



SUMMARY



Customer

Altru Specialty Pharmacy
Altru Health System

Industry

Specialty Pharmacy

Challenge

After seven years of growth, the pharmacy began to explore the performance of its shipping packouts to make sure it could maintain its mission: to enhance care and improve the overall health and well-being of its patients.

Solution

Altru ultimately chose Zebra's package performance qualification (PPQ) testing to show that packouts were configured and performing correctly. Testing is conducted in two phases to allow Zebra to capture and thoroughly analyze all the information required to prepare the PPQ report.

Results

Altru has instituted best practices throughout the shipping process that deliver peace of mind for the pharmacy, as well as its patients. Another benefit is that the PPQ testing will help the pharmacy achieve URAC accreditation.

Altru Specialty Pharmacy

Keeping medication in proper temperature range – winter, spring, summer, and fall

About Altru Specialty Pharmacy

Altru Specialty Pharmacy is a part of Altru Health System, which serves people in North Dakota and parts of Minnesota. What began in 2014 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 well-being of its patients.

Background

According to Rosemary Kalenze, PharmD, Outpatient Pharmacy Manager for Altru, the pharmacy initially thought it would be best to test the performance of its medication packages using 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°F in the summer," explains Kalenze. "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 Zebra's third-party Package Performance Qualification (PPQ) testing to show that its packouts were configured and performing correctly.

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°C 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 Kalenze. In phase one, 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 Zebra, which analyzed the captured data.

"We learned a lot in that initial evaluation of our packaging," Kalenze says. Zebra gave Altru guidance on coolers and other packing materials best for cold chain shipments to help improve its packout design. "We made a few tweaks with the intent of giving patients even greater confidence in the medications we deliver – and Zebra was a great help through the entire process," Kalenze says. Altru then moved on to phase two for further testing of the passing phase one package design.

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Rosemary Kalenze, PharmD,
Outpatient Pharmacy Manager
Altru Specialty Pharmacy



In phase two, 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, Zebra collected the time-temperature data, this time using the information to prepare a PPQ Report that shows the qualification of the packouts.

Aside from ensuring packages performed the way it needed them to, Kalenze says one of the most significant benefits has been instituting best practices throughout the shipping process. “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.”

Altru went on to complete its second round of PPQ testing with ease. “We tested controlled room temperature (CRT) and refrigerated shipments during the summer to ensure packouts keep medication from getting too hot,” says Kalenze. “With all we learned in our previous testing, the process the second time around was much smoother and we successfully passed phase one on the first try.”

The Results

The specialty pharmacy was also pleasantly surprised to find that the PPQ testing would help with its URAC accreditation, which it began working toward in October 2019. “A lot of URAC’s requirements are centered on providing documented proof that medication temperatures are monitored and maintained,” says Kalenze. “And everything we have done will apply.”

Looking Forward

Altru’s next step was to test CRT packages during the colder seasons and retest refrigerated packouts. “Regular, seasonal PPQ testing is just so important,” Kalenze 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 the pharmacy delivers – 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.”

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