

## **Automotive Internal Auditor Pocket Guide: Process Auditing to ISO/TS 16949:2002**

*Roderick A. Munro*

This new pocket guide is an essential resource for anyone in the automotive industry. It's designed to be used as a reference manual for conducting internal audits to ISO/TS 16949:2002 using a new process approach. The book will assist internal auditors with planning and performing process audits in order to become more effective as an auditor and satisfy top management, auditees, and external customers. It includes practical case studies along with the body of knowledge for the ASQ CQIA and CQA certifications, a glossary of terms, and a list of acronyms.

2004 kierresidottu 244 sivua

**Tilausnumero: H1217**

ISBN 978-0-87389-617-7



## **TS 16949: Insight from a Third-Party Auditor With a Process Approach Audit Checklist**

*Karen Welch*

Finally, a comprehensive process audit checklist has been developed to be used with ISO/TS 16949:2002! This checklist does what many others do not: It groups the questions by process rather than by standard clauses, thus automatically guiding the auditor to conduct a process approach audit. This manual was developed to assist anyone involved with conducting or planning quality system audits, including quality auditors, quality managers, quality system coordinators, management representatives, and quality engineers. In addition, potential auditees in any function or position should find the questions useful in preparing for an audit. The manual includes: a brief overview of the process approach; discussion of problem areas often found by third party auditors; the process audit checklist; and forms to be used in conjunction with the process audit checklist to increase audit effectiveness.

2005 pehmeäkantinen 248 sivua

**Tilausnumero: H1256**

ISBN 978-0-87389-654-2





## Journey to Excellence: How Baldrige Health Care Leaders Succeed

*Kathleen J. Goonan, MD, Joseph A. Muzikowski, and Patricia K. Stoltz*

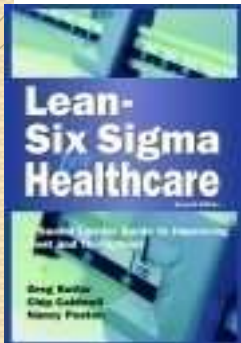


This book is based on several years study of the nine Baldrige Award winners from health care. It describes how these organizations approached their "Baldrige journey" and what other health care leaders should do to reap similar benefits. To fully understand the journey for these nine organizations and their return on investment, the authors studied each of their 50-page award applications, presentations at national and regional meetings, and other publications by or about them. Additionally and most importantly, CEOs and other senior leaders were interviewed at length. The questions asked of these leaders followed three basic themes:

How did you successfully use the Baldrige framework to drive improvement? What would you recommend other organizations do to gain the value you have from a Baldrige journey? What can we learn from you that would help other organizations manage their improvement journeys to maximize the value they gain?

248 sivua. ISBN 978-0-87389-735-8. Pehmeäkantinen. 2009

**Tilausnumero:** H1327



## Lean-Six Sigma for Healthcare, Second Edition: A Senior Leader Guide to Improving Cost and Throughput

*Chip Caldwell, Greg Butler, and Nancy Poston*

This book's unique focus on the role of healthcare leaders and the lessons learned were uncovered during the authors' research of over 200 U.S. hospitals' performance. It was written specifically for CEOs, the "C-Suite," and senior leaders who desire to harness the power of Lean-Six Sigma as their major strategic weapon for progress, as well as those charged to coach them. It is intended for those organizations that operate active Lean-Six Sigma initiatives, but have yet to successfully attack high leverage processes like "In Quality Staffing" and recovering significant Cost of Quality from throughput improvements. It is also intended for senior leaders who have yet to tackle Lean-Six Sigma as their major organization-wide strategic weapon. However, it is also a must-read for managers at all levels, quality professionals, and Lean-Six Sigma Black Belts who desire to aid in assuring that their organizations' improvement efforts attack strategically versus the all-to-common tactical, project-by-project approach that suboptimizes the power of Lean-Six Sigma. Further, the book, accompanying CD, and supporting website is full of electronic checklists, tools, templates, suggestions for additional reading, and many recommended 1-hour and 2-hour learning sessions for senior leaders and managers. The changes in this second edition include the following:

