

## Toxicity Evaluations: ICH Guidelines and Current Practice

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### 1. CHAPTER OVERVIEW

This chapter is provided to address the conduct of non-clinical\* toxicity studies in the drug development process and specifically the role of the International Conference on Harmonization (ICH) of the Technical Requirements for the Registration of Pharmaceuticals for Human Use guidances in current toxicology practices. This chapter should be useful to the beginning toxicologist as well as persons in the pharmaceutical industry with no formal training in toxicology, but whose roles may require them to be involved in the design and conduct of the studies. The seasoned toxicologist also might find this chapter to be a good review of current practices. My hope is that this chapter will be a springboard into knowledge and as such, I have provided numerous Internet addresses at which to find additional information.

The chapter is divided into four major sections. In the first section, an introduction to the ICH process is provided. It is important as one moves into the actual ICH topics to have a basic understanding of the parties to

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\*As these toxicity studies are conducted prior to the initiation of clinical trials, the word “pre-clinical” is often used. However, as toxicity studies are also conducted during the course of clinical trials, it is perhaps more correct to refer to these studies as “non-clinical”.