



FDA INSPECTION CHECKLIST

What to Expect When They're Inspecting

Food Industry Counsel, LLC is pleased to provide you with the most comprehensive and useful FDA Inspection Checklist available. With the passage of the Food Safety Modernization Act (FSMA), the Food and Drug Administration (FDA) was given the mission of overhauling the safety of the nation's food supply. The new FSMA regulations written by FDA are now coming into effect, and the agency is now aggressively enforcing its new rules during routine inspections. Within the coming years, FDA investigators will conduct an onsite inspection of every food facility in the U.S.¹

Here are FDA's new enforcement priorities during routine unannounced inspections:

- 1** | To carefully critique each company's written food safety programs and verification records to ensure they are compliant with the new FSMA requirements;
- 2** | To conduct extensive Zone 1, Zone 2, Zone 3 and Zone 4 microbiological sampling inside all food facilities to find evidence of pathogenic contamination;
- 3** | To require recalls if the percentage of FDA samples testing positive for *Listeria Monocytogenes*, *Salmonella* or other pathogens exceeds FDA thresholds;
- 4** | To compare the DNA fingerprints of any pathogens found in the facility against the >1,000,000 human isolates stored in the CDC's PulseNet database to identify any matches, and then require food product recalls if any matches are found;
- 5** | To initiate broader investigations, including criminal investigations, against food companies whose products are found to have caused human illness.

Against this backdrop, all companies should begin taking steps to prepare for their next FDA inspection. Companies can use the following checklists to ensure that they have completed the needed preparations before the FDA investigators arrive, to help effectively navigate the inspection process once the inspection is underway, and to appropriately respond to any FDA criticisms once the FDA inspection concludes.

¹ The FDA employees performing these routine onsite inspections are not referred to as "FDA inspectors," but rather as "FDA investigators." The concern with this terminology is that some FDA investigators may be more inclined to find violations since their title presumes, in advance of any facility visit, that violations have already occurred.

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United States. Congress



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Guide to U.S. Health and Health Care Policy Thomas R. Oliver, 2014-09-03 Guide to U S Health and Health Care Policy provides the analytical connections showing students how issues and actions are translated into public policies and institutions for resolving or managing health care issues and crises such as the recent attempt to reform the national health care system The Guide highlights the decision making cycle that requires the cooperation of government business and an informed citizenry in order to achieve a comprehensive approach to advancing the nation s health care policies Through 30 topical operational and relational essays the book addresses the development of the U S health care system and policies the federal agencies and public and private organizations that frame and administer those policies and the challenges of balancing the nation s health care needs with the rising costs of medical research cost effective treatment and adequate health insurance Key Features The 30 topical essays investigate the fundamental political social economic and procedural initiatives that drive health and health care policy decisions affecting Americans at the local regional and national levels Essential themes traced throughout the chapters include providing access to health care national and international intervention nutrition and health human and financial resource allocation freedom of religion versus public policy discrimination and health care policy universal health care coverage private health care versus publicly funded health care and the immediate and long term costs associated with disease prevention treatment and health maintenance A Glossary of Key Health Care Policy Terms and Events a selected Master Bibliography and a thorough Index are included This must have reference for political science and public policy students who seek to understand the issues affecting health care policy in the U S is suitable for academic public high school government and professional libraries **Federal Regulatory Guide** CQ Press, 2024-05-31 The Nineteenth Edition of the Federal Regulatory Directory is a comprehensive guide for understanding the complex world of federal regulation It provides detailed profiles of the most important regulatory agencies including their history priorities actions and landmark decisions The book also features overviews of independent and self regulatory agencies as well as the global and state level impacts of federal regulation Whether you are new to the topic or an expert the Federal Regulatory Directory can be a valuable resource for students researchers professionals and anyone who wants to understand how federal regulation works and how it affects their daily lives Publication Catalog of the U.S. Department of Health and Human Services United States. Department of Health and Human Services, Monthly Catalog of United States Government Publications United States. Superintendent of Documents, 1986 **Monthly Catalogue, United States Public Documents** , 1980 **A Practical Guide to Food and Drug Law and Regulation** Kenneth R. Piña, Wayne L. Pines, 2002 Compilation of Selected Acts Within the Jurisdiction of the Committee on Energy and Commerce United States, 1981 **Consumers' Guide** , 1943 **The ASQ Metrology Handbook** Heather A. Wade, 2023-01-04 The ever changing fields of science and technology have made huge leaps thanks in part to improvements in measurements Without

