Annual Product Review Sop Template

Failure to follow one's own procedures is the single most-cited violation of the Good Manufacturing Practices (GMP) regulations. In this workshop in a book, Dr. Paul Sanghera, the best selling author of several books in science and technology, presents cohesive, concise, yet comprehensive introduction to the fundamentals of Standard Operating Procedures (SOPs) in context of Good Manufacturing Practices (GMP), quality assurance, and quality control. Those who can benefit from this book include students and professionals in biotechnology, health science, and other industries: especially those who are trying to meet the FDA regulations on SOPs. This is a general book for the beginners to develop a basic understanding about SOPs. Also the busy executives and managers will find this book useful for a quick introduction to SOPs. The material is presented in the format of lecture notes, which are self-contained, comprehensive within the scope of the book, and presented in an easy-to-follow logical learning sequence. All concepts are explained from scratch with enough examples and exercises. Example SOP templates are provided to put the concepts in practical context. Topics Include: *Introduction to SOPs *Effective SOPs *Producing Effective SOPs *Living with Approved SOPs: following, monitoring, and controlling SOPs *Process Based Approach to SOPs *Solutions to Self Test Exercises * Example SOP Templates *Glossary of terms Author Bio Dr. Paul Sanghera, an educator, scientist, technologist, and an entrepreneur, has a diverse background in all the fields on which biotechnology and health sciences are based including physics, chemistry, biology, computer science, and math. He holds a Master degree in Computer Science from Cornell University, a Ph.D. in Physics from Carleton University, and a B.Sc. with triple major: physics, chemistry, and math. He has taught science and technology courses all across the world including San Jose State University and Brooks College. Dr. Sanghera has been involved in educational programs and research projects in biotechnology. He has authored and co-authored more than 100 research papers published in well reputed European and American research journals. As a technology manager, Dr. Sanghera has been at the ground floor of several technology startups. His responsibilities included process development and quality assurance at companies such as Netscape and MP3. He is the author of several best selling books in the fields of science, technology, and project management. He lives in Silicon Valley, California, where he currently serves as Adjunct Professor at California Institute of Nanotechnology.

This publication focuses on the critical methods that can be used to dramatically improve the fiscal closing process. The Record to Report (R2R) or Fiscal Closing Process is at the core of the controllership function. The process includes transaction processing, internal and external reporting, and the internal controls—the people, processes, and technology—that constitute the corporate organizational hierarchy. CFOs, controllers, and corporate finance departments require timely, accurate, and consistent data to make appropriate operational and strategic decisions and fulfill statutory, regulatory, and compliance requirements with accurate and timely data. The Fast Close Toolkit offers both strategic and tactical suggestions that can significantly improve the fiscal closing process and provides guidance on new legislation requirements, systems and best practice processes. Checklists, templates, process narratives, and sample policies are provided for every component of the fiscal close. Investors and shareholders expect fast and easy access to the data created by current business activities in the information-driven digital age. The Fast Close Toolkit provides the necessary tools and expert advice to improve the fiscal closing process. Authoritative and up to date, this book: Identifies the bottlenecks that can impact the and improvethe fiscal close process and provides best practices to help alleviate these challenges Defines the Record to Report (R2R) and recommends the roles and responsibilities for fiscal close processes flow Offers the internal controls to use for the end-to-end fiscal close process Describes approaches for risk management, R2R, and fiscal close benchmarking Identifies KPIs for all aspects of the R2R process Provides the mechanism for developing a financial close scorecard Recommends leading practices for both external and internal reporting Provides guidance on how strategic planning, the budget and forecast processes can be streamlined to enhance the fiscal close and internal reporting results Written by a respected expert on internal controls and the fiscal closing process, The Fast Close Toolkit is a valuable source of information for professionals involved in controllership and have responsibility for the fiscal close.

Fully updated and revised to include the latest information since publication of the first edition in 1989, the Second Edition of this highly praised reference covers all aspects of the Food and Drug Administration's (FDA) Good Laboratory Practice (GLP) regulations and techniques for implementation. The book details specific standards and general guidelines for the management of efficient and effective research environment. A guide to the current standards and requirements of good laboratory management, the book examines essential theoretical principles for anticipating new and emerging interpretations of GLP in a variety of laboratory settings.

