

Consumer Safety Officer Competencies and Key Behaviors

Competency Title	Competency Definition	Key Behaviors
1. Consumer Safety Proficiency	Maintains and applies a comprehensive set of scientific and regulatory knowledge of consumer safety and related fields.	<ol style="list-style-type: none"> 1. Serves as a resource to CVM staff and others (e.g., other government agencies, general public) in areas related to consumer safety 2. Gains a comprehensive understanding of consumer safety-related issues associated with products under review 3. Keeps abreast of crucial and precedent-setting issues under review within the Office, Center, Agency, regulated industry, and in the field of consumer safety
2. Information Gathering	Locates appropriate sources of data and information; Obtains and stores this information in support of approval process and research activities and goals.	<ol style="list-style-type: none"> 1. Compiles administrative records on submissions, resubmission, and other amendments (e.g., (J)INADs, NADAs, Food Additive Petitions, Division of Animal Feed submissions) 2. Obtains information from multiple databases (e.g., RFR, STARS, FACTS) 3. Obtains information from web-based sources (e.g., CFR, Animal Drugs at FDA.gov) 4. Consults with professionals within the Center, other government agencies, international entities, academia, and industry to gain information 5. Inputs data into appropriate computer tracking systems and databases 6. Compiles administrative records on regulatory cases applicable to a review or hearing

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3. Information Analysis	<p>Analyzes and interprets scientific data and information regarding animal drugs, food ingredients, and devices submitted for review.</p> <p>Analyzes and interprets regulatory information, inspectional observations, facts and opinions regarding animal drugs, food ingredients, and devices.</p>	<ol style="list-style-type: none"> 1. Uses judgment based on personal regulatory background and understanding of legislation, policy, and program definitions in order to recognize serious problems and issues 2. Performs regulatory reviews of information submitted by sponsors 3. Reviews labeling for drugs to determine compliance with labeling requirements of the law and regulations 4. Evaluates sponsored submissions to ensure they conform to appropriate laws, regulations and policies 5. Recommends whether a submission can be approved 6. Recommends to the sponsor areas of deficiency which warrant improvement 7. Performs regulatory reviews of information submitted by interested parties (e.g., public, regulated industry, other government agencies, foreign entities) 8. Analyzes information on the development, processing, and distribution of regulated products 9. Reviews labeling for drugs, foods, and other regulated articles to determine compliance with labeling requirements of the law and regulations 10. Evaluates inspectional submissions to ensure they conform to standard operating procedures 11. Recommends whether a regulatory action should be pursued 12. Identifies areas which warrant further study or improvement

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4. Scientific & Regulatory Advisement	Advises on animal and public health issues related to FDA-regulated veterinary products.	<ol style="list-style-type: none"> 1. Provides recommendations for administrative/regulatory actions (e.g., deficiency letters, information request letters, approvability or disapproval, warning letters) 2. Participates in the decision making process concerning the actions that will be taken regarding deficiencies (e.g., labeling, record keeping, manufacturing) 3. Interprets applicable laws, regulations, and policies 4. Prepares letters communicating FDA determinations regarding submission or inquiries 5. Responds to inquiries or sponsor submissions of deficiencies which have been recognized and recommends actions 6. Provides authoritative advice and guidance to customers to gain compliance with applicable laws, policies, and regulations 7. Participates in the development and implementation of regulations and policies pertaining to new drugs intended for animal use 8. Provides responses to general inquiries from the regulated industry 9. Participates in the development and implementation of regulations and policies pertaining to new drugs, devices, and feed intended for animal use 10. Prepares communications (e.g., press releases) regarding FDA regulatory decisions or requests for information from the regulated industry 11. Provides responses to general inquiries from the scientific community, regulated industry, consumers and others 12. Advises officials in other interrelated programs within and outside of the Center regarding inspection and investigation methods and procedures necessary to accomplish compliance, enforcement, and regulatory objectives 13. Addresses professional groups on the areas of personal expertise 14. Delivers outreach messages through a variety of media (e.g., conferences, workshops) in order to encourage an understanding of and compliance with Federal regulations, policies, and standards 15. Delivers training through a variety of media

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5. Review Process Management	<p>Applies expert knowledge of CVM operations to develop and manage an active review process.</p> <p>Applies expert knowledge of CVM operations to develop and manage tasks related to the protection of animal and public health.</p>	<ol style="list-style-type: none"> 1. Ensures that assignments occur in a timely manner as defined by regulatory requirements 2. Decides the methods to use in achieving work goals and objectives 3. Develops new procedures to solve critical or novel problems or perform more refined analyses 4. Ensures review activities are aligned with laws, regulations, policies, regulatory programs, and precedents which govern the Agency 5. Ensures that communication occurs between team members based on the needs of the project and individuals 6. Assures that regulatory decisions are properly supported by evidence 7. Resolves inconsistencies between reviews or omissions in the review process 8. Prioritizes project or program implementation 9. Identifies and justifies program staffing, equipment, and other resource needs 10. Resolves inconsistencies between historical precedents and current policies