



## SUMMARY



### Customer

Altru Specialty Pharmacy  
Grand Forks, ND

### Industry

Specialty Pharmacy

### Challenge

Validation of shipment packaging to maintain medication efficacy in extreme environments

### Solution

- Seasonal Package Performance Qualification (PPQ) testing

### Results

- Reassurance that critical medications are delivered to patients in good condition
- Confirmation of packout design for seasonal temperature excursions
- Enhanced best practices in internal packout operations and materials
- Met URAC requirements for documented proof of temperatures monitored and maintained

# Keeping Medication in Proper Temperature Range

Altru Specialty Pharmacy is a part of Altru Health System, which serves people in the city of Grand Forks as well as much of North Dakota and extending into Minnesota.

What began seven years ago as a grassroots effort with one technician working in partnership with the PharmD has grown to include three full-time technicians and three full-time pharmacists. Still, the specialty pharmacy's mission has remained the same – to enhance care and improve the overall health and wellbeing of their patients.

According to Rosemary Kalenze, PharmD, Outpatient Pharmacy Manager for Altru, they began to explore testing the performance of their medication packages based on Joint Commission accreditation requirements in addition to US Pharmacopeia (USP) best practices for good storage and distribution of drug products, which many accreditation agencies use as a guideline. "We live and work in a climate that can be -40°F in the winter and 100° in the summer," explains Rosemary. "To be sure we are giving our patients the best possible care, it's important to know we are sending drug products in such a way that they remain both effective and safe."

Altru ultimately chose Temptime's third-party Package Performance Qualification (PPQ) testing to validate that their packouts were configured and performing correctly.

"Regular, seasonal PPQ Testing is just so important," Rosemary says. "Our patients trust us – and we need to continually earn that trust with every single shipment that goes out."



M-300 wireless sensors measured temperatures inside the medication packaging at regular intervals.

## Package Performance Qualification

The specialty pharmacy did its first round of testing in 2019. “We started with our refrigerated packouts, which need to be kept between 2° and 8°C. We tested in cold weather to make sure packages were staying in range for the amount of time we anticipated shipments to take,” says Rosemary. In Phase 1, Altru included two different wireless sensors. An M-300 measured temperatures inside the medication packaging at regular intervals and an S-400 monitored the external ambient temperature in the outer box. Test packages were sent to Temptime, who analyzed the data captured.

“We learned a lot in that initial evaluation of our packaging,” Rosemary says. Temptime gave Altru guidance on coolers and other packing materials best for cold chain shipments to help improve their packout design. “We made a few tweaks with the intent of giving patients even greater confidence in the medications we deliver – and Temptime was a great help through the entire process.” Altru then moved on to Phase 2 for further testing of the passing Phase 1 package design.

In Phase 2, test packages were prepared in the same way, but this time shipped to various geographies using different modes of transportation such as courier and FedEx. Again, Temptime collected the time-temperature data, this time using the information to prepare a PPQ Report that validates the qualification of the packouts.

Aside from ensuring packages performed the way they needed them to, Rosemary says one of the most significant benefits has been instituting best practices throughout our shipping processes. “Now every shipment of refrigerated medication is packed the same way,” she says. “In the past – there were no specific guidelines. So one person might include one icepack in a shipment where another might put in three, which could cause medication to freeze.”

“A lot of URAC’s requirements are centered on providing documented proof that medication temperatures are monitored and maintained, and everything we’re already doing will apply.”

Altru recently finished its second round of PPQ testing. “With all we learned in our previous testing, the process this time around was much smoother and we successfully passed Phase 1 on the first try,” Rosemary said.

**SUCCESS STORY**  
ALTRU SPECIALTY PHARMACY

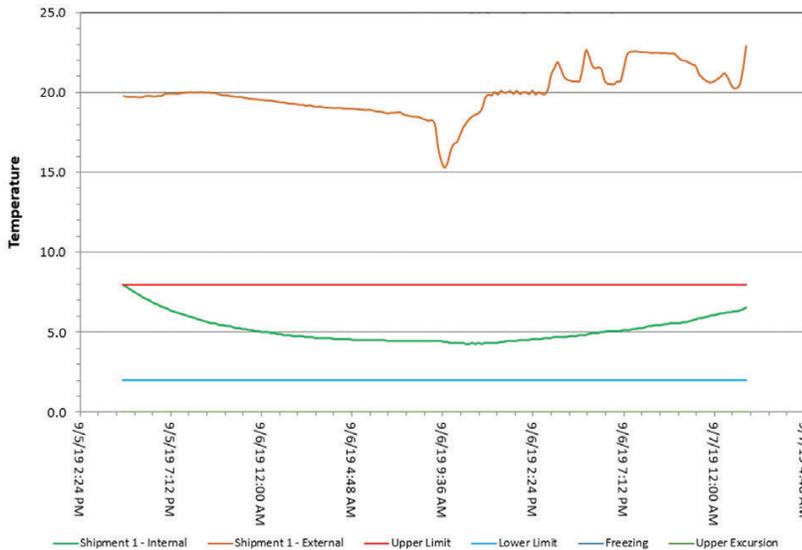
The specialty pharmacy was also pleasantly surprised to find that the PPQ testing would help them with their URAC accreditation, which they began working toward in October of 2019. “A lot of URAC’s requirements are centered on providing documented proof that medication temperatures are monitored and maintained, and everything we’re already doing will apply.”

Altru’s next step will be to test CRT packages during the colder seasons and retest refrigerated packouts. “Regular, seasonal PPQ Testing is just so important,” Rosemary says. “Our patients trust us – and we need to continually earn that trust with every single shipment that goes out.” More than that, she adds, most of the drugs they deliver – such as cancer medications – are critical to patients. “They have to arrive on time and in good condition, it’s imperative.”

In the end, she says, PPQ testing just delivers peace of mind – for the pharmacy as well as for patients.



Altru pharmacy staff used guidance from Temptime’s Phase 1 testing to improve their packout design.



Results demonstrate that the Altru Retail Pharmacy shipping boxes are capable of providing the desired temperature environment for shipment of temperature sensitive products, maintaining temperature within 2°C to 8°C for a minimum of 33-hours under the conditions studied. All recorded temperatures inside the shipping containers were within the lower limit of 2°C and an upper limit of 8°C for up to 33-hours.

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