This guidance will assist processors of fish and fishery products in the development of their Hazard Analysis Critical Control Point (HACCP) plans. Processors of fish and fishery products will find info. that will help them identify hazards that are associated with their products, and help them formulate control strategies. It will help consumers understand commercial seafood safety in terms of hazards and their controls. It does not specifically address safe handling practices by consumers or by retail estab., although the concepts contained in this guidance are applicable to both. This guidance will serve as a tool to be used by fed. and state regulatory officials in the evaluation of HACCP plans for fish and fishery products. Illustrations. This is a print on demand report.

Manual and is a supplement to the United States Pharmacopeia (USP) for pharmaceutical microbiology testing, including antimicrobial effectiveness testing, microbial examination of non-sterile products, sterility testing, bacterial endotoxin testing, particulate matter, device bioburden and environmental monitoring testing. The goal of this manual is to provide an ORA/CDER harmonized framework on the knowledge, methods and tools needed, and to apply the appropriate scientific standards required to assess

the safety and efficacy of medical products within FDA testing laboratories. The PMM has expanded to include some rapid screening techniques along with a new section that covers inspectional guidance for microbiologists that conduct team inspections. This manual was developed by members of the Pharmaceutical Microbiology Workgroup and includes individuals with specialized experience and training. The instructions in this document are guidelines for FDA analysts. When available, analysts should use procedures and worksheets that are standardized and harmonized across all ORA field labs, along with the PMM, when performing analyses related to product testing of pharmaceuticals and medical devices. When changes or deviations are necessary, documentation should be completed per the laboratory's Quality Management System. Generally, these changes should originate from situations such as new products, unusual products, or unique situations. This manual was written to reduce compendia method ambiguity and increase standardization between FDA field laboratories. By providing clearer instructions to FDA ORA labs, greater transparency can be provided to both industry and the public. However, it should be emphasized that this manual is a supplement, and does not replace any information in USP or applicable FDA official guidance references. The PMM does not relieve any person or laboratory from the responsibility of ensuring that the methods being employed from the manual are fit for use, and that all testing is validated and/or verified by the user. The PMM will continually be revised as newer products, platforms and technologies emerge or any significant scientific gaps are identified with product testing. Reference to any commercial materials, equipment, or process in the PMM does not in any way constitute approval, endorsement, or recommendation by the U.S. Food and Drug Administration.

Writing and Managing SOPs for GCP is the first book to discuss managing Standard Operating Procedures (SOPs) for Good Clinical Practice (GCP) from conception to retirement. It recommends approaches that have a direct impact on improving SOP and regulatory compliance. Throughout the text, the book provides a user’s point of view to keep topics focused on the practical aspects of SOPs and SOP management. The idea of specifically calling out approaches to SOP creation and maintenance in an effort to make it easier for users to stay in compliance is a theme found throughout all book chapters. Examples in each chapter provide accurate reflections of real-world experiences to illustrate the discussion. The book also includes an example "SOP of SOPs" along with an associated SOP template.

The rapid development of HPLC instrumentation and technology opens numerous possibilities - and entails new questions. Which column should I choose to obtain best results, which gradient fits to my analytical problem, what are recent and promising trends in detection techniques, what is state of the art regarding LC-MS coupling? All these questions are answered by experts in ten self-contained chapters. Besides these more hardware-related and technical chapters, further related areas of interest are covered: Comparison of recent chromatographic data systems and integration strategies, smart documentation, efficient information search in internet, and tips for a successful FDA inspection. This practical approach offers in a condensed manner recent trends and hints, and will also display the advanced reader mistakes and errors he was not aware of so far.

To support the broadening spectrum of project delivery approaches, PMI is offering A Guide to the Project Management Body of Knowledge (PMBOK® Guide) – Sixth Edition as a bundle with its latest, the Agile Practice Guide. The PMBOK® Guide – Sixth Edition now contains detailed information about agile; while the Agile Practice Guide, created in partnership with Agile Alliance®, serves as a bridge to connect waterfall and agile. Together they are a powerful tool for project managers. The PMBOK® Guide – Sixth Edition – PMI's flagship publication has been updated to reflect the latest good practices in project management. New to the Sixth Edition, each knowledge area will contain a section entitled Approaches for Agile, Iterative and Adaptive Environments, describing how these practices integrate in project settings. It will also contain more emphasis on strategic and business knowledge—including discussion of project management business documents—and information on the PMI Talent Triangle™ and the essential skills for success in today's market. Agile Practice Guide has been developed as a resource to understand, evaluate, and use agile and hybrid agile approaches. This practice guide provides guidance on when, where, and how to apply agile approaches and provides practical tools for practitioners and organizations wanting to increase agility. This practice guide is aligned with other PMI standards, including A Guide to the Project Management Body of Knowledge (PMBOK® Guide) – Sixth Edition, and was developed as the result of collaboration between the Project Management Institute and the Agile Alliance.

