

# Biosafety In Industry

**Elizabeth Gilman Duane, MS, RBP, CBSP**  
**Biosafety Officer**  
**Chair, Corporate Biosafety Committee**

**NIH IBC Conference**  
**June 25, 2009**

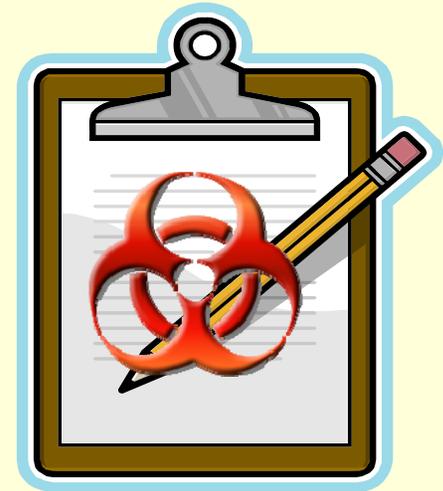


# Wyeth

# Agenda

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- **Wyeth Facts**
- **Corporate Biosafety Program**
- **Site Biosafety Programs**
- **Electronic Biohazard Agent Registration (eBAR)**
- **Institutional Biosafety Committees**
- **Biosafety Program Components**



# Wyeth Facts

- One of the world's largest research-driven pharmaceutical and health care products companies.
- A leader in the discovery, development, manufacturing and marketing of pharmaceuticals, vaccines, biotechnology products and non-prescription medicines that improve the quality of life for people worldwide.
- Products are sold in more than 145 countries.
- Unique research and technology base encompassing small molecules, biopharmaceuticals, genetic engineering that will give us the next wave of innovative therapies, and vaccines.



**Wyeth**

# Wyeth At A Glance

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- **Mission**

- ▶ We bring to the world pharmaceutical and health care products that improve lives and deliver outstanding value to our customers and shareholders.

- **Vision**

- ▶ Our vision is to lead the way to a healthier world. By carrying out this vision at every level of our organization, we will be recognized by our employees, customers and shareholders as the best pharmaceutical company in the world, resulting in value for all.

- **Fast Facts**

- ▶ Founded in 1926 under the name American Home Products Corporation
- ▶ Headquartered in Madison, NJ
- ▶ Operating in more than 100 countries
- ▶ 47,500 employees worldwide

- **Major Divisions**

- ▶ Wyeth Pharmaceuticals
- ▶ Wyeth Consumer Healthcare
- ▶ Fort Dodge Animal Health

# Wyeth Firsts

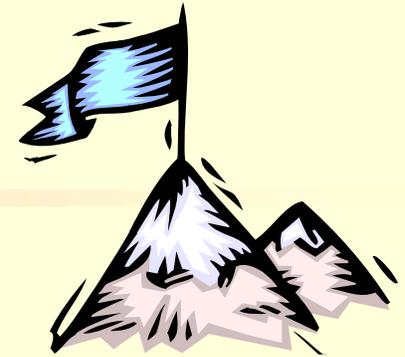
- The first firm to produce penicillin commercially
- The first oral form of live trivalent poliovirus vaccine in the United States
- The development of a heat-stable, freeze-dried vaccine and the bifurcated needle, which led to the worldwide eradication of smallpox
- The first Haemophilus b conjugate vaccine licensed for use in infants in the United States for protection against bacterial meningitis
- The first diphtheria/tetanus/acellular pertussis (DTaP) vaccine available in the United States
- The first in a new class of rheumatoid arthritis drugs known as biologic response modifiers
- The first albumin-free formulated recombinant factor VIII product
- The first vaccine for the prevention of invasive pneumococcal disease in infants and toddlers
- The first targeted chemotherapy agent using monoclonal antibody technology
- The first canine Lyme disease and Lyme combination vaccines
- The first recombinant feline leukemia vaccine
- The first modified-live canine parvovirus vaccine
- The first West Nile Virus vaccine for horses



