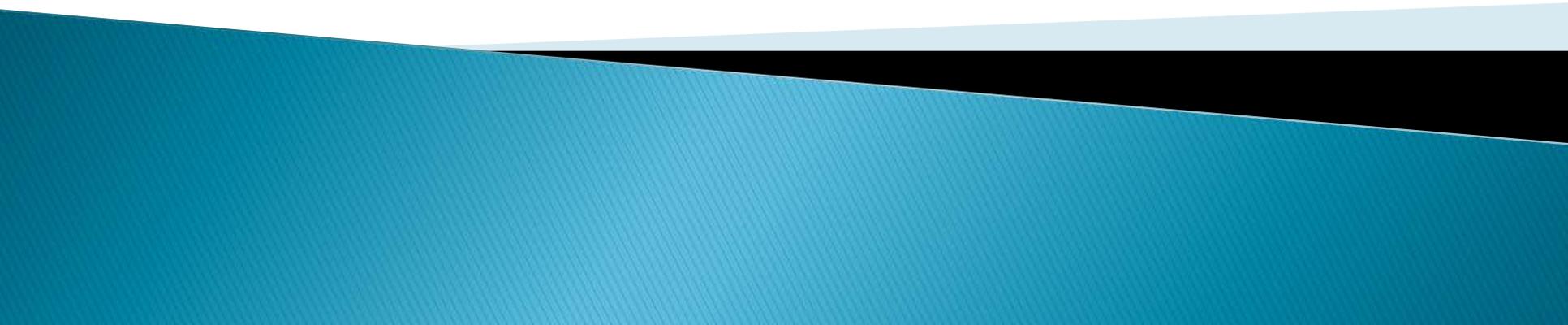


REGULATORY AFFAIRS – Protecting Public Health

Overview of the Role of The Regulatory Professional

NIH, Bethesda, MD February 14, 2012



Disclaimer:

- ▶ **The opinions and information in this presentation are those of the author, and do not necessarily reflect the views and/or policies of the Food and Drug Administration or its staff. The Food and Drug Administration will not be bound by any of the comments or information contained in this presentation.**
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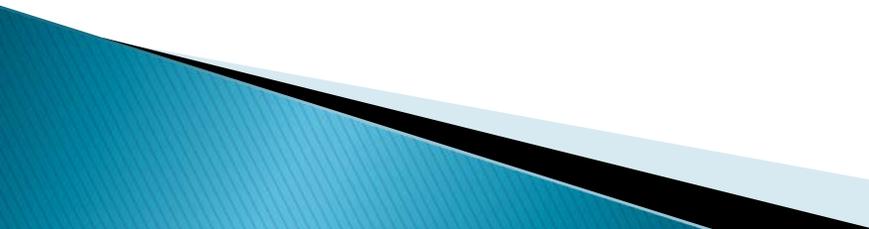
Careers in Regulatory – Outline

- ▶ **Regulatory Affairs at the Hub**
 - ▶ **Responsibilities**
 - ▶ **Who is in the field?**
 - ▶ **Is this for you?**
 - ▶ **Process Flow – introduction to rate limiting steps**
 - ▶ **Preliminary Results**
 - ▶ **Creating Value**
- 

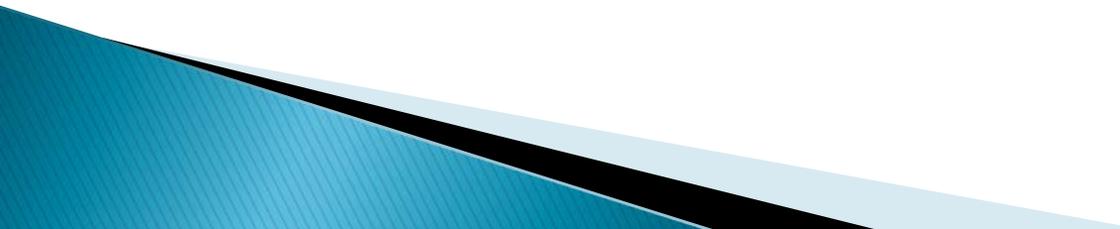
Protecting Public Health

- ▶ **Food & Drug Administration Mission:**
 - “Protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation’s food supply, cosmetics, and products that emit radiation”
- ▶ **Office of Compliance Mission:**
 - “To promote and protect public health through strategies and actions that minimize consumer exposure to unsafe, ineffective, and poor quality drugs”
- ▶ **Center for Drug Evaluation & Research Mission:**
 - “To promote and protect the public health by ensuring that safe and effective drugs are available to Americans”

