

REGULATORY AFFAIRS

1. Which organization is responsible for setting food safety standards at the national level?
 - a) FDA (Food and Drug Administration)
 - b) USDA (United States Department of Agriculture)
 - c) FSSAI (Food safety standard authority of India)
 - d) FSIS (Food Safety and Inspection Service)
2. Which food safety regulation requires food manufacturers to provide accurate labeling information about allergens?
 - a) FDA Food Safety Modernization Act (FSMA)
 - b) USDA Organic Certification
 - c) European Union Food Information to Consumers Regulation
 - d) Canada's Food and Drug Regulations
3. What is the maximum allowable level of microbial contamination in fruit juices?
 - a) 10 colony-forming units (CFU) per milliliter
 - b) 100 CFU per milliliter
 - c) 1,000 CFU per milliliter
 - d) 10,000 CFU per milliliter
4. Which of the following is NOT a common allergen that must be declared on beverage labels?
 - a) Milk
 - b) Soy
 - c) Wheat
 - d) Caffeine
5. What is the minimum required pH level for acidified beverages to prevent microbial growth?
 - a) pH 2.5
 - b) pH 4.0
 - c) pH 5.5
 - d) pH 7.0
6. Which of the following statements about food allergen labeling is true?
 - a) All allergens must be listed in bold font on the label.
 - b) Allergen labeling is optional for small juice and b.
 - c) Only the top eight allergens need to be declared.
 - d) Allergen information must be listed in a separate document.
7. Which of these is a basic labeling requirement according to FOOD SAFETY AND STANDARDS (PACKAGING AND LABELING) REGULATIONS, 2011
 - a) Date of manufacture
 - b) Veg/ Non- Vegetarian Food
 - c) Best before
 - d) All of these
8. ISO 9001: 2008 Quality management systems deals with
 - a) Fundamentals and vocabulary
 - b) Guidelines for performance improvements

- c) Customer Satisfaction
- d) Requirements for quality management
9. According to the FSS act, the full form of COA is:
 - a) Certificate of approval
 - b) Certificate of authority
 - c) Certificate of analysis
 - d) Certificate of Assessment
10. In food factory the ISO 22000 is for?
 - a) Increasing profits
 - b) Managing food safety
 - c) Employee welfare
 - d) None of the above
11. How can ISO 9001 assist food industry organizations in meeting regulatory requirements?
 - a) ISO 9001 provides a comprehensive list of all applicable regulations.
 - b) ISO 9001 offers a framework for organizations to establish and maintain regulatory compliance.
 - c) ISO 9001 exempts organizations from regulatory inspections.
 - d) ISO 9001 eliminates the need for organizations to comply with regulations.
12. Which regulatory aspect ensures that food packaging materials are safe for use?
 - a) Food Safety and Hygiene regulations
 - b) Quality Standards regulations
 - c) Import and Export regulations
 - d) Environmental and Sustainability regulations
13. Which regulatory category focuses on preventing deceptive or misleading advertising on food packaging?
 - a) Food Safety and Hygiene regulations
 - b) Quality Standards regulations
 - c) Labeling and Packaging regulations
 - d) Advertising and Marketing regulations
14. _____ of the Food Safety and Standard Regulations, 2011, specifies the standards for various infant products.
 - a) 2.1.9
 - b) 2.2.9
 - c) 2.4
 - d) 2.3
15. What does the term "net weight" refer to in food packaging regulations?
 - a) The total weight of the food product, including packaging
 - b) The weight of the food product without packaging
 - c) The weight of the food product after cooking or preparation
 - d) The weight of the packaging material used for the food product

16. The basic purpose of establishing food standards is _____.
 - a) To promote unfair trade in food.
 - b) To ensure food safety and quality.
 - c) Protection of public health and risk
 - d) To ensure fair trade in food.

Regulatory Affairs Questions Answers

PATHAN AZHER KHAN



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FDA Regulatory Affairs David Mantus, Douglas J. Pisano, 2014-02-28 FDA Regulatory Affairs is a roadmap to prescription drug biologics and medical device development in the United States Written in plain English the concise and jargon free text demystifies the inner workings of the US Food and Drug Administration FDA and facilitates an understanding of how the agency operates with respect to compliance and product approval including clinical trial exemptions fast track status advisory committee procedures and more The Third Edition of this highly successful publication Examines the harmonization of the US Federal Food Drug and Cosmetic Act with international regulations on human drug biologics and device development research manufacturing and marketing Includes contributions from experts at organizations such as the FDA National Institutes of Health NIH and PAREXEL Focuses on the new drug application NDA process cGMPs GCPs quality system compliance and corresponding documentation requirements Provides updates to the FDA Safety and Innovation Act FDASIA incorporating pediatric guidelines and follow on biologics regulations from the 2012 Prescription Drug User Fee Act PDUFA V Explains current FDA inspection processes enforcement options and how to handle FDA meetings and required submissions Co edited by an industry leader Mantus and a respected academic Pisano FDA Regulatory Affairs Third Edition delivers a compilation of the selected US laws and regulations as well as a straightforward commentary on the FDA product approval process that is broadly useful to both business and academia

