Preface



THIS THIRD VOLUME OF APHEResis: Principles and Practice, 4th edition, is dedicated to apheresis practice in the ever-growing field of cellular therapy and biothera-

peutics. In this book, we attempt to summarize information necessary for apheresis practitioners to better understand their role in the complex process of creating cellular therapy products. It is not intended to be an exhaustive source of information, but rather a primer to learn about elements of the cellular therapy process.

This volume's chapters are organized to start with general topics applicable to many apheresis procedures and progress to detailed discussions of specific topics unique to the collection and processing of cellular therapies. Some of the topics, by necessity, overlap with information provided in Volumes 1 and 2 of this series, but many of the topics are unique to this volume. We also made an editorial decision to include the topic of extracorporeal photopheresis (ECP) in this volume, as it bridges therapeutic apheresis and immunotherapy. (See the book's table of contents for chapter listings.)

First, in many jurisdictions ECP belongs to cellular therapy. This makes sense, as it is the only apheresis modality that reinfuses ultraviolet/psoralen-treated cells from the patient back to the patient, most commonly in the same session. Second, it also resembles a cell therapy manufacturing process because it has discrete steps that occur extracorporeally, either in the apheresis suite (on-line) or in a laboratory (off-line). Furthermore, the treatment may be spread over time (eg, cryopreserved psoralen-treated cells). We hope that the readers see our rationale more clearly when perusing Chapter 10.

We also included in this volume thorough descriptions of regulatory, quality, and facility requirements faced by apheresis facilities involved in cellular therapy product manufacturing. We hope that the reader finds them useful in their daily practice.

Finally, we strongly encourage readers to familiarize themselves with chapters related to processing facilities, in other words, what happens to the apheresis products so carefully collected after they leave our facilities. This information also underscores the importance an apheresis facility plays in the complex and interwoven logistics of cellular therapy product manufacturing.

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