CHAPTER OVERVIEW

Section 5: Toxicity Testing Methods

Learning Objectives

After completing this lesson, you will be able to:

- Explain modern approaches to testing for and assessing toxicity.
- Identify sources of information related to alternatives to using animals to assess toxicity.
- Explain how clinical investigations and epidemiology studies are used to evaluate toxicity to humans.

In this section...

Topics include:

What We've Covered

This section included the following key points:

- The 3Rs concept of using test methods replace the use of animals with other types of studies and approaches, reduce the number of animals used in studies, and refine study procedures to cause less pain or stress to animals.
- ALTBIB is a comprehensive starting point provided by NLM to find information related to alternatives to animal testing.
- Animal tests for toxicity have been conducted prior to and in parallel with human clinical investigations.
- Standardized animal tests have been developed for testing:
  - Acute toxicity
  - Subchronic toxicity
  - Chronic toxicity
  - Carcinogenicity
  - Reproductive toxicity
  - Developmental toxicity
  - Dermal toxicity
  - Ocular toxicity
  - Neurotoxicity
  - Genetic toxicity
- Modern approaches to toxicity testing are preferred over animal testing and include:
  - *In vitro* methods, which are performed outside living organisms.
  - *In silico* methods, which are performed using computers and computer simulation.
  - Chip models, which include human cell cultures placed on computer chips for study.
- Approaches used for testing pharmaceuticals include:
  - Clinical investigations, in which human subjects are studied with clinical observations and laboratory measurements.
  - Epidemiological studies, involving observation of humans exposed to xenobiotics in their regular life or occupation.
  - Reports of adverse reactions to drugs.
- Consumer products and the chemicals they contain are tested through:
  - *In silico* data from computer models.
  - *In vitro* data from tests performed as alternatives to animal testing.
  - Animal study data.
  - Human data from premarketing and postmarketing studies.

Coming Up...

In the next section, we will explore the concept of risk assessment.
