

DISCOVER ISO 9001:2015

THROUGH PRACTICAL EXAMPLES

A STRAIGHTFORWARD WAY TO
ADAPT A QMS TO YOUR OWN BUSINESS



CARLOS PEREIRA DA CRUZ

Discover ISO 9001:2015 Through Practical Examples

Carlos Pereira da Cruz

Discover ISO 9001:2015 Through Practical Examples

*A Straightforward Way to Adapt a QMS to Your
Own Business*

Advisera Expert Solutions Ltd
Zagreb, Croatia

Copyright ©2017 by Carlos Manuel Gonçalves Pereira da Cruz

All rights reserved. No part of this book may be reproduced, stored in a retrieval system, or transmitted in any form or by any means, electronic, mechanical, photocopying, recording, or otherwise, without written permission from the author, except for the inclusion of brief quotations in a review.

Limit of Liability / Disclaimer of Warranty: While the publisher and author have used their best efforts in preparing this book, they make no representation or warranties with respect to the accuracy or completeness of the contents of this book and specifically disclaim any implied warranties of merchantability or fitness for a particular purpose. This book does not contain all information available on the subject. This book has not been created to be specific to any individual's or organization's situation or needs. You should consult with a professional where appropriate. The author and publisher shall have no liability or responsibility to any person or entity regarding any loss or damage incurred, or alleged to have been incurred, directly or indirectly, by the information contained in this book.

First published by Advisera Expert Solutions Ltd
Zavizanska 12, 10000 Zagreb
Croatia
European Union
<http://advisera.com/>

Editor: Dejan Kosutic

ISBN: 978-953-8155-15-4

First Edition, 2017

ABOUT THE AUTHOR



Carlos Pereira da Cruz is the author of several books about strategy, the balanced scorecard, ISO 9001, and ISO 14001. He has 30 years of experience helping various organizations including industrial, healthcare, and service companies in the implementation of management systems. He holds numerous certificates, among them ISO 9001 Lead Auditor and ISO 14001 Lead Auditor.

TABLE OF CONTENTS

About the Author.....	5
List of figures	7
1. The reason for this book.....	10
2. Why is ISO 9001 usually implemented the wrong way?	12
3. Altix: An introduction to the case study	14
4. Analyzing the Altix strategy	15
5. Linking the strategic side with ISO 9001: 2015	27
6. How ISO 9001:2015 helps the company strategy.....	33
7. The strategic side of management review in ISO 9001: 2015.....	35
8. Analyzing Altix's operations.....	37
9. How do we map a process?.....	42
10. From a process to a group of interacting processes	59
11. Using processes to model the way Altix operates	61
12. Relating processes and strategy	64
13. Describing a process.....	69
14. Competences of people in a process.....	73
15. What infrastructure is needed to operate a process?	77
16. What should we expect from a process?.....	80
17. Identify the risks associated with the process	81
18. Assess the risks associated with a process	83
19. What to improve in a process, and how.....	88
20. Monitoring the process.....	91
21. Initial corrections	93
22. Improvements after the corrections	98
23. Relating the operational side of the company with ISO 9001: 2015.....	102
24. Relating strategic and operational aspects simultaneously	112
25. A word about internal audits.....	114
26. ISO 9001 is an opportunity, not a burden	118

Bibliography	119
Index	120

LIST OF FIGURES

Figure 1 : The company Altix as a black box	14
Figure 2: The ecosystem of interested parties around Altix.....	17
Figure 3: The requirements of a relevant interested party (Altix customers).....	19
Figure 4: The Altix strategy map.....	20
Figure 5: A SWOT analysis for Altix	23
Figure 6: Different results in the future must come from a different organization in the future	24
Figure 7: Example of monitoring plan.....	25
Figure 8: The Plan-Do-Check-Act cycle	27
Figure 9: Linking good business practices at the strategic level with ISO 9001:2015 clauses.....	32
Figure 10: How ISO 9001:2015 can be used as a source of ideas about requirements to follow when developing the strategic side of a company	34
Figure 11: Altix as a converter of inputs into outputs.....	37
Figure 12: Using the organizational chart to show how a company works	38
Figure 13: Organizational charts easily generate organizational silos.....	39
Figure 14: The flow of work in a vertical organization	40
Figure 15: The flow of work in a horizontal organization.....	40
Figure 16: Repairs R Us – A black box.....	43
Figure 17: Repairs R Us – Main input and output.....	43
Figure 18: Flowchart of activities	45
Figure 19: Extra work, extra cost, damaged reputation.....	47

