

REPEAT DOSE TOXICITY STUDIES

SHAYNE COX GAD

Gad Consulting Services, Cary, North Carolina

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1 INTRODUCTION

In the broadest sense, subchronic and chronic studies for pharmaceutical products can incorporate any of the routes used to administer a therapeutic agent, use any of a number of animal models, and conform to a broad range of experimental designs. They can be two weeks long (what used to be called “subacute” studies because they were conducted at dose levels below those employed for single dose or acute studies) or last up to a year. Another name for these studies is repeat dose studies [1, 2]—that is, those studies whereby animals have a therapeutic agent