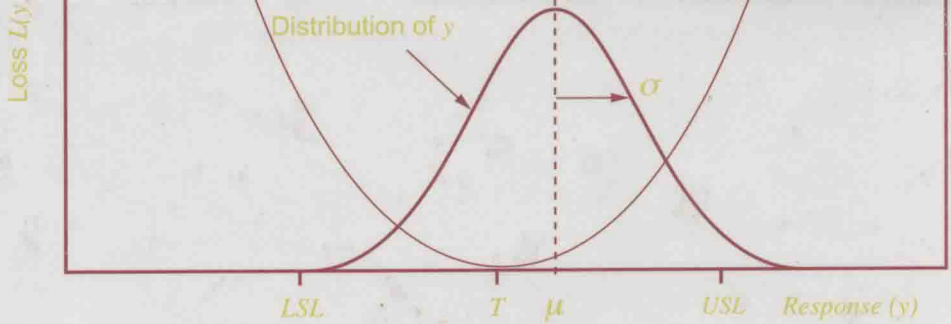
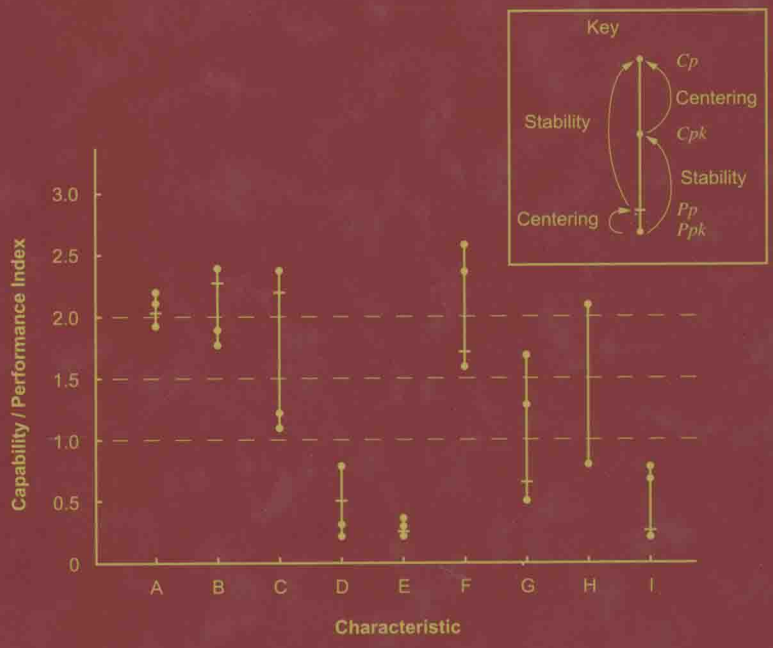


INDUSTRIAL STATISTICS

Practical Methods and Guidance for Improved Performance

ANAND M. JOGLEKAR



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Practical Methods and Guidance for Improved Performance

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WILEY
A JOHN WILEY & SONS, INC., PUBLICATION

Published by John Wiley & Sons, Inc., Hoboken, New Jersey.
Published simultaneously in Canada.

Library of Congress Cataloging-in-Publication Data:
Joglekar, Anand M.
Industrial statistics : practical methods and guidance for improved performance / Anand M. Joglekar.
p. cm.
Includes bibliography references and index.
ISBN 978-0-470-49716-6 (cloth)
1. Process control–Satistical methods. 2. Quality control–Statistical methods. 3. Experimental design. I. Title.
TS156.8.J62 2010
658.5072'7–dc22

2009034001

Printed in the United States of America
10 9 8 7 6 5 4 3 2 1

INDUSTRIAL STATISTICS

To the memory of my parents
and to Chhaya and Arvind

The following age-old advice deals with robust design and continuous improvement at the personal level.

You have control over your actions, but not on their fruits.
You should never engage in action for the sake of reward,
nor should you long for inaction.
Perform actions in this world abandoning attachments
and alike in success or failure,
for yoga is perfect evenness of mind.