Figure 20: Flowchart of activities and objects	49
Figure 21: Flowchart of activities, objects, and participants (part I)	51
Figure 22: Flowchart of activities, objects, and participants (part II)	52
Figure 23: Flowchart of activities, objects, and participants (part III)	53
Figure 24: Flowchart of activities, objects, participants, and relevant documents	54
Figure 25: Alternative routes for making decisions	55
Figure 26: Simplifying the flowchart of verbs	56
Figure 27: A simplified flowchart for the core process of a car repair shop	57
Figure 28: Interaction of processes with other processes	59
Figure 29: Flowchart of the main activities of Altix	62
Figure 30: Legend to read the flowchart of the main activities of Altix	62
Figure 31: Main processes of Altix	63
Figure 32: Objectives produced from the black box	64
Figure 33: Objectives produced from the main processes	64
Figure 34: Altix as a set of processes producing objectives	65
Figure 35: Objectives as a function of processes	65
Figure 36: Relationship between processes and strategic objectives	66
Figure 37: Relationship between strategic objectives, processes, and strategic projects	68
Figure 38: Inputs and providers table	70
Figure 39: Outputs and receivers table	70
Figure 40: Flowchart of process 4 (Send orders to factories)	71
Figure 41: Monitoring plan for process 4 (Send orders to factories)	71

Figure 42: The Commercial Assistant job description for process 4 (Send orders to factories)	74
Figure 43: The infrastructures in the context of process 4 (Send orders to factories)	77
Figure 44: The infrastructures in the context of a process (Buy raw materials – reception phase).....	78
Figure 45: Risk evaluation matrix.....	84
Figure 46: Process 4 (Send orders to factories) - risks assessment	85
Figure 47: Process 4 (Send orders to factories) – decisions about risks.....	87
Figure 48: Risks, process and improvement project.....	90
Figure 49: Balancing two cycles: control and improvement.....	94
Figure 50: Linking monitoring, correction, and improvement..	96
Figure 51: The “5 Why’s” technique	99
Figure 52: Example of chart using sparklines	100
Figure 53: Linking good business practices at the operational level with ISO 9001:2015 clauses	108
Figure 54: Cross check between ISO 9001:2015 clauses and the operational side of Altix	109
Figure 55: Linking Altix processes and ISO 9001:2015 clauses from section 8	110
Figure 56: Linking ISO 9001:2015 and the strategic and operational sides of a company.....	112
Figure 57: Internal audit diagram	114
Figure 58: Audits as a process	116

1. THE REASON FOR THIS BOOK

I believe with greater and greater conviction that the most practical way to understand the implementation of ISO 9001 requires a company to look at the standard as if they have never had a Quality Management System, with no knowledge of previous ISO 9001 versions, and with the least amount of baggage.

Unfortunately, most companies that look at the standard to prepare to meet its requirements have a way of thinking that has been introduced by consultants since the first version, in 1987.

So, let's try to look at the 2015 version as if we were ignorant.

A person who is ignorant of ISO 9001, in the truest sense of the word:

- doesn't think of conformity (compliance) – he thinks about performance
- doesn't think of complying with the standard's requirements – he thinks of reaching objectives while avoiding constraints and potentially negative situations

Have you worked with ISO 9001 in the past?

Which was your experience: comply with the standard, or improve performance?

While I write these lines, I am preparing to audit a small company that had been certified for seven years, but in 2010, as a result of the economic crisis, decided to let the certification and the company's quality system expire, because they concluded that the investment didn't pay off. At this moment,

because a multi-national company (a potential new customer) demands it, the company decided to relaunch the implementation of the quality system and certify it. This audit will serve to take a snapshot of the current situation, and it will be the basis for designing a realistic project to re-implement the Quality Management System.

