

FIFTH EDITION

HANDBOOK

THE ASQ CERTIFIED QUALITY ENGINEER

SCOTT A. LAMAN, Editor



THE ASQ CERTIFIED QUALITY ENGINEER HANDBOOK

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Preface

The purpose of this book is to help people become better quality engineers, with American Society for Quality (ASQ) certification being a tool toward that end. For many purchasing this book, you probably have a good idea about what a quality engineer is and how you fit the bill with your strengths and experience. Congratulations and thank you for choosing this valuable vocation!

For others, let's begin with what quality engineering is. It is not just one field. Quality engineers can be found in product design, manufacturing, post-market surveillance, supplier development, and auditing, for example. Some of us work on the front end of new product development, crossing into reliability engineering and proactive design assurance. Others are continuous improvement and failure analysis experts, utilizing product and process performance information and solving problems identified during manufacturing and use. Some quality engineering disciplines are more technical, some are more interpersonal, and all have various levels of leadership and management.

Quality engineering crosses all demographics, generations, and educational backgrounds. It provides a unifying influence to an organization by its nature of using objective evidence, facts, and data. Few people come out of high school or college knowing that they want to be a Quality Engineer. However, occasionally someone does. More often, however, after several years of working and being exposed to many functions in an organization, a person will decide that quality engineering is what they want to do.

Much comes down to natural inclination and knowing yourself. Have you seen yourself migrate toward using mathematical tools and numbers? Do you consider yourself to have excellent attention to detail, the ability to think and present logically and clearly, and the capability of identifying problems and helping solve them? Can you discern when to take a strong stand on an issue for compliance or safety, and when there may be a gray area involved or give-and-take needed to optimize an outcome? Have others pointed out any of these characteristics in you?

With the foundation built on your natural abilities and interests, your education, and your experiences, ASQ certification can formally get your arms around what has proudly become your professional identity. Think of it as a present, a gift to yourself and by extension to your organization and professional network. In that way, the package is the certified quality engineer (CQE) body of knowledge (BoK), consisting of seven major areas:

- Management and leadership
- The quality system

- Product, process, and service design
- Product and process control
- Continuous improvement
- Quantitative methods and tools
- Risk management

The bow and ribbon on the package are the certification itself, prestigious peer recognition for passing a difficult exam to demonstrate that you really do understand and are ready to apply this broad and comprehensive body of knowledge.

Every five to seven years, the body of knowledge of an ASQ certification is re-evaluated and updated. A comprehensive process is followed, and at the end we move right into producing the references and study guides to help people prepare for the updated exam. A group of people begin to update the exam question bank by deleting, adding, and revising questions as necessary. At the same time, a separate, independent group of people begin updating ASQ training and certification preparation materials, of which this handbook is one.

The process to update a handbook is somewhat involved and takes an army of people, who you will see listed in the Acknowledgments. Quality Press provides a gap assessment between the old and new bodies of knowledge and handles logistics such as contracts and agreements. If there is one part of the process that stands out as most important, it is the selection of authors, which for this book are a collection of renowned experts in their fields and experienced contributors to other publications. Editing then becomes a matter of taking the individual contributions of the authors, fitting their content into the handbook in the logical sequence per the body of knowledge, filling gaps with some writing yourself, and polishing it all to make it look consistent.

For this edition of *The ASQ Certified Quality Engineer Handbook*, the following is a summary of changes. These changes were made to cover the new body of knowledge comprehensively and clearly. It was also acknowledged that certain content, while still of value to quality professionals of all kinds, was no longer part of the body of knowledge for this certification. The following list is being provided to be thorough in communication and honest about what has been changed and removed.

- New content
 - Cost-benefit analysis and responsible, accountable, consulted, and informed matrix (RACI) as quality management system deployment techniques in Chapter 1
 - Assessing risks in audit planning and implementation in Chapter 2
 - Critical to quality as a design input in Chapter 3
 - Hazard analysis and use failure mode and effects analysis as reliability/safety/hazard assessment tools in Chapter 3
 - Overall equipment effectiveness (OEE) as a Lean tool in Chapter 5
 - 5 Whys as a corrective action tool in Chapter 5

- Data automation and database integration as data collection methods in Chapter 6
- An entirely new chapter 7 on risk management
- Restructured content
 - Risk management tools were moved from Chapter 7 to Chapter 3 as part of reliability/safety/hazard assessment tools.
 - Continuous improvement tools and methodologies were aligned with the body of knowledge in Chapter 5.
 - Quality function deployment (QFD) was moved from Chapter 1 to Chapter 3.

Regarding this book's writing style, attempts were made to simplify and reduce the number of words needed to make the point. Microsoft Word was very helpful to identify opportunities for improvement in this area. For example, using the CQE BoK philosophy of Lean, simply replacing the approximately 100 previous usages of "in order to" and "a number of" with "to" and "several" made an impact on word count and readability.

Ultimately, this book was built upon the foundation laid by an outstanding group of editors of previous editions, who are mentioned in the next section.

