

# ATS Finding the Comfort Zone for Pharmaceuticals

Maintaining the right temperature controls during storage and delivery has been a long-standing challenge for transporting pharmaceuticals. From mainstay over-the-counter products such as sunscreen, to highly sensitive injectable medications, anything that carries a DIN (drug identification number) must be stored and transported within strict temperature control guidelines.

BY DENISE J. DEVEAU



**W**hile the regulations for storing and transporting pharmaceuticals have been in place for many years, it was in November 2005 that Health Canada formalized requirements for temperature management programs. This formalization placed an increased burden on companies to enforce detailed documentation and reporting procedures.

A daunting challenge for some perhaps. But AstraZeneca was one pharmaceutical company that was well ahead of the procedural game. A client of ATS Andlauer Transportation Services for close to 10 years, AstraZeneca has been using ATS' Ambient Shipping Program. This offering was conceived and developed by company founder Michael Andlauer in anticipation of the growing demand in logistics services for the pharmaceutical industry. AstraZeneca was one of the very first to use this innovative program to ensure that its products are always kept in the required 15 to 25 degree Celsius range – from the production facility to the customers' doors.

## ABOUT ASTRAZENECA

With over 1,400 employees, AstraZeneca is one of Canada's and the world's leading pharmaceutical companies. The company offers a number of products in key therapeutic areas, including Crestor®, Nexium®, Seroquel®, Atacand®, Symbicort®, and Arimidex® that are shipped to customers throughout the country.

AstraZeneca's central warehousing and distribution, packaging and commercial operations are based in Mississauga. According to Scott Gibson, project manager, Logistics, for AstraZeneca's International Trade and Transportation Management Group, the company uses the ATS Ambient Program for approximately 80 percent of its shipments across Canada.

"One of the biggest logistics components that AstraZeneca and other pharmaceuticals face today is legislative requirements," he says. "Now that temperature control procedures must be validated, it makes it challeng-

ing for operators to prove compliance at all times. Fortunately, as an early adopter of the ATS Ambient Program, we're old hands at dealing with those requirements. For years, we have been able to prove that every shipment remains within the required temperature ranges and can provide the supporting data."

## A NEW WORLD OF COMPLIANCE

A renewed focus on compliance is something that is not exclusive to the Canadian pharmaceutical industry. The worldwide regulatory environment for the shipping, handling and storage of pharmaceutical products has tightened considerably. The U.S., Australia, the European Union, the United Kingdom, and the WHO are all intensifying their scrutiny of shipments. A major concern for all is that once products leave manufacturers' sites, their quality and efficacy can be compromised by temperature changes brought about by environmental and other factors during the distribution process.

In Canada, pharmaceuticals are faced with particular challenges such as volatile swings in weather conditions and the need to travel vast distances between population centres. These unique conditions can make temperature management programs more difficult and expensive to manage.

In order to comply with the formalized guidelines set out by Health Canada today, customers need suppliers that have the technologies, systems and procedures that will provide a controlled climate for the life of each shipment. In addition, logistics suppliers must be able to provide proof of temperature (POT) from point of origin to point of delivery for all pickup and delivery vehicles, line haul trailers and temperature managed facilities.

## THE HIGH COST OF COMPLIANCE

This level of complexity is one of the major reasons why offerings such as the ATS Temperature Management Program are not



typical fare for logistics firms. As Mike Beard, Director of Marketing for ATS, explains, temperature management logistics for the pharmaceutical markets is a time-consuming and expensive process that many logistics companies simply won't take on. "It's quite a daunting prospect. For one thing, it requires a lot of

investment. While a typical trailer might cost \$35,000, for example, equipping a temperature controlled one runs about \$100,000 or more. They have to have special insulation and cooling systems. Sensors have to be in place to map temperatures from front to back, bottom to top."

As he says, all sorts of things have to be taken to the "nth degree," including temperature monitoring, vehicle tracking, cleanliness and security. "Just the training itself is a major undertaking because you have to include everyone from dock workers and drivers to sales and customer service."

He adds that keeping pace with legislative requirements and customer needs also means frequent upgrades to back-end systems, monitoring and tracking equipment and communications devices. "We've already gone through three iterations of our technology since we started."

Over the years, ATS has refined its system considerably, adding increasingly advanced tracking capabilities that allow users to find out anything they need to know about their shipments in near real time, including temperature ranges, truck location and direction. All information is automatically recorded and updated. "When customers sit through audits, they're impressed by the level of sophistication of the documentation, standards of procedures (SOPs) and the cleanliness of all our operations," says Beard.

#### STAYING ON TRACK

Gibson confirms that near real-time access to information is a critical part of the value proposition for AstraZeneca. "When we were audited in the past, it used to take 48 hours or more to track a shipment and provide the required information. The easiest part of the ATS solution today is the ability to access any information I need online in very close to real time and generate reports. Now when Health Canada asks for information, I can provide the data down to a specific shipment on a specific day. I'm confident the technology is in place to satisfy legislative requirements and reporting is no longer a burden."

An added bonus for AstraZeneca is that with a fleet of 65+ temperature managed vehicles, ATS is one of the few operators that can handle deliveries to a majority of its Canadian customers. "One of the most challenging aspects of our business is the last mile delivery. ATS is one of the rare few that can handle getting product to the destination in a compliant format," says Gibson.

"For pharmaceuticals, standards are their business," concludes Beard. "It's up to us as logistics people to ensure that all procedures are written out, that we follow them, that our people are trained, that we have a fail-safe system and that the technology works." ■

## How the Temperature Management Program Works

The Temperature Management process ensures that all ambient storage rooms and docking procedures between trailer and warehouse facility are controlled, monitored, verified and documented. Key features include:

- Two audits are conducted by trained dock employees before the shipment leaves the facility.
- Doorway areas are sealed for loading and unloading.
- Drivers must inspect and sign three separate audits.
- Five sensors monitor temperatures at the front, rear, upper and lower areas of the trailer enclosure. These include two sensors for testing air temperature, two liquid sensors that approximate the internal temperature of the shipped products, and one door sensor. Readings from each sensor are transmitted to the dispatch centre every six minutes via cellular links.
- If the temperature rises to 23°C or falls to 17°C (i.e., comes within 2° of the threshold) an automatic alert is sounded and the driver is notified to adjust the temperature controls.
- Drivers are also required to inspect the system every four hours.
- Monitors, controls and alarms are installed in all temperature-managed warehousing facilities.
- Drivers and loaders must be trained and certified every three years in monitoring, tracking, code identification, loading and temperature adjustment procedures.
- All location and temperature information on shipments can be provided to customers in near real time, online.

#### Health Canada Guide 0069 guidelines on the warehousing and transportation of temperature-controlled products

Drug products must be shipped and stored in a manner that does not risk exposure to temperatures outside recommended storage conditions; potentially impacting the safety and effectiveness of the drug product.

Temperatures should be controlled and monitored using calibrated monitoring devices, and records of temperature and alarms, where applicable, should be maintained.

Monitoring is conducted at points representing the extremes of the temperature range based on temperature mapping.

Storage practices and loading configurations should not lead to the obstruction of air distribution... [there must be] sensors for continuous monitoring and alarms located at the points representing the temperature extremes.

Written procedures should be available describing the actions to be taken in the event of temperature excursions outside the labelled storage conditions.

The transport process... should prevent damage and maintain the integrity and quality of the drug products. ■