**Wyeth**

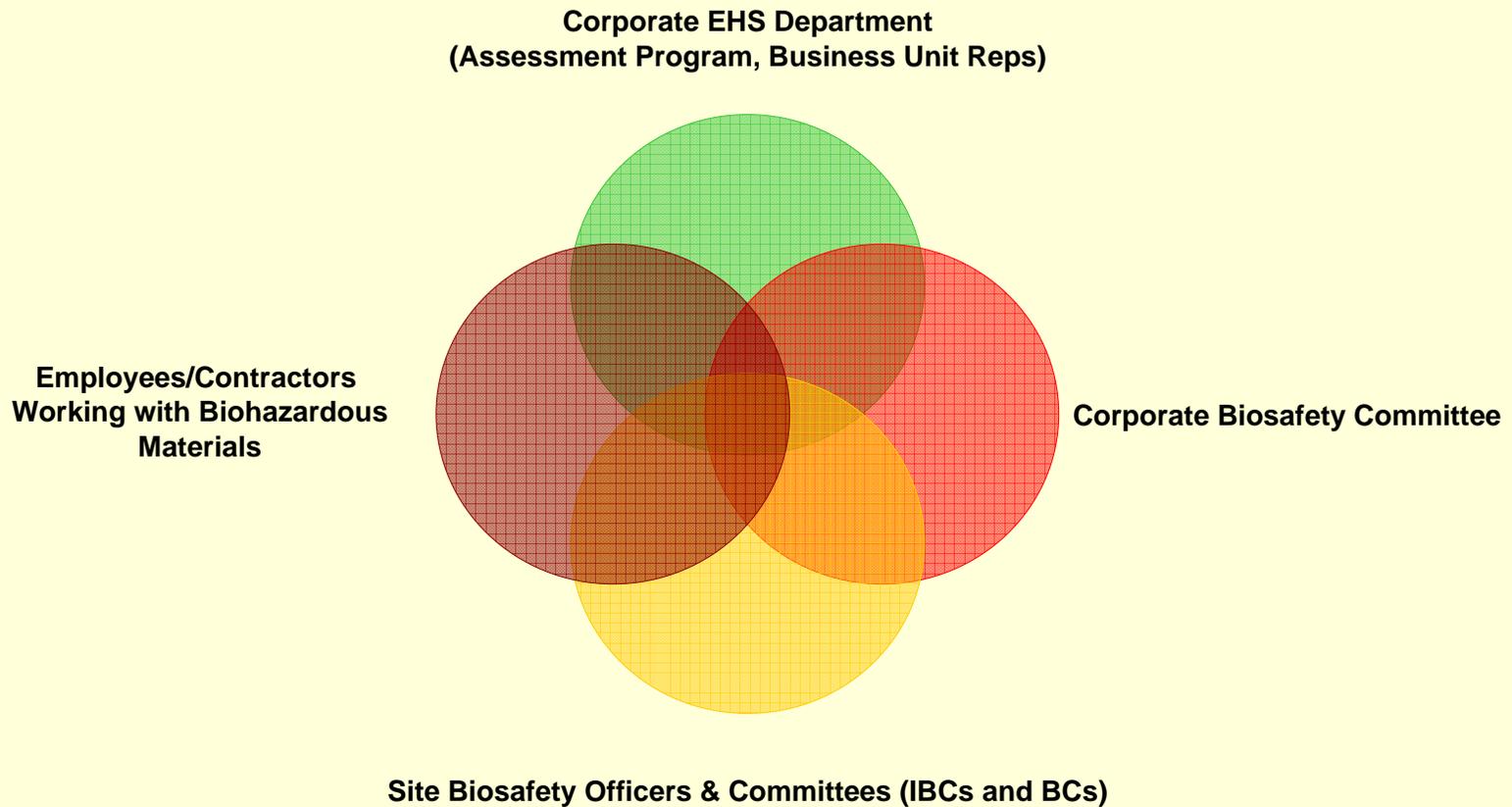
# Challenges

