

Case Study: Shoppers Specialty Drug Mart

Shoppers Drugmart Specialty Health Network Passes Health Canada Audit and Reduces Packaging and Shipping Costs

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Introduction to Shoppers Drug mart Specialty Health Network

Shoppers Drug Mart Specialty Health Network Inc. has been providing patient assistance services in the Canadian market for more than 20 years, serving thousands of patients coast to coast. Their industry leadership in infusion / injection clinics and national specialty pharmacy network allows patients across Canada to receive high-quality support and service.

The company's six pharmacy locations in Canada distribute drugs directly to patients and networks at over 1,600 pharmacies. This National Specialty Pharmacy network employs pharmacists with advanced therapeutic knowledge, to not only dispense specialty products, but ensure cold chain and ambient temperature control to ensure medication reaches patients promptly and in optimal condition.

The Challenge: Health Canada Audit Compliance



During a recent audit by Health Canada, the company was cited for not using qualified packaging via Canadian temperature profiles, resulting in multiple

packaging failures. These inconsistencies in temperature control at the packaging level required a root analysis to determine the reasoning behind it and a change in philosophy that packaging need only be specified from testing in chambers.

"At this stage, we needed to conduct a full analysis of our transportation processes, packaging design and testing," said Irina Burcescu of Shoppers, "We turned to the leaders in this field, Infitrak, to help us align Health Canada requirements to our internal processes and packaging systems."

Analysis of the Transportation Process

Mesa Labs was brought in to first analyze the transport process, documenting temperatures within trailers and transport containers to determine where potential risks may occur. This included origin and destination, duration, transportation modes and then defined worst case destinations for shipments.

We felt we were in capable hands throughout the entire process and were extremely happy with the results," said Irina Burcescu of Shoppers.



Customer: Shoppers Drugmart Specialty Health Network

Customer challenge: Health Canada Qualification, Packaging Failures

Services conducted: Temperature mapping, gap analysis, packaging qualification and validation, gel conditioning validation, SOP/GDP documentation & training, and real-time monitoring.

TempTrust packaging models:

- 137071 and 137092 for day to day business
- 17073 and 137135 for specific drug requirements
- Reusable TempTrust 13 Quart Rugged for individual patient deliveries
- Reusable TempTrust 80 Quart Rugged for multiple patient deliveries

Results: Passed Health Canada audit, reduced cost of packaging and shipping costs, optimized SOPs and other internal processes.

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“We matched our temperature profile database with their process and wrote complete sets of documentation to define the Shopper’s profile,” said Jean Bedard, VP of Cold Chain Operations at Mesa Labs. The fact that we already had a complete database of temperature profiles from past experience meant that we could reduce the cost and timeframe of this assessment dramatically.”

“I would estimate that we saved Shoppers’ a year of profiling analysis and several thousand. It also prevented temperature deviations and allowed us to develop preventive actions that reduced drug failures,” added Bedard.

After review and signoff, new design test and qualification pack outs were tested in environmental chambers. This included three sizes of TempTrust qualified packaging systems, in two temperature ranges (refrigerated and ambient). After testing, the gel conditioning process was validated to align with the company’s current QMS.

Field performance qualification (PQ) for each packaging container was then conducted for all four seasons to prove the qualification and assessment was done correctly and that all pack outs were performing as expected. Adjustments were then made to address internal processes. Mesa Labs then wrote their SOPs for packaging prep and trained Shoppers’ personal to conduct testing of future pack outs in every season.



The Result: A Successful Health Canada Audit and Reduction in Product Failures

After a follow up review with Health Canada auditors, the Shoppers’ packaging system (container, PCMs, processes and components) was approved as being fully compliant, meeting not only the temperature performance needs dictated by the Health Canada standard, but exceeding those profiles.

“Not only was the team an irreplaceable resource to us during the assessment and testing, but the results were exactly as they promised. We got clear data that told us exactly what actions were needed, and the outcome was right on target: a passed audit and a more cost-effective packaging solution.”

Irina Burcescu, Shoppers Specialty Drug Mart,

The resulting performance allows cost reductions in many ways: reducing cost associated with temperature excursions and decreasing the weight of the pack outs. Having reliable chamber and field testing data also allowed Shoppers’ to reduce the amount of refrigerant used based on length of transit and final destination.

In addition, by adding a real-time monitoring platform to all freezers and applying the associated data, a gap analysis resulted in additional enhanced SOPs.

Mesa Labs, a trusted leader in pharmacy cold chain management since 2002

Since 2002 Infitrak, now Mesa Labs, has designed and developed comprehensive cold-chain solutions that protect a product’s integrity and ensures patient and consumer safety. Mesa Labs is the only company with all three areas of compliance-based, temperature controlled services and products: packaging, consulting, and real-time monitoring. This translates into a team that is with you all the way from raw materials to end user. For more information, visit us at www.temptrust.mesalabs.com.