– Bhagavad Gita 2.47–48

Mahatma Gandhi encapsulates the central message of Gita in one phrase: *nishkama karma*, selfless action, work free from selfish desires. Desire is the fuel of life; without desire nothing can be achieved. *Kama*, in this context, is selfish desire, the compulsive craving for personal satisfaction at any cost. *Nishkama* is selfless desire. *Karma* means action. Gita counsels—work hard in the world without any selfish attachment and with evenness of mind.

Mahatma Gandhi explains—By detachment I mean that you must not worry whether the desired result follows from your action or not, so long as your motive is pure, your means correct. It means that things will come right in the end if you take care of the means. But renunciation of fruit in no way means indifference to results. In regard to every action one must know the result that is expected to follow, the means thereto and the capacity for it. He who, being so equipped, is without selfish desire for the result and is yet wholly engrossed in the due fulfillment of the task before him, is said to have renounced the fruits of his action. Only a person who is utterly detached and utterly dedicated is free to enjoy life. Renounce and enjoy!

– Adapted from Bhagavad Gita by Eknath Easwaran

PREFACE

This book is based upon over 25 years of teaching and consulting experience implementing statistical methods in a large number of companies in industries as diverse as automotive, biotechnology, computer, chemical, defense, food, medical device, packaging, pharmaceutical, and semiconductor among many others. The consulting assignments have resulted in many success stories—large cost reductions, rapid product development, regaining lost markets, dramatic reductions in variability, and troubleshooting manufacturing. Over ten thousand participants have attended my seminars on statistical methods. All these interactions—the technical problems the participants brought forward, the prior statistical knowledge they had, and the questions they asked—have shaped the writing of this book.

Much of the technical work in industry relies upon the coupling of known scientific and engineering knowledge with new knowledge gained through active experiments and passive observations. Accelerating this data-based learning process to develop high-quality, low-cost products and bringing products to market rapidly are key objectives in industry. The fact that statistical methods are a necessary ingredient in accomplishing these objectives is as true today, if not more so, as it was 25 years ago. The use of statistical methods by all technical individuals in industry, which number in the millions, continues to be an important need.

Four major changes have occurred during the past several years that have influenced the writing of this book:

1. With the advent of personal computers and statistical software, the need to understand statistical computations, in the detail necessary for hand calculations, has reduced dramatically. Today, the job of number crunching can and is delegated to a software package. The statistical computations described in great

detail in various textbooks on statistics are interesting to know but their mastery is no longer necessary to make good applications. This means that the focus has to be on explaining concepts and logic, practical guidance on the correct use of statistical methods, interpretation of results, and examples to demonstrate how to use the methods effectively.

2. As a result of the various iterations of quality approaches—TQM, BPM, Process Reengineering, Six Sigma—there is a greater awareness and focus on the use of statistical methods even in industries where such use was almost nonexistent a short time ago. People are more familiar with statistical methods than they were years ago. This means that a certain degree of statistical knowledge on the part of the audience can be presumed. I have based the knowledge that can be presumed on my experience with the audience.
3. International competition and the need for much higher productivity have resulted in increased workload for technical individuals. There is less time to do more work in! This means that information needs to be presented compactly and in a focused manner dealing with only those issues that are of the highest practical importance. The book needs to be concise and to the point.
4. Managers and black belts are now responsible to promote and implement statistical methods in a company, a job that previously was being done almost exclusively by statisticians. Managers and black belts have various degrees of statistics knowledge but they are not full-fledged statisticians. They need help to implement statistical methods. The book needs to include guidance on implementation.

