Biologic Medications and the Specialty Pharmacy

A Practical Reference Guide for Ensuring Product Efficacy and Patient Safety through Proper Cold Chain Management

SENSITECH
United Technologies
SUPPLY CHAIN VISIBILITY

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Introduction

The pharmaceutical drug market is changing rapidly due to evolving patient needs and innovations in research, product development and technology from manufacturers. To achieve better patient outcomes from complex diseases, many manufacturers are producing a wide array of biologic pharmaceuticals, or specialty medications, that treat everything from autoimmunity, dermatitis and hemophilia, to cancer, multiple sclerosis and diabetes.

> According to the U.S. Food & Drug Administration (FDA), biologic products include vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues and recombinant therapeutic proteins. The FDA notes that biologics can be composed of sugars, proteins, nucleic acids or complex combinations of these substances, as well as living entities such as cells and tissues.

Unlike traditional small-molecule drugs that are chemically synthesized, large-molecule, biologic medicines are manufactured via more structurally complex biotechnology processes. Because of their components and structure, biologics are extremely sensitive to heat and cold temperatures outside of the acceptable range established by manufacturers. To maintain the proper temperatures that ensure the greatest level of product efficacy and patient safety, everyone in the pharmaceutical supply chain must take specific steps to avoid temperature excursions. This paper focuses only on the pharmacy segment, and in particular, the critical role that pharmacists and pharmacy technicians who work in specialty pharmacies have in maintaining proper temperature management for biologic drugs.

Pharmacies, pharmacists, and technicians are required by law and accreditation to ensure the proper cold chain handling, storage and distribution of biologic medicines when under their management. The handling, storage and distribution requirements are different and more complex for specialty drugs because harmful and destructive temperature excursions can result in modifications in a product's structure or a possible degradation. This not only affects the efficacy of the products, but more importantly, these changes in the biologics could also seriously affect the prescribed patient therapy and safety.

Proper cold chain handling, storage and distribution requirements include stringent temperature control and continuous monitoring. These strategies must be in place from the time the biologics are received until they are distributed, whether within the pharmacy, or while shipped direct to a patient or physician.

As one small example, let's consider what is involved in ensuring proper temperature control in direct-to-patient (DtP) shipments from one state to another. A pharmacy must be aware of the potential environmental challenges and shipping conditions of a product that is shipped via multiple in-transit transfers and hand-offs across geographies and temperature zones. Without proper monitoring, any temperature variations or lack of control during the in-transit chain of custody could significantly affect the temperature quality of the products and their efficacy throughout the shipping cycle.

The laws and guidance around proper handling, storage and distribution are complex. To help specialty pharmacists and technicians gain a better understanding of these requirements, this paper examines the challenges, risks and industry best practices for temperature monitoring. It also outlines the specific guidelines for compliance with current government and state regulations and the achievement of specialty pharmacy accreditations. Ultimately, the information presented here is intended to help specialty pharmacists and technicians better understand how to protect product integrity and efficacy, while delivering the utmost in patient safety.

The Projected Growth of Biologic Pharmaceuticals

The requirements for proper and effective temperature management in the supply chain will only continue to accelerate. This is especially true as manufacturers move from small molecule pharmaceuticals to next-generation biotherapies, such as cell-based therapies, gene therapies and regenerative medicines, which promise new breakthroughs in patient care.

Here are a few trends in this market:

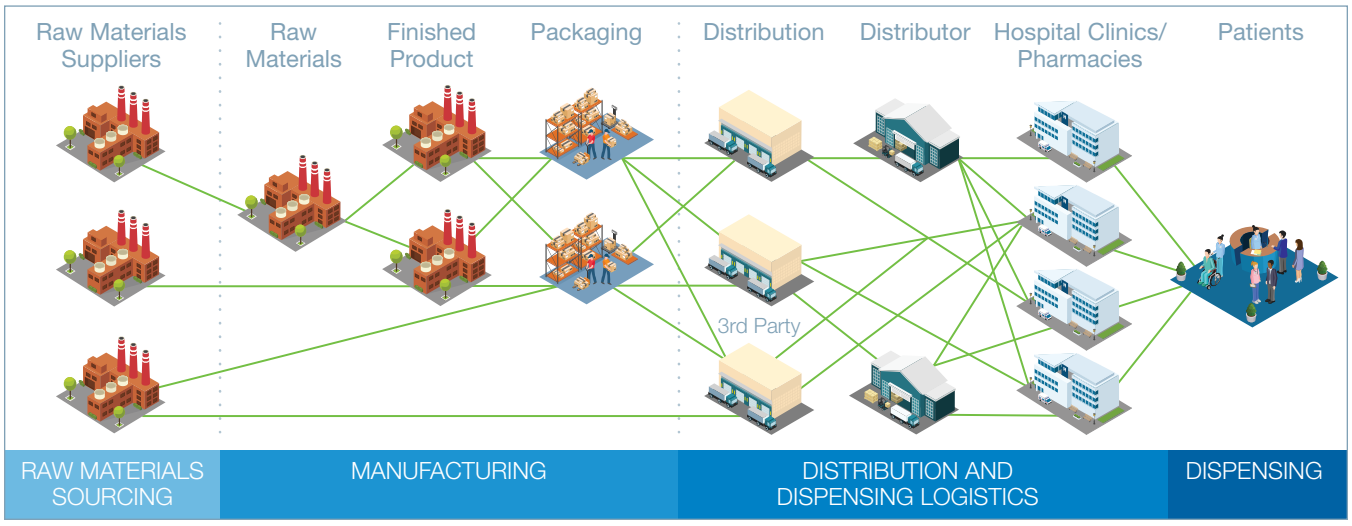
- The overall global market for pharmaceuticals was projected to reach nearly $1.2 trillion in revenue in 2022, with an estimated growth of 6.3% CAGR through 2022.
- Of those products, $283 billion will require refrigerated storage and transport. This segment alone is projected to grow by 70% by 2021, a rate that is more than twice the expected growth of non-refrigerated products.[1]
- With a look to the evolving specialty drug market and biologics, this segment is expected to grow to $318 billion in 2018, which represents 41% of the overall pharmaceutical spend in developed markets.[2]
- In 2017, 49% (28 out of 57) of the drugs that were approved by the U. S. Food and Drug Administration (FDA) are temperature sensitive. The majority (23) of them require strict 2-8°C refrigerated storage and transportation, while the remaining five products require below zero or cryogenic temperatures.[3]