This handbook features contributions from a team of expert authors representing the many disciplines within science, engineering, and technology that are involved in pharmaceutical manufacturing. They provide the information and tools you need to design, implement, operate, and troubleshoot a pharmaceutical manufacturing system. The editor, with more than thirty years' experience working with pharmaceutical and biotechnology companies, carefully reviewed all the chapters to ensure that each one is thorough, accurate, and clear.

With its coverage of Food and Drug Administration regulations, international regulations, good manufacturing practices, and process analytical technology, this handbook offers complete coverage of the regulations and quality control issues that govern pharmaceutical manufacturing. In addition, the book discusses quality assurance and validation, drug stability, and contamination control, all key aspects of pharmaceutical manufacturing that are heavily influenced by regulatory guidelines. The team of expert authors offer you advice based on their own firsthand experience in all phases of pharmaceutical manufacturing.

When a pharmaceutical company decides to build a Quality System, it has to face the fact that there aren't any guideline that define exactly how such a system has to be built. With terms such as quality system, quality assurance, and quality management used interchangeably, even defining the system's objectives is a problem. This book provides a pr

Implementing the requirements of ISO 9001 can be a daunting task for many organizations. In an attempt to develop a system that will pass the registration audit, we are tempted

to establish processes with the primary purpose of conforming to the requirements of ISO 9001. In doing so, however, it is easy to lose sight of the primary intent of the standard: to continually improve the effectiveness of the quality management system (QMS) implemented at our organization. This book is intended to help managers, quality professionals, internal audit coordinators, and internal auditors implement a practical internal audit process that meets the requirements of ISO 9001:2015 while adding significant, measurable value to the organization. The tools, techniques, and step-by-step guidelines provided in this book can also be used by those organizations that have a well-established internal audit process but are looking for easy ways to make that process more effective. The tools in the appendices of this book have also been provided on the enclosed CD to facilitate your customizing them to fit the specific needs of your organization.

A collection of recommended procedures for analysis and specifications for the determination of pharmaceutical substances, excipients and dosage forms intended to serve as source material for reference by any WHO member state.

WHO's international guidelines, written and physical standards developed under the aegis of this Expert Committee for more than 60 years are designed to serve all Member States, international organizations, United Nations agencies, regional and interregional harmonization efforts, and underpin important initiatives, including the prequalification of medicines, the Roll Back Malaria Programme, Stop TB, essential medicines and medicines for children. The Forty-seventh WHO Expert Committee on Specifications for Pharmaceutical Preparations adopted 26 new monographs and general texts for inclusion in The International Pharmacopoeia,/I>. The specifications under development are internationally applicable test methodologies for anti-infective, antimalarial, antituberculosis, contraceptives and antiretroviral medicines, as well as medicines for children. In addition, the following four written standards were adopted in the area of quality assurance and are now available for implementation : * Release procedure for International Chemical Reference Substances (update); * WHO guideline on quality risk management (new) * WHO guideline on variations to a prequalified product (update) * Collaborative procedure between the WHO Prequalification of Medicines Programme and national medicines regulatory authorities in the assessment and accelerated national registration of WHO-prequalified pharmaceutical products (new).

Ten Strategies of a World-Class Cyber Security Operations Center conveys MITRE's accumulated expertise on enterprise-grade computer network defense. It covers ten key qualities of leading Cyber Security Operations Centers (CSOCs), ranging from their structure and organization, to processes that best enable smooth operations, to approaches that extract maximum value from key CSOC technology investments. This book offers perspective and context for key decision points in structuring a CSOC, such as what capabilities to offer, how to architect large-scale data collection and analysis, and how to prepare the CSOC team for agile, threat-based response. If you manage, work in, or are standing up a CSOC, this book is for you. It is also available on MITRE's website, www.mitre.org.