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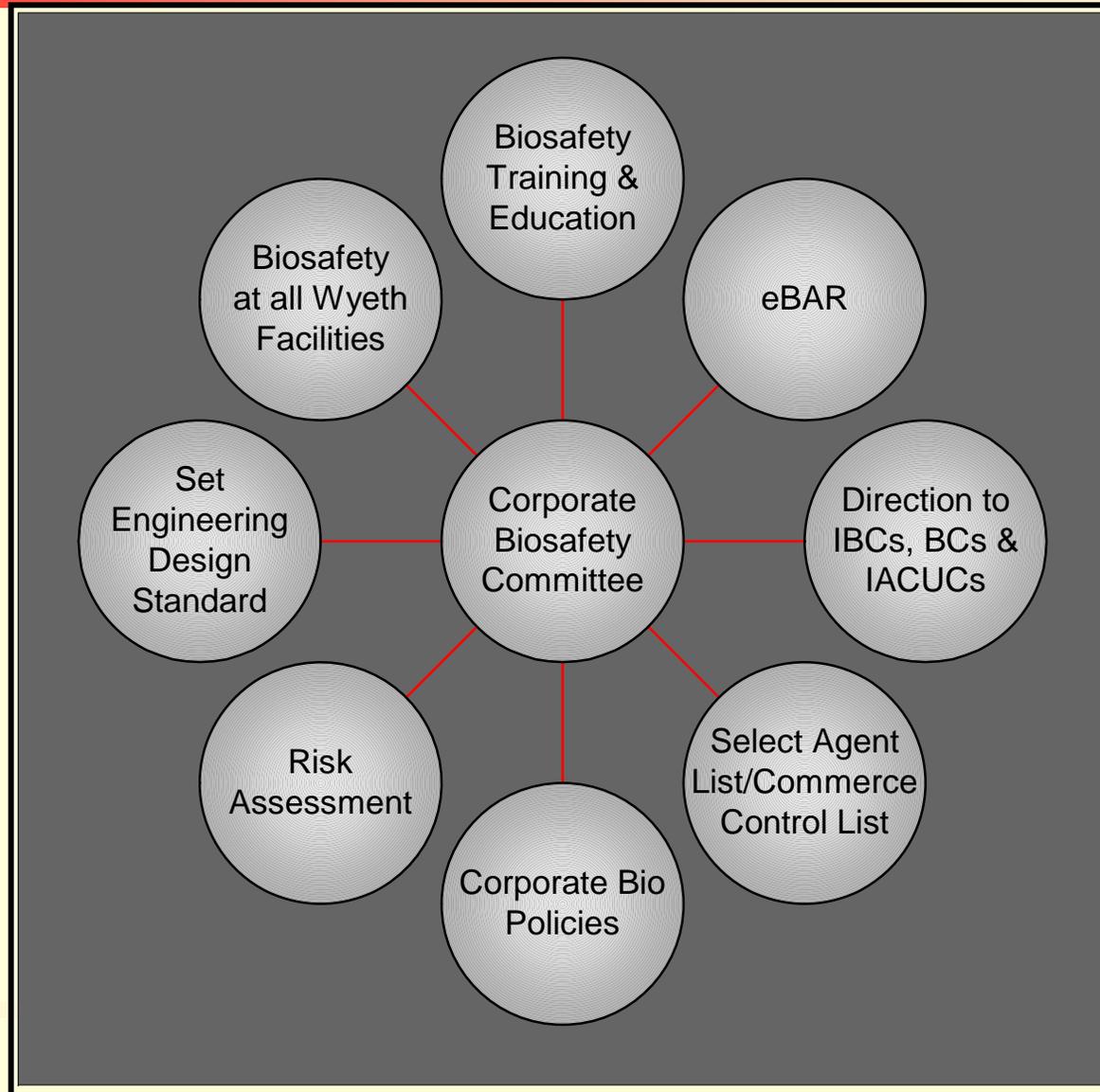


