

Occupational Toxicology in Pharmaceutical Industry

1 INTRODUCTION

Most of the assessment of toxicology and safety of therapeutics is focused on the patients who are to benefit from the new medicine. However, there are two other groups of individuals (each of which has different exposure profiles) that one must be concerned about: health care providers (nurses, pharmacists, and physicians) who provide and/or administer the drugs and individuals involved in manufacturing them. The concerns here are in the realm of occupational toxicology.

Modern toxicology has its roots in the occupational environment. The earliest recorded observations relating exposure to chemical substances and toxic manifestations were made about workers. These include Agricola's identification of the diseases of miners and Pott's investigation of scrotal cancer incidence among chimney sweeps. Occupational toxicology, as its name implies, concerns itself with the toxicological implications of exposure to chemicals in the work environment.

In this chapter we will examine occupational toxicology as it applies to and is currently practiced in the pharmaceutical industry. This industry, which by definition involves biologically active compounds, has been a driving force in the development of the science of toxicology. The need for a thorough safety evaluation of potential therapeutics prior to marketing approval has driven