240 sivua. ISBN 978-0-87389-759-4. Kovakantinen.. 2009

**Tilausnumero:** H1250



## Lean Six Sigma for the Healthcare Practice: A Pocket Guide

*Roderick A. Munro*

This book is for those in healthcare practices whose customers/payers may be encouraging or requiring them to use Lean Six Sigma in the workplace, or to simply improve the way healthcare is being provided. The book is intended to be a basic, easy-to-read, quick and handy reference to the process improvement topics that are so important in healthcare. The first seven sections of the book cover the basics of Lean Six Sigma ("What is Lean Six Sigma?" through a "Lean Six Sigma Road Map for the Practice") and how it can be applied and implemented in the Practice. The remainder of the pocket guide gives a brief description of the various tools and methodologies used in Lean Six Sigma. Each discussion has purposefully been kept short and simple to allow for basic understanding. Also included are tips of how or when to use the tool.

252 sivua. ISBN 978-0-87389-760-0. Kierresidottu. 2009

**Tilausnumero:** H1361



## The Public Health Quality Improvement Handbook

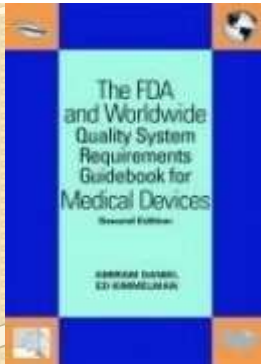
*Ron Bialek, John W. Moran, and Grace L. Duffy*

Little in the current world is simple. Nothing comes in a box for us to add water and stir. There are those, however, who have been successful and who are willing to share their success. The messages in *The Public Health Quality Improvement Handbook* are from leaders, physicians, practitioners, academics, consultants, and researchers who are successfully applying the tools and techniques they share. The chapters are written to support the leaders and workforce of our public health community.

There has never been a better time or a more needed one for us to harness the energy, enthusiasm, hard work, and dedication of our public health workforce to make a lasting difference. By effectively using quality improvement tools and techniques, we can and will improve our nation's health.

480 sivua. ISBN 978-0-87389-758-7. Kovakantinen. 2009

**Tilausnumero:** H1362



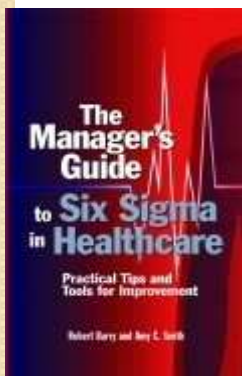
## The FDA and Worldwide Quality System Requirements Guidebook for Medical Devices, Second Edition

*Daniel, Amiram; Kimmelman, Edward*

This new and expanded second edition maintains the organizational approach of the first and includes the requirements and guidance contained in the Quality System Regulation (QSR), the ISO 13485:2003 standard, the ISO/TR 14969:2004 guidance document, and, as appropriate, a number of the FDA and Global Harmonization Task Force (GHTF) guidance documents. This second edition also addresses a number of additional topics, such as the incorporation of risk management into the medical device organization's QMS, QMS issues related to combination products, the key process interactions within a QMS, effective presentation of and advocacy for a QMS during FDA inspections and third-party assessments, and future FDA compliance and standards activities.

Authors' notes giving guidance derived from the authors' sixty years of regulatory compliance experience. This guidance book is meant as a resource to manufacturers of medical devices, providing up-to-date information concerning required and recommended quality system practices. It should be used as a companion to the regulations/standards themselves and texts on the specific processes and activities contained within the QMS.

336 sivua. ISBN 978-0-87389-740-2. Kovakantinen. 2008  
Tilausnumero: H1332



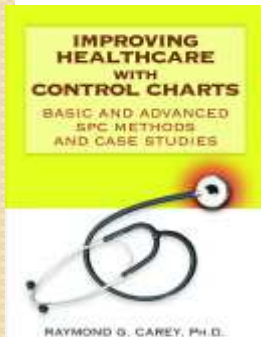
## The Manager's Guide to Six Sigma in Healthcare: Practical Tips and Tools for Improvement

*Robert Barry and Amy C. Smith*

Six Sigma reinforces current developments in healthcare management: evidence based medicine, service line management, and magnet nursing. Six Sigma fits the real healthcare world, dealing with manual tasks and the exceptional needs of patients. This book provides guidance to an organizational strategy that attains and sustains results. It explains how to use in-hand data to improve patient safety, patient service, and patient care for data-informed decision making. A section is also included on finite capacity scheduling models, a key issue in hospital productivity improvement.

