

Biologist Competencies and Key Behaviors

Competency Title	Competency Definition	Key Behaviors
1. Biology Proficiency	Maintains and applies a comprehensive set of scientific knowledge of biological systems 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 one or more areas related to biology (e.g., animal related issues, nutrition, physiology, environmental toxicology, biochemistry) 2. Gains a comprehensive understanding of biology-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 biology 4. Participates in meetings with the pharmaceutical, food/feed, and devices industry and Center staff to discuss issues pertaining to biology and related fields 5. Participates in meetings with Federal agencies, industry, academia, and Center staff to discuss issues pertaining to biology and related fields 6. Prepares reports and/or manuscripts for publication in scientific literature and the Agency

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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. Reviews scientific literature, methodology, and other information available to the Center (e.g., manuals, journal articles, other technical references) for information pertinent to the issue under investigation 2. Coordinates with scientists within the Center, other government agencies, international entities, academia, and industry to exchange information and research findings 3. Identifies and obtains pertinent sources of information such as journal articles and technical references (e.g., methods manuals, standard operating procedures, protocols) 4. Gathers information on complex, long-range, and emerging issues and conflicts in the scientific/regulatory field 5. Searches for pertinent information using applicable computer-based databases 6. Develops and provides a detailed description of data requirements (e.g., working with sponsor to develop study designs or protocols, guidance documents for research) 7. Requests additional information, tests, and data when a submission is not adequate 8. Requests and receives clinical and non-clinical (e.g., in vitro) data and histories of affected animals for review 9. Monitors post-marketing reports (e.g., drug experience, feed ingredients, devices) 10. Uses discretion with sensitive information 11. Inputs data into appropriate computer tracking systems and databases 12. Generates clinical and non-clinical (e.g., in vitro) data of affected animals

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3. Information Analysis	Analyzes and interprets scientific data and information regarding animal drugs, food ingredients, and devices to draw conclusions and recommendations.	<ol style="list-style-type: none"> 1. Analyzes results of experiments to determine whether data generated is accurate and valid 2. Determines if the appropriate experimental design was employed in the development and collection of data 3. Utilizes appropriate mathematical modeling and statistical methods to analyze research results 4. Interprets the scientific implications of results of biological studies 5. Evaluates the metabolism, absorption, distribution and elimination of chemical entity from tissues and organs 6. Critically evaluates existing literature and interprets data resulting from studies 7. Studies various factors that could possibly influence or lead to causes and solutions for environmental impact of chemical entities 8. Studies various factors that may lead to the development of safety (e.g., target animal, human food, environmental) and efficacy standards for drugs, foods, and devices 9. Supports all decisions or conclusions with a scientific rationale 10. Provides results of analysis to policy makers 11. Reviews information in support of approval and authorization packages, including sponsors' submissions, scientific reviews, product labeling, approval and authorization letters, Memoranda of Understanding, draft regulations, Freedom of Information summaries, and environmental documents 12. Determines whether the information is sufficient to assess conformity with current Good Manufacturing Practice requirements and applicable FDA regulations 13. Evaluates interactions between animals, chemical entities (e.g., drugs, foods, metabolites), and the environment 14. Analyzes the content and meaning of drugs, foods, and devices advertisements and promotional labeling to ensure that they are not incomplete, false, or misleading 15. Assists in determining whether previously approved products should be withdrawn on the basis of new information 16. Determines whether the information is sufficient to assess conformity with current Good Laboratory Practice requirements and applicable FDA regulations

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4. Scientific & Regulatory Advisement	Serves as an authoritative source of information and guidance on biology issues related to animal drugs, foods, devices, laws, regulations, and policies.	<ol style="list-style-type: none"> 1. Provides recommendations for the solution of a variety of biology-related issues 2. Participates in meetings with industry and government officials as a representative of CVM 3. Participates in the development of biology-related guidance and policy documents for the manufacturing and control of animal drug and feed products 4. Participates in the development of policy documents regarding biological issues 5. Collaborates with colleagues in FDA and other Federal agencies on interrelated programs 6. Serves as an authoritative source of information and advice on the research, manufacturing, and/or labeling of animal drugs and food ingredients 7. Alerts appropriate authority of potential biology-related problems which may have an impact on the Center and the stakeholders 8. Assists other FDA and CVM scientists in completion of their tasks by providing expert knowledge with respect to biology 9. Delivers outreach messages on biological topics through a variety of media (e.g., conferences, workshops, seminars, publications) in order to promote Center mission 10. Recommends field investigations be conducted by FDA District personnel of applicants' facilities to assure compliance with pertinent regulations 11. Briefs staff and the Division Director on scientific interpretations and analyses 12. Provides advice and guidance regarding compliance with policies, decisions, and regulations to officials in the regulated industry and State, local, and international entities 13. Briefs staff and the Division Director on regulatory interpretations and analyses

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5. Research/ Review Process Management	Applies scientific knowledge and understanding of CVM operations to develop and manage the research/review process.	<ol style="list-style-type: none"> 1. Coordinates with the program Director to formulate, develop, and shape research program goals 2. Identifies and selects areas for study and research 3. Sets short-term priorities and prepares schedules for completion of work within set deadlines 4. Leads a team in the conception and formulation of research/review methods to use in achieving work goals and objectives 5. Monitors and evaluates the progress of the research/review process 6. Makes recommendations on the future needs of the laboratory (e.g., instruments, personnel, methods) 7. Ensures research/review activities are aligned with laws, regulations (e.g., Good Laboratory Practices), and policies 8. Ensures that regular communication occurs between team members based on the needs of the project and individuals

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6. Laboratory Operations	Ensures the proper care of animals used by research programs by adhering to and enforcing applicable legislation and policies; Performs analytical procedures using laboratory apparatus based on research requirements.	<ol style="list-style-type: none"> 1. Reviews or conducts research studies involving a variety of animal species 2. Determines the appropriate equipment or instrumentation to use based on sample type and research requirements 3. Ensures the humane handling, husbandry, maintenance, transportation, housing, and veterinary care of animals 4. Assists in treatment administration, physical examinations, and sampling 5. Provides animal surgical support as required by other researchers 6. Operates analytical equipments and instruments 7. Provides guidance and trains technical support personnel regarding laboratory procedures, techniques, and equipment maintenance and repair 8. Adheres to and enforces applicable safety regulations and CVM policies (e.g., Good Laboratory Practices) 9. Recommends new equipment based on program requirements, schedules, demonstrations, and participates in procurement request 10. Keeps and maintains laboratory records