Preface

THE WORD *AUDIT* COMES FROM the Latin word *auditus* (a hearing). As a noun, audit describes the investigation of whether work processes, systems, and products adhere to written standards. The term is used as a verb to describe the process of performing an audit.

The American Society for Quality (ASQ) defines an audit as a systematic, independent, and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled.[1]

The quality plan in the cellular therapy (CT) laboratory documents the structure, responsibilities, and processes and procedures to support the objective of safe CT infusions.[2] Audits are used as part of the quality assurance (QA) system to verify that systems function as intended and that requirements are met.

The objectives of this document are to describe how audits in the CT laboratory accomplish the following:

- Document compliance.
- Enhance a quality system.
- Assist with error reduction.

This book outlines how to design, perform, and follow-up on audits and provides samples and suggestions for forms and audit topics.

Suzanne H. Butch, MA, MLS(ASCP)SBB^{CM}, CQA(ASQ)
Theresa A. Downs, MT(ASCP)SBB, CQA(ASQ)
Sandra K. Hoffmann, MT(ASCP)SBB, CQA(ASQ)