The term 'medical devices' covers a wide range of equipment essential for patient care at every level of the health service, whether at the bedside, at a health clinic or in a large specialised hospital. Yet many countries lack access to high-quality devices, particularly in developing countries where health technology assessments are rare and there is a lack of regulatory controls to prevent the use of substandard devices. This publication provides a guidance framework for countries wishing to create or modify their own regulatory systems for medical devices, based on best practice experience in other countries. Issues highlighted include: the need for harmonised regulations; and the adoption, where appropriate, of device approvals of advanced regulatory systems to avoid an unnecessary drain on scarce resources. These approaches allow emphasis to be placed on locally-assessed needs, including vendor and device registration, training and surveillance and information exchange systems.

Spanning every critical element of validation for any pharmaceutical, diagnostic, medical device or equipment, and biotech product, this Second Edition guides readers through each step in the correct execution of validating processes required for non-aseptic and aseptic pharmaceutical production. With 14 exclusive environmental performance evaluati

The book Lifehack calls "The Bible of business and personal productivity." "A completely revised and updated edition of the blockbuster bestseller from 'the personal productivity guru'"—Fast Company Since it was first published almost fifteen years ago, David Allen’s Getting Things Done has become one of the most influential business books of its era, and the ultimate book on personal organization. “GTD” is now shorthand for an entire way of approaching professional and personal tasks, and has spawned an entire culture of websites, organizational tools, seminars, and offshoots. Allen has rewritten the book from start to finish, tweaking his classic text with important perspectives on the new workplace, and adding material that will make the book fresh and relevant for years to come. This new edition of Getting Things Done will be welcomed not only by its hundreds of thousands of existing fans but also by a whole new generation eager to adopt its proven principles.

With global harmonization of regulatory requirements and quality standards and national and global business consolidations ongoing at a fast pace, pharmaceutical manufacturers, suppliers, contractors, and distributors are impacted by continual change. Offering a wide assortment of policy and guidance document references and interpretations, this Sixth Edition is significantly expanded to reflect the increase of information and changing practices in CGMP regulation and pharmaceutical manufacturing and control practices worldwide. An essential companion for every pharmaceutical professional, this guide is updated and expanded by a team of industry experts, each member with extensive experience in industry or academic settings.

This User’s Guide is intended to support the design, implementation, analysis, interpretation, and quality evaluation of registries created to increase understanding of patient outcomes. For the purposes of this guide, a patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes. A registry database is a file (or files) derived from the registry. Although registries can serve many purposes, this guide focuses on registries created for one or more of the following purposes: to describe the natural history of disease, to determine clinical effectiveness or cost-effectiveness of health care products and services, to measure or monitor safety and harm, and/or to measure quality of care. Registries are classified according to how their populations are defined. For example, product registries include patients who have been exposed to biopharmaceutical products or medical devices. Health services registries consist of patients who have had a common procedure, clinical encounter, or hospitalization. Disease or condition registries are defined by patients having the same diagnosis, such as cystic fibrosis or heart failure. The User’s Guide was created by researchers affiliated with AHRQ’s Effective Health Care Program, particularly those who participated in AHRQ’s DEcIDE (Developing Evidence to Inform Decisions About Effectiveness) program. Chapters were subject to multiple internal and external independent reviews.

The first systematic, hands-on auditing guide for today'spharmaceutical laboratories In today's litigious environment, pharmaceutical laboratories aresubject to ever stricter operational guidelines as mandated

by theFDA, and must be able to establish and demonstrate sustainableoperational practices that ensure compliance with the current goodmanufacturing practice (CGMP) regulations. David Bliesner'sEstablishing a CGMP Laboratory Audit System: A Practical Guide isdesigned to provide laboratory supervisors and personnel with astep-by-step, hands-on audit system that they can rely on to ensuretheir facility remains compliant with all current and futurerequirements. Focusing on a "team approach," the author usesdetailed flowcharts, checklists, and descriptions of the auditingprocess to help readers develop a new audit system or upgrade theircurrent system in order to: * Improve current compliance * Demonstrate sustainable compliance * Produce data for federal inspections * Avoid regulatory action Enhanced with detailed checklists and a wealth of practical andflexible auditing tools on CD-ROM, this book provides an idealresource for new and future laboratory personnel, and an excellentmeans for keeping existing industry practitioners up to date on thenuances of operating a consistently compliant pharmaceuticallaboratory.