The Complexity and Risks in the Biologics Cold Chain

The pharmaceutical supply chain starts with the receipt of raw materials for manufacturing and ends with the delivery and subsequent administration of medical products or therapies to patients. As shown below in the Pharmaceutical Supply Chain diagram, this chain is very complex. In the case of biologic pharmaceuticals, all of the steps in manufacturing as well as storage and distribution require strict adherence to proper temperature maintenance to preserve product efficacy and achieve the anticipated therapeutic patient outcome.

Specialty pharmacies are part of this chain, so compliance with current legal and recommended cold chain practices, as discussed in "A Framework of Compliance for Specialty Pharmacies and Pharmacists" section of this paper, are mandated. To fully and properly comply requires awareness, in-depth education and training in order to meet the requirements for temperature control and continuous monitoring for the storage, handling and distribution of biologics while under the responsibility of the specialty pharmacy. It also requires proper equipment and supplies, along with special standard operating procedures (SOPs), for the refrigeration and shipping of these products while under the control of the pharmacists and technicians.

Pharmaceutical Supply Chain



Source: What Is Supply Chain Management?, Professor Ladimer S. Nagurney, University of Hartford, 2013

Case in point: The impact of thermal packaging and shipping routes

Thermal packaging and shipping are two critical areas that could result in a temperature excursion of a biologic drug if the proper requirements are not followed as a specialty pharmacy ships the product to a patient or physician. For instance, let's say a product is shipped from a pharmacy in Illinois to a home or office location in Florida. Depending on the assigned route, the designated carrier most likely picks up the package at the pharmacy by truck, and then delivers it to the nearest airport for air transport. The final leg of the journey to the patient or physician is once again by ground transport.

Within this delivery path, the packaging used in the shipping of the biologics could be exposed to a number of extreme temperature ranges because of conditions such as these:

- Over the path of this shipment, there clearly will be differences in geography, local ambient temperatures, and humidity, all of which can inherently cause temperature excursions. This is especially of concern in summer or winter months when there can be extreme high or low temperatures, depending on the geography.
- The initial pick up and transport by a carrier may also cause temperature changes because the transport vehicles may not have reliable refrigeration to maintain proper temperature control.
- Additionally, during air transport, the packages may be subject to freezing cargo hold temperatures, where external temperatures can be as low as -40 degrees Celsius (-40 degrees Fahrenheit) at or above altitudes of 30,000 feet.
- As products are offloaded from the plane, if the tarmac is not temperature-controlled or protected, the biologics could once again be exposed to extreme weather conditions and temperature variations.
- While there is typically a referenced time of delivery established by the carrier, delays due to weather, traffic or mechanical issues can interfere, resulting in late deliveries and shipments that are subject to even more temperature excursions.

Commercially available thermal packing is designed to maintain a specific internal temperature range for shipments. However, the reliability of the packaging during shipping, and therefore the integrity of the sensitive cargo, is assured only if the designed pack out, with materials such as gel packs and dunnage, are properly configured. If there are temperature excursions such as the ones described above, then the packaging reliability can be adversely impacted.

If at any time during this journey the temperature of the biologic product is outside of an acceptable range, the product could be compromised. Without proper temperature controls and continuous monitoring, these kinds of excursions could go unnoticed, which would present significant risks to the patients who will ultimately be using the products.

How Real Are Temperature-Excursion Risks?

Sensitech Inc., a global leader in supply chain visibility, recently conducted a study for a group of U.S. pharmacists to find out if there were temperature excursions when biologic products were shipped from their pharmacies to patients. A key goal of this study was to understand if and how the internal temperatures of the packages were affected by frozen gel packs and exterior temperatures. Additionally, the study helped to identify correct distribution processes for couriers, overnight priority, same day and ground shipments.

