Competencies for All CDER Staff

1. Organizational Commitment

Definition: The ability to partner in the organization's mission, demonstrate commitment, and to uphold the values in the organization.

Behaviors:

1. Partners in FDA's mission and upholds the values in the organization
2. Demonstrates personal and professional integrity and presents a positive image of FDA in all interactions
3. Understands the need to use the regulatory process to protect the public health while allowing appropriate drug development
4. Committed to continuous learning, maintaining and developing professional expertise on scientific and technical aspects areas of relevant discipline by keeping current on technical and scientific literature, and through active participation in conferences and internal and external working groups

2. Time & Resource Management

Definition: The ability to set objectives, establish schedules, manage one's own time efficiently to promote productivity, use resources efficiently, and to search for less costly ways of doing things.

Behaviors:

1. Sets objectives, establishes work schedules, and tracks work consistent with office and/or division priorities and changing workload
2. Plans, organizes and prioritizes work by applying effective methods and tools, and staying focused on what is important
3. Keep colleagues, team members and managers appropriately informed
4. Manages multiple tasks concurrently and utilizes resources effectively

3. Teamwork

Definition: The ability to partner with team members to achieve goals, foster cooperation and to work effectively with diverse groups.

Behaviors:

1. Collaborates with others to meet schedules and accomplish common goals
2. Actively applies the principles of Equal Voice
3. Fosters cooperation, facilitates exchange of ideas, shares and seeks knowledge and provides feedback to others
4. Raises different perspectives when necessary and understands the impact of different work styles on team dynamics
5. Accepts constructive criticism and uses it to improve performance
6. Appreciates diversity in style and perspective and treats others with respect
7. Promotes a learning environment and encourages sharing of knowledge among team members
8. Meets team deadlines

4. Command of Technology and Information Resources

Definition: The ability to effectively and efficiently utilize technology and information resources in order to accomplish goals.

Behaviors:

1. Seeks and uses internal and external office automation and information resources and technological tools such as computers, computer software applications, databases, and other tools to improve performance and to accomplish work tasks
2. Efficiently uses software applications such as Outlook, Word, Excel, and PowerPoint to accomplish tasks

5. Communication

Definition: The ability to achieve goals by communicating effectively using the most appropriate and efficient manner, methods and media.

a. Written Communication

Definition: Ensuring that written work and information are complete, accurate, clear and succinct by using appropriate formats, templates and language.

Behaviors:

1. Writes clearly and succinctly using good, technical writing principles to express facts and interpretations in a convincing and organized manner
2. Considers reader's needs when developing documents
3. Understands timeliness of communication and promotes efficient communication
4. Comprehends regulatory/guidance documents and interprets and analyzes information and data accurately
5. Reads to understand both what is written and identifies what is omitted; reads both for details and the big picture

b. Oral Communication

Definition: Ensuring that ideas and concepts are communicated verbally in a clear, effective and appropriate manner.

Behaviors:

1. Communicates effectively in a variety of settings, including one-on-one, small or large groups
2. Effectively and appropriately responds to challenging questions
3. Clearly expresses ideas and facts, in a way appropriate to the situation and audience
4. Practices "active listening" by patiently hearing other people and responding constructively, and appropriately
5. Maintains open communication with supervisors and colleagues to identify and address potential problems in a timely fashion
6. Develops and conducts clear and effective presentations using appropriate principles, techniques and tools

6. Knowledge of CDER-Wide Regulations, Policies & Procedures

Definition: The ability to apply up-to-date regulatory knowledge, organizational guidance, and standard operating procedures to meet regulatory requirements.

Behaviors:

1. Consistently and appropriately maintains knowledge and applies Federal laws and other applicable regulations
2. Recognizes the need for revising or drafting new policies and regulations, ensures consistency, and communicates regulatory information accurately and timely
3. Applies Agency, Center, Office, and Division policies, procedures and guidance relevant to their work and consistently meets compliance standards

Competencies for All CDER Drug Review Staff

The competencies described in categories 7 through 9 below apply only to those CDER staff directly involved in the drug review process.

7. Critical Analysis and Judgment

Definition: The ability to critically analyze, synthesize and interpret pertinent data and information to make sound judgments throughout the drug review process.

Behaviors:

1. Applies a broad and knowledgeable perspective in interpreting data and information to make sound conclusions and help solve difficult, complex issues in the pre and post market regulatory process
2. Consistently applies professional and pertinent drug-review standards and uses critical thinking throughout the pre and post market regulatory process
3. Consistently makes sound judgments and findings in the applications/submissions, including possible risk factors in a timely manner
4. Provides practical suggestions and recommendations to team leader(s) and team members for decisions
5. Is willing to approach new ideas and concepts with an open mind
6. Regularly steps back to regain an objective, holistic view of the work being done and how it fits in the larger scheme of things
7. Provides practical, reasonable arguments to support findings and recommendations

8. Conduct of Review

Definition: Knowledge of the overall CDER drug review process and the ability to apply good practices in the performance of drug review tasks throughout that process.

Behaviors:

1. Understands the regulatory drug life cycle (including pre-IND, IND, NDA/BLA, and post-marketing) and the roles and responsibilities of CDER professionals throughout the review process
2. Consistently and appropriately applies up-to-date regulatory knowledge, organizational guidances, and standard operating procedures in reviewing IND, NDA, and BLA submissions; and uses consults as needed
3. Applies the constructs of the Safety First initiative and considers potential safety and risk factors and risk assessment methodologies throughout the drug review process
4. Applies relevant Federal laws and FDA regulations, MAPPs and guidances as they relate to CDER drug reviews
5. Applies knowledge of regulatory history of the drug and related drug products as part of the review process
6. Analyzes submitted data and information using scientifically appropriate methods and makes valid conclusions and recommendations
7. Analyzes product labels and provides recommended language for product labeling per current labeling guidance and policies (as appropriate to discipline)
8. Recognizes that reviews are conducted in a hierarchical environment which may impact regulatory outcome

9. Knowledge of CDER Scientific Disciplines

Definition: The ability to use and apply an understanding of basic science, methods, processes and procedures in medical and review disciplines related to drug review process.

Behaviors:

1. Uses and applies related knowledge in basic science of clinical practice, clinical pharmacology, chemistry, biochemistry, pharmacology/toxicology, bioequivalence, and statistics

2. Comprehends and evaluates the application of pertinent concepts and knowledge from other disciplines in the review process related to product development
3. Consistently seeks opportunities to enhance mathematical, scientific, technical, or professional expertise

CDER Core and Drug Review Staff Competencies
Position-specific competencies also available