The World Health Organization (WHO) Expert Committee on Specifications for Pharmaceutical Preparations advises the Director-General of WHO in the area of medicines quality assurance. It provides independent expert recommendations and guidance to ensure that medicines meet standards of quality, safety and efficacy in all WHO Member States. Its advice is developed through a broad consensus-building process and covers all areas of quality assurance of medicines, from their development to their distribution to patients. In the area of quality control, the Expert Committee reviewed new and revised specifications and general texts for inclusion in The International Pharmacopoeia, and received the annual report of the European Directorate for the Quality of Medicines & HealthCare (EDQM), the custodian centre for International Chemical Reference Substances (ICRS). The Committee adopted a number of monographs, general texts and ICRS. It noted the report on Phase 6 of the External Quality Assurance Assessment Scheme (EQAAS) and on new approaches to ensure sustainability of this scheme through user fees. The Committee further acknowledged the progress of good pharmacopoeial practices (GPhP), and adopted the document on GPhP which was prepared by the consecutive international meetings of world pharmacopoeias. In the various quality assurance-related areas the Expert Committee was presented with a number of new and revised guidelines related to good manufacturing practices (GMP), distribution and trade of pharmaceuticals and regulatory practice. It adopted 10 guidelines as listed below as well as 22 new specifications and general texts for inclusion in The International Pharmacopoeia. The Committee took note of ongoing work to promote collaboration and information exchange through the good regulatory practice project and welcomed the development of a comprehensive set of guidelines for all national regulatory authorities through this project.

The U.S. Department of State charged the Academies with the task of producing a protocol for development of standard operating procedures (SOPs) that would serve as a complement to the Chemical Laboratory Safety and Security: A Guide to Prudent Chemical Management and be included with the other materials in the 2010 toolkit. To accomplish this task, a committee with experience and knowledge in good chemical safety and security practices in academic and industrial laboratories with awareness of international standards and regulations was formed. The hope is that this toolkit expansion product will enhance the use of the previous reference book and the accompanying toolkit, especially in developing countries where safety resources are scarce and experience of operators and end-users may be limited.

Good Manufacturing Practices for PharmaceuticalsCRC Press

Commonly known as the Orange Guide, this book remains an essential reference for all manufacturers and distributors of medicines in Europe. It provides a single authoritative source of European and UK guidance, information and legislation relating to the manufacture and distribution of human medicines.

Principles of Parenteral Solution Validation: A Practical Lifecycle Approach covers all aspects involved in the development and process validation of a parenteral product. By using a lifecycle approach, this book discusses the latest technology, compliance developments, and regulatory considerations and trends, from process design, to divesting. As part of the Expertise in Pharmaceutical Process Technology series edited by Michael Levin, this book incorporates numerous case studies and real-world examples that address timely problems and offer solutions to the daily challenges facing practitioners in this area. Discusses international and domestic regulatory considerations in every section Features callout boxes that contain points-of-interest for each segment of the audience so readers can quickly find their interests and needs Contains important topics, including risk management, the preparation and execution of properly designed studies, scale-up and technology transfer activities, problem-solving, and more

This open access book provides a concise yet comprehensive overview on how to build a quality management program for hematopoietic stem cell transplantation (HSCT) and cellular therapy. The text reviews all the essential steps and elements necessary for establishing a quality management program and achieving accreditation in HSCT and cellular therapy. Specific areas of focus include document development and implementation, audits and validation, performance measurement, writing a quality management plan, the accreditation process, data management, and maintaining a quality management program. Written by experts in the field, Quality Management and Accreditation in Hematopoietic Stem Cell Transplantation and Cellular Therapy: A Practical Guide is a valuable resource for physicians, healthcare professionals, and laboratory staff involved in the creation and maintenance of a state-of-the-art HSCT and cellular therapy program.

A new edition of one of Zola's lesser-known novels from the Rougon-Macquart Cycle Finding the young Angélique on their doorstep one Christmas Eve, the pious Hubert couple decide to bring her up as their own. As the girl grows up in the vicinity of the town's towering cathedral and learns her parents' trade of embroidery, she becomes increasingly fascinated by the lives of the saints, a passion fueled by her reading of the Golden Legend and other mystical Christian writings. One day love, in the shape of Félicien Hautecoeur, enters the dream world she has constructed around herself, bringing about upheaval and distress. Although it provides a detailed portrait of provincial 19th-century life and it adheres to a naturalist approach, The Dream eschews many of the characteristics of Zola's other novels of the Rougon-Macquart cycle—such as a pronounced polemical agenda or a gritty subject matter—offering instead a timeless, lyrical tale of love and innocence.

Covers the discovery development,regulation, manufacturing, and commercialization of drugs and dosage forms. Includes pharmaceuticals,pharmacokinetics, analytical chemistry, quality assurance, toxicology and the manufacturing process.

