

Preface

Dr. Gad was privileged to start his career in toxicology more than 30 years ago in a testing laboratory that was a hybrid of a company lab and a contract testing lab. The Chemical Hygiene Fellowship of Carnegie Mellon Institute of Research (later known as Bushy Run Labs) was a near perfect environment to learn the practical aspects of regulatory toxicology testing while also being pushed to stay abreast of the then rapidly flowering science of toxicology. Though he has not worked in the contract research environment full time since then, the insights, work ethic, and friendships from those days have been invaluable.

Alternatively, Dr. Spainhour started his career working for a small ethical pharmaceutical company by the name of Smith, Kline & French Ltd. During his tenure there managed to work in a variety of different disciplines in drug development, providing opportunities to understanding the mechanics of how drugs were discovered and developed. Eventually, Dr. Spainhour opted for an opportunity to work for a very small CRO, Pharmakon Research Laboratories and learned first-hand what contract research is all about and successfully grew and developed that business. The things that he learned along the way and the relationships that he established have been of critical importance in formulating his current views and strategies today.

At least through the point of completion of initial studies in humans, most pharmaceutical and medical device development is performed by one form or another of contractor. It is only because of contract research organizations (CROs) that the recent advances in basic science have been translated to the medical wonders that have become available the last 10 years, with the CROs providing the essential regulatory compliant underpinnings of science and technology. Success in pharmaceutical and medical device development requires many things, but the probability of a positive outcome is vastly improved if the individuals and companies seeking to develop these new products truly understand the “tools” before them. Improving that understanding is the objective of this book.

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