The research project included these initiatives:

- Samplings of internal and external temperatures
- Summer and winter studies to represent hot and cold profiles
- Ambient temperature profiles from exterior temperature data for pack-out design.

The results were surprising, as the study showed that 80% of the pharmacies' direct-to-patient (DtP) shipments failed to maintain proper temperatures throughout the shipping cycle. These pharmacists were unaware they were improperly using frozen gel packs and that positioning them in direct contact with the product's packaging during shipping would cause temperature excursions. These improper procedures often caused thermal shock, dropping the temperature of products to below -5 degrees Celsius, which is a major excursion outside of the manufacturer's stated label temperature requirements for product efficacy.

Improper Use of Gel Packs

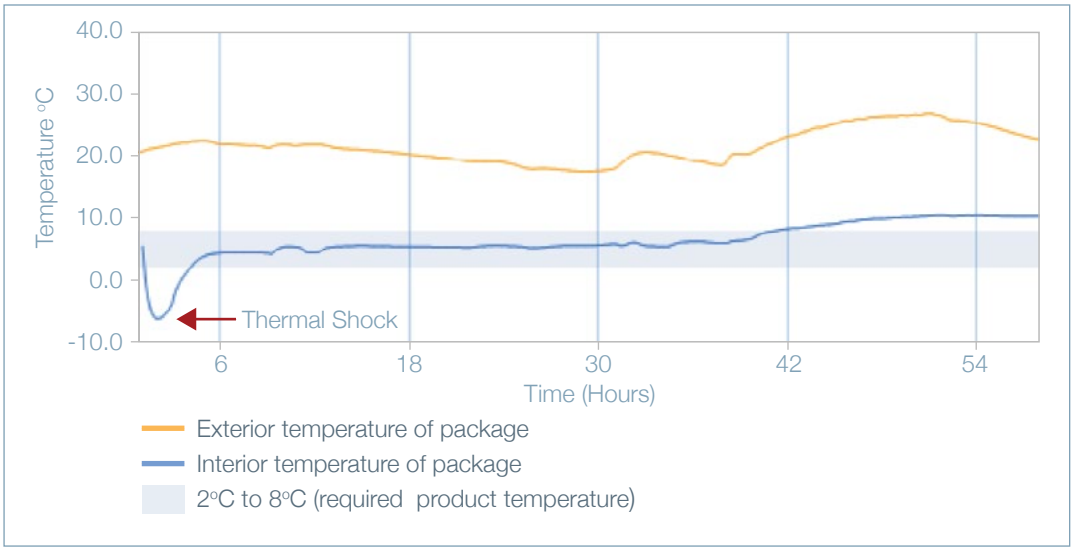


Figure 1. Example of thermal shock based on the improper positioning of a gel pack.

Source: Sensitech Inc.

The pharmacists also increased the probability of thermal shock (Figure 1) and risk when they placed the products in their thermal packaging containers in refrigerators prior to the carrier pickups. This accelerated the drops in the internal temperatures and added compromising risk to the efficacy of the products.

As mentioned earlier, temperature excursions, such as overexposure to heat or cold during storage or shipping, can degrade or inactivate temperature-sensitive drugs, adulterating their efficacy and endangering patients with issues such as harmful drug interactions or failed therapies.

One single temperature excursion—or even a simple change in temperature—is all it takes to compromise a product's stability and destroy a complete supply of a biologic product. The following factors could easily create a compromising situation for a biologic in a specialty pharmacy:

- Extreme temperature variations in the everyday storage and handling in a pharmacy's facility
- The age and quality of refrigeration equipment
- The lack of SOPS for the proper handling of the drugs
- Temperature fluctuations from refrigerator defrost cycles, or the opening and closing of refrigerator doors (Figures 2 and 3).

Harmful Refrigerated Storage Excursions

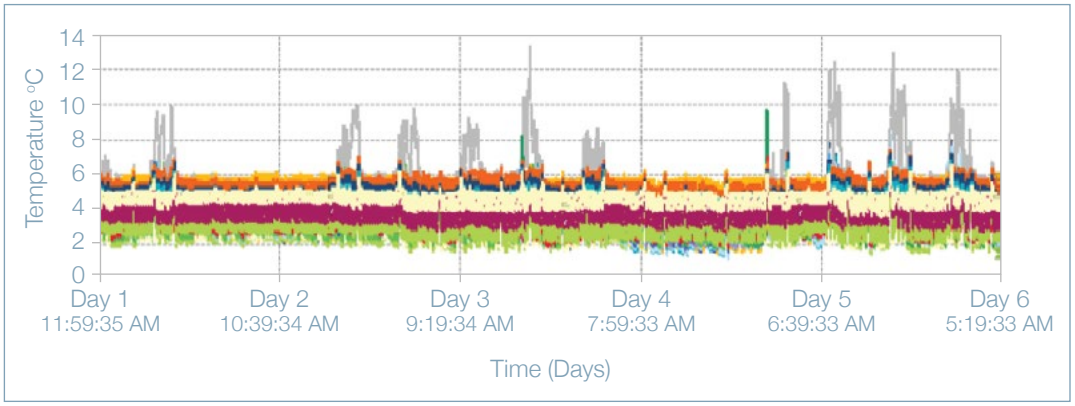


Figure 2. Open doors in a refrigerated storage area for excessive amounts of time can cause harmful temperature excursions like the ones shown here. Each color represents a different packaged product with its own unique monitor. Any products with temperatures above 8 degrees Celsius or below 2 degrees Celsius have been exposed to temperature excursions that could cause product damage.