Achieving, maintaining and improving accuracy, timeliness and reliability are major challenges for health laboratories. Countries worldwide committed themselves to build national capacities for the detection of, and response to, public health events of international concern when they decided to engage in the International Health Regulations implementation process. Only sound management of quality in health laboratories will enable countries to produce test results that the international community will trust in cases of international emergency. This handbook was developed through collaboration between the WHO Lyon Office for National Epidemic Preparedness and Response, the United States of America Centers for Disease Control and Prevention (CDC) Division of Laboratory Systems, and the Clinical and Laboratory Standards Institute (CLSI). It is based on training sessions and modules provided by the CDC and WHO in more than 25 countries, and on guidelines for implementation of ISO 15189 in diagnostic laboratories, developed by CLSI. This handbook is intended to provide a comprehensive reference on Laboratory Quality Management System for all stakeholders in health laboratory processes, from management, to administration, to bench-work laboratorians. This handbook covers topics that are essential for quality management of a public health or clinical laboratory. They are based on both ISO 15189 and CLSI GP26-A3 documents. Each topic is discussed in a separate chapter. The chapters follow the framework developed by CLSI and are organized as the "12 Quality System Essentials".

Meant to aid State & local emergency managers in their efforts to develop & maintain a viable all-hazard emergency operations plan. This guide clarifies the preparedness, response, & short-term recovery planning elements that warrant inclusion in emergency operations plans. It offers the best judgment & recommendations on how to deal with the entire planning process -- from forming a planning team to writing the plan. Specific topics of discussion include: preliminary considerations, the planning process, emergency operations plan format, basic plan content, functional annex content, hazard-unique planning, & linking Federal & State operations.

Comprehensive Preparedness Guide (CPG) 101 provides Federal Emergency Management Agency (FEMA) guidance on the fundamentals of planning and developing emergency operations plans (EOP). CPG 101 shows that EOPs are connected to planning efforts in the areas of prevention, protection, response, recovery, and mitigation. Version 2.0 of this Guide expands on these fundamentals and encourages emergency and homeland security managers to engage the whole community in addressing all risks that might impact their jurisdictions. While CPG 101 maintains its link to previous guidance, it also reflects the reality of the current operational planning environment. This Guide integrates key concepts from national preparedness policies and doctrines, as well as lessons learned from disasters, major incidents, national assessments, and grant programs. CPG 101 provides methods for planners to: Conduct community-based planning that engages the whole community by using a planning process that represents the actual population in the community and involves community leaders and the private sector in the planning process; Ensure plans are developed through an analysis of risk; Identify operational assumptions and resource demands; Prioritize plans and planning efforts to support their seamless transition from development to execution for any threat or hazard; Integrate and synchronize efforts across all levels of government. CPG 101 incorporates the following concepts from operational planning research and day-to-day experience: The process of planning is just as important as the resulting document; Plans are not scripts followed to the letter, but are flexible and adaptable to the actual situation; Effective plans convey the goals and objectives of the intended operation and the actions needed to achieve them. Successful operations occur when organizations know their roles, understand how they fit into the overall plan, and are able to execute the plan. Comprehensive Preparedness Guide (CPG) 101 provides guidelines on developing emergency operations plans (EOP). It promotes a common understanding of the fundamentals of risk-informed planning and decision making to help planners examine a hazard or threat and produce integrated, coordinated, and synchronized plans. The goal of CPG 101 is to make the planning process routine across all phases of emergency management and for all homeland security mission areas. This Guide helps planners at all levels of government in their efforts to develop and maintain viable all-hazards, all-threats EOPs. Accomplished properly, planning provides a methodical way to engage the whole community in thinking through the life cycle of a potential crisis, determining required capabilities, and establishing a framework for roles and responsibilities. It shapes how a community envisions and shares a desired outcome, selects effective ways to achieve it, and communicates expected results. Each jurisdiction's plans must reflect what that community will do to address its specific risks with the unique resources it has or can obtain. Planners achieve unity of purpose through coordination and integration of plans across all levels of government, nongovernmental organizations, the private sector, and individuals and families. This supports the fundamental principle that, in many situations, emergency management and homeland security operations start at the local level and expand to include Federal, state, territorial, tribal, regional, and private sector assets as the affected jurisdiction requires additional resources and capabilities. A shared planning community increases the likelihood of integration and synchronization, makes planning cycles more efficient and effective, and makes plan maintenance easier.