To prepare an audit, the auditor must know its objective and must prepare a checklist. That's why I have studied the company documentation in order to prepare the audit. The SME also provided me with a folder that I read with a mixed feeling of curiosity and disappointment, where I found the internal and external audits carried out over the course of eight years. There was not a single note about benchmarks, objectives, or targets – rather, I saw many reports of non-conformities in documents, and more documents, and still more documents.

That is what I see too often: Quality Management Systems with too few or too many documents, but concentrated on listing tasks that people must perform. And people perform their tasks, and companies remain certified, but nothing else happens. No, don't blame the external auditors. Their client, the registrar (certification body), asks them: "Does the company comply with ISO 9001?" Very rarely do they ask: "Is the system effective? Is it useful? Is the system the driving force of development?"

2. Why is ISO 9001 usually implemented the wrong way?

This book is about how to build a Quality Management System from scratch without looking at ISO 9001; the standard will naturally come afterwards when we show the relationship between sound management practices and ISO 9001 clauses (as you will see in chapters 4 and 22). However, I have to invite the reader for a previous reflection about a definition of ISO 9000:2015, the definition of management system:

A management system is a “set of interrelated or interacting elements of an organization to establish policies and objectives and processes to achieve those objectives.”

Have you ever looked at the definition of *management system*?

My interpretation is that a management system is not a set of papers, nor is it a list of activities. A management system is action in order to achieve the desired results. First, an organization must define its overall guidelines (policies, though I prefer the word “strategy”). Objectives and targets arise from these guidelines, and the reason for the management system to exist is to transform itself and change the company in order to achieve these objectives and targets in a sustainable way.

Thus, a management system must be seen, above everything, as a tool to achieve a portfolio of objectives and targets aligned with the strategy of the organization. And, that is what is lacking in many management systems. Most of the consultants “were born” for the job in a time when there was an ISO standard about vocabulary: ISO 8402; or, they “were taught” by the good practices of other consultants of that time. With ISO

8402 (please, grasp your chairs!) the definition of *management system* was:

“It is the structure, the responsibilities, the procedures, the processes and the resources that an organization needs to implement the quality management in order to achieve the objectives established in the Quality Policy.”

Compare the two definitions – the second one is really pre-historical. It’s no wonder that many quality systems concentrate solely on compliance. As a matter of fact, I learned this through a quote from Napoleon: “To understand someone, you have to understand what the world looked like when they were twenty.”

There are no such things as hazards and coincidences.

Management systems produce what was introduced in their DNA at the time they were generated. If what was indoctrinated was exclusively “We want a certification!”, then they will be certified – but don’t wait for anything else, because a system cannot generate something it was not designed for.

The approach of this book intends to demonstrate how to build a Quality Management System focused on producing results, and which can be certified, this certification being a by-product rather than the main objective (without any negative connotation).

3. ALTIX: AN INTRODUCTION TO THE CASE STUDY

Let's begin by choosing one company to serve as an example. We choose Altix, a company that designs and develops its own shoe models, with its own brands, which they present at international tradeshows. Its clients choose the models, and then order samples to show in their shops or in shops they work with. After that, Altix receives the orders, processes them, and sends them to factories where the production is outsourced.

Altix does not own factories. The orders are dispatched from its warehouse or from the warehouses of the outsourced factories.

Let's represent Altix as a black box:



Figure 1 : The company Altix as a black box

Why a black box?

That's a metaphor: a black box because, to begin with, we are not interested in what is done inside Altix in detail. In this first stage, we are only interested in the results generated by Altix.

Altix, like any other company, has two sides: the strategic one and the operational. Let's focus first on the strategic side.

4. ANALYZING THE ALTIX STRATEGY

The strategic side deals with profound questions, topics well above the day-to-day business:

- What is Altix, and what is its business?
- Why does Altix exist?
- What makes it different? What is its competitive advantage?
- What business objectives does it pursue, and what targets does it want to achieve?
- What is it going to do to achieve them?
- How will it monitor its journey toward the desired future, a place where it will be meeting the targets?

