TRACKING THE PATH OF ANTINEOPLASTIC HAZARDS 
WITH BUREAU VERITAS’ CHEMOALERT SOLUTION

BACKGROUND

Dana-Farber Cancer Institute is one of the world’s leading providers of cancer research and care. Founded in 1947, the Boston-based hospital has a staff of nearly 4,600, treating more than 62,000 patients a year and engaging in 700 clinical trials.

As Dana Farber is a teaching facility, their scientists are eager to advance the state of knowledge to have a positive impact on patient care. As would be expected in a leading healthcare institution, operations at Dana-Farber are carefully managed to ensure the safety of patients and staff.

The opening of a new care center in 2011 provided a unique opportunity to investigate residual surface contamination related to the formulation and administration of antineoplastic drugs used in chemotherapy. There was tremendous interest in this issue from Dana-Farber clinicians and the Oncological Nursing Society, but no hard data.

Dana-Farber’s commissioning of the Yawkey Center for Cancer Care, a new ‘chemo-naïve’ facility, provided an ideal testbed for this occupational hygiene research.

We’ve been working to come up with some kind of OEL (occupational exposure limit), something where we could say “we as a professional group are comfortable with the guidelines and their rationale”

- Melissa McCullough

BUSINESS CHALLENGE

A study that could establish the sources and extent of workplace contamination is critical. However, the research needed to overcome a number of practical hurdles. One was the need for an unbiased, third party test and analytics supplier. Prior to 2011, most research was conducted by laboratories tied to specific product suppliers.
A second challenge was the need for innovative sample collection and testing protocols. At the beginning of the study, there were no sampling and analytical methods that could adequately test for a wide range of potential contaminants and it is impossible to swab a single, small surface (such as a doorknob or vial) a dozen or more times to support multiple discrete tests.

A third issue involved the timescale for the research. The study needed to establish a null initial value for the facility and then track contaminants over an extended period. This would establish whether contaminants are a residual that accumulates over time creating exposure risk to employees and patients or a dynamic of continually-changing compounding, transportation and clean-up activities.

These are important questions – but the kind that can only be answered with repeated tests during different periods, which increased the logistical complexity of the project. Addressing these questions required a high degree of scientific rigor because of the health implications of the materials at nanogram and microgram levels.

“There is risk with these materials at an invisible level, and the health effects from residual exposure are chronic, presenting no clinically observable effects in the exposed individual. Bottom line is that you don’t see the hazard, you don’t perceive the effects, so there are no warning properties at all.”
- Matthew Meiners

WHY BUREAU VERITAS?

Dana-Farber reached out to Bureau Veritas because of our depth of scientific expertise and unique research capabilities.

“This isn’t a soft science; analytical science is a direct, hard science, and Bureau Veritas was uniquely qualified for this project.”
- Melissa McCullough

Dana-Farber also noted that in addition to being a capable, independent laboratory, Bureau Veritas was a great company to work with, providing supplies, being very straightforward and available for questions. Indeed, Bureau Veritas had developed a solution – ChemoAlert™. The kit includes all materials and instructions for sampling, is simple to use, and employs cutting-edge analytical technology. ChemoAlert™ evolved rapidly and in lockstep with Dana-Farber’s demands.
Bureau Veritas modified procedures to include more drugs that could be tested from a single swab test to meet Dana-Farber's sampling program. Early in the process, two swabs were needed to test for five drugs, while now, Bureau Veritas is capable of testing for 14 of the most commonly administered hazardous drugs per swab, which greatly expands the scope of usefulness in research investigation and USP<800> compliance sampling.

The initial sampling plan was developed collaboratively with McCullough identifying compounds and sensitivities (their targets), and Bureau Veritas performing the product development and analysis. Bureau Veritas’ investment in Dana-Farber’s success wasn’t limited to testing; Bureau Veritas also worked with Dana-Farber to develop analytics and trending information supporting the study.

"[Bureau Veritas] wants to know what you’re doing, so that they know how they can help you. They have some really nice people—they’re not just smart, they’re nice."
- Melissa McCullough

KEY RESULTS

With Bureau Veritas’ support, Dana-Farber was able to conduct recurring tests in many different areas of the hospital. An initial set of tests was done to confirm the absence of contaminants in the chemo-naïve facility, with further sampling events at 100, 280 and 465, days after hazardous drugs were introduced into and used in the building.

The ongoing testing yielded fascinating and important insights into the mechanism of migration of hazardous drugs in a healthcare environment.

"We did see increasing amounts where you’d expect to see them, for example in and around compounding labs, but also found things that we weren’t thinking about at all, [contaminants in areas such as nursing stations, where they weren’t expected]."
- Melissa McCullough

In each unexpected situation, the data provided a foundation for further investigation to identify the vehicles and processes leading to drug migration, and ultimately, solutions. Dana-Farber found low hanging fruit that they were able to work on.

In all, a total of more than 500 wipe samples were used to test for 5-Fluorouracil, Cyclophosphamide, Methotrexate and Paclitaxel. The sampling method itself used two solvents methanol and water (MeOH and H2O) and swabs (CleanTips Polyester Alpha Texwipe TX714A).
Armed with the results of the research, Dana-Farber was able to both provide insight to the cancer treatment community and improve the institution’s processes and practices. At a process level, McCullough was able to spearhead a new decontamination procedure for spill cleanup. At the cultural level, increased clinician awareness of the spread of hazardous materials has led to a higher standard of health and safety in the workplace, with staff being a lot more cognizant that these drugs are hazardous.

Personal protection equipment [PPE] compliance has gone up so much “that the graphs [tracking PPE] have become boring – 98% to 99% every time…but impressive,” says McCullough.

FUTURE DIRECTIONS

The foundational research conducted by Dana-Farber has immediate application across the healthcare sector, as USP (the U.S. Pharmacopeial Convention, the standards’ body whose work is enforceable by the U.S. Food and Drug Administration) is introducing new regulations governing hazardous drug handling in healthcare settings. The Dana-Farber study, supported by Bureau Veritas, will help guide institutions to proven methods of improving their processes and staff awareness.

Meanwhile, there is a continuous increase in the complexity of challenges faced by cancer care facilities. McCullough lauds Bureau Veritas’ achievement and the evolution of ChemoAlert™ to date, but adds that there is still work to be done as they begin testing for immunological drugs.

In the fast-paced world of cancer care, both institutions like Dana-Farber and suppliers like Bureau Veritas will continue to invest and improve the leading edge of science in their respective realms. As such, Bureau Veritas maintains ongoing partnerships with globally recognized pharmaceutical companies and today’s drug innovators to develop the sampling and analytical methods for the drugs of tomorrow, before they arrive in clinical environments.