

Preface

“Plans are worthless; but planning is everything.”

–Dwight D. Eisenhower

As with the above quote, this resource is not about a document; rather, it is about a process. A facility may need to ask, “Why should we expand our services to include biotherapies?” Or, the facility may need to say, “We are committed to this opportunity, so how do we increase the likelihood of success?” In either case, key points need to be considered by diverse stakeholders.

- What product(s) will be collected or prepared?
- Where do we start volume-wise?
- Where do we expect the product volume to be in 5 to 10 years?
- What alterations or additions to the existing space will be needed?
- How can we attract enough qualified staff?
- What will the annual operations budget numbers look like?
- How will we make sure the revenues exceed the expenses?
- What risks are entailed?
- How can our existing activities be leveraged to enhance the new activities?
- How long is this all going to take?

The answers to these and similar questions will reflect the uniqueness of each facility or institution, yet there are some commonalities that others have discovered as they entered the biotherapies field. *Getting Started in Processing for Biotherapies* outlines the major processes to be considered in planning for a new or expanded laboratory and shares how to move it through from conception to reality. Readers will notice a variety of terms being used in the content. This a natural consequence of progress in a rapidly expanding area of medical practice—newly approved treatments;

novel procedures; and professionals eager to learn what their future opportunities might include.

This resource is intended to assist those facilities and professionals at the beginning of a journey into processing biotherapy materials. The content addresses some level-setting basic concepts and requirements and highlights possible options to consider before proceeding with action. Specific topics include the type of work to be performed; quality management aspects; regulatory oversight; support and ancillary services often overlooked; and the very critical choices to be made involving space, equipment, supplies, and staffing. The narrative, illustrations, references for further study, and helpful tools in the appendices are all intended to help readers get a solid start in the process of planning for a new program launch.

Many thanks go to the collaborative group of authors who have made this resource possible. They have shared their knowledge in one of the best AABB traditions and done so expeditiously. Readers are encouraged to provide feedback and keep an eye out for future resources that take a deeper dive into the topics of interest.

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Editor