- **Pre-2001**
  - ▶ All site biosafety programs were independent
  - ▶ No corporate governance or biosafety committee
- **2001**
  - ▶ Betsy Gilman Duane joins Wyeth
- **2002**
  - ▶ Corporate Biosafety Committee is formed
- **2003**
  - ▶ Richard Fink joins Wyeth
- **Pre-2004**
  - ▶ No consistent platform across the corporation for project registrations
- **2004**
  - ▶ Electronic Biohazard Agent Registration (eBAR) is launched
- **2009**
  - ▶ Potential acquisition of Wyeth by Pfizer

# Who's Involved in Managing Biosafety Risks?



# Wyeth's Biosafety Management System



# Who We Are And What We Do...

- **Corporate Biosafety Committee**

- ▶ Founded in 2002
- ▶ 15 members, subject matter experts, from all business units
- ▶ Quarterly committee meetings and periodic subgroup meetings
- ▶ Present papers and posters at international meetings
- ▶ Serve as guest auditors in Corporate EHS Assessment Program
- ▶ Serve as a resource for all Wyeth sites



# Biosafety Staffing & Reporting Structure

- **Corporate Biosafety Officer**
  - ▶ Also directs a site EH&S program
- **Corporate Biosafety Committee**
  - ▶ Meets quarterly, chaired by the Biosafety Officer
- **Site Biosafety Officers**
  - ▶ Also direct site EH&S programs or are EH&S specialists
- ***No one is full-time for biosafety, all have collateral duties***
- ***No dedicated administrative assistance***



# Examples of Past Corporate Projects

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- Participated in the development of the International Biorisk Management Standard
- Developed 5 Corporate **Biosafety Policies** and Associated Resources
- Developed and teach *Biosafety Essentials* training course
- **Biosafety Resources**
- Assist sites with regulatory compliance
- Created eBAR (Electronic Biohazard Agent Registration) application for project registration

# Corporate Biosafety Policies

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- **Biosafety Policy Series**

- ▶ 601 / Biosafety Program
- ▶ 602 / Biological Agent, Material and Toxin Registration
- ▶ 603 / Bloodborne Pathogens
- ▶ 604 / Herpes B Virus Prevention
- ▶ 605 / Worldwide Select Agent Policy



- **The Corporate EHS website contains each policy along with supporting information, templates, sample documents, etc.**

# Biosafety Resources

- Newsletters
- Website
- Email Announcements
- Annual Symposium



Volume 2, Issue 2  
November 2005

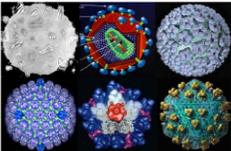
## BioSafety News

**In This Issue:**

- Viral Vectors
- Viral Vector Review and Approval
- Vector Profiles
  - Adenoviruses
  - Herpesviruses
  - Lentiviruses
  - Retroviruses
  - Baculoviruses
- Vector Safety Issues
- Containment Levels
- 2005 Training Dates

**Viral Vectors**

Viral vectors are common tools in the biomedical research laboratory. Over the past few years many of these vectors have been engineered with safety in mind. Nonetheless, there are some basic requirements for working safely with viral vectors. This issue of *BioSafety News* will review Wyeth biosafety requirements for work with viral vectors as well as provide a brief overview of common vector systems in use at Wyeth and potential safety hazards.



As always, let us know what topics you are interested in and we'll address them in future issues.

**Viral Vector Review and Approval**

In March 2005 an electronic application, eBAR, was deployed to all Wyeth facilities where biohazardous materials are used and stored. The Electronic Biohazardous Agent Registration (eBAR) application may be accessed at <http://mside@wyeth.com/bar>. Please [home.asp](http://home.asp) and is to be used for registration of all viral vectors, including those that are replication-deficient. Each site has a Biosafety Committee and/or Institutional Biosafety Committee. Committee members, in conjunction with the Site Biosafety Officer, review and approve the use of viral vectors prior to acquisition and use. Contact your Site Biosafety Officer for additional information or assistance with eBAR. Projects involving administration of viral vectors to animals require Institutional Animal Care and Use Committee (IACUC) review and approval.