This book is specially written for the technical professionals in all industries. This audience includes scientists, engineers, and other technical personnel in R&D and manufacturing, quality professionals, analytical chemists, and technical managers in industry—supervisors, managers, directors, vice presidents, and other technical leaders. Most of this audience is engaged in research, product design, process design, and manufacturing, either directly or in support roles. A significant portion of their job is to make decisions based upon data. To do this well, they need to understand and use the statistical methods. This book provides them with the main concepts behind each of the selected statistical method, examples of how to use these methods, and practical guidance on how to correctly implement the methods. It also includes an extensive chapter on questions and answers for the reader to practice with. The material is presented in a compact, easy-to-read format, minimizing the mathematical details that can be delegated to a computer unless mathematical presentation illuminates the concepts. Most of this audience has access to some statistical software package (software 2009). Many are not interested in the details of statistical computations. For those who are so inclined, this book provides recommendations for further reading. Many in this audience such as technical managers, technical leaders, and black belts also have the responsibility to help guide the implementation of the statistical methods. This book identifies questions they should ask to help accomplish this objective.

This book concisely communicates 10 practically useful statistical methods widely applicable to research, product design, process design, validation, manufacturing, and continuous improvement in many different industries. The following criteria were used to select the statistical methods and particularly, the emphasis placed on them in this book.

1. The selected method is widely applicable in R&D and manufacturing in many industries.
2. The method is underutilized in industry and wider use will lead to beneficial results.
3. The method is being wrongly used, or wrong methods are being used, to solve the practical problems at hand.
4. There are misconceptions regarding the method being used that need to be clarified.

ORGANIZATION OF THE BOOK

This book contains 11 chapters. The last chapter includes a test (100 practical questions) and answers to the test. People familiar with the subject matter may take the test and then decide what to focus on, whereas others may read the book first and then take the test. Brief outlines of the remaining 10 chapters follow:

1. *Basic Statistics: How to Reduce Long-Term Portfolio Risk?* This chapter introduces the basic statistical concepts of everyday use in industry. These concepts are also necessary to understand practical statistical methods described in the remaining chapters of this book. Most people in industry, including those who have just joined, are interested in investing their 401k contributions in stocks, bonds, and other financial instruments to earn high returns at low risk. This question of portfolio management, which formed the basis of the Nobel Prize-winning work of Prof. Markowitz on mean–variance optimization, is used as a backdrop to explain the basic statistical concepts such as mean, variance, standard deviation, distributions, tolerance intervals, confidence intervals, correlation and regression. The properties of variance, and in particular, how risk reduction occurs by combining different asset classes are explained. The chapter ends with questions to ask to help improve the use of basic statistics.
2. *Why Not to Use a t-Test and What to Replace It With?* It was almost exactly 100 years ago that the t-distribution and the t-test were invented by W. S. Gosset. This important development provided the statistical basis to analyze small sample data. One application of a t-test in industry today is to test the hypothesis that two population means are equal. Decisions are often made purely based upon whether the difference is signaled as statistically significant by the t-test or not. Such an application of the t-test to industrial practical

problems has two bad consequences: practically unimportant differences in mean may be identified as statistically significant and potentially important differences may be identified as statistically insignificant. This chapter shows that these difficulties cannot be completely overcome by conducting another type of t-test, by computing sample sizes, or by conducting postexperiment power computations. For practical decision-making, replacing the t-test by a confidence interval for difference of means resolves these difficulties. Similar arguments apply to all other common hypothesis tests, such as the paired t-test and the F-test. Many practical applications are considered throughout the chapter. The chapter ends with questions to ask to help improve data-based decision making.