Nomination of Richard G. Darman United States. Congress. Senate. Committee on Governmental Affairs, 1989 *Inspection standards of vegetable imports* United States. Congress. Senate. Committee on Agriculture, Nutrition, and Forestry. Subcommittee on Foreign Agricultural Policy, 1978

Handbook of Validation in Pharmaceutical Processes, Fourth Edition James Agalloco, Phil DeSantis, Anthony Grilli, Anthony Pavell, 2021-10-28 Revised to reflect significant advances in pharmaceutical production and regulatory expectations Handbook of Validation in Pharmaceutical Processes Fourth Edition examines and blueprints every step of the validation process needed to remain compliant and competitive This book blends the use of theoretical knowledge with recent technological advancements to achieve applied practical solutions As the industry's leading source for validation of sterile pharmaceutical processes for more than 10 years this greatly expanded work is a comprehensive analysis of all the fundamental elements of pharmaceutical and bio pharmaceutical production processes Handbook of Validation in Pharmaceutical Processes Fourth Edition is essential for all global health care manufacturers and pharmaceutical industry professionals Key Features Provides an in depth discussion of recent advances in sterilization Identifies obstacles that may be encountered at any stage of the validation program and suggests the newest and most advanced solutions Explores distinctive and specific process steps and identifies critical process control points to reach acceptable results New chapters include disposable systems combination products nano technology rapid microbial methods contamination control in non sterile products liquid chemical sterilization and medical device manufacture

DRUG REGULATORY AFFAIRS:

COMMON INTERVIEW QUESTIONS & ANSWERS PATHAN AZHER KHAN,2024-11-25 This comprehensive questionnaire with answers for Drug Regulatory Affairs written by industry experts educators and professionals is designed to bridge the gap between HR and candidates by offering common interview questions specific to Drug Regulatory Affairs Thus it enhances jobseeker s preparation and confidence The author aims to revolutionize the healthcare and pharmaceutical and research industries by equipping professionals with the knowledge and skills they need to ace their interviews jobs As the pharmaceutical and healthcare industry continues to evolve and expand there is a growing demand for professionals with specialized knowledge and skills in such areas We have gone the extra mile to develop specialized tools and support in this book such as career guidance exclusively for job seekers Our vision is to empower job seekers and professionals like you to take charge of their careers by providing them with the necessary market knowledge Key Features A trusted companion for job seekers with authentic data and references DRA Technical Interview Q A Everything a Candidate Needs in One Place Updated with Current Affairs Useful for Pharmacy Medicine and other healthcare sectors competitive exams Learn Technical Skills to get hired Proctor V. Davis ,1996 **Title News** ,1976 **Harvard Law Review** ,2013 House of Commons Debates, Official Report Canada. Parliament. House of Commons,1990 **California. Court of Appeal (3rd Appellate District). Records and Briefs** California (State)., Consolidated Case s C011166 Number of Exhibits 1 *California. Supreme Court. Records and Briefs* California (State)., Court of Appeal Case s C011450 lead C011166 Number of Exhibits 2

Environmental TQM John T. Willig,1994 Shows how companies can apply the concepts and methods of total quality management to their interaction with the environment Emphasizes going beyond compliance with regulations to creating an environmental strategy that will make the company more competitive First published in 1992 No index Acidic paper Annotation copyright by Book News Inc Portland OR Balla V. Gambro, Inc ,1990 *Food, Drug, Cosmetic Law Reporter* ,1963 Records & Briefs New York State Appellate Division , **American Journal of Hospital Pharmacy** ,1991 Consumer Sourcebook ,2005 **Physician's Desk Reference, 1990** Edward R. Barnhart,1990 With more than 1 600 color grids this year s edition of the 40 year bestseller is comprised of 2 000 pages of detailed information on nearly 3 000 drugs Product illustration drawings have been added as a new feature *Feed Management* ,1986 **Inside E.P.A. Weekly Report** ,1999

Regulatory Affairs Questions Answers Book Review: Unveiling the Magic of Language

In an electronic era where connections and knowledge reign supreme, the enchanting power of language has become much more apparent than ever. Its capability to stir emotions, provoke thought, and instigate transformation is really remarkable. This extraordinary book, aptly titled "**Regulatory Affairs Questions Answers**," written by a very acclaimed author, immerses readers in a captivating exploration of the significance of language and its profound effect on our existence. Throughout this critique, we will delve into the book's central themes, evaluate its unique writing style, and assess its overall influence on its readership.

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