
Contents

	Preface	vii
Chapter 1	Introduction	1
Chapter 2	Case Studies	3
	Patient Misidentification • Reagent Failure • Laboratory Mismanagement • Communication Failure • Fraud	
Chapter 3	Approaches to Managing Quality and Patient Safety	17
	Statistical Process Control • Total Quality Management • Toyota Production System (Lean Production) • COSO • Consensus Standards • Failure Mode Effects Analysis and Root Cause Analysis • Monitoring • Human Error Research	
Chapter 4	Regulation and Accreditation	49
	Principal Regulations • Overview of Regulatory Requirements • Regulatory Noncompliance • Regulatory Context of CAP Programs	
Chapter 5	Specific Quality and Patient Safety Risks	61
	Identifying Important Risks • Patient and Specimen Identification • Order Communication • Specimen Collection and Handling • Appropriate Use of Laboratory Services • Introducing New Tests • Ongoing Quality Management of Tests • Reference Ranges • Reference Laboratories • Reporting Results • Administration of Blood Products • Interpretation of Results • Correcting Reporting Errors • Personnel • Information Management • Turnaround Time • Laboratory Organization	
Chapter 6	Quality Improvement	155
	Learning from Customers • Learning from Incidents	
Chapter 7	The Laboratory Quality Management Plan	167
	Purpose • Authority • Relation to Other Quality Programs • Plan Elements • Plan Format • Implementing the Plan • Sample Plans	
	Glossary	199
	Notes and References	219
	Index	243