Put yourself in the shoes of the top management team: What do they want for Altix? They want the company to be successful. How do you begin building a successful company?

NOTE: The following numbers at the beginning of the sentences are a sort of GPS you can use later on to relate each sentence with parts of ISO 9001:2015.

1 Choose the right **purpose**, its reason for being. What is Altix's business? What does it really offer to the market? A company never sells the product or the service that is in its catalogue; it sells the results that those products and services provide to its clients.

Purpose: Comfortable footwear for demanding senior customers.

2 Formulate a **strategic orientation** for the company so that it may stand out, so that it may differentiate itself and gain a competitive advantage. What makes it different? In what aspect does it intend to make the difference?

Comfortable footwear, for **demanding senior customers**. Not the traditional older generation customer, but one that is looking for something that is outside the box, with a bolder design, that meets the needs of those who lived through the turbulence and cultural revolution during the 1960s as a young adult, and who cannot stand the boring footwear their parents and grandparents wore when they were the same age. Comfortable footwear for **shops and retail nets** that serve this kind of consumer, and that want exclusivity, small series, quick repositions, and a reliable partner.

3 When formulating a strategic orientation, the Altix top management must identify which **relevant interested parties** and which **relevant requirements** it wants to focus on, which form the basis to build what may be called "the ecosystem where the company operates."

Altix identified three relevant interested parties:

- **consumers** (Altix does not deal directly with consumers, but it must know them in order to meet their needs and provide value. In the end, the consumer is king.)
- **shops and retail nets** (These are Altix's customers. The company considered the market segment they work in – medium-high price, their geographic situation, size, and credit insurance – as selection criteria.)
- **outsourced factories** (Despite being providers, Altix decided to consider them as relevant interested parties, because it intends to develop long-term partnerships that are beneficial for both parties. In the past, Altix suffered some troubles because, at the last minute, some outsourced factories decided not to produce because they were already busy with other clients.)

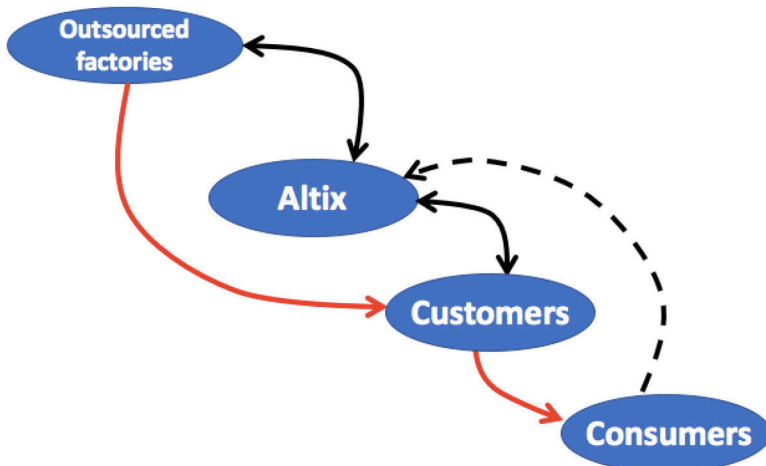


Figure 2: The ecosystem of interested parties around Altix

The red arrows show the product flow – the shoes leave the factories for retail (Altix customers), and then go from the retail to the consumers.

The black arrows (continuous lines) represent information flow – from Altix to the factories, instructions about manufacture, packaging and shipping, and the delivery dates. Altix and the factories also exchange information about delivery planning and the evolution of production and delivery.

The black dotted line shows the flow of information that Altix intends to receive in order to know if its creativity is meeting the taste and preference of the target consumers.

About its target customers (retail outlets), Altix wrote:

- They have credit insurance.
- They cater to the upper-middle class.
- They are medium in size.
- They are prepared to take risks; they do not simply deal with the safety of established brands.
- They look for a way to fight online sales by offering an exclusive and personalized product.