It is the first book made with strictly management in mind, organized for quick and easy reference. Each topic starts with a check list and follows with additional information in increasing detail. The practical tips and tools included are made to be immediately applicable.

272 sivua. ISBN 978-0-87389-651-1. Pehmeäkantinen. 2005  
Tilausnumero: H1243

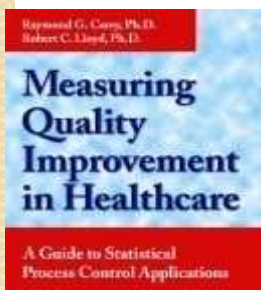


## Improving Healthcare with Control Charts: Basic and Advanced SPC Methods and Case Studies

*Raymond G. Carey*

Do you feel you are drowning in a sea of data and wondering how you can learn from all of this information? While measuring quality efforts in healthcare is essential to the overall performance of any healthcare organization, it is also very complex, leaving many feeling overwhelmed and with a lot of unanswered questions: What are SPC methods and can they really help to improve healthcare? How can control charts be used to monitor key processes and outcomes? How can physicians use control charts to improve their clinical practice?

223 sivua. ISBN 978-0-87389-562-0. Kovakantinen. 2003  
Tilausnumero: H1165



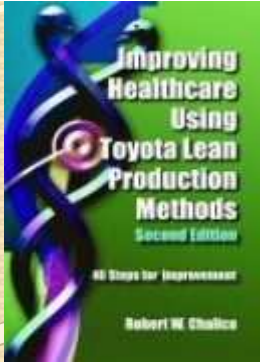
## Measuring Quality Improvement in Healthcare: A Guide to Statistical Process Control Applications

*Robert C. Lloyd, Ph.D.; Raymond G. Carey, Ph.D.*

This ground-breaking book addresses the critical, growing need among health care administrators and practitioners to measure the effectiveness of quality improvement efforts. Written by respected healthcare quality professionals, *Measuring Quality Improvement in Healthcare* covers practical applications of the tools and techniques of statistical process control (SPC), including control charts, in healthcare settings.

The authors' straightforward discussions of data collection, variation, and process improvement set the context for the use and interpretation of control charts. Their approach incorporates "the voice of the customer" as a key element driving the improvement processes and outcomes. The core of the book is a set of 12 case studies that show how to apply statistical thinking to health care process, and when and how to use different types of control charts. The practical, down-to-earth orientation of the book makes it accessible to a wide readership.

194 sivua. ISBN 978-0-52776-293-3. Pehmeäkantinen. 2001  
Tilausnumero: H1091



## Improving Healthcare Using Toyota Lean Production Methods: 46 Steps for Improvement, Second Edition

Chalice, Robert

What differentiates this book from other healthcare improvement books is that it is the only currently available book that presents a simple recipe of 46 lean steps for healthcare providers to reduce cost and improve quality. By taking these straightforward steps, healthcare providers can adopt the same lean methods which have enabled companies like Toyota to become so successful. The first part of the book explains cost and quality issues facing U.S. healthcare. From that understanding, the second part then teaches healthcare providers a 46-step recipe to reduce costs and improve quality by using Toyota Lean Production methods. With industry experts citing that as much as 40% of the total cost of healthcare production is attributed to wasteful processes, it is logical that reducing waste will lower costs. This is the basis of this book.

320 sivua ISBN 978-0-87389-713-6. Pehmeäkantinen. 2007

Tilausnumero: H1306

## On Becoming Exceptional: SSM Health Care's Journey to Baldrige and Beyond

Sister Mary Jean Ryan, FSM

This book does not deliver five or 10 magical steps to levitate your organization to excellence. Instead, it tells a story of mundane realities – hard work, dozens of mistakes, and the extraordinary commitment of thousands of people. It deals with blind alleys, unpopular decisions, incremental improvements, and even a few breakthroughs. In other words, it deals with the real world of flawed organizations and human beings. So if your taste in the business-management aisle of the bookstore runs toward fantasy, please keep looking. If, on the other hand, you are interested in learning from someone who will readily admit her – and her organization's – myriad faults, multiple mistakes, and constant doubts, *On Becoming Exceptional* is your book. CEO Sister Mary Jean Ryan tells the story of how SSM Health Care made its way through the turbulence to become the first health care organization to receive the Malcolm Baldrige National Quality Award – given by the President of the United States for outstanding achievement in quality.