Volume 3, Issue 3  
Fall 2006

## BioSafety News

**From the Editor:**  
This issue of *BioSafety News*

### Introduction to Centrifuge Safety

Centrifuges are among the most common pieces of laboratory equipment. They come in various sizes and vary in rotation—eg. micro-centrifuges, bench top, and floor centrifuges with speeds of low thousands to ultrahigh speeds up to 100,000 rpm or more.



What are the multiple hazards associated with this instrument? According to a survey by the National Institute for Occupational Safety and Health (NIOSH), the majority of centrifuge accidents are caused by user errors such as:

- Not securing the rotor to the drive pin on the rotor
- Not securing the lid
- Not securing the rotor to the drive pin on the rotor
- Not securing the lid
- Not securing the rotor to the drive pin on the rotor
- Not securing the lid

Other common user errors include:

- Operating beyond the rotor's maximum speed without reducing the rated speed
- Operating swinging bucket rotors with buckets not locked
- Operating rotors that are not able to operate freely on a horizontal rotor.

As always, let us know what topics you are interested in and we'll address them in future issues.

**1998 accident with a Beckman ultracentrifuge that exploded (see page 3).** Exploding rotors can release enough energy to cause the centrifuge to move with such force that they have been able to break through walls and cause personal injury.

The rotor, the primary component of the centrifuge, is the main safety concern. Rotors have a limited life span because of the high stress they are exposed to, which results in metal fatigue.

On the occasion of a failure, for example, if the centrifuge shell contained the rotor, the rotor can detach from the drive shaft and become a projectile. On the occasion, the rotor can protrude from the centrifuge as occurred in a

Wyeth

# eBAR....Adding value to the business

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- **eBAR = Electronic Biohazardous Agent Registration**
- **Web-based application, developed in house for worldwide use**
- **Facilitates worldwide compliance with biosafety regulations**
- **Replaced a variety of site-based paper forms**
- **Allows principal investigator to register and update:**
  - ▶ Recombinant DNA
  - ▶ Microorganisms
  - ▶ Human and Non-Human Primate Materials
  - ▶ Biological Toxins (microbial and non-microbial)
- **Allows site biosafety officer and biosafety committees to review and approve**
  - ▶ 45 site biosafety officers
- **Allows the Legal Department to monitor which sites have regulated agents.**

# What does eBAR look like?

## Biohazard Agent Registration (BAR)

### BAR

#### Home

Submit BAR Form

Search BAR Forms

Help

#### User

#### Administration

SBO Group

Administrator Group

Corporate Group

## Welcome to the Biohazard Agent Registration Application

- To submit a new online BAR Form click here.
- To search for existing online BAR Form click here.
- If you have any questions, comments, or concerns, please direct all inquires to your local Site Biosafety Officer.

### Who uses this application?

The biohazardous agent registration (BAR) application manages data and information related to biohazardous agents used or stored at any Wyeth research and development or manufacturing location. Principal investigators, laboratory managers and manufacturing managers use this application to submit a BAR form electronically for new projects and for periodic updates on existing projects.

Once submitted, a BAR form is automatically routed to the Site Biosafety Officer (SBO) responsible for that location. All reviews and approval are done on-line with email notifications sent when actions are taken.

To get more information, visit the on-line Help or download the [User Guide](#).

## Help

### BAR User Guide

Click here to download the BAR User Guide.

### Principal Investigator/Supervisor Use

How do I submit a BAR Form?  
 How do I update a BAR Form?  
 How does a Site Biosafety Officer(SBO) review a BAR Form?  
 How does an Authorized Reviewer and/or someone from the Corporate Group view a BAR Form?  
 How do I search a BAR Form(s)?  
 How do I generate BAR Form Reports?

### Application Administrator

How do I edit the Site Biosafety Officer(SBO) list?  
 How do I add users to the Administrative or Corporate groups?  
 How do I remove users from the Administrative or Corporate groups?

### General BAR Form

What BAR Form parts do I need to complete, if I choose yes for screening question 1?  
 What BAR Form parts do I need to complete, if I choose yes for screening question 2?  
 What BAR Form parts do I need to complete, if I choose yes for screening question 3?  
 What BAR Form parts do I need to complete, if I choose yes for screening question 4?  
 What BAR Form parts do I need to complete, if I choose yes for all the screening question?

