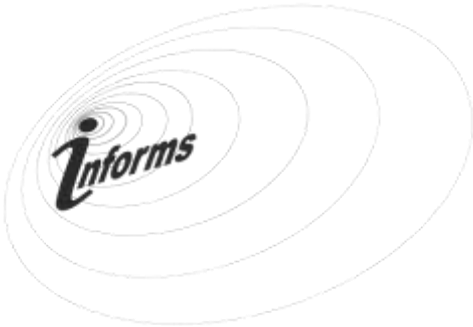
Value Adding Quality Systems

a design that improves performance

Erik J. van den Wijngaard



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Not content but structure
is where
the advantage is to be gained.

Having structure defined
one can
focus on content

Preface

With this book I hope to inspire managers and those involved in creating and maintaining quality systems to create systems that serve the company instead of being a burden. Quality systems are there to improve the company's performance and not to be the focus of attention.

Although there are many books available that broadly describe quality management systems, they leave the details up to the reader. This book was written because it is my opinion that the details are where the major improvements are to be gained.

Most individual quality sub systems are created with the right intention but they lack efficiency due to the fact that they are not designed as one whole. They are missing the integrated design, attention for the business processes and lacking interaction between the systems. All of these elements should be considered from the very beginning when implementing quality systems.

The quality system design presented in this book can be applied to various types of companies of any size. I provide examples of incorrect and less efficient implementations that are found in different industries. For the less obvious situations, the reasoning behind the proposed solutions is provided.

The quality system described in this book also aligns with the standards and regulations applicable to various industries. While the book specifically describes the details concerning the design of a quality system, it also explains

the mechanisms behind an effective quality management system and should therefore not only be used by quality professionals but also by management at every level.

Understanding how an effective quality system works will enable managers to utilize the quality system in order to add value to the company.

to
my loving wife and children
who
allowed me the time
to
write this book

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1 Introduction

Why aren't quality systems delivering the results they promised? Even with the continuous updates presented in standards like ISO9000 for general products and services, ISO13485 and FDA 21CFR820 for medical devices, and EU GMP and FDA 21CFR210/211 (including the ICH documentation) for pharmaceutical products it seems like the effort required to run and maintain a quality system costs more than the benefits it brings. As a result, employees feel frustrated and are not happy with any 'improvement' of the quality system as it will cost them effort to implement and will result in more work in the end.

The problem is often not the improvement itself but the fact that it needs to be implemented upon an existing system. These systems were built to operate without any interaction to other information systems and were not specifically designed for the purpose they are currently being used and they were definitely not designed for efficiency. As a result, daily operations are focused on the quality system itself and not on the business it should manage.

It should be noted that this book differentiates between a 'quality system' and 'quality management system'. This is because a quality management system controls how the company is operated. The operation is documented as content of a quality system. The quality system is the system that allows a quality management system to function effectively and efficiently.

The book also differentiates between quality and compliance. Many regulated companies focus on compliance as that is the expectation from the authorities. By doing so, they miss the opportunity to strive for quality. The difference between the two concepts is the same as that between quality systems and quality management systems. Compliance sets requirements on the content of a quality management system, whereas quality concerns how the system assures consistency and control. Due to the fact that authorities expect elements of a quality system in a quality management system, the definitions of compliance and quality may get confused. However, without having an efficient quality system design a company will have a hard time maintaining its compliance.

The quality system design presented in this book provides a logical approach to an effective quality system. It ensures control over the quality system's content and includes interfaces with the company's daily operations. The proposed system is designed top-down but the book provides guidance for building it bottom-up. The book starts with a discussion of the foundation of every quality system, which involves the right mindset from management and the willingness to document. The next layer above the foundation implements a Deming[1] control circle using documents, records, deviations and changes.

Once the base of the quality system is established, the interactions with the company's daily operations are added. We will first focus on the internal organization before

[1] *William Edwards Deming (October 14, 1900 - December 20, 1993)*

designing the interfaces with external parties. This then completes the quality system, which leads to the next step: creating content.

I will provide guidance on how to structure the content of the quality system and explain the different information types used within the quality management system. Finally, all aspects of this book are brought together and I will provide guidance on implementation order and examples of how to adapt the ideas described in this book to existing systems. The book ends with some final thoughts about automation and continuous improvement.

I do not claim that creating or maintaining an effective quality system does not require any effort. But having an effective quality system will save money in the long run. An effective quality system prevents duplication of work, provides clear instructions, ensures control, saves time and reduces the number of errors. Thus, more product will produced with less waste.

Some will find the approach in this book too structured and feel that it gives them too little freedom. The question is if employees should put effort and time into rethinking quality procedures over and over again. An effective quality system is about control and does not directly add value to the products or services. Just like with driving, it is important to focus on where you are going and not to rethink over and over which pedal is the gas and which is the brake. This book defines the quality system activities upfront in a logical structure so that they can be performed automatically, allowing the company to focus on their product or service.

2 The foundation

Before building a quality system there first should be a foundation to build on. We don't build skyscrapers on sand but too often quality systems are built without a solid base. If a quality system is not built upon a well defined foundation, each part of the system will define its own foundation, that may not be compatible with the next part.

The foundation for a good quality system consists of two elements. First, there needs to be commitment and involvement from management. If management does not believe in the power of a quality system but is only interested in compliance or the sign on the wall, a quality management system is doomed to fail. The second element is documentation. Without documentation there can be quality but it will not be assured. A good quality system is about quality assurance. This means that the elements that matter and secure the future of the company need to be documented.

2.1 Management

The first requirement for a solid quality system is that management has a strong belief in quality systems. Too often management wants a quality system for marketing reasons or because of customer expectations. But if all management wants is a sign on the door stating that they are 'compliant', they never get the full benefit of a properly operating quality system. Standardization organizations, such as ISO and ICH, also recognize the importance of management involvement and include activities for