3. *Design of Experiments: Is It Not Going to Cost Too Much and Take Too Long?* In industry, there continues to be insufficient understanding and applications of the important subject of design of experiments. There is also a misconception that designed experiments take too long and cost too much. This chapter shows how, through efficient and effective experimentation, designed experiments accelerate learning and thereby accelerate research and development of products and processes. It illustrates the many pitfalls of the commonly used one-factor-at-a-time approach. It explains the key concepts necessary to design, analyze, and interpret screening and optimization experiments. It identifies the considerations that must be well thought through for successful applications of the design of experiments. Many practical applications are considered throughout the chapter. The chapter ends with questions to ask to help implement and improve the use of designed experiments.
4. *What Is the Key to Designing Robust Products and Processes?* Robust design method needs to be more widely understood and implemented. It adds two important dimensions to the classical design of experiments approach. The first important dimension is an explicit consideration of noise factors that cause variability and ways to design products and processes to counteract the effects of these noise factors. This chapter explains the basic principle of achieving robustness. Robust design means reducing the effect of noise factors by the proper selection of the levels of control factors. Robustness can be achieved only if control and noise factors interact. This interaction is the key to robustness. The design and analysis of robustness experiments is illustrated by examples. The second important dimension of robust design is a way to improve product transition from bench scale research to customer usage such that a design that is optimal at the bench scale is also optimal in manufacturing and in customer usage. Knowledge gained at the laboratory stage does not easily transfer during scale-up because of control factor interactions. The ways to reduce control factor interactions are explained. These two new dimensions have major implications toward how R&D should be conducted. Many practical applications are considered throughout the chapter. The chapter ends with questions to ask to help implement and improve the use of the robust design method.

5. *Setting Specifications: Arbitrary or Is There a Method to It?* Specifications for product, process, and raw material characteristics are often poorly set in industry. This chapter begins with the meaning of specifications and the implications of predefined specifications toward variability targets that must be met in R&D and manufacturing. The basic principles of setting specifications using three different approaches are explained with several examples. The three approaches are empirical approach, functional approach, and minimum life cycle cost approach. The functional approach includes worst case, statistical, and unified specifications. Many practical applications are considered throughout the chapter. The chapter ends with questions to ask to help improve specification development.
6. *How to Design Practical Acceptance Sampling Plans and Process Validation Studies?* The design of acceptance sampling plans and process validation studies is inadequately done in industry. This chapter clarifies the misconceptions that exist in industry regarding the protection provided by the sampling plan. These misconceptions occur because insufficient emphasis is placed on understanding the operating characteristic curve of a sampling plan. Once the acceptable quality level (AQL) and the rejectable quality level (RQL) are selected, the software packages instantly design the sampling plans. The chapter provides practical guidance on how to select AQL and RQL. It explains the connection between AQL and RQL to be used for process validation and the AQL and RQL to be used in manufacturing for lot acceptance. Often, validation studies are designed with inadequate sample sizes because this connection is not understood. Many practical applications are considered throughout the chapter. The chapter ends with questions to ask to help improve the design of validation studies and acceptance sampling plans.
7. *Managing and Improving Processes: How to Use an At-A-Glance-Display?* Statistical process control is widely used in industry. However, control charts are indiscriminately used in some companies without realizing that they are useful only if the process exhibits certain behavior. Control charts are often implemented without an adequate consideration of the risk and cost implications of the selected chart parameters. Also, quality reviews are often inefficient and ineffective. This chapter explains the fundamental rationale behind the development of control charts. It provides practical guidance to select subgroup size, control limits, and sampling interval. And it provides an at-a-glance-display of capability and performance indices making it easier to plan, monitor, review, and manage process improvements. Many practical applications are considered throughout the chapter. The chapter ends with questions to ask to improve process management.
8. *How to Find Causes of Variability by Just Looking Systematically?* This chapter deals with the much underutilized topic of variance component analysis. Reducing variability is an important objective in manufacturing. Variance components analysis helps identify the key causes of variation and the contribution of each cause to the total variance. This chapter explains the basic principles

of variance components analysis, how such an analysis can be done with data routinely collected in manufacturing, and how the results can be used to develop cost-effective improvement strategies. The principles of designing variance component studies, including the appropriate selection of the degrees of freedom for each variance component, are explained. Many practical applications are considered throughout the chapter. The chapter ends with questions to ask to help find causes of variability and make cost-effective improvement decisions.