### Edit Rights for Reports

PI/Supervisor  
 SBO  
 Corporate Group  
 Authorized Reviewers  
 Administrators Group

## PRINCIPAL INVESTIGATOR/SUPERVISOR USE

### How do I submit a BAR Form?

- Step 1. Access the BAR application at <http://insidewyeth.com/bar>. If you are not already logged into Insidewyeth, you will have to log in and then will be redirected to the BAR application. There is no need to log in separately to the BAR application – it uses your Insidewyeth login credential that is stored in Internet Explorer.
- Step 2. To create a BAR Form, click on the Submit Bar Form link on the left navigation or click on the here link from the first bullet on the right panel.
- Step 3. Complete all 4 screening questions on the Submit Bar Form page. Depending on the answers, different parts of the BAR Form will appear for the user to fill out. Refer to General BAR Form section for more details on which Parts of the BAR form are required.  
 Note: If all 4 screening questions are answered “No”, that indicates that the user does not store or use biohazardous materials. No BAR Form is required.
- Step 4. Click the Save & Next button after answering the 4 screening questions or click the Reset button to reset all fields on the page to their original values.  
 Note 1: As you proceed through the BAR Form, you must click Save & Next before leaving each page or your responses will be lost.

# Biohazard Agent Registration (BAR)

BAR

Home

**Submit BAR Form**

Search BAR Forms

Help

**User Administration**

SBO Group

Administrator Group

Corporate Group

## Submit BAR Form

Principal Investigators and Laboratory Supervisors, please answer the following questions regarding biohazardous materials that you may store or use in your research or QA/QC laboratory, or manufacturing facility. You will be the owner of this BAR Form. Click here if you need help getting started.

### Initial BAR Screening Questions

- \*1. Does your project involve recombinant DNA/RNA (including NIH exempt experiments) or genetic elements of microorganisms or toxins?  Yes  No
- \*2. Does your project involve infectious agents such as bacteria, viruses (including replication incompetent), viral vectors, fungi, chlamydia, rickettsia, parasites or prions? Note that this includes microorganisms used in QA/QC laboratories.  Yes  No
- \*3. Does your project involve human materials or non-human primate materials?  Yes  No
- \*4. Does your project involve biological toxins (microbial and/or non-microbial)? Note that this includes toxins used in QA/QC laboratories.  Yes  No

**WARNING: As you proceed through the BAR Form, you must click Save & Next before leaving each page or your responses will be lost.**

Save & Next

Reset

\* Required Fields

# Scope of Wyeth IBC's

- **Site may choose to have one committee to review Recombinant DNA and biohazardous materials, or both an IBC and a Biosafety Committee**
  - ▶ **Biohazardous Materials**
    - Microorganisms
    - Viral Vectors
    - Human Materials
    - Non-Human Primate (NHP) Materials
    - Biological Toxins (microbial / non-microbial)
- **Wyeth does not have any NIH funded grants or contracts**
- **Some sites are located in communities with rDNA Ordinances**



# Recruitment of IBC Members

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- **Wyeth Members**

- ▶ Representation from all departments or therapeutic areas

- **Community Members**

- ▶ Local communities are a good source (colleges & universities, businesses)
- ▶ Wyeth is a good neighbor (support events, sponsor internships)



# Site IBC / BC Membership

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- **IBC = BC + 2 community members**
- **Members from:**
  - ▶ Departments / Therapeutic Areas
  - ▶ EH&S / Biosafety
  - ▶ Occupational Health
  - ▶ Animal Care / IACUC
  - ▶ Laboratory Support Services
  - ▶ Other

# IBC / BC Meeting Logistics

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- **Corporate Biosafety Committee meets quarterly**
- **Site IBC's meet at least 1x/year**
- **Site BC's meet as needed, typically at least 2x/year**
- **The chair is NOT the Site Biosafety Officer**
- **Site Biosafety Officer facilitates the meetings**



