A regulatory verification program with hygiene monitoring: From reformulation, preparation to administration of cytotoxic drugs in compounding pharmacies, human and animal health care centers

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Many Cytotoxic Drugs (CTD) are known human carcinogens. Even low levels of exposure to these chemicals can cause cancer as well as miscarriages, birth defects and other irreversible adverse effects. Stringent control measures are therefore needed to prevent occupational exposure to Cytotoxic Drugs (CTD) and their wastes. CTD use at 4 compounding pharmacies, 25 human and animal health care centers across New South Wales (NSW) were verified for compliance with Work, Health and Safety (WHS) legislation on the effectiveness of their exposure control measures. A total of four hundred and forty-five (445) surface swab samples were analyzed to detect the restricted carcinogen cyclophosphamide and other CTD. Compliance with the Australian WHS legislation for systematic chemical management, including procedures for safe use of carcinogens, in all workplace visited was satisfactory. Although SDS was available at all workplaces, it is noted, most workers especially veterinary nurses, require further training to raise awareness on the health hazards of CTD. Surface contaminations were detected in surface swab samples collected from locations associated with CTD reformulation, preparation, delivery, storage, treatment and waste disposal. Results suggest that despite having good documentation and safe systems for handling CTD in all workplace visited, CTD contamination was detected even in clean area where no CTD exposure is expected. Level of CTD contaminants ranged from 3.45 to 462 and 4.8 to 7686 mg per sample in health care centers and in compounding pharmacies respectively. The level of contamination was relatively low in health care centers. Highest contamination was detected in an Australian owned compounding pharmacy where high risk task was conducted by a trained professional. To eliminate or minimize workers exposure to CTD contaminant requires a hierarchy of hazard control. Integration of hygiene monitoring into the regulatory documentation verification program can provide an evidence-based approach to change workers' behavior for a more stringent work practices. Our study shows presence of CTD contamination in most workplaces despite evidence of good systems of chemical management. The contaminations detected appear to be residuals attributed to lack of stringency in workers safe work behavior. Better worker awareness on the health hazards of CTD is recommended to engage workers’ in preventive behaviors.

Biography
V Fung has completed her Doctor of Philosophy in Biochemical Toxicology in Imperial College of Science, Technology & Medicine, London, United Kingdom. She is a UK registered Toxicologist. She has worked as a Regulatory Scientist for over 10 years in the area of pharmaceuticals and industrial chemicals. Presently she is the Principal Inspector in Australia SafeWork NSW’s, hazardous chemicals services group. She has authored over 20 peer-reviewed publications in chemical hygiene and toxicology.

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