
Preface

This colour atlas follows in the footsteps of the *Atlas of Experimental Toxicological Pathology*, edited and authored by Gopinath, Prentice, and Lewis and published by MTP Press Ltd, Lancaster, UK, in 1987. This atlas is still widely used and is recognised as one of the standard reference texts in this field. This latest version is an update with numerous new illustrations that the authors have collected over the years, and with references and information pertaining to recently developed drug classes, including biologics.

The field of toxicological pathology has expanded vastly, and although several excellent textbooks on toxicological pathology have been published over the past two decades, the authors still feel that this atlas has a significant role to play and will be useful for practising toxicological pathologists of all levels of experience.

Toxicological pathology is a subspeciality of pathology and is a comparatively young profession, dealing mainly with the pathology of laboratory animals used in toxicity studies. As such, it includes a variety of animal species that are used in this field. Different strains of rats, mice, beagle dogs and nonhuman primates form the bulk of animals used in safety assessment studies. Rabbits, hamsters, mini-pigs, guinea pigs, and chickens form a smaller proportion of these studies. Less commonly, domestic animals including goats, sheep, and cattle are also used in these studies. This makes veterinarians, by virtue of their training, ideally suited as candidates for toxicological pathologists.

Toxicity studies are generally driven by protocols designed by various governmental regulatory bodies, mainly from Europe, the USA and Japan. These studies are carried out to assess potential toxicity of the test substances. The test articles may be novel pharmaceuticals, agrochemicals or chemical entities, and include biologics such as vaccines and antibodies.

Toxicity studies are designed with one or more control groups and a few incremental dose levels of the test substance that are selected to represent multiples of the potential exposure levels in humans. The high doses are chosen to induce toxicity in target organs, and lower doses are used to determine no effect levels and no adverse effect levels where possible. With pharmaceuticals, these studies provide information on potential risk during human use and also on side effects during therapy. With chemicals and agrochemicals, these provide data on potential human hazard due to either industrial or environmental exposure. Exposure through either the food chain or the water supply, due to contamination of the environment by use on crops or soil, are also causes for concern.

Toxicity studies are carried out by different routes of administration that mimic expected routes of human exposure. These include dietary, oral, inhalation and parenteral administration. Parenteral routes include subcutaneous, dermal, intradermal or intravenous (bolus or continuous infusion) administration. The duration of the studies varies according to the intended use of the test substance and may vary from a single dose to a few days to lifelong exposure. The aim of all toxicity studies is to assess the potential risk of the test substance to man when in use.

Pathology is an integral part of these studies at termination, as all animals are subject to autopsies and tissue preservation followed by histopathological evaluation and reporting. A full list of organs/tissues is routinely processed from control animals and some or all treated groups, according to the study protocol and using standard operating procedures. By

comparing the results between treated and control groups, the pathologist identifies treatment-related changes and target organs. A sound knowledge of the background pathology of the strain/species of the animals used and of the induced lesions associated with different compound classes is essential for accurate evaluation and interpretation of these studies. This atlas includes a few common spontaneous lesions, but the illustrations are primarily of induced lesions, mostly of a nonneoplastic nature. A few examples of induced rodent tumours from carcinogenicity studies are included. The atlas is organised into different chapters based on systemic pathology. Each chapter has illustrations with legends that briefly identify the changes and a text that explains the changes with references wherever possible. Most of the illustrations are recently sourced from the authors' own collections. A small number that have been used from the previous atlas are acknowledged. The atlas includes some rare examples of unique lesions found during toxicity studies over many years.

It is hoped that the atlas will be useful as a bench reference for practising pathologists and will also be used as a reference text by other experts from related fields.

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