

U.S. Department of Commerce

Corrective and Preventive Action Request (CPAR)

R1 DRAFT 9/27/10

CPAR #

PART 1 - ORIGINATION

1. Originator
Name

Organization

Phone

E-Mail

2. Type

☐

Corrective Action
(Actual Nonconformance)

☐

Preventive Action
(Potential Nonconformance)

3. Source

☐

Audit - Internal

☐

Customer Complaint / Feedback

☐

Audit External

☐

Product / Service Problem

4. Date of CPAR Request

____/____/____

5. Audit Number, if applicable

6. Process / Procedure, if known
Document Title / Number

Reference Paragraph

ISO 14001:2004, Para. _____

7. Description of Problem (Cite Objective Evidence)

Preventative Action Form

Gordon Harnack



Preventative Action Form:

The Preventive Action Handbook Denise Robitaille, 2003-02 How do we harness the elusive concept of preventive action People often think of preventive action as the extra thing you do after you've finished corrective action like an extra coat of sealant Actually preventive actions are the initiatives you establish to minimize the number of corrective actions you conduct The Preventive Action Handbook is a great guide for defining the process writing the procedure establishing criteria developing plans and reporting back to management It will help you benefit from a fundamental management tool that has a direct relationship to your organization's bottom line The Preventive Action Handbook will help you make your preventive action process more organized more efficient and more productive The book's basic precepts hold true for any size organization It can be used by quality managers ISO 9000 management representatives production supervisors production group leaders customer service managers quality technicians or anyone else involved in corrective action The book includes sample forms that guide you through the corrective action process in a logical and straightforward manner The forms may be photocopied They include Preventive Action Organizer Worksheet Matrix of Preventive Actions Preventive Action Initiative Preventive Action Plan

The Continual Improvement Process Craig Cochran, 2003 Continual improvement is not optional It is a condition of survival Every organization must have systematic methods for making smart decisions attacking problems improving its products and services and repelling competitors Anything less than a systematic disciplined approach is leaving your future in the hands of chance This book presents a range of practical methods for driving continual improvement throughout the organization The starting point is leadership with a clear definition of mission strategy and key measures These themes are then carried throughout the enterprise informing everyone on the issues that matter most to survival and success Strategic approaches for the deployment of metrics review of organizational performance effective problem solving internal auditing process orientation and cultural development are also described in detail Practical tools and examples are provided at every step of the way enabling immediate implementation of the concepts This book is more than a guide to continual improvement it is a guide to leading and managing any organization

The ISO 14001 Implementation Guide Suzan L. Jackson, 1997-02-20 With the establishment of new international standards for environmental management systems EMS many managers are faced with the daunting and often bewildering task of creating management systems that enable their companies to conform to these standards In their haste and confusion however many companies implement bureaucratic ineffective systems that add no real value to their businesses The ISO 14001 Implementation Guide Creating an Integrated Management System shows you how to use the ISO 14001 standard to improve your company's productivity and profitability while meeting registration requirements Using a practical business oriented approach this authoritative book details the background and development of the ISO 14000 series of standards fully explains the requirements of 14001 and offers hands on guidance on how to implement an effective EMS It highlights common but

costly mistakes and leads you step by step through the creation of an EMS that will result in a more competitive business as well as a cleaner environment Suzan L Jackson draws on her experience as an ISO 9000 and ISO 14000 consultant and trainer and as a member of the U S Technical Advisory Group to ISO Technical Committee 207 which is developing the ISO 14000 environmental management standards With her insider s perspective Jackson demonstrates how the implementation of a cohesive well defined management system helps cut costs increase efficiency and focus energies In addition she provides insights into ways of successfully integrating ISO 9000 ISO 14001 and other management systems The ISO 14001 Implementation Guide provides a wealth of proven tips techniques and tools that help ensure smooth trouble free and efficient EMS implementation including critical success factors flowcharts for setting up the elements of an environmental management system helpful tips and advice for avoiding common pitfalls With its timely straightforward and on target advice The ISO 14001 Implementation Guide is the definitive practical guide for environmental and quality professionals and managers who need to develop an environmental management system that will improve business as well as meet the ISO 14001 standard An excellent and very readable workbook on how to integrate management systems into an organization ISO 14001 will be an important but difficult step into the future for much of U S industry this book should be close at hand for those taking that step Dorothy P Bowers Vice President Environmental and Safety Policy Merck Co Inc Suzan Jackson s book provides vital guidance and answers Her book can be quite helpful to those who are considering establishing a new environmental management system or those who just want a better understanding of ISO 14001 John Master Former Director Environmental Health and Safety ARCO Chemical Co A remarkably easy to read highly authoritative guide to a very complex standard Suzan Jackson shows us how environmental management and business improvement are no longer mutually exclusive goals Robin Gildersleeve President INFORM International Forum for Management Systems Inc Written by a recognized ISO expert and member of the U S Technical Advisory Group to ISO Technical Committee 207 which is preparing the ISO 14000 environmental management standard this invaluable guide shows you how to Learn to use an environmental management system to improve the overall effectiveness and profitability of the company Meet the requirements of ISO 14001 Develop and implement a cohesive well defined environmental management system Integrate an EMS with other management systems Formulate an environmental policy and draw up strategic plans and objectives for your company Monitor and measure the effectiveness of the system keep records and take preventive and corrective action

