Resource Reviews

Proactive Supplier Management in the Medical Device Industry
James B. Shore and John A. Freije. 2016. ASQ Quality Press (https://asq.org/quality-press). 120 pages.
ISBN: 978-0-87389-931-4

Reviewed by Dan Zrymiak

This book provides an overview of the basic items that the medical device quality practitioner will need to refer to frequently for supply chain management: sourcing selection, evaluation, controls, and summaries of key tools and techniques. This book is intended as a supplement to the more extensive body of knowledge in quality and continual improvement for medical devices, and although it includes many references to industry practices, it should not be considered a substitute for consulting government regulations. It is best to treat this book as a project resource for managing the different phases of partnerships with suppliers. The book also includes a CD with additional presentations, references, checklists, and examples of forms to support change notification and process control. For clarity, the book uses a flowchart to help the reader navigate to the appropriate content with respect to process, process activities, and expected deliverables.

The first portion introduces the reader to the specific regulations and bodies (that is, ISO, FDA) that regulate and define the key terms for medical device supplier management. Purchasing controls exist to ensure safe and effective devices are distributed for use. Enforcement protocols are outlined to alert the reader to the criticality of these practices, to reduce the potential of regulatory penalties. Planning is described as a response to assessment and prequalification of suppliers based on risks and business need. The evaluation, selection, and onboarding of suppliers, based on their total risk factor (TRF), are demonstrated to the reader with usable examples. The authors combine product severity, quality system maturity, financial strength, lead times, and order capacity to derive a balanced TRF value for selection and prioritization. The evaluation combined initial analysis with audit steps to establish whether the supplier should be added to an ongoing approved supplier list from whom products and services can be procured.

The second portion covers controls. This section describes controls (that is, source inspection, incoming inspection, sampling plans) that can be used for product assurance. Creating a strategic supplier map helps define the controls needed for critical items and how they should be directed. An example of a process control plan demonstrates additional control approaches. Audit findings and performance issues can be resolved with a supplier corrective action request (SCAR), and the authors show the steps for communicating and escalating these issues within the corrective and preventive action (CAPA) framework. Supplier quality agreements (SQA) are shown as both a way to fulfill regulatory specifications and strategically manage the partnership with the supplier. The SQA should define expectations, responsibilities, accountabilities, contacts, approvals, scope, compliance, and other attributes needed for regulatory compliance.

The third portion explains how a company can manage total cost of ownership (TCO) to optimize and consolidate its supply chain into a manageable quantity of trusted partners and advisors. TCO is calculated as the product of other cost types (that is, quality, delivery, inventory, freight/shipping). The book describes an analysis method to review supplier activity and performance, and categorize the portfolio accordingly. By tracking product needs, supplier performance, refusal to adapt or comply with regulations, and other behavior patterns, the organization knows when to activate its exit plans with suppliers. Suppliers can be deactivated and reactivated based on the needs and demands of the business

As a resource, this book provides a highly readable and usable reference for both quality assurance and supplier management projects and programs. Although this was intended for those working with medical devices and contains many pertinent regulations, the value from this book can be leveraged for any quality management systems that require proactive supply chain management. The benefit of this reference comes from its Socratic headings (for example, "Why Do I Need This?" "What Content Is Needed?" and "How Will It Be Done?"), which pose and answer the types of questions expected by the reader. The authors insert summaries and takeaways before and after each chapter and at the end of the book to reinforce the key points. I recommend this as a book that quality managers in medical device organizations

can use to collaborate with the purchasing and logistics functions of their organizations to jointly and proactively manage their supply chain for regulatory compliance, quality assurance, and strategic business benefit.

The Knowledge Illusion: Why We Never Think Alone
S. Sloman and P. Fernbach. 2017. New York: Penguin (http://www.penguin.com/). 296 pages.
ISBN-10: 039918435X
ISBN-13: 978-0399184352

Reviewed by Morgan Benton

Everyone suffers under the knowledge illusion—people *think* they know more than they actually know. Sloman and Fernbach explain that to act, human brains have evolved to create and store abstract representations of concepts, allowing human beings to navigate physical and social environments. However, people are almost universally fooled into believing that because they know, for example, how and when to flush a toilet, they also understand how a toilet works. Scratch the surface, though, and one finds that most people's explanatory depth is incredibly shallow. This book attacks this question: If every individual knows so little, how have people accomplished so much as a society?

