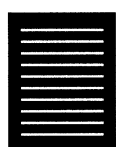


Preface



THE FIELD OF CELLULAR THERAPY is defined by rapid innovation and profound complexity. As we unlock the potential of living cells to treat and cure a vast array of diseases, the professionals on the front lines from the collection facility to the clinical bedside are faced with a growing number of challenges that defy easy answers. The very nature of these novel therapies means that professionals often find themselves in uncharted territory, where established best practices are still being developed and regulatory guidance is continually evolving. It is in this “gray area” between the guidelines and the complex realities of patient care that the most critical problem-solving occurs.

Since 2018, the “Solve It! Scenarios in Cellular Therapy” sessions at the AABB Annual Meeting have become an essential forum for addressing these very challenges. The consistently high attendance and robust discussions at these sessions have underscored a significant need within the community for practical, case-based resources. Feedback from attendees has been clear: these scenarios provide immense value, directly affecting their ability to troubleshoot the complex events that arise in their daily practice. This book was born from that need, with the goal of capturing the spirit and substance of these vital discussions and placing them into the hands of professionals everywhere.

Solve It! Cellular Therapy Scenarios is a curated compilation of the most instructive and compelling cases from the Annual Meeting sessions. We have selected the best and most relevant examples to serve as a readily accessible and lasting resource. Each scenario in this book is designed to provide a systematic approach to problem-solving. We begin by presenting a realistic problem, followed by the key questions readers should be asking. We then offer suggested answers and recommended actions, best practices, and guidance on the regulations and standards that apply to each situation.

Although many of the regulatory references and standards discussed in this book are based on United States practices and frameworks, readers practicing outside the United States should also ensure compliance with their own national, regional, and local regulations, accreditation requirements, and institutional policies applicable to cellular therapy and biotherapies.

This collection is intended for a broad audience, from those just beginning their careers to seasoned professionals seeking to sharpen their skills.

By providing a durable and accessible format for these challenging scenarios, this book aims to foster ongoing professional development and contribute to the advancement of biotherapies. The ultimate goal is to empower readers with the confidence and competence to navigate the exciting and ever-evolving landscape of cellular therapies, ensuring that the promise of these transformative treatments becomes a reality for patients everywhere.

The editor would also like to extend sincere thanks to Jennifer Chain, William (Bill) Ward, and Brenda Alder for their thoughtful revisions and valuable comments, which greatly contributed to the quality and clarity of this work. Special appreciation is also extended to all the authors for making this project possible, including Ronit Reich-Slotky, Yvette C. Tanhehco, Indira Guleria, and Asawari Bapat. In addition, heartfelt thanks are given to Christina Celluzzi for her unwavering support and guidance throughout the development of this resource.

Vasiliki E. Kalodimou, BSc (Hons), MSc, PhD,
CABP(H)(AABB), IARMES
Editor