Then, it built the following scheme to characterize what makes these target customers happy:



Figure 3: The requirements of a relevant interested party (Altix customers)

4 Considering the purpose and the strategic orientation of Altix, its top management team, still thinking at the black box level, at the strategic level, established **a set of objectives** for its business that were aligned with the defined strategic orientation.

Altix, a year before thinking about the implementation of a Quality Management System, had already developed a balanced scorecard for its business; therefore, it decided to use the indicators of the balanced scorecard as its quality objectives, the most important objectives for its business.

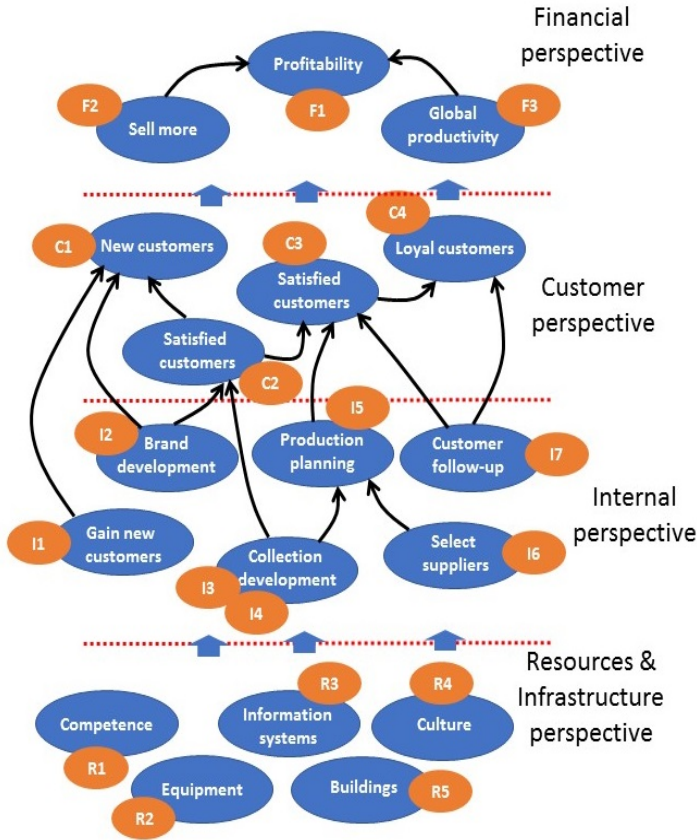


Figure 4: The Altix strategy map

For example, in the Process perspective, the strategic objectives were defined as:

P1.1 Conversion rate of proposals to new customers (target of 27% conversion rate)

P1.2 Compliance rate of "New Customers Plan" (target of at least 85% of the plan completed)

P.2.1 Compliance rate of “Marketing Plan” (target of at least 85% of the plan completed)

P.3.1 Compliance rate of “Collection Design Plan” (target of at least 95% of the plan completed)

P.3.2 Success rate of the collection: Quantities? Replacements? Average price? Margin? (target of at least an increase of 10% in the number of pairs)

P4.1 Compliance rate of collection dates (target of at least 95% of the collections sent to tradeshow)

P4.2 Number of incidents with collection (target of no more than 1 incident per collection)

P5.1 Client complaint rate (target of no more than 5 complaints per season)

P5.2 Internally detected errors rate (target of no more than 3% of production errors)

P5.3 Compliance rate of delivery dates (target of at least 80% of the agreed delivery dates)

P5.4 Hourly efficiency (target of at least X pairs per person, per hour)

P6.1 Compliance rate of delivery dates (target of at least 95% of the agreed delivery dates)

P6.2 Rate of complaints about suppliers (target of no more than 2 complaints per season)

P6.3 Suppliers C rate (target of no more than 2 suppliers rated with C classification per season)

P7.1 Compliance rate of the “Customers’ Follow-up Plan” (target of at least 95% of the plan completed).

5 Altix does not work in vacuum, far away from reality. It is immersed in reality, working in a specific internal and external context that has influence on its capacity and potential. This demands answers to two questions:

6 Are there **external factors** that are relevant for Altix’s competitive environment, which will help or hurt efforts to achieve its objectives? And, are there **internal factors** that may also be relevant to the achievement of those objectives?