metrology these areas may not have experienced exponential growth Developed by experts in the field as a comprehensive and practical reference The ASQ Metrology Handbook Third Edition provides a foundation for understanding metrology as well as calibration principles and practices This handbook is ideal for not only metrology professionals but also calibration professionals including calibration technicians and technologists quality professionals workers in testing laboratories consultants and instructors Whether you are entering a new phase of your career field investing in your own continuous improvement journey training your fellow calibration practitioners or preparing for ASQ s Certified Calibration Technician CCT exam this handbook provides the information guidance and knowledge to help you achieve your goals New to this Third Edition A thorough explanation of ISO IEC 17025 2017 The 2019 Redefinition of the International System of Units Updated and expanded chapters including information about training and competency software validation statistics decision rules and risk uncertainty in measurement mass and weighing force and chemical and biological measurements and uncertainties

Compilation of Selected Acts Within the Jurisdiction of the Committee on Interstate and Foreign Commerce

United States,1979 Nutrition in Public Health Arlene Spark,2007-05-11 Nutrition plays a key role in many areas of public health such as pre term delivery cancer obesity diabetes and cardiovascular and renal diseases Government nutrition policy therefore bears a huge influence on the nation s biggest health concerns There is a clear need for information on this topic that unarguably holds the key to the primar Food Amendments of 1974 United States. Congress. Senate. Committee on Commerce. Consumer Subcommittee,1974 **Food Amendments of 1974, Hearings Before the Subcommittee for**

Consumers Of..., 93-2, February 8, March 11, and 25, 1974 United States. Congress. Senate. Committee on Commerce,1974 Purchasing Andrew H. Feinstein,Jean L. Hertzman,John M. Stefanelli,2017-04-03 Purchasing Selection and Procurement for the Hospitality Industry 9th Edition is a learning centered text that includes several pedagogical enhancements to help students quickly acquire and retain important information It is written for those who will be involved with some phase of purchasing throughout their hospitality careers This text covers product information as well as management of the purchasing function and how this relates to a successful operation It also acts as a comprehensive reference guide to the selection and procurement functions within the hospitality industry Purchasing Selection and Procurement for the Hospitality Industry is the comprehensive and up to date hospitality purchasing text available today

Importers Manual USA Edward G. Hinkelman,Myron Manley,Karla C. Shippey,James L. Nolan,Wendy Bidwell,Alexandra Woznick,2005 The manual is highly organized for ease of use and divided into the following major sections Commodity Index how to import data for each of the 99 Chapters of the U S Harmonized Tariff Schedule U S Customs Entry and Clearance U S Import Documentation International Banking and Payments Letters of Credit Legal Considerations of Importing Packing Shipping Insurance Ocean Shipping Container Illustrations and Specifications 72 Infolists for Importers

Recommendations and Guidelines Concerning AIDS ,1988 Guide to the Presidency Michael Nelson,2015-05-01

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Data Integrity and Data Governance Robert D McDowall, 2018-11-06 Data integrity is the hottest topic in the pharmaceutical industry Global regulatory agencies have issued guidance after guidance after guidance in the past few years most of which does not offer practical advice on how to implement policies procedures and processes to ensure integrity These guidances state what but not how Additionally key stages of analysis that impact data integrity are omitted entirely The aim of this book is to provide practical and detailed help on how to implement data integrity and data governance for regulated analytical laboratories working in or for the pharmaceutical industry It provides clarification of the regulatory issues and trends and gives practical methods for meeting regulatory requirements and guidance Using a data integrity model as a basis the principles of data integrity and data governance are expanded into practical steps for regulated laboratories to implement The author uses case study examples to illustrate his points and provides instructions for applying the principles of data integrity and data governance to individual laboratory needs This book is a useful reference for analytical chemists and scientists management and senior management working in regulated laboratories requiring either an understanding about data integrity or help in implementing practical solutions Consultants will also benefit from the practical guidance provided

Guide to Handling FDA Food Inspections Richard Laurence Frank, Robert A. Hahn, 2002

The FDA and Worldwide Current Good Manufacturing Practices and Quality System Requirements Guidebook for Finished Pharmaceuticals José Rodríguez-Pérez, 2014-08-15 This guidance book is meant as a resource to manufacturers of pharmaceuticals providing up to date information concerning required and recommended quality system practices It should be used as a companion to the regulations standards themselves and texts on the specific processes and activities contained within the QMS This book includes chapters on US current Good Manufacturing Practice GMP international GMP global GMP guides and harmonization detailed analysis of the requirements and guidances missing subparts what inspectors are looking for and the price of noncompliance It also includes an appendix with two tabulated

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