9. *Is My Measurement System Acceptable and How to Design, Validate, and Improve It?* Some key questions often asked in industry are: How to know if the measurement system is adequate for the job? How to design a robust measurement system? How to demonstrate that the measurement system is acceptable, and if not, how to improve it? This chapter provides the acceptance criteria for measurement system precision and accuracy, for both nondestructive and destructive measurements. The rationale for the acceptance criteria is explained. The principles of designing cost-effective sampling schemes are explained. An example is presented to show how robust product design ideas can be used to design a robust measurement system. A design of experiments application is considered to demonstrate how to cost-effectively validate a measurement system and how to develop specifications for measurement system parameters. A gage repeatability and reproducibility application is considered to demonstrate how the acceptability of the measurement system can be assessed and how the measurement system can be improved if necessary. Many practical applications are considered throughout the chapter. The chapter ends with questions to ask to design and improve measurement systems.
10. *How to Use Theory Effectively?* While technical professionals learn a great deal of theory during their undergraduate and graduate education, theory is often not extensively and effectively used, perhaps because it is felt that theory does not work perfectly in practice. There is much to be gained, however, by the judicious combination of theory and data. The purpose of this chapter is to introduce the subject of model building, both empirical modeling based purely upon data and mechanistic modeling based upon an understanding of the underlying mechanism. A theoretical equation for coat weight variability of controlled release tablets is derived to demonstrate how mechanistic models can be built. The equation permits the coating process settings to be optimized without much experimentation. Many practical applications are considered throughout the chapter. The chapter ends with questions to ask to help put greater emphasis on the use of theoretical knowledge coupled with data.

HOW TO USE THIS BOOK

This book can be used in many ways. It can be used for self-study. It can be used as a reference book to look up a formula or a table, or to review a specific statistical method.

It can also be used as a text for quality-statistics courses or engineering-statistics courses for seniors or first-year graduate students at various universities. It should help provide university students with a much-needed connection between statistical methods and real world applications.

The topics in the book are generally arranged from those most useful in R&D to those most useful in manufacturing. Readers who wish to study on their own should first review the table of contents, decide whether they are or are not generally familiar with the subjects covered in the book, and then take the appropriate one of the following two approaches.

For those generally not familiar with the subject

1. Start reading the book from the front to the back. Go over a whole chapter keeping track of topics that are not clear at first reading.
2. Read through the chapter again, paying greater attention to topics that were unclear. Wherever possible, try to solve the examples in the chapter manually and prove the concepts independently. Note down the key points learned from the chapter.
3. If you feel that you have generally understood the chapter, go to the last chapter that contains test questions. These questions are arranged in the order of the chapters. Solve the questions pertaining to your chapter. Compare your answers and reasons to those given in the answer section of the last chapter. If there are mistakes, review those sections of the book again.
4. Obtain an appropriate software package, type in the data from various examples and case studies given in the book, and ensure that you know how to get the answers using the software of your choice.
5. Think about how these statistical methods could be applied to your company's problems. You are bound to find applications. Either find existing data concerning these applications or collect new data. Make applications.
6. Review your applications with others who may be more knowledgeable. Making immediate applications of what you have learned is the key to retain the learning.

For those generally familiar with the subject

1. Start by taking the test in the last chapter. Take your time. Write down your answers along with the rationale. Compare your answers and rationale to that given in the last chapter. Circle the wrong answers.
2. Based upon the above assessment, identify the chapters and sections you need to study. For these chapters and sections, follow the six steps outlined above.

There are many books written on the material covered in each chapter of this book. I have recommended appropriate books for further reading should additional information become necessary. Most of these books focus on one or two topics in considerable

detail. Also recommended is my previous book *Statistical Methods for Six Sigma in R&D and Manufacturing*, published by Wiley in 2003, which should be treated as a companion book to the present offering.

I hope that you, the reader, will find this book helpful. If you have suggestions and comments, you can reach me at www.JoglekarAssociates.com.

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