



Cellular Therapy: Principles, Methods, and Regulations

American Association of Blood Banks (AABB)

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This manual was designed as a compendium of state-of-the-art practices and methods for cellular therapy to aid in the development and operation of a clinical cellular therapy facility. Designed for those in academia, government and industry, it is also an essential reference for those in regulatory affairs and quality assurance as well as for laboratory technologists, managers, directors, physicians and scientists. Through descriptions of the rationale and methodology for a variety of cell processing and evaluation techniques, it will assist laboratory staff in developing procedures that comply with applicable regulations and standards. In addition to numerous examples and templates for laboratory document preparation, several methods are provided that include a general overview of the critical steps, materials and equipment used in each process. Each section has been compiled and edited by a team of experts in the field, with subchapters contributed by specialists in the specific subject matter. Also included is a fully searchable CD-ROM with appendices on Methods and Forms in Word format so they can be fully customized.

Chapters cover:

Regulatory considerations:

Including FDA perspectives, IND and BLA processes, sample outlines, etc.

Quality assurance:

Including process control, records, audits, safety, equipment, personnel, etc.

Facilities:

Aseptic processing, computer systems, validation and general procedures.

Process development:

Assessment of process elements, assay development and risk assessment.

Product collection:

Marrow, apheresis and cord blood techniques.

Clinical processing:

Including storage, shipping, and disposal; patient preparation, infusion, and reactions; processing methods and product problems; etc.

Product characterization:

Including viability, potency, cytotoxicity, contamination, testing, etc.

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