Source: Sensitech Inc.

Improperly Functioning Refrigeration

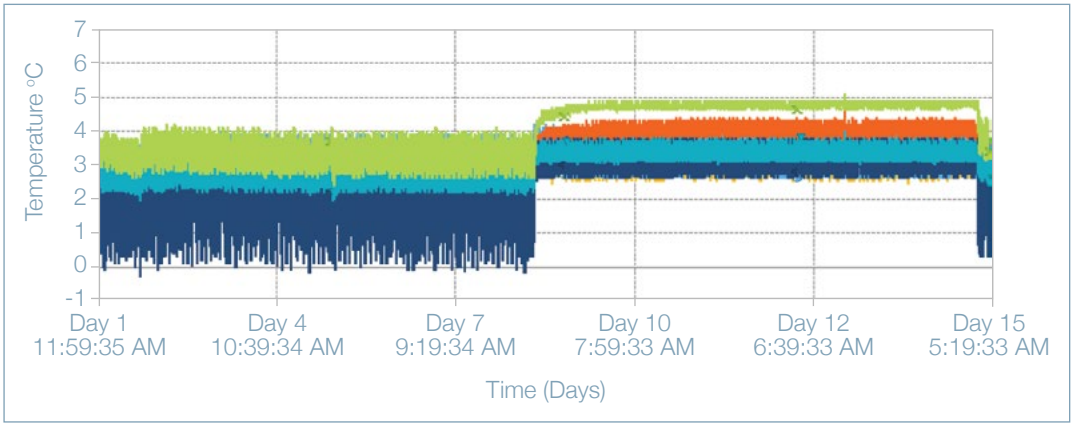


Figure 3. This refrigerated storage area was not functioning properly during the first seven days of this study, which caused temperature excursions and product risk. Each color represents a different packaged product with its own unique monitor. Any products with temperatures above 8 degrees Celsius or below 2 degrees Celsius have been exposed to temperature excursions that could cause product damage.

Source: Sensitech Inc.

The costs of non-compliance

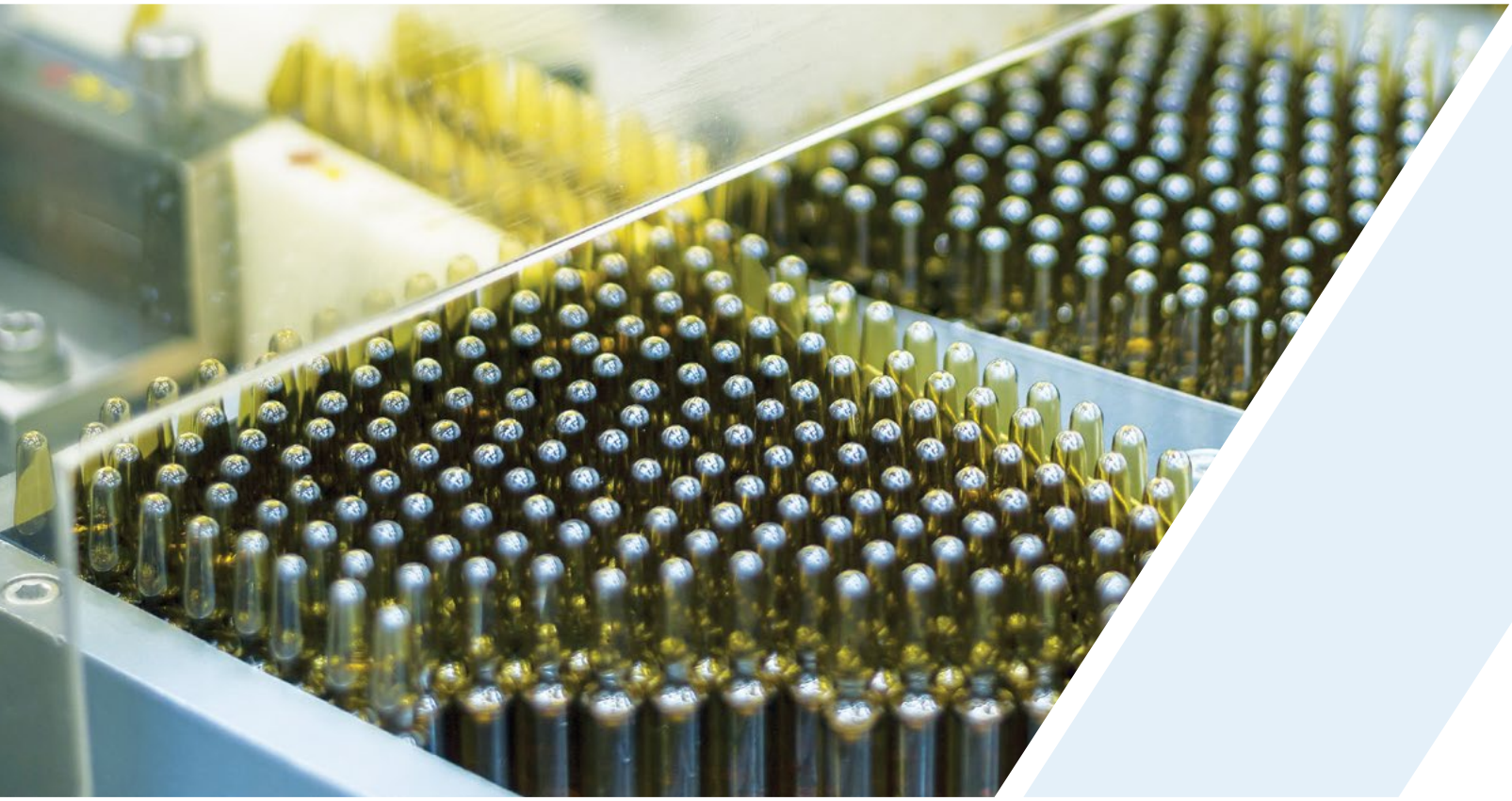
Medication mishandling can result in costly errors and risks to the patients, along with high fines for pharmacies. For instance, a quick look at pharmacy malpractice statistics offers these insights:

