

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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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 **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

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United States,1979 *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 **Recommendations and**

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another which provides results from elections and polls and statistics from each office 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 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 *Nutrition* Sharon K. Zoumbaris, 2009-07-23 Nutrition addresses the most hotly debated topics in the news today obesity food safety irradiation and vegetarianism and also describes the currently accepted principles of good nutrition for men women and children Despite the abundance of advice on food and diet more Americans are obese than ever before diabetes rates are skyrocketing and more foods are recalled due to contamination It is high time for non biased answers to the question of what is healthy and safe to eat Nutrition provides those answers The book explains basic guidelines for healthy eating along with the government s role in nutrition It examines the issues of food safety and technology and the debates about genetically modified foods organic foods and vegetarian dining Food bans such as those on trans fats are discussed as are vitamins and supplements After tracing the history of the study of nutrition and identifying principal researchers the book examines seven major controversies in nutrition today This basic guide to healthy eating will give both students and adults the tools they need to choose a diet that is healthy and safe Salmon Wars Catherine Collins, Douglas Frantz, 2022-07-12 A Pulitzer Prize winning correspondent and a former private investigator dive deep into the murky waters of the international salmon farming industry exposing the

unappetizing truth about a fish that is not as good for you as you have been told A decade ago farmed Atlantic salmon replaced tuna as the most popular fish on North America s dinner tables We are told salmon is healthy and environmentally friendly The reality is disturbingly different In Salmon Wars investigative journalists Douglas Frantz and Catherine Collins bring readers to massive ocean feedlots where millions of salmon are crammed into parasite plagued cages and fed a chemical laced diet The authors reveal the conditions inside hatcheries where young salmon are treated like garbage and at the farms that threaten our fragile coasts They draw colorful portraits of characters such as the big salmon farmer who poisoned his own backyard the fly fishing activist who risked everything to ban salmon farms in Puget Sound and the American researcher driven out of Norway for raising the alarm about dangerous contaminants in the fish Frantz and Collins document how the industrialization of Atlantic salmon threatens this keystone species endangers our health and environment and lines the pockets of our generation s version of Big Tobacco And they show how it doesn t need to be this way Just as Eric Schlosser s Fast Food Nation forced a reckoning with the Big Mac the vivid stories scientific research and high stakes finance at the heart of Salmon Wars will inspire readers to make choices that protect our health and our planet

Congressional Record United States. Congress,2000 The Congressional Record is the official record of the proceedings and debates of the United States Congress It is published daily when Congress is in session The Congressional Record began publication in 1873 Debates for sessions prior to 1873 are recorded in The Debates and Proceedings in the Congress of the United States 1789 1824 the Register of Debates in Congress 1824 1837 and the Congressional Globe 1833 1873

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