



SUMMARY



Customer

AON PHARMACY
American Oncology Network, LLC

Industry

Pharmaceutical

Challenge

To satisfy strict URAC guidelines on accreditation, AON needed to provide detailed documented proof and reports of its performance qualification testing for monitoring and maintaining pharmaceutical temperatures. It also needed a solution that would be easy to use and interpret by its pharmacy staff.

Solutions

- Zebra TransTracker Shipment Indicators
- Zebra PPQ testing

Results

Its packouts really got the job done. No medications ever fell out of range. Test results demonstrated that the AON Pharmacy small 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 24 hours.

AON Pharmacy

Tools of the Trade for Keeping Patient Medication Stable

About AON Pharmacy

Launched in September of 2018 as an offshoot of the Florida Cancer Specialists & Research Institute, AON Pharmacy is a specialty pharmacy dedicated entirely to dispensing oral oncology medications. Based on its rapid growth, this type of “specialized” specialty pharmacy is clearly an idea that’s right for the times.

“We started with just three employees, shipping medications to patients in about nine states via FedEx,” says Doug Braun, Pharmacy Manager for AON Pharmacy. “As we approached our first anniversary, we had 17 employees and plans in place to expand our reach to all 50 states.”

Background

Like any specialty pharmacy, many of the medications it sends to patients are temperature sensitive. “Some need refrigeration while others simply need to stay within a recommended temperature range to avoid degradation,” Braun explains. To monitor temperatures during shipment, AON opted for Zebra’s TransTracker indicators, which are manufactured by Temptime. TransTrackers are single-use devices that give patients a visual indication of whether their medication has gotten too hot or reached freezing temperatures during transit. The pharmacy includes a TransTracker in all shipments that require refrigeration.

“We chose TransTracker because Florida Cancer Specialists was already using the technology,” says Braun. “We knew firsthand from its experience the value of the product as well as the good service Zebra provided.” This level of service, he says, is vital to AON. “Getting the right help from people we need to lean on is what matters to us.”

That’s why the pharmacy turned to Zebra for guidance when it came time to conduct performance qualification testing with its packaging.

Performance Qualification (PQ) Testing

Adding new patients in states across the country meant AON would be shipping to a greater variety of climates. “We wanted to be sure our shipments were maintaining proper temperatures so the medications we provide arrived within their stability profile,” Braun says. This was the impetus for AON’s decision to conduct PQ testing. Having already

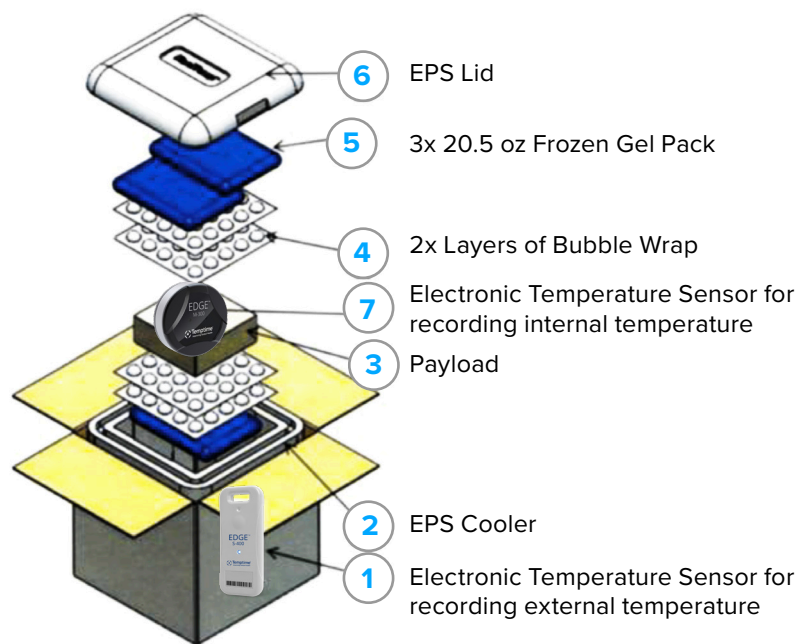
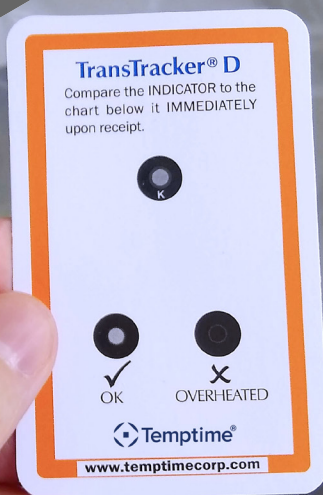
“We knew what we wanted to do, but I wasn’t sure how to go about it. Just out of the normal course of conversation with my rep at Zebra, I discovered that they offered third-party PQ testing services.”

