

Financial and Safety Benefits of Closed System Transfer Devices

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December, 2017

About the Author -

Cathy Bratt- Rico is considered a top pioneer of closed system drug transfer devices in Canada and has been working in the pharmaceutical and medical device industry for more than 25 years. Prior to launching Innovative OncoSolutions Inc., Cathy held a variety of senior sales and marketing positions in the pharmaceutical and medical industry including Sales Director, Pharmacy Solutions for Becton Dickinson (BD) Medical Surgical Systems. Cathy graduated with a Bachelor of Arts degree and then received an Honours Bachelor of Science (Pharmacology/ Toxicology) both from the University of Western Ontario located in London, ON.

Executive Summary

Equashield, LLC recently hosted a first of its kind International Safe Handling Summit for Closed System Transfer Devices (CSTDs). Hospital pharmacists, pharmacy purchasing decision makers, industry key opinion leaders and International distributors from across Asia, Europe and the Americas from 14 countries met to listen and exchange ideas. At the Summit, advantages for using CSTDs in the preparation and administration of drugs were highlighted and there was significant interest and discussion on the financial and safety implications of using CSTDs and the effect these are having on the industry as a whole.



This paper addresses the key advantages tabled at the Summit for using CSTDs and the financial and safety benefits for cancer centres, hospitals and clinics.

Advantages of Closed System Transfer Devices

Closed System Transfer Devices are used in both compounding in the pharmacy and bedside administration of chemotherapeutic drugs. EQUASHIELD® has a full suite of products designed specifically for pharmacy and bedside administration.

Various purported CSTDs vary in several respects including ease of use and type of interface between the syringe and the infusion set or vial. Standard syringes used in many CSTDs risk drug contamination on the syringe plunger. Among the many reasons for this is that the inner walls of the barrel become contaminated and the barrel comes into contact with the syringe plunger. By closing off this route of exposure, using a CSTD such as EQUASHIELD®, you can decrease surface contamination in health care facilities and can reduce the risk of hazardous drug exposure on administrative staff, patients, and families.

CSTD Compounding Variances When Compounding an IV Piggyback from a Liquid Dose Vial

Use of a CSTD Syringe	PhaSeal	ChemoLock	EQUASHIELD®
Number of Packages to Open	2	2	1
Setup Step 1	Draw ambient air into a syringe	None	None
Assembly	Luer-lock syringe to PhaSeal injector	Luer-lock syringe to ChemoLock	None
Connecting Method	Push-Turn-Push	Push to lock	Push
Setup Step 2	Inject air from syringe into the vial	None	None
Additional Steps for Transfer of Liquids	None	Push-Pull-Push technique required during the whole injection procedure of diluents	None
Flow Rate/Strains on User (relative)	Slow/high	Slow/high	Fast/low
Disconnecting Method	Pull-Turn-Pull	Pinch two levers/pull	Pull

A very important consideration in CSTD adoption is that there are standards, policies and procedures that are being adopted and implemented worldwide for CSTDs. One example is in the U.S.- the USP (United States Pharmacies) 800 has standards in draft stating that CSTDs must be used in administration. Of course, this is only part of the solution. In order to keep the products for administration uncontaminated, a CSTD should be used for preparation as well. CSTDs are becoming a standardized device to minimize these risks.

Financial Benefits of Closed System Transfer Devices

In addition to safety, which is the overarching reason for use, it has become clear that this technology can preserve the sterility of drugs beyond what is normally expected. For example, if the stability of a drug vial once punctured is 12 hours, the drug must be discarded after 12 hours even if sterility is maintained. However, if you have a drug that is stable for 30 days once punctured and you can demonstrate that the drug maintained sterility for, say 7 days, you may then consider extending the sterile date. This could have significant cost savings by eliminating waste of expensive drug products. A major advantage in using CSTDs is that they extend drug sterility.

This is a major cost benefit to medium and high volume pharmacies in helping to offset the cost of CSTD implementation. Studies¹ are showing that CSTDs and EQUASHIELD® in particular are preventing and/ or eliminating microbial contamination and extending the “use-by” date following multiple withdrawals under extreme-use conditions. By eliminating drug waste there can be substantial total savings in overall drug preparation and administration.

For example, depending on the size and traffic in the drug centre pharmacy, adhering to ISO Class 5 environment and not discarding partial vials after 6 hours as per USP 797 could save approximately 1% of your total drug expenditures. An example of total yearly savings is Sunnybrook Health Sciences. Using EQUASHIELD® on every single-use vial in their system Sunnybrook estimated net savings of approximately \$2.1M yearly.

COST SAVINGS IMPLICATIONS

- Annual drug wastage in the cancer centre pharmacy, adhering to chemical stability and preparation in an ISO Class 5 environment, but not discarding partial vials after 6 hr as per USP<797> was ~\$185,000 in 2014/15. This represents ~1% of drug expenditures.
- Annual estimates of drug wastage in 2015/16, abiding USP<797> would be in excess of \$2.7M.
- If we were to use a CSTD on every single use vial in our system, the drug cost savings to our system is estimated to exceed \$2.5M annually.
- The incremental cost of the CSTD within the outpatient oncology program is estimated at \$400,000 annually, based on drug expenditures of \$20.4M and approximately 25,000 patient treatment visits.
- Net cost savings would be ~\$2.1M

Safety Benefits of Closed System Transfer Devices

The major route by which health care employees can be unintentionally exposed to cytotoxic drugs are through absorption through skin or mucous membranes after direct contact with the drugs from surfaces or objects that are contaminated with cytotoxic drugs. Without a pressure equalization system, differences in pressure can lead to the generation of aerosols and vapours that may escape

¹Evaluation of the Sterility of Single-Use Vials Undergoing Multiple Access, Department of Pharmacy, Sunnybrook Health Sciences 2016

into the air and expose the environment, patients, and health care professionals to hazardous drugs. CSTDs are inherently designed with engineering controls to protect health care professionals from hazardous medications.

The EQUASHIELD® closed system drug transfer device system is a fully closed syringe, with a lid encapsulating the rear section of the syringe cylinder, which acts to isolate the plunger rod and the syringe barrel from the environment. The syringe barrel itself provides the reservoir of air needed to fill the vacuum that is created when drugs are drawn out; and, when liquid is inserted into the vial, the natural place for the over-pressurized air to go is into the syringe barrel.

EQUASHIELD® is a completely airtight, leak proof and user-friendly system that complies with CSTD standards around the world. The design mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapour concentrations outside the system from all possible routes of exposure.

About IOS

Innovative OncoSolutions (IOS) is a Canadian pharma-oncology provider of safe and cost-effective clean room environments and closed system drug transfer devices (CSTDs) to the Canadian healthcare market. Our CSTDs are validated closed systems and our clean rooms are NAPRA compliant. This offers a safe and reliable environment for clinicians and patients in the preparation and administration of hazardous/non-hazardous drugs.

We are a privately held Canadian company and sole distributor for our products in Canada.