- The costs associated with medication errors can exceed $29 billion annually and even reach up to $72 billion a year.
- Reportedly, over one million people are injured and nearly 100,000 people die each year due to medication errors.[4]

How much of the above errors relate to the storage, handling and distribution of temperature-sensitive drugs like biologics is unknown, but these drugs are high-cost, high-touch medications with annual per-patient treatment costs that can exceed $100,000. A single shipment of such a product could have a value of $50 million or more.[5]

If the temperature excursion of a biologic is recognized to cause a degraded state, the cost to replace it could be two to three times the initial expense of the product. Expenditures such as reverse logistics for disposal, remanufacturing, quality investigation and repair of brand loyalty and reputation all can be quite costly. If a pharmacy needs to replace a single shipment of a $100,000 product, or worse, shipments to multiple patients due to a temperature excursion—there could be significant consequences for its business.

Consequently, it is in the best interest of both pharmacies as a business, and pharmacists and technicians as individuals, to understand the best way to execute temperature management compliance.



A Framework of Compliance for Specialty Pharmacies and Pharmacists

As mentioned earlier, there are laws, standards, guidelines and requirements for the storage, handling and distribution of temperature-sensitive specialty drugs throughout the cold supply chain for all the entities involved. Adhering to legal or advisory information can help to ensure that the products remain unadulterated.

For specialty pharmacies, pharmacists and technicians, there are several existing and evolving governing bodies with regulations, guidelines and best practice recommendations, including:

- State boards of pharmacy
- The U.S. federal government
- Accreditation associations
- Non-profit organizations

State boards of pharmacy

Pharmacists and pharmacy technicians should be familiar with state boards of pharmacy, as each state has its own board which regulates licensing and provides oversight to wholesalers and pharmacies practicing in that state. It's important to note that pharmacies, pharmacists and pharmacy technicians must be licensed in the primary state they practice in, as well as any state to which they distribute products.

Temperature management guidelines vary per state, and individual state boards are continually updating their regulations to keep up with the evolving landscape of the pharmaceutical industry. For instance, the Oregon state board of pharmacy passed new rules surrounding

the storage of vaccines. The board recognized the importance of temperature management pertaining to vaccines and implemented new temperature monitoring requirements. Now, pharmacies that administer vaccines in Oregon must use a continuous temperature monitoring system with automated data logging capabilities while the products are in storage.

State boards often include practices and guidelines from the following organizations in their requirements; however, this also varies widely from state to state.

The U.S. federal government

Manufacturers must adhere to several federal regulations and, therefore, these regulations inherently apply to pharmacists and technicians as well.

For instance, manufacturers must comply with the Food and Drug Administration (FDA) Code of Federal Regulations (CFR), including Title 21 Part 210 and Part 211. These regulations offer requirements on manufacturing practices for the processing, packaging, holding or distribution of general drugs. Manufacturers must also comply with Title 21 Part 600 for biologics; these regulations include, among other requirements, guidance on temperatures during shipment. The FDA audits manufacturers based on these regulations.

USP <659> is a standard on packaging and storage requirements from the United States Pharmacopeia, and outlines temperature requirements for all products with label claims. USP <659> was mandated in 2016. In July 2018, the USP released for public comment additional changes to USP <659> that now include a new product temperature category called Controlled Cold Temperature. Changes also include the addition of a definition of MKT (Mean Kinetic Temperature) that was originally in USP <1079>. The USP also released new requirements for USP <1079> that include a risk-based approach and define the requirements for all supply chain participants who handle products, from the manufacturer to the patient, including pharmacists.

