SafeBridge CONSULTANTS, INC.

Industrial Hygiene Control Program Elements In Pharmaceutical Operations

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The following elements should be in place to assure management, workers and clients that potential health risks related to chemicals used in pharmaceutical production processes are minimized.

- The primary element to control workplace exposures is to use engineering controls. Effective local exhaust ventilation isolation and/or enclosure should be in place for process points and all dust generating steps of the operation. Emphasis should be placed on closed material transfer systems and process containment with no open handling of potent compound powders.

- A thorough program of reviewing the toxicology and potency of new compounds to be manufactured and new materials to be used should be in place.

- An effective hazard communication and training program should be in place for all employees so that everyone understands the nature of the risks.

- Processes should be evaluated and characterized through complete and documented industrial hygiene monitoring surveys to confidently predict the exposure potential they present. Periodic survey updates should be performed.

- Clean/dirty/decontamination areas should be established.

- Negative/positive air pressure relationships and buffer zones (where necessary) should be established (i.e., anteroom/gowning room/airlock) and monitored (either manually or automatically) on a regular basis. One-way traffic into and out of the processing suite is preferred.

- Area access should be restricted as appropriate.

- Local exhaust ventilation system testing and maintenance should be in place including at least annual face velocity measurements of all hood and duct velocities and fan speed measurements. Records should be kept of testing and maintenance and repairs made as required.

- A change control system should be in place to prevent unwarranted or inadvertent removal of exposure controls such as local exhaust hoods, modification of blast gate settings, modification of enclosures and process containment devices.

- Process weighing steps should be done only in approved isolator, weigh booths and/or powders weighing hoods (including laboratory scale operations). Laboratory operations require that an OSHA conforming Chemical Hygiene Program be in place.

- A Personal Protective Equipment (PPE) program should be established and appropriate for all processes including protective garments, gloves, respirators, eye protection and foot wear. Training on PPE should be done.

- Powered air purifying respirators (PAPRs) with HEPA cartridges or supplied-air respirators should be used as a secondary means of exposure control where potent compound exposure potential is possible, as indicated by air monitoring data.

- Effective cleaning and decontamination procedures (with PPE requirements) should be established for equipment and operating suites.

- A hearing conservation program should be established to monitor and document high noise areas. If high noise areas exist, then regulatory elements must be in place such as training, audiometry, hearing protection and noise abatement.

- A personal hygiene and uniform laundering program should be in place.

- A comprehensive health surveillance program for all production workers should be established by a competent occupational physician.

- Effective environmental controls and procedures to prevent contamination of wastewater and air with products should be in place and maintained.

This document is not intended to fully address process hazards from a safety or environmental prospective. The elements mentioned here to protect worker health could be part of a comprehensive process hazards analysis and control system.

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