Douglas Braun, CSP, PharmD, RPh

achieved its ACHC accreditation, the company began the process to attain URAC accreditation as well. URAC’s guidelines required pharmacies to conduct PQ testing annually or any time a change is made to its packout. “The difference is that ACHC simply wants to know that you have processes and procedures in place for monitoring and maintaining temperatures,” Braun explains. “URAC requires documented proof and reports that show the results.” It was important to AON that its PQ testing procedures resulted in data that was detailed enough to satisfy URAC’s requirements while also being usable and easy to interpret by pharmacy staff.

In the end, AON chose Zebra’s PPQ testing. During the first phase, Zebra sent electronic temperature sensors to AON along with instructions for programming the sensors to monitor a specific temperature range.

AON followed its usual standard operating procedure for packing and included the sensors within the packouts to monitor both internal and ambient temperatures. The packages were then shipped to Zebra’s testing facility for an initial performance evaluation. Sensors recorded temperatures every 10 minutes from the time they left AON’s facility until they arrived at their final destination. Zebra then downloaded and analyzed the data from the sensors and provided initial data and feedback to AON. All shipments must maintain the temperature range being tested for a specified duration in order to pass Zebra’s phase one evaluation and move on to phase two.



In the second phase of PQ testing, Zebra personnel visited AON onsite to assist with testing and documenting procedures. “Our Zebra rep observed our refrigerated packout procedure and made sure that we were putting the temperature sensors in the correct spot,” says Braun. “She also made sure the sensors were active, programmed with the correct parameters and ready to start recording data so that we would get the information we needed.” The pharmacy sent several test packages out to various locations and climates. Even though it sends temperature-sensitive medications overnight, AON requested Zebra to provide performance data for 48 hours to see what might happen in the case of shipping delays.

The Results

The biggest surprise for the pharmacy was that its packouts were really getting the job done. “I thought we’d see medication start in a normal range and then warm up some,” says Braun. “That didn’t happen – and if anything, some packages actually got colder than I expected for brief periods.” Still, no medications ever fell out of range. “The PQ testing was a great way to validate that our packages were configured properly and didn’t need modifications,” he says.



Shipment 1: AON-NJ-Temperature Profile (24hrs)



Shipment 2: AON-IN-Temperature Profile (24hrs)

Test results demonstrated that the AON Pharmacy small 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 24 hours.

Looking Forward

“We do know that as we expand our footprint, we are going to have to be prepared for all kinds of temperature extremes,” says Braun. “We hadn’t thought about medication getting too cold or freezing when we were only shipping throughout the Southeast.” AON plans to add additional packout configurations that protect both refrigerated and room temperature medications shipped to colder climates, into Alaska for instance. AON plans to wait until winter before testing any new packouts. The company will also conduct PQ testing regularly, both to ensure it is meeting patient needs as well as to comply with URAC accreditation requirements.

Right now, the pharmacy only uses TransTracker for monitoring heat exposure. “I expect we’ll be evaluating if we want to monitor both heat and freeze events based on our expansion plans,” Braun says. It just makes sense to give patients that peace of mind since exposure to either excessive heat or freezing temperatures can be detrimental to medication stability. “We explain to our patients what they’ll be getting and what they need to look for before we send them their medication.” So far, the pharmacy has had no patients calling in to say medication has gone out of range. Braun says this is critical to AON since the oncology medications it distributes can cost anywhere from \$7,000 to \$20,000. “Having to replace even one shipment would have significant financial consequences for us, not to mention inconvenience our patients,” he says.

Confirming that its packouts worked as needed wasn’t the only validation AON got out of the PQ testing. “Working with Zebra through this process just solidified my confidence in them,” Braun says. “We’re in this day and age where customer service is lacking. It’s become the new norm, but not with Zebra. When I call, I get a callback – usually the same day. If they say they are going to do something, they follow through. It’s refreshing.”

“We found Zebra sensors super straightforward to set up,” Braun explains. “We had no issues, no need to call tech support – everything was easy and worked well. That’s exactly what we were looking for.”

 **ZEBRA**

Custom Temperature Profile
Summary Report

2020-31 Shipping Box

*Temptime is now a part of Zebra Technologies

Tap into the future of temperature monitoring at www.zebra.com/temppmonitoring



NA and Corporate Headquarters
+1 800 423 0442
inquiry4@zebra.com

Asia-Pacific Headquarters
+65 6858 0722
contact.apac@zebra.com

EMEA Headquarters
zebra.com/locations
contact.emea@zebra.com

Latin America Headquarters
+1 866 230 9494
la.contactme@zebra.com