CASE STUDY: INDUSTRIAL HYGIENE

Tracking the Path of Antineoplastic Hazards with Maxxam’s 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 a teaching facility, scientists at Dana-Farber are eager to advance the state of knowledge to have a positive impact on patient care, and 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. As Melissa McCullough of Dana-Farber noted, “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. 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.

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 to establish whether they are, in the words of Maxxam’s Matt Meiners, “a residual...that accumulates over time creating exposure risk to employees and patients,” or a dynamic of continually-changing

SUMMARY

Sector: Industrial Hygiene
Client: Dana-Farber Cancer Institute
Challenge:
• Track the spread of antineoplastic drugs in a chemo-naïve
Solution:
• Develop testing methods capable of identifying multiple hazardous drugs from a wide variety of surfaces
• Work with lead scientists to collect and analyze data demonstrating transport and dispersal patterns
Key Results:
• Dana-Farber changed procedures and controls to enhance workplace and patient safety
• Results changed culture, making staff much more cognizant of the importance of following PPE guidelines
• Maxxam contributed to advanced research that addresses evolving regulatory requirements

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compounding, transportation and clean-up activities. These are important questions – but the kind that can only be answered with repeated tests across different periods, which also increased the logistical complexity of the project. Addressing these questions requires a high degree of scientific rigor. Meiners described the health implications as: “You don’t want to see any of the material getting in the body – [these compounds are] very active at extremely low levels. At levels you can’t see...you’re talking about nanograms to micrograms of material. 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.”

Why Maxxam?
Dana-Farber reached out to Maxxam because of its depth of scientific expertise and unique research capabilities. As Dana-Farber’s McCullough observes, “this isn’t a soft science; analytical science is a direct, hard science, and Maxxam was uniquely qualified for this project.”

McCullough also noted that in addition to being a capable, independent laboratory, Maxxam was “a great company to work with...providing supplies, being very straightforward, being very available for questions.” Indeed, Maxxam had developed a solution – ChemoAlert™, which includes all materials and instructions for sampling, is simple to use, yet comprehensive and employs cutting-edge analytical technology. ChemoAlert™ evolved rapidly and in lockstep with Dana-Farber’s demands. Maxxam’s Meiners reflected that Maxxam “modified procedures to include more drugs that could be tested from a single swab test.” Early in the process, two swabs were needed to test for five drugs, while now, Maxxam 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.

Maxxam’s investment in Dana-Farber’s success wasn’t limited to testing – Maxxam also worked with Dana-Farber to develop analytics supporting the study. Meiners likens the process to engineering, with McCullough identifying “targets – substances and sensitivities,” and Maxxam performing the product development and analysis. “She provided the specifications,” Meiners says, “and we figured out how to achieve them.” The effort was clearly appreciated, with McCullough observing that Maxxam “wants to know what you’re doing, so that they know how they can help you,” and adding “They have some really nice people – they’re not just smart, they’re nice.”

Key Results
With Maxxam’s support, Dana-Farber was able to conduct recurring tests in many different areas of the hospital. An initial set of tests were 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. As McCullough stated, “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. 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: “we found low hanging fruit that we 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.”

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 Maxxam 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 Maxxam’s achievement and the evolution of ChemoAlert™ to date – but adds that there is still work to be done, as “we’re going to have to start to test for immunological drugs.”

In the fast-paced world of cancer care, both institutions like Dana-Farber and suppliers like Maxxam will continue to invest and improve the leading edge of science in their respective realms. As such, Maxxam 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 the clinical environments.