

# WHY BECOME A CERTIFIED BIOMEDICAL AUDITOR?

**As a Certified Biomedical Auditor (CBA)** you will be a professional who understands the principles of standards, regulations, directives, and guidance for auditing a biomedical system while using various tools and techniques to examine, question, evaluate, and report on that system's adequacies and deficiencies. A CBA analyzes all elements of the system and reports on how well it adheres to the criteria for management and control of process safety.

---

## What Are the Core Competencies of a CBA?

- Comprehend different types of audits, audit roles and responsibilities, and the ethical, legal, and professional issues associated with audits.
- Apply and understand a broad variety of biomedical quality management system requirements including U.S. and foreign regulatory laws and regulations (e.g., Code of Federal Regulations, 21 CFR 820) and international standards for quality (e.g., ISO 9001, ISO 13485).
- Understand quality tools such as Pareto charts, cause and effect diagrams, flowcharts, statistical process control (SPC) charts, check sheets, scatter diagrams, histograms, and plan-do-check-act (PDCA).
- Identify and apply standards related to risk management, hazard detection, and sterilization for aseptically processed and terminally sterilized products.
- Evaluate risk management programs and requirements for complaint handling, vigilance, medical device reporting (MDR), and tracking and product recall processes. Review validation procedures for laboratory testing and use appropriate methods for analyzing, detecting, and controlling nonconformances.
- Identify and describe biocompatibility terms and test selection rationale in accordance with applicable standards and guidelines. Evaluate environmental controls and determine whether utilities require qualification, validation, or maintenance.
- Recognize the elements of the software development life cycle for products, processes, and quality systems.

## What Is the Value to Your Company?

- Ensure conformity to industry standards and compliance with regulations and requirements regarding quality systems, complaints, MDRs, product classification, and more.
- Understand industry auditing tools like FDA Quality System Inspection Technique (QSIT) and risk-based auditing.
- Mitigate expensive risks using appropriate sterilization methods and processes.
- Improve processes by implementing quality tools and techniques.

## What Is the Value to You?

- An improved skill set qualifies you for more positions within modern business environments.
- CBAs make an average of \$91,500 per year; compared to those without certification, who make approximately \$72,508.\*

---

\*Please see the current Quality Progress Salary Survey at: [asq.org/qualityprogress/](https://asq.org/qualityprogress/).



## Qualifications and Requirements for CBA Certification

Candidates must have five years of work experience in a full-time, paid role in the field of biomedical auditing, including one year in a decision-making position.

### Education

Candidates who have completed a degree from a college, university, or technical school can waive some part of the five-year experience requirement as follows (only one of these waivers may be claimed):

- Associate's degree—one year waived
- Bachelor's degree—three years waived
- Master's or doctorate degree—four years waived

## Biomedical Auditor Learning Resources and Certification Preparation

- Biomedical Auditor Exam Preparation Class
- *The Biomedical Quality Auditor Handbook, Second Edition*
- Biomedical Division—an ASQ professional network

### Recertification Required?

Yes, every three years.

### How to Enroll for Certification

Visit [asq.org/cert](https://asq.org/cert)

# MARKETPLACE INFORMATION

#### COMMON JOB FUNCTIONS

Biomedical Auditor
Biomedical Engineer
Project Manager
Quality Audit Manager
Quality Engineer
Quality Manager
Regulatory Expert
Regulatory Manager
Supplier Quality Engineer

#### COMMON INDUSTRIES

Cardiovascular Devices
Consulting and/or Third-party Auditing
General Hospital Devices
Implants and Prosthetic Devices
In Vitro and Diagnostic Devices
Manufacturing Equipment/Components for Biomedical Industries
Medical Device Industry
Pharmaceutical Industry
Surgery and Life Support Devices

### Key Markets

- Risk management (ISO 14971)
- Risk-based decision making
- FDA 21 CFR 820 compliance
- ISO 13485