144 sivua. ISBN 978-0-87389-715-0. Pehmeäkantinen. 2007

Tilausnumero: H1308



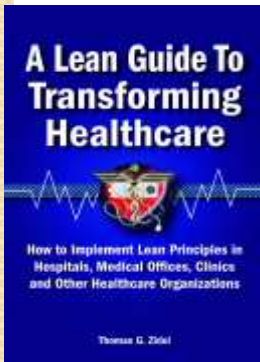
## A Lean Guide to Transforming Healthcare: How to Implement Lean Principles in Hospitals, Medical Offices, Clinics, and Other Healthcare Organizations

Zidel, Thomas G.

This book is an implementation manual for lean tools and principles in a healthcare environment. Lean is a growth strategy, a survival strategy, and an improvement strategy. The goal of lean is, first and foremost, to provide value to the patient/customer, and in so doing eliminate the delays, overcrowding, and frustration associated with the existing care delivery system. Lean creates a better working environment where what is supposed to happen does happen. On time, every time. It allows clinicians to spend more of their time caring for patients and improves the quality of care these patients receive. A lean organization values its employees and encourages their involvement in organizational initiatives which, in turn, sustains hospital-wide quality improvements. The opportunities for lean in healthcare are limitless.

192 sivua. ISBN 978-0-87389-701-3. Pehmeäkantinen. 2007

Tilausnumero: H1295



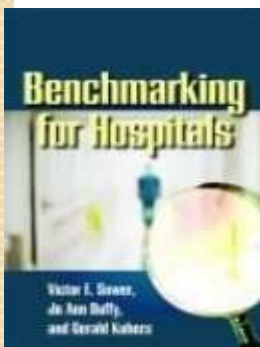
## Benchmarking for Hospitals: Achieving Best-in-Class Performance without Having to Reinvent the Wheel

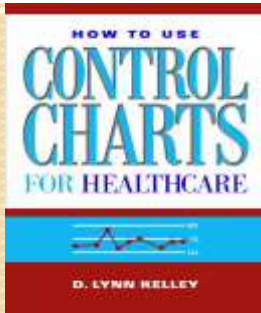
Sower, Victor; Duffy, Jo Ann; Kohers, Gerald

This book is about benchmarking in hospitals—identifying and learning how best-in-class hospitals achieved excellence. It is organized to allow readers with no prior knowledge of the benchmarking process to understand and apply it. The first half of the book discusses the basic benchmarking process as applied to outcome measures, operational processes, and strategic processes. The second half of the book contains case studies documenting best-in-class processes in hospitals that are benchmark standards. These case studies of best-in-class hospitals not only enable the reader to understand how they attained that status, but contain sufficient detail to actually enable hospitals to conduct their own “first cut” at benchmarking. The case studies document the initial state of the process under study, the motivation for improvement, the process by which improvement was attained, obstacles encountered and overcome, and the state of the new process. The processes selected for benchmarking are applicable to all hospitals, not just large research and teaching hospitals. The intent is to provide more than just outcome measures to hospitals endeavoring to improve their own processes.

224 sivua ISBN 978-0-87389-722-8. Pehmeäkantinen. 2007

Tilausnumero: H1314





## How to Use Control Charts for Health Care

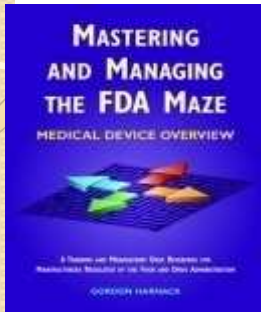
Kelley, D. Lynn

In *How to Use Control Charts for Healthcare*, author Lynn Kelley presents an array of quality tools for the healthcare professional, emphasizing the use of control charts.