Human beings store vast amounts of knowledge in the people and things that surround them. They implement design affordances—that is, they shape objects to suggest what should be done with them. ("Looks like a handle? Maybe I should grab it!") They assemble teams of people with complementary talents. They carry the internet in their pockets. And while one's ability to collaborate is undoubtedly a gift, there is a downside: since nobody has time to study *every* issue, people outsource the majority of their beliefs to the community with which they most identify. While people think their ideas are grounded in logical, rational thought, in fact, most of what people believe is tribal. No wonder there are such stark disagreements among various segments of society today!

The book's message is succinct: Intelligence is collective. As Isaac Newton said, "If I have seen further, it is by standing on the shoulders of giants." This book makes a powerful argument that should society act as if it truly understands these concepts, there are profound implications for the ways people organize education, government, and business, and for the ways that people make decisions.

The Certified Six Sigma Master Black Belt Handbook
T. M. Kubiak. 2012. ASQ Quality Press (https://asq.org/quality-press). 672 pages.
ISBN: 978-0-87389-805-8

Reviewed by Rebecca Simmons

This book is for individuals preparing to sit for the ASQ Certified Master Black Belt (CMBB) exam, as well as professionals seeking a Lean Six Sigma reference book. The format aligns with the body of knowledge for the ASQ Certified Master Black Belt exam, and includes a CD-ROM specifically aimed at helping individuals prepare to sit for that exam, and, as a result, I would definitely recommend it as a reference to those people. Those who have significant experience in the role of Black Belt and are moving into (or are interested in moving into) a Master Black Belt role will also find this to be a useful desktop reference. Managers and leaders in existing Lean Six Sigma programs can benefit from the book's reminders of many of the "critical to success" components of a Lean Six Sigma effort.

Unlike many books devoted to the topic of Six Sigma, there is one chapter fully devoted to methodologies. The author makes the reasonable assumption that the reader already has significant familiarity and experience with these methodologies, and is primarily interested in how a Master Black Belt supports enterprisewide planning and deployment, cross-functional competencies, project management, training design and delivery, and mentoring. These topics constitute the entire focus of the book, with a single section devoted to some of the advanced measurement methods and tools that Master Black Belts should know. The topic headings, index, and numerous appendices (including a glossary of terms) make it easy to search for, and locate, specific topics of interest.

The book delves into many aspects of a Lean Six Sigma program that are critical but generally not well addressed in other references geared toward practicing Black Belts, making this very helpful to those seeking to develop their skills or move beyond leading their own project teams and play a larger role in organizational leadership. Topics such as organizational culture, theories of motivation,

creativity and innovation tools, and adult learning theory can greatly influence the successful selection and completion of projects. These topics are important and relevant to those who wish to succeed in a leadership role and are frequently overlooked. Understanding and applying the information provided can greatly enhance project success while positively impacting results in any organization.

The information included in *The Certified Six Sigma Master Black Belt Handbook* is useful, up to date, and often overlooked by other comparable resources, which extends the usefulness of the book beyond just exam prep. However, the body of knowledge organizational format sometimes results in redundancy or "awkward placement of discussion" (the author's own words), and this may prove frustrating to individuals desiring to read the book from cover to cover or who are not interested in exam preparation. In addition, there are enough references to both the Certified Six Sigma Green Belt and Black Belt handbooks that readers without one (or both) may find themselves seeking information from other sources. Those with significant experience and/or education in Lean Six Sigma will likely find a great deal of useful and relevant information if seeking to be, or currently serving as, a Master Black Belt.

Virginia Cyber Range
Multiple contributors. 2017. (http://virginiacyberrange.org).

Reviewed by Nicole M. Radziwill

With the goal of becoming a national resource for cybersecurity education, a consortium of 10 colleges and universities has joined forces to build a menu of courseware and lab exercises to help students learn more about cybersecurity. As described on their website, the Virginia Cyber Range is "a cloud-hosted, virtual environment where students practice what they have learned in immersive, hands-on laboratory exercises to complement their cybersecurity courses."

There are many unique features for their courses. No special software is needed, and all lab exercises are supported by easy setup or virtual machines. By delivering virtual machines with the courseware, the cyber range removes one of the primary barriers to entry for high schools and community colleges: developing the infrastructure to be able to explore cybersecurity issues. Resources will be provided at no cost to public high schools and colleges in Virginia.

I have been working with the coordinators of the Virginia Cyber Range since June to deploy an introductory course in cybersecurity for industrial control systems and smart cities, with a strong foundation in standards-based quality management and risk management. As a result of my experience with this organization, I know that all of the materials are rigorously reviewed and edited, and that the organizers care very much about providing students with a balanced view of the cybersecurity landscape.

For those who are at a public school in Virginia and want to introduce cybersecurity or related concepts into their courses, the Virginia Cyber Range should be the first stop. For those outside of Virginia who have similar needs, these readers may still want to consult this organization to direct them to resources.