I hope you find this edition to be helpful in preparing for the certification exam and as a reference to help you succeed in your profession.

Acknowledgments

First, thank you to the giants in quality engineering who laid the foundation to this book by serving as editors of previous editions.

- Roger W. Berger
- Donald W. Benbow
- Ahmad K. Elshennawy
- H. Fred Walker
- Connie M. Borrer
- Sarah E. Burke
- Rachel T. Silvestrini

Next, the Quality Press editorial staff was tremendously helpful in providing guidance and removing roadblocks, some of which seemed significant enough hurdles that this project could have been derailed. Simple advice ranged from determining the scope of the content (what should be in and out of the book) to reducing manuscript file size. A breakthrough at one critical point was the suggestion to use skilled people to produce the equations and mathematical symbols, which I was stuck on but apparently is simple *if* you know how to do it.

- Lillian McAnally, Managing Editor, Quality Press
- Erica Barse, Associate Editor, Quality Press

This project, and editing a book is certainly a project by any measure, could not have been completed if I were not surrounded by an incredibly knowledgeable group of authors, who each took on an area of new content in their area of expertise. They also provided guidance during the project to optimize communications and information flow. This is also a call out to a few of the ASQ Technical Communities. The certified quality engineer exam does not have a sponsoring division like some exams do. Therefore, to obtain the assistance needed to determine contributing authors, I reached out to leadership in ASQ divisions whose focus is on areas including in the CQE BoK. The Audit Division, the Quality Management Division, and the Statistics divisions all provided at least one author, who are listed below followed by the subject(s) each contributed.

- Matthew A. Barsalou, BorgWarner Systems Engineering GmbH – Critical to quality, control chart selection
- Andrew Davison, Genesys Spine – Assessing audit risks, 5 Whys, and auditing standards
- Denis Devos, Devos Associates Inc. – Cost-benefit analysis and responsible, accountable, consulted, and informed matrix
- Harish Jose, Bausch + Lomb Synergetics – Overall equipment effectiveness
- Dr. Michael Mladjenovic, The Sensei Group – Data automation and database integration
- Jayet Moon, Terumo Medical Corporation – Risk management and tools

Two graduate students from the Georgia Institute of Technology produced the mathematical content and at times went above and beyond by finding editing improvements.

- Sweta Senthil
- Manav Sheth

Others provided additional sets of eyes and risk management subject matter expertise in the form of pre-submission reviews.

- Barry Craner, CQA-Associates
- Veronica Cavendish-Stephens, Auchincloss-Stephens International

Now it gets more personal. Over the years, there have been many people who have believed in me and given me a chance to advance in quality engineering when at each step of the way, someone else told me that the next step was not possible. It has been a journey. Thank you to ...

- Stephen Uliana, Mitsubishi Chemical Advanced Materials, for providing my first quality engineering opportunity at Quadrant Engineering Plastic Products and for supporting my initial, brash career venture into attaining ASQ certifications.
- Jeffrey P. Lewis, Globus Medical, for being the hiring manager to provide my first so-titled quality engineering position at Arrow International (now Teleflex).
- Scott McKently, Owens & Minor, for promoting me into my first and second quality engineering management positions at Teleflex.
- Robert Z. Phillips, Siemens Healthineers, for providing support and stretch opportunities at Teleflex to prepare me for continued growth.
- Julius Aviza for providing additional new opportunities at Teleflex that led to my job growing into the quality systems area including medical device management representative responsibilities.

- Michael Byrnes, ASQExcellence, who identified me to edit *The ASQ Certified Medical Device Auditor Handbook* a couple years ago, which led to a similar opportunity with this handbook.

The company Teleflex was mentioned several times above. I would like to acknowledge the organization as a whole for recognizing the importance of individual development plans and for fully supporting ASQ certifications and activities that lead to personal growth that can be translated to the job. It is a win for all and not taken for granted.

Finally, I would like to thank my wife, Krista, for patiently tolerating my work on this book at every opportunity for several months. That support was essential.

List of Acronyms

AHP: analytical hierarchy process
AIAG: Automotive Industry Action Group
AND: activity network diagram
ANOVA: analysis of variance
AQL: acceptable quality limit
AQP: advanced quality planning
ARL: average run length
ASN: average sample number
ASQ: American Society for Quality
ASTM: American Society for Testing and Materials
ATE: automated test equipment
ATI: average total inspection
BoK: body of knowledge
cdf: cumulative density function/cumulative distribution function
CL: center line
CLA: center line average
CM: configuration management
CMM: coordinate measuring machines
COPQ: cost of poor quality
COQ: cost of quality
CQE: certified quality engineer
CSA: Canadian Standards Association
CtQ: Critical to Quality
df: degrees of freedom
dFMEA: design failure mode and effects analysis
DMAIC: define, measure, analyze, improve, control
DMRCS: define, measure, reduce, combine, select
DoD: Department of Defense
DOE: design of experiments
DPMO: defects per million opportunities