The book provides a link between these tools and the accreditation standards relating to performance improvement as set by the Joint Commission on Accreditation for Healthcare Organizations (JCAHO). Kelley provides a complete how-to reference guide for control charts, with easy to understand instructions, examples, and the extensive use of graphics. In addition, each chapter's instructions are followed with examples for practice and training.

196 Sivua ISBN 0873894529. Pehmeäkantinen. 1999

Tilausnumero: H1019



## Mastering and Managing the FDA Maze: Medical Device Overview

Harnack, Gordon

There is a mountain of information on FDA regulation and compliance for medical device manufacturers. The task is daunting and very few busy manufacturers are regulatory mountain climbers. Reading the regulations provides only a small part of the picture. Understanding what the regulations mean and how compliance can be achieved in your environment is key.

In *Mastering and Managing the FDA Maze*, graphic icons organize the text and provide a visual aid to definitions, regulations, procedures, documents, records, and points to remember. Applicable chapters also end with an FDA Investigator Icon, which summarizes what the FDA investigator will expect to see during an investigation.

304 sivua. ISBN 978-0-87389-455-5. 8.5 x 11. Pehmeäkantinen. 1999

Tilausnumero: H1033



## Safe and Sound Software: Creating an Efficient and Effective Quality System for Software Medical Device Organizations

Faris, Thomas H.

This book provides information and recommendations to help regulatory affairs and quality managers and consultants of software medical device design and development organizations navigate the complex course of regulatory compliance, operational excellence, product quality, and customer satisfaction to create an effective and efficient quality system. Software organization executives, functional managers, and other interested coworkers can also utilize this book to secure a general understanding of the subject matter. Many consulting firms, industry associations, and educational institutions present regulatory and quality training opportunities to regulatory and quality students and professionals. However, most training events focus on specific topics or requirements, such as ISO 9000, FDA Quality System Regulations, Six Sigma, vendor qualification, and software design control. Regulations and standards typically provide concise statements of requirements, but not much more.

This book fills that gap in information available to regulatory and quality professionals in the software medical device industry. The resultant operational management system outlined in Part II, the Software Medical Device Quality System Guidelines, provides these professionals with recommendations and considerations for implementing the potentially duplicative requirements in a manner that reduces the bureaucracy of the system and adds value toward satisfying the organization's objectives. Part II is also included on a CD-ROM accompanying the book.

368 sivua. ISBN 978-0-87389-674-0. Pehmeäkantinen. 2006

Tilausnumero: H1262



## Development of FDA-Regulated Medical Products: Prescription Drugs, Biologics and Medical Devices

Elaine Whitmore

Many changes to the classification and regulation of prescription drugs, biologics, and medical devices have occurred since the previous edition of this book was published in 1997 under the title *Product Development Planning for Health Care Products Regulated by the FDA*. This revised edition includes: updated facts and figures; expansion of subjects that have grown more critical, such as clinical outcomes, human factors, and marketing objectives; and additional new topics such as the role of product development in hazard analysis, recalls, and product liability. The author also covers the Food and Drug Administrations Modernization Act (FDAMA), along with discussions on Intellectual Property, Pharmacoeconomics, and Technological and Medical Trends.

224 sivua. ISBN 978-0-87389-613-9. Kovakantinen. 2004

Tilausnumero: H1198



## Lean Doctors: A Bold and Practical Guide to Using Lean Principles to Transform Healthcare Systems, One Doctor at a Time

Aneesh Suneja with Carolyn Suneja

Tilausnumero: H1387

Foreword by Michael F. Gutzeit, M.D., Chief Medical Officer and Vice President of Quality, Children's Hospital of Wisconsin This practical, how-to book clearly and succinctly takes the reader through six proven "success steps" for implementing lean in any healthcare environment:

1. Create physician flow
2. Support physician value-added time
3. Visually communicate patient status
4. Standardize everyone's work
5. Lay out the clinic for minimal motion
6. Change the care delivery model

184 pages. ISBN 978-0-87389-785-3. Soft Cover. 2010

## Quality Function Deployment and Lean-Six Sigma Applications in Public Health

Grace L. Duffy, John W. Moran, and William J. Riley

Tilausnumero: H1382

The purpose of this book is to introduce the concepts embedded in quality function deployment (QFD) and Lean-Six Sigma to help Public Health professionals implement quality improvement within their agencies. The tools and techniques of QFD and Lean-Six Sigma are designed to augment a robust PDCA or PDSA problem-solving process, not replace it.