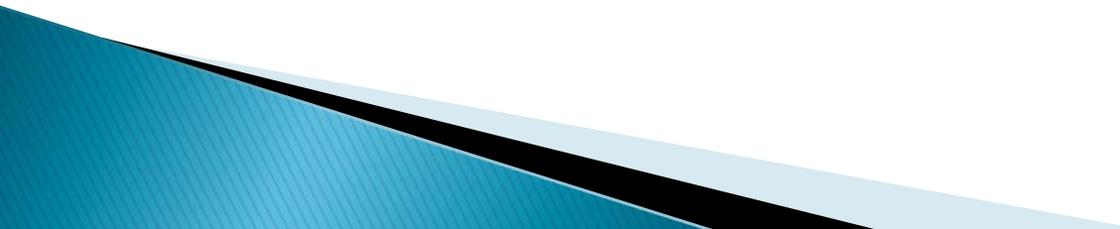
Getting the Job Done Right

- ▶ **Managing uncertain outcomes**
 - ▶ **“Make it Happen”**
 - ▶ **Applying proven systems principles:**
 - **Analyzing the problem in sub-components (parts) rather than whole**
 - **Reconstructing the parts and applying sound principles**
 - ▶ **Exercising of Judgment/Analytical**
- 

Field Diversity and Experience

- ▶ **Scientifically Accurate**
 - ▶ **Professional**
 - ▶ **Collaborative**
 - ▶ **Time Management**
- 

Multi-Faceted – Multi-Disciplinary

- ▶ **Food Drug & Cosmetic Act**
 - ▶ **Wide Range of Specialties**
 - ▶ **First Point of Contact**
 - ▶ **Assimilation of Information**
- 

When Investing – Do Your Research

- ▶ **Is a Regulatory Career Right for You?**
 - What are your interests?
 - What are your skills?
 - What skills do you need to develop?
 - How willing are you to prepare for a career in Regulatory Affairs?
- 

Plan Beyond Tomorrow

- ▶ **What is your Career Goal?**
 - Strategically think about the steps to accomplish your goal
 - Work time into the career goal
 - Be Proactive

Be Proactive and Factor Time

▶ Current Job Ad. 02-14-12

- Senior level Regulatory Affairs professionals. Responsible for collection, preparation and assembly of documentation required for Investigational New Drug Applications (IND), Investigational Medicinal Product Dossiers (IMPD) and Clinical Trial Applications (CTA) for biologic oncology products.
- Responsible for supporting cross-functional activities pertaining to regulatory meetings, including the development of briefing documents and conduct of meeting rehearsals.
- Proactively identifies potential regulatory issues and recommends solutions to Regulatory Affairs management.
- Leads team(s) responsible for development of regulatory submissions within assigned product portfolio. Interacts with other project team members to ensure the timely preparation and receipt of information required for regulatory submissions. Interacts with internal and external partners as necessary to support product development.
- Monitors related corporate activities for regulatory compliance, including nonclinical, clinical, research and development/manufacturing.
- Conducts and analyzes regulatory research to understand past precedence and the current competitive landscape. Evaluates and communicate impact of relevant regional regulations, guidance, current regulatory environment and competitor labeling.
- Identifies priorities and key issues in complex situations and solves these problems with minimal assistance.
- Is conversant and able to influence colleagues in multiple scientific areas.
- Educates internal stakeholders on implications of regulations.
- Provides preparation and planning support for meetings with regulatory agencies.
- Develops timeline for responding to inquiries from regulatory agencies and ensures issues are addressed in a timely manner.
- Identifies and appropriately communicates potential risks.
- Requirements
 - A minimum of 4 years in Regulatory Affairs with an additional 2 years in a related field of biopharmaceuticals or equivalent.
 - Prior oncology and early development (IND filing) experience desired.
 - Education: BS/MS in a scientific discipline.

Start Preparing Now – Strengthen Your Selling Point

▶ Is your Resume Up-to-Date?

- Use Your Resources (NIH Career Office)
 - Attend Regulatory Functions / Join Organizations (RAPS, etc.)
 - The Regulatory Field is Constantly Moving and Evolving – Do your research, stay up-to-date
 - Continuing Education Programs (Degrees and Certificates)
 - Take the Time to Network
- 

Value is in the Delivery

- ▶ **QUALITY**
 - ▶ **COMPLIANT**
 - ▶ **PROJECT MANAGEMENT**
 - ▶ **INTEGRITY**
- 

Presentation Information

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