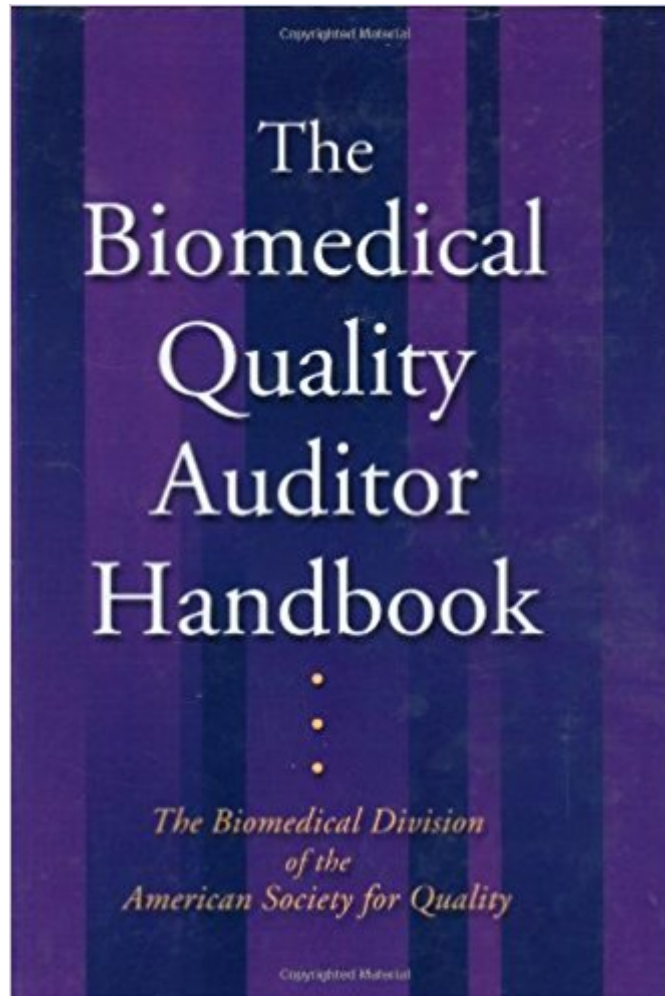




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# The Biomedical Quality Auditor Handbook



## Synopsis

This new handbook is an excellent resource to support the body of knowledge for the Quality Auditor-Biomedical Certification. It serves as a reference to the application of quality auditor principles to the biomedical industry including coverage of medical devices. Content focuses on the understanding of domestic and international concepts and principles of biomedical quality auditing and includes related regulations, directives, standards, and guidance. A specific listing of each requirement is provided along with observations concerning compliance and adherence to the rules.

## Book Information

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## Customer Reviews

Lack of detailed information about many topics in the ASQ CBA Body of Knowledge (BOK) makes this book of very little use for those preparing for the ASQ Certified Biomedical Auditor (CBA) examination. For example, the book fails to include many key facts concerning the numerous FDA regulations, FDA guidance documents and EU, ISO, IEC, and other standards in the BOK. Such facts include the extent to which certain standards incorporate or parallel content in others ("comparable" standards), what important content in one standard is not included in a comparable standard, and details in any of these standards which frequently appear in the ASQ CBA Examinations.

This is an updated review of product:Quality of product: 5/5Helpfulness of seller: 5/5UPS delivery service: 3/5. Seller contends that they shipped on time and that the UPS shipment was cause for

delay. Original review left February 28, 2012: "I was buying this for an ASQ exam, and ordered expedited (1-day) delivery so I could begin studying. Unfortunately it arrived 3 days late and when I tried to contact the seller asking for tracking number I did not receive a response. The quality of the book is great, and matched the ordering description so I am happy to have received it eventually."

Good resource but it is the older revision.

I ordered this book for my boss who uses it for her work as director of Quality Systems and Compliance.

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