# Care & Feeding of IBC Members

- IBC meetings typically held over lunch or dinner
- There is no honorarium for community members
- Wyeth pays for members (including community members ) registration at local conferences and seminars
- Many Wyeth sites promote “personal safety goal” that is agreed upon by employee and his/her supervisor and is included in employee’s goals for the year
  - ▶ IBC membership can be a personal safety goal



# Charters & Policies

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- **Corporate**

- ▶ 5 Biosafety Policies
- ▶ Corporate Biosafety Committee Charter

- **Sites**

- ▶ May have site specific biosafety policies that are based on the Corporate Policies
- ▶ IBC and BC Charters are site specific

# Public Transparency

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- **Some IBC's operate in communities where there are local ordinances:**
  - ▶ Cambridge & Andover, MA
- **Prior to 2009, one Wyeth site was registered with the NIH OBA as there was an NIH contract in place.**
- **IBC community members are the “eyes and ears” for the local community and understand their respective roles and responsibilities.**

# Project Review Process

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- **Principal Investigator (or lab manager or suite supervisor) completes an eBAR and submits the eBAR.**
- **eBAR routes to Site Biosafety Officer who reviews the eBAR for completeness and then:**
  - ▶ Approves the eBAR
  - ▶ Administrative approves the eBAR and then has review/approval by IBC or BC at next meeting
  - ▶ Requires full IBC or BC approval
- **eBARs are approved for one year**
  - ▶ Changes (personnel updates for example) are made by PI as they occur
  - ▶ Yearly update and resubmission are required

# Handling of Conflicts of Interest

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- **The PI cannot vote on his/her eBAR.**
- **The goal is to reach consensus rather than a count of yes or no “votes”.**
- **Site IBCs and BCs are encouraged to request assistance from the Corporate Biosafety Committee if they would like an eBAR review, have questions or concerns, or cannot come to consensus.**

# Strategies for Capturing All Research

- **IBC/BC Committee Membership has representation by all therapeutic areas at the site.**
- **The Site Biosafety Officer is seen as “friend” and as someone who can facilitate the research.**
- **The Site Biosafety Officer actively works with all levels of the department to learn of proposed new projects.**
  - ▶ Semi-Annual VP “Walkabouts”
  - ▶ Quarterly inspections by Lab Safety Reps
  - ▶ Metrics for eBAR reviews
- **Safety is included in yearly performance review.**



# IBC / BC / IACUC Interactions

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- IBC's and BC's include members from site IACUC (typically veterinarians)
- IACUC's include members from EH&S / Biosafety
- IACUC's require "hazard form" completion and review and signature from Biosafety Officer for any in-vivo use of biohazardous materials
- eBAR requires IACUC protocol number
- IACUC protocol requires eBAR number



# Medical Surveillance



- **Corporate and site based programs**
- **New hire physicals**
- **Surveillance programs based on materials of concern:**
  - ▶ Vaccinations
    - HBV offered for human material use
    - Project specific (e.g. rabies)
  - ▶ Animal Allergy
  - ▶ PPD Testing (for CFA use, NHP work)
  - ▶ Chemicals and other hazards



# Training

- **IBC Members**

- ▶ Site Biosafety Officer provides training for new members
- ▶ R&D Site Biosafety Officers are completing an online training program for IBC Members in late 2009

- **Laboratory/Scientific Personnel**

- ▶ New hire biosafety training
- ▶ Periodic retraining (e.g. yearly for bloodborne pathogens)
- ▶ Group-specific training
- ▶ Other (biosafety cabinet use, sharps safety, lentivirus lab, etc.)



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# Industry-Based IBCs Are Unique...

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- There are no NIH-funding sources, therefore no registration with NIH OBA is necessary....but the NIH Guidelines are considered the gold standard.
- Employees have personal safety goals and the fact that safety is included in performance reviews motivates employees.
- Resources are available for developing and implementing corporate-wide applications such as eBAR that provide consistency and compliance across the corporation.

# Questions?

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**Betsy Gilman Duane**  
**[egilman@wyeth.com](mailto:egilman@wyeth.com)**



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