One of the ways manufacturers attempt to ensure supply chain compliance with these regulations, including at the pharmacy level, is through the inclusion of specific product storage temperature requirements in drug monographs and on product packaging.

The federal government also offers other guidance for proper temperature management, which is helpful to pharmacists and technicians as well, especially when referenced in state board regulations. For instance, the Center for Disease Control (CDC) issues standards for temperature monitoring in its Vaccine Storage & Handling Toolkit, which was updated in January 2018.[6]

In addition, the Prescription Drug Marketing Act (PDMA) is a law of the U.S. federal government that offers guidelines to ensure the safety of pharmaceuticals.

The FDA may conduct inspections of pharmacies when necessary. For example, if there were reported adverse patient reactions and a subsequent concern as to the health of the greater patient population, any pharmacy involved in the occurrence would be included in an inspection.

Industry accreditation associations

To assure and affirm credibility and quality with payers, pharmacies often look to secure specialty pharmacy accreditation through organizations such as:

- URAC (formerly the Utilization Review Accreditation Commission)
- Accreditation Commission for Health Care (ACHC)
- The Center for Pharmacy Practice Accreditation (CPPA)

Each of these associations offer pharmacists accreditation for adherence to nationally accepted standards in healthcare.

For instance, URAC is an independent nonprofit organization that promotes health care quality through its accreditation, education and measurement programs. URAC keeps current with the pharmaceutical industry at the pharmacy level, and has adapted its accreditation requirements in response to the changing regulatory landscape. For specialty pharmacies, the organization offers accreditation programs that specifically cover temperature monitoring, including these reference standards for pharmacy operations:

- PHARM-OP 6: Shipping
- PHARM-OP 7: Cold Chain Distribution: Process Controls and Monitoring System
- PHARM-OP 8: Product Handling, Storage, and Inventory

The ACHC offers programs that are designed to enhance pharmacy business operations while ensuring compliance, and the CPPA focuses on programs for pharmacy practice sites.

Other influencing organizations

Another key organization that is widely recognized in the pharmaceutical industry is the United States Pharmacopeia (USP), a scientific nonprofit organization that sets federally recognized public standards of quality for medicines, dietary supplements and foods.

For pharmacies, USP guidelines are often recognized as one of the most comprehensive, up-to-date set of guidelines and laws offered as industry best practices.* These include:

- <1079> Good Storage and Shipping Practices**
- <1118> Monitoring Devices–Time, Temperature and Humidity**
- <659> Packaging and Storage Requirements***

*In July 2018, the USP proposed updates for USP <659> and USP <1079> with new guidelines for pharmacists; the implementation of these new guidelines is expected to be in early 2019.

**Guidance

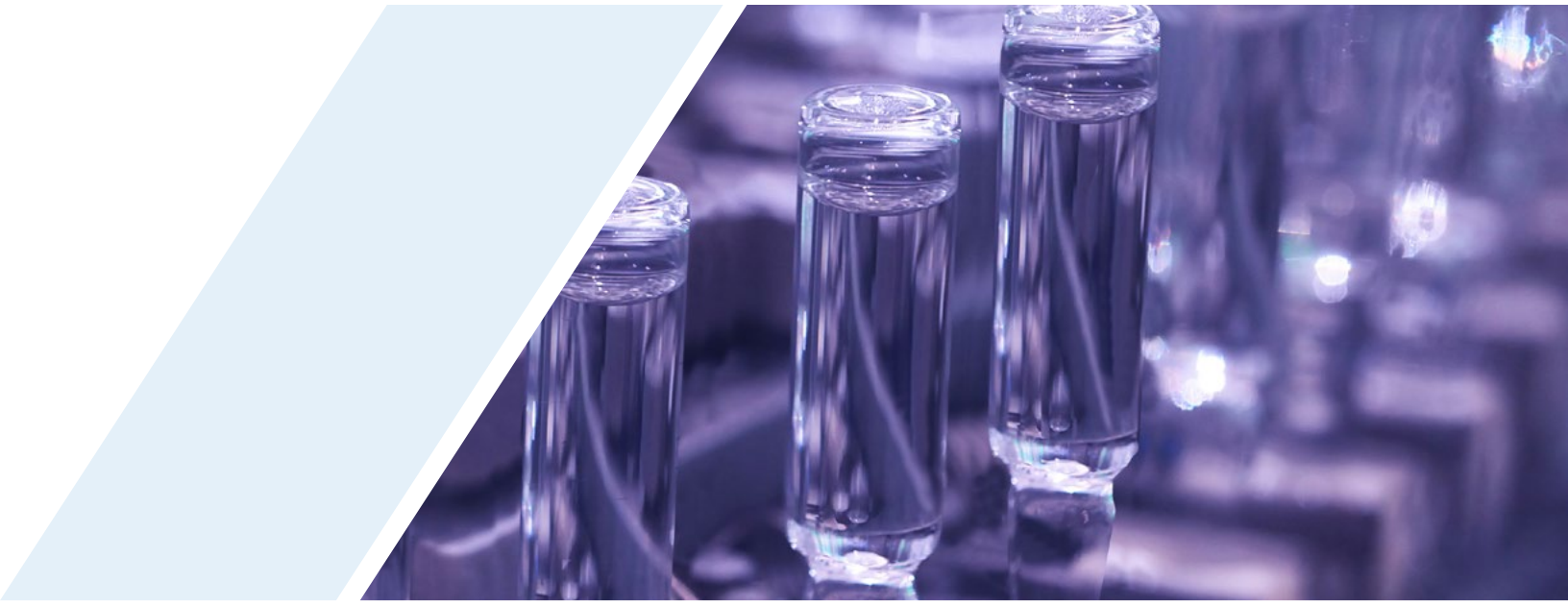
***Mandated legal requirements under the directives of the FDA as of May 2016

