



Contract Research and Development Organizations: Their Role in Global Product Development

Shayne C. Gad, Charles B. Spainhour

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The last 10 years have seen a seismic shift in therapeutic product development and testing. In both the pharmaceutical (both small and large molecule) and medical device sectors, the vast majority of testing and evaluation of products is not performed within innovator companies, but rather has been outsourced to a growing universe of commercial organizations. The authors both have more than 30 years experience in this field, and both have worked within innovator companies, for CROs, and as consultants in the field. *Contract Research and Development Organizations: Their Role in Global Product Development* has been crafted by these authors to provide a how to guide for all aspects of working with CROs in selecting, working with and ensuring the best possible desirable outcome of having the R&D function, or substantial parts of it, outsourced. It uses as the exemplary case nonclinical safety assessment, biocompatibility and efficacy testing which are to be performed to select the best possible candidate compound, device or formulation and then moving the resulting regulated therapeutic medical product into and through the development process and to marketing approval. But also covered are the contract synthesis of drug substances and corresponding manufacture of biologics and manufacture of products, formulation development, clinical evaluation, regulatory and document preparation support, and use of consultants.

Included in the volume are an exhaustive listing of those CROs in the (drug and device) safety evaluation sector and their contact information and capabilities, and extensive similar listing for the other types of contract service providers. Also included are guidances on how to monitor ongoing work at contract facilities and audit check lists for GLP, GMP and GCP facilities. These listings are international in scope, and a specific chapter addresses working with some of the newer international CROs.

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