At the time when the balanced scorecard was being constructed, Altix created a SWOT Analysis with the main internal and external factors that create and shape the context where Altix operates. The company decided to update the SWOT Analysis in order to keep up with an evolving context.

(This part of the book is not displayed in the free preview)

BIBLIOGRAPHY

ISO 9000:2015, Quality management systems -- Fundamentals and vocabulary, International Organization for Standardization, 2015

ISO 9001:2015, Quality management systems – Requirements, International Organization for Standardization, 2015

FD X50-176 Octobre 2005, Outils de management - Management des processus

Kaplan, Robert; Norton, David; The Strategy-Focused Organization: How Balanced Scorecard Companies Thrive in the New Business Environment, HBSP, 2000

Pereira da Cruz, Carlos, Balanced Scorecard – Concentrar uma organização no que é essencial, Editora Vida Económica, 2006

INDEX

- activity, 43
- Altix, 14, 22, 23, 26, 27, 33, 61, 63, 64, 65, 67, 74, 75, 82, 85, 87, 88, 91, 95, 102, 108, 112, 113
- audit, 10, 114, 116
- audit checklist, 11, 116
- auditor, 11
- Balanced Scorecard, 22, 26
- benchmark, 11
- case study, 48, 50, 58
- certification, 10
- certification body, 11
- client, 25
- Commercial Assistant, 73, 74, 81, 85
- Commercial Director, 73
- competitive advantage, 15
- conformity, 97
- consultant, 10
- cost, 47
- customer, 70, 85
- delivery, 18
- Deming cycle, 94
- documentation, 11
- economic crisis, 10
- external audit, 11
- external factor, 22, 24
- flowchart, 57, 58, 81
- hierarchy, 38
- implementation, 10, 26
- improvement, 48, 96
- Industrial Director, 73
- information flow, 18
- inputs, 37
- internal audit, 11
- internal factor, 22
- investment, 10
- ISO 19011, 114
- ISO 8402, 13
- ISO 9001, 10, 33, 61, 108, 110, 112, 113, 114, 118
- management review, 35
- management system, 12, 33, 35
- manufacture, 18
- non-conformity, 97
- objective, 66
- outputs, 37
- packaging, 18
- partnership, 66
- PDCA cycle, 27, 94, 100, 111
- pricing manual, 42, 44, 48, 53
- process, 66, 71, 80, 81, 89, 92, 93, 96
- process approach, 42, 59
- production, 18
- purpose, 16, 19, 69
- quality control, 92
- quality management system, 10, 96
- Quality Policy, 13
- Repairs Are Us, 42, 49, 50
- risk, 18, 83, 86, 88
- SDCA cycle, 100
- SME, 11
- stakeholders, 35, 92
- strategic initiative, 29

strategy, 12, 31, 35, 79
SWOT Analysis, 22
Technical Director, 73

top management, 15, 26, 35
work order, 48
work plan, 42, 44, 48, 53

Discover ISO 9001:2015 Through Practical Examples

A Straightforward Way to Adapt a QMS to Your Own Business

Author and experienced quality management consultant Carlos Pereira da Cruz has written this book with one goal in mind: to offer you a practical and straightforward way to adapt your Quality Management System to your business, while meeting the requirements of ISO 9001:2015. Without struggle, stress, or headaches.

Inside, you will learn:

- ✓ A straightforward way to adapt your QMS to your own business
- ✓ More than 50 case studies, charts, diagrams, and tables to help you develop your own QMS
- ✓ What procedures to put in place to operate your QMS
- ✓ The roles and competencies of the people involved in the process
- ✓ The risks you may face and how to deal with them
- ✓ How to monitor and improve your QMS
- ✓ How a practical approach to your QMS can help meet the requirements of ISO 9001:2015 without effort
- ✓ All this, and much more . . .

Written in plain English, *Discover ISO 9001:2015 Through Practical Examples* will help you understand the relationship between your regular business operations and ISO 9001:2015, instead of implementing the standard purely to prove compliance.