Many state boards of pharmacy refer to the above standards and these recommendations in their regulatory guidance to pharmacists.

Recently, the USP also published a Stimuli Article on "The Use of Mean Kinetic Temperature to Aid Evaluation of Temperature Excursions: Proper and Improper Application." The information in the article can help the pharmacist make the proper quality decision when dealing with temperature excursions.

Another influencing organization is the Parenteral Drug Association (PDA), which is a leading global provider of science, technology and regulatory information and education for the pharmaceutical and biopharmaceutical community. Its Pharmaceutical Cold Chain Interest Group (PCCIG) has issued seven technical reports that provide specific guidance regarding cold chain best practices, including last-mile distribution practices, temperature-controlled risk management and temperature-controlled systems.

Finally, there are also manufacturing and distribution practices (GXPs) that offer varying degrees of guidance as well.



What Is the Definitive Source for Compliance?

For pharmacists and technicians, remaining current with all the various directives mentioned above can be daunting.

And while the state boards are the primary governing body for pharmacies and their employees, the differences for temperature monitoring from state to state can be confusing. For example, for retail community pharmacies, here is a glimpse at these variances based on data from the Interactive Pharmacy Temperature Compliance Map compiled by Bula Intelligence.

- Four (4) states have the most stringent temperature monitoring control standards, where temperature monitoring is required, and state laws address incidents and excursions.
- Ten (10) states have specific monitoring control standards where monitoring is required, but no laws.
- Twelve (12) have specific temperature control standards based on USP standards or manufacturers' recommendations.
- Twelve (12) states have only minimum (adequate or sufficient) standards for temperature monitoring.
- Thirteen (13) states have no law that is specific to pharmacies and temperature monitoring, although there are exceptions with requirements or standards that refer to manufacturers, the CDC and other related guidelines, such as Vaccines for Children (VFC).

In related research, at the time of release, Sensitech reviewed state board websites and discovered:[7]

- Only 29 states have requirements for temperature management for the storage of temperature-sensitive pharmaceuticals. Of those, 14 states refer to USP standards.
- Only 18 states have requirements for temperature management during the distribution of drugs, 10 of which refer to USP standards.

Although some states are up to date with the most relevant guidelines, there are others that lag behind, which could open the door for improper temperature management. For instance, using the Bula Intelligence map above and the intra-state shipment example mentioned earlier in which products were shipped from Illinois to Florida, Illinois has minimum standards while Florida has little to no requirements.

As another example, here is a look at the state board shipping guidelines for two nearby states, Georgia and Alabama.[8]

- **Shipping guidelines in Georgia:** Georgia's state board of pharmacy states: "A mail order pharmacy shall ensure that all prescription medications are delivered to the patient in accordance with standards of the manufacturer, United States Pharmacopeia, Federal Food and Drug Administration and other recognized standards. A pharmacy shall ensure integrity of any drug requiring temperature control other than 'room temperature storage' that is delivered by mail order and provide a notification to the patient of the timeliness in addressing the proper storage of the medication. The shipping method may include the use of temperature tags, time temperature strips, insulated packaging, or a combination of these."
- **Shipping guidelines in Alabama:** Meanwhile, in nearby Alabama, the state board of pharmacy offers this as guidance: "The pharmacy maintains adequate storage or shipment containers and shipping processes to ensure drug conduct stability and potency. Such shipping processes shall include the use of appropriate packaging material and/or devices to ensure that drugs are maintained at an appropriate temperature range to maintain the integrity of the medication throughout the delivery process."

While there are similarities in the guidance between the two states, there are also significant differences, which can lead to improper shipping practices. The state board in Georgia, for instance, specifically says shipping tags, time temperature strips and insulated packaging may be required for the shipping of pharmaceutical products that require temperature control other than room temperature storage. The state board in Alabama is less specific, noting that the shipping pharmacy must ensure that the drug is maintained at an appropriate temperature range to ensure the integrity of the medication. The Georgia statute specifically calls out for temperature monitoring, while the Alabama statute alludes to the use of appropriate packaging material or devices to ensure the drug is maintained under the appropriate temperature range.