The tools and techniques of QFD and Lean-Six Sigma can help problem-solving teams by providing insight into customer needs and wants, design and development of customer-centric processes, and mapping value streams. Both QFD and Lean-Six Sigma focus on doing the most with the resources we have. Each of these megatools supports efforts to expand our community support programs and to increase the effectiveness of internal capacities. This dual external/internal focus offers an excellent partnership of quality improvement tools for Public Health.

224 pages. ISBN 978-0-87389-787-7. Hard Cover. 2010

## Medical Device Design and Regulation

Carl T. DeMarco

Tilausnumero: H1415

The intent of this book (MDDR, for short) is to present an introduction to, and overview of, the world of medical device regulation by the United States Food and Drug Administration (FDA), and the relationship of this regulatory scheme to the design and development of medical devices. In providing this information, the book covers the broad range of requirements, which are presented within eight major topics: background and regulatory environment, device design control, nonclinical testing, clinical testing, marketing applications, post-market requirements, quality systems/GMPs, and compliance/enforcement. This book provides students and professionals in the medical device industry with a road map to the regulation of medical devices. It provides a broad understanding of the breadth and depth of medical device regulation by collecting in one textbook coverage of the regulatory scheme for medical devices in terms that are suitable for engineers, scientists, and healthcare providers. The vast amount of information available on the subject is distilled into a concise and coherent presentation.

368 pages. ISBN 978-0-87389-816-4. Hardcover. 2011



## CAPA for the FDA-Regulated Industry

José Rodríguez-Pérez

Tilausnumero: H1398

Medical devices, biopharmaceutical, and traditional drug manufacturing companies devote an important part of their resources to dealing with incidents, investigations, and corrective and preventive actions. The corrective and preventive action system is known as the CAPA system. It is second to none in terms of frequency and criticality of its deviations, and most of the regulatory actions taken by the FDA and foreign regulators are linked to inadequate CAPA systems. This guidance book provides useful and up-to-date information about this critical topic to thousands of engineers, scientists, and manufacturing and quality personnel across the life sciences industries. Understanding and improving the CAPA system as a whole is the focal point of this book, the first of its kind dealing exclusively with this critical system within this highly regulated industry. By helping those in this industry improve their CAPA systems, it will be a crucial aid in their mission of producing safe and effective products.

168 pages. ISBN 978-0-87389-797-6. Hard Cover. 2011

## Root Cause Analysis and Improvement in the Healthcare Sector: A Step-by-Step Guide

Bjørn Andersen, Tom Fagerhaug, and Marti Beltz

Tilausnumero: H1379



Healthcare organizations and professionals have long needed a straightforward workbook to facilitate the process of root cause analysis (RCA). This is that book. In a workbook-style format, it walks through the RCA process step-by-step, with a wide range of real-world examples. It includes up-to-date information on the use of RCA in satisfying mandatory reporting requirements, and slays the myth that the process is onerous and fraught with barriers. Both print and (on an accompanying CD-ROM) electronic worksheets and templates are provided for the reader's use.

The insights are equally applicable to acute care hospitals, rehabilitation facilities, long-term care facilities, outpatient surgery centers, ambulatory services, and general office practices. It is organized so as to be used by the most naive of users for the most basic RCA issues, and there is also a separate section for more advanced users or more complex issues.

Also included is an adaptable, ready-to-use presentation with scripting to aid readers in explaining RCA, garnering support for the use of its techniques, and training others.

256 pages. ISBN 978-0-87389-780-8. Spiralbound. 2010

## Onko yrityksessäsi tarve kehittää toimintaa, mutta omat resurssit eivät riitä?

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- LEAN & Six Sigma
- työntutkimus
- työergonomia ja –menetelmien suunnittelu
- osto- ja hankintatoimen kehittäminen
- tiimi- ja organisaatiovalmennus
- johtamisvalmennus

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