications, making them safer for public use.
- **Broad Accessibility:** Commercial manufacturers can produce medications on a scale that meets the needs of large populations, ensuring wide distribution.
- **Research Funding:** Large pharmaceutical companies often have substantial resources

to devote to research, bringing innovative drugs to market [49].

Challenges in Commercial Manufacturing:

- **Cost and Affordability:** The extensive R&D and manufacturing processes can lead to high drug costs, limiting accessibility for some patients [50].
- **Market Dynamics:** The focus on high-volume, standardized drugs may overlook niche patient populations with specific needs.
- **Regulatory Compliance:** The stringent requirements imposed by regulatory bodies can slow down drug development and increase operational costs [51].

Future Trends in Compounding Pharmacy Regulations:

The realm of compounding pharmacy plays a critical role in healthcare, offering customized medications tailored to meet the unique needs of individual patients. This practice involves the preparation, mixing, assembling, altering, packaging, and labeling of a drug or drug product based on a prescription from a licensed healthcare professional. While compounding pharmacies provide valuable services to various patient populations, they also pose significant challenges regarding safety, efficacy, and regulatory oversight. As we move further into the 21st century, understanding the future trends in compounding pharmacy regulations is essential for ensuring patient safety and public health [52].

Compounding pharmacies are regulated at both the federal and state levels in the United States. The Food and Drug Administration (FDA) oversees drug manufacturing and sets standards for drug safety and efficacy, while individual state pharmacy boards manage pharmacy operations within their jurisdictions. Following high-profile incidents of contamination and adverse events related to compounded drugs, such as the 2012 fungal meningitis outbreak caused by contaminated steroids produced by the New England Compounding Center, federal and state regulatory frameworks became more prominent. The Drug Quality and Security Act (DQSA) of 2013 established clear guidelines for compounding

pharmacies, introducing two distinct categories of compounding: traditional compounding and outsourcing facilities. This act highlighted the need for better oversight to mitigate risks associated with compounded medications [53].

One of the most significant trends in the future of compounding pharmacy regulations is the potential for increased federal oversight. As healthcare continues to evolve and the need for compounded medications remains a constant, the FDA will likely enhance its regulatory framework to include stricter guidelines on the conditions under which compounding pharmacies can operate. This could encompass more rigorous inspection protocols, increased reporting requirements for adverse events, and expanded definitions of what constitutes compounding versus manufacturing [54].

In particular, the role of outsourcing facilities—which can produce larger quantities of compounded medications without the same restrictions as traditional compounding pharmacies—is likely to come under closer scrutiny. The FDA may introduce new regulations that require these facilities to adhere to current Good Manufacturing Practices (cGMP), which would raise the bar for quality assurance and patient safety. A trend towards more collaborative oversight between state boards and federal agencies could emerge, leading to a more unified approach to regulatory compliance [55].

The advancement of technology in healthcare will significantly influence the regulatory landscape of compounding pharmacies. Increasingly, pharmacies are utilizing sophisticated software and automation systems to improve accuracy and efficiency in drug preparation. As these technologies become more prevalent, regulators will need to establish standards and guidelines to ensure that automated systems do not compromise the safety and quality of compounded medications [56].

Moreover, the demand for transparency in data reporting is on the rise. Stakeholders, including patients, healthcare providers, and regulatory bodies, seek a clearer understanding of compounding practices, outcomes, and potential risks. Future regulations may require pharmacies to implement robust data management systems that track medication preparation processes, patient outcomes, and adverse event reporting. This data-driven approach would facilitate a continuous

feedback loop, allowing compounding pharmacies to improve their practices while enabling regulators to identify trends and areas of concern [57].

The essence of compounding pharmacy is to provide individualized medications that address unique patient needs. However, this individuality can also complicate standardization efforts in regulatory practices. As healthcare shifts towards value-based care and personalized medicine, there may be a push for regulations that strike a balance between customization and standardization. Regulatory frameworks may evolve to establish benchmarks for safety and quality while allowing sufficient flexibility to accommodate the diverse needs of patients [58].

This trend may result in the development of a category of "advanced compounding," where pharmacies can create innovative formulations that can be standardized to meet specific clinical guidelines while still allowing for tailored treatment plans. Such innovations could lead to improved patient outcomes and enhanced safety profiles, provided they are accompanied by vigilant regulatory oversight [59].

With the complexities of compounding pharmacy evolving, there will likely be increased emphasis on training and continuing education for pharmacists and pharmacy technicians. Future regulatory standards may include mandatory training programs focused on the nuances of compounding, quality control, and risk management. By equipping practitioners with the necessary skills and knowledge, the likelihood of medication errors can decrease, ultimately enhancing patient safety [60].

Furthermore, continuing education requirements may extend beyond initial licensing, necessitating ongoing professional development in compounding practices. This trend underscores a commitment to lifelong learning and accountability, ensuring that pharmacy professionals remain abreast of the latest advancements, regulatory changes, and technological innovations [61].

Future compounding pharmacy regulations will also benefit from increased involvement of patient and practitioner advocacy groups. Stakeholders will likely push for regulations that advocate for patient safety, access to compounded medications, and treatment options personalized to their conditions.

Advocacy groups can play a vital role in shaping regulations by providing insights on patient experiences, emphasizing the need for safe practices while preserving access to necessary compounded medications [62].

As these groups become more vocal, regulators may respond by implementing policies that prioritize patient-centered care while ensuring the integrity of the compounding process. Their involvement may lead to more comprehensive regulations that consider the perspectives of both patients and industry professionals [63].

Conclusion:

In conclusion, understanding compounding pharmacy involves recognizing the vital role it plays in delivering personalized medication solutions that meet the unique needs of patients. The intricate processes involved in compounding—ranging from the careful assessment of patient requirements to the meticulous preparation and quality control of customized formulations—underscore the pharmacist's expertise and commitment to patient care. Regulatory frameworks play a critical role in ensuring these practices are safe and effective, balancing the need for innovation with stringent safety standards.

As compounding pharmacies navigate challenges such as evolving regulations, public health concerns, and the need for enhanced quality assurance, they must remain adaptable and vigilant. Future trends indicate a growing integration of advanced technologies and stricter compliance measures that will further enhance the integrity and reliability of compounded medications. Overall, a comprehensive understanding of both the processes and the regulations governing compounding pharmacy is essential for safeguarding public health and advancing tailored therapeutic options.

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