Another example that could provide confusion within the pharmacy is in regards to product storage and how temperature monitoring is conducted. Some state boards still recommend recording temperatures in storage areas using non-electronic thermometers twice a day on paper logs. This is a process that was dropped by the CDC and USP several years ago in favor of electronic monitoring.

Based on these widely differing guidelines, how can pharmacists ensure that they are remaining compliant in a way that best guarantees patient safety throughout their chain of responsibility? What key standards should they follow to avoid compromising product and patient health?

A Practical Guide to Maintaining Product Efficacy

To assure quality of biologic pharmaceuticals, as well as product efficacy and the therapeutic benefit of the prescribed drugs, a qualified risk-based quality management process is the best approach for the employees in a specialty pharmacy.

This process presents a practical guide that:

- Ensures the proper temperature management during the handling, storing and distribution of specialty pharmaceutical products per the manufacturer's specific stated label temperature requirements.
- Assists pharmacists and technicians in complying with mandated obligations, including state board of pharmacy regulations and accreditation requirements such as those administered by URAC.
- Provides pharmacists and technicians with industry-accepted best practices like USP standards.

Here is a quick glance at what a comprehensive quality management process would include in a pharmacy:

Overall guidelines

- **Pharmacy risk assessment.** To understand their level of compliance, specialty pharmacies must assess the existing risk associated with their storage and handling environments, as well as its shipping protocols, for specialty pharmaceuticals.
- **Standard procedures and protocols.** Operational protocols and internal SOPs for the storage, handling and distribution of these products must be established, set in place and monitored. This includes guidelines for the operation of the refrigeration units—down to the level of best practices for opening and closing refrigeration doors—as well as for the conformity and placement of thermal packaging pack-out materials.

Storage and handling guidelines

- **Equipment validation.** To ensure proper temperatures, refrigeration and storage equipment must be fully operational and have scheduled periodic preventive maintenance inspections and servicing, along with appropriate documentation.
- **Electronic temperature monitoring.** A key best practice is the continuous monitoring of product temperatures using electronic temperature monitoring technology with excursion alarm capabilities. Electronic monitoring devices should be used in all refrigerators, compounding rooms, freezers and product handling areas to assure the proper temperatures are aligned with the manufacturer's stated requirements. The devices should be properly validated and calibrated, which ensures their accuracy. The devices should also continuously download and save temperature data so that it can be

reviewed when excursions occur or to ensure proper maintenance of the equipment and environment.

- **Mapping studies.** Thermal map studies should periodically be conducted on all areas to ensure that a consistent, uniform and compliant temperature is maintained wherever the product is located.
- **Alert policies and protocols.** There should also be policies in place so temperature excursion alarms are properly addressed. There should be a record of all necessary data (date, time, equipment, location and responsible authority) so any corrective and preventative actions (CAPA) can be put in place. For instance, the CDC recommends that an alarm system be linked to a smart device so a responsible person on the pharmacy team can quickly address issues such as a power outage or a mechanical issue with a refrigeration unit.

Distribution and packaging guidelines

- **Shipping processes.** For DtP or physician shipments, there needs to be an assessment of the environmental changes during shipments and the time in transit, including the actual time allowed for delivery and patient acceptance. Based on this information, the proper procedures and packaging can be put in place to protect the products throughout this entire cycle.
- **Shipping studies.** To ensure proper distribution, shipping studies can be performed during both a summer and winter season to generate a hot and cold profile and include any specific geographic shipping routes and location. The results of these assessments can identify vulnerable points, such as improper packaging or storage during shipping. The studies can be compared with the current thermal packaging validation documentation from the manufacturer, and subsequent changes can be made to assure proper temperature control for each direct shipment based on the findings of the study.
- **Packing materials.** Thermal packaging is required for most biologic product shipments. Pharmacy employees must be aware of the impact of other packaging materials, such as gel packs or dunnage, on the products as well. Temperature monitoring devices should be included in packages to see if temperature excursions occur during the product's shipping cycle.

The above guidelines include requirements already in place for some state boards, and draw on URAC accreditation requirements as well as USP standards, all of which are continually evolving as the market changes.

Conclusion

While achieving compliance can be a complex task, the insights and guidelines offered here provide specialty pharmacists and technicians with the best approach for maintaining product quality, potency and efficacy.

Ensuring that equipment and packaging is in compliance, and that temperatures are maintained in each phase through the use of electronic monitoring devices during the storage, handling and distribution are the best ways for specialty pharmacies to ensure patient safety.

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[7] Note: State Boards of Pharmacy are continually updating their guidelines so please refer to each state directly for the latest guidance.

[8] This information may have changed since the publication of this report. Please consult each board for the most up-to-date information.

About

Sensitech

Sensitech Inc. is a world leader in supply chain visibility. Our innovative monitoring products and services help to maintain the quality, integrity and security of our customers' valuable products at every step in their journey, all around the world. For nearly three decades, leading companies in the food, pharmaceutical, industrial, consumer goods and other industries have relied on Sensitech to help protect their products—and their bottom lines.

Content Contributors

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