The Laboratory Quality Assurance System Thomas A. Ratliff, 2005-02-25 Both the 17025 1999 standard and especially ANSI ISO ASQ 9001 2000 standard require that a laboratory document its procedures for obtaining reliable results The Laboratory Quality Assurance Manual details to the user how to prepare a new laboratory quality assurance manual which will be appropriate to use as a procedures manual for a particular laboratory a sales tool to attract potential customers a document that can be to answer regulatory questions and ultimately a tool to become a registered ISO 9001 2000 Lab and

gain related certifications based on the standard The Laboratory Quality Assurance Manual Incorporates changes to ANSI ISO ASQ 9001 2000 pertaining to laboratories Provides blank forms used in preparing a quality manual Provides information on the interrelationship of ANSI ISO 17025 1999 and ANSI ISO ASQ 9001 2000 *The ISO 9000 Quality System* Debby L. Newslow,2001-02-26 Author is a certified Quality Assurance Lead Auditor who has worked with more than 100 companies seeking ISO 9000 certification One of the only books on ISO 9000 compliance written exclusively for the food industry Examples are based on real world cases although company names and other identifying details are not included to protect privacy These examples can be invaluable to food companies who want to avoid potential pitfalls Relates ISO 9000 to other quality and safety assurance management systems *Encyclopedia of Forensic and Legal Medicine* ,2015-09-29

Encyclopedia of Forensic and Legal Medicine Volumes 1 4 Second Edition is a pioneering four volume encyclopedia compiled by an international team of forensic specialists who explore the relationship between law medicine and science in the study of forensics This important work includes over three hundred state of the art chapters with articles covering crime solving techniques such as autopsies ballistics fingerprinting hair and fiber analysis and the sophisticated procedures associated with terrorism investigations forensic chemistry DNA and immunoassays Available online and in four printed volumes the encyclopedia is an essential reference for any practitioner in a forensic medical healthcare legal judicial or investigative field looking for easily accessible and authoritative overviews on a wide range of topics Chapters have been arranged in alphabetical order and are written in a clear and concise manner with definitions provided in the case of obscure terms and information supplemented with pictures tables and diagrams Each topic includes cross referencing to related articles and case studies where further explanation is required along with references to external sources for further reading Brings together all appropriate aspects of forensic medicine and legal medicine Contains color figures sample forms and other materials that the reader can adapt for their own practice Also available in an on line version which provides numerous additional reference and research tools additional multimedia and powerful search functions Each topic includes cross referencing to related articles and case studies where further explanation is required along with references to external sources for further reading **Handbook of Investigation and Effective CAPA Systems** Jose (Pepe)

Rodriguez-Perez,2022-02-15 Worldwide regulatory agencies perform many inspections annually and all too often investigation and CAPA system violations are at the top of the list of infractions Life sciences regulated companies not only FDA regulated ones must ensure their investigation and CAPA systems look beyond the usual suspects to identify other quality issues in order to minimize risks including safe ones and reduce costs Enhancements to this third edition include A new section linking the investigation and CAPA programs with the overall quality culture of the company Fully updated current versions of regulations including U S FDA EU ISO 9001 and ISO 13485 Updated inspectional observations from the U S FDA and U K MHRA A revised investigation and CAPA processes chapter which has an improved barrier analysis section

including detailed flowcharts describing the barrier analysis process New charts and information related to the investigation of human errors the human factor section includes information about training and competence A new chapter devoted to analytical laboratory investigations including a section covering the invalidation of testing results Updated forms and examples of the different elements of the investigation and CAPA plan including new case studies a revised diagnostic tool used for investigating human error Jose Pepe Rodriguez Perez PhD is president of Business Excellence Consulting Inc BEC a Puerto Rico based consulting training and remediation firm that focuses on the areas of regulatory compliance FDA regulatory training and risk management He is a biologist with a doctoral degree in biology from the University of Granada Spain Over his career he has served as an educator a technical services manager and as a science advisor to the FDA

Mastering and Managing the FDA Maze Gordon Harnack, 2014-07-18 The number of FDA regulations and the agency's increased expectations is staggering and their content tedious creating a regulated industry need for compliance insight and appropriate detail This book is the reference needed to successfully navigate through the FDA maze The target audiences for this desk reference include Regulatory professionals who know their responsibility to keep their firm's employees trained and competent on FDA device regulations and who need a preliminary desk reference that can be used throughout their enterprise to help train and ensure compliance Neophytes who know nothing about FDA but need a resource that provides both broad and specific information in sufficient detail to be useful Beginners who know a little about FDA need to know more and need a reference tool to help them be more effective and productive on the job Intermediates who know enough about FDA to know they need to know more and who need a reference tool that provides them with both more basics and executable detail Busy managers who need to know regulatory requirements and FDA expectations in order to manage compliance in their specific activity Busy executives CEOs COOs and operations managers whom FDA holds responsible for all regulatory compliance who also need a desk reference with specific information to quickly assess regulatory compliance identify potential noncompliance and review corrective preventive and compliance actions

Principles And Practice Of Total Productive Maintenance BIKASH. BHADURY, 2012 Special Study: Report on Approach and Landing Accident Prevention Forum, October 24-25, 1972 United States. National Transportation Safety Board, 1972

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