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Application of Pathology in Safety Assessment

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1. INTRODUCTION

1.1. Positioning of Pathology

Pathology contributes two main aspects to toxicological studies, namely results from

- Clinical pathology for detection of *biochemical toxicity* and from
- Postmortem examinations for detection of *structural toxicity*

Pathological investigations are a cornerstone for the assessment of the general toxicity of a compound and postmortem examinations are *the* endpoint in life-time rodent bioassays (carcinogenicity studies) (1). Pathology has also become increasingly important for research support (2–5) and histopathological examinations are performed for the clarification of certain macroscopic findings in reproductive toxicology studies (not covered in this chapter) (6).

Pathology is a holistic investigative tool, which allows conclusions to be drawn as to the overall integrity or sickness of an individual. In-life observations and clinical pathology findings in blood, serum, and urine are important elements of a toxicity study. However, they are rarely the basis for crucial decisions such as discontinuation of development of a compound in