

# Biotechnology

## Basics of the Industry

- What is Biotech?
- How are they funded?
- Prospect to Prescription – How a drug comes to market
- Research Facilities – The Basics
- Research Facilities – Generic Lab Space
- Research Facilities – What does it cost?
- Biosafety Levels
- Manufacturing Space
- Vivarium Space
- 7X24 Biotech Mission Critical Components

# What is “Biotech”?

- Research Institutions (UW, Hutch, SBRI, ISB)
- Pharmaceutical (Merck, Eli Lilly, Pfizer)
- Therapeutics (Amgen, Icos, Chiron)
- Diagnostics (Biocontrol, Ostex)
- Genomics/Informatics (Rosetta, Combimatrix)
- Agriculture (Alcide, Eden Biosciences)

# How Are They Funded?

- Federal Government Grants
- National Institute of Health Grants (NIH)
  - Direct vs. Indirect Cost Allocation
- Private Placements
  - Venture Capital, Angel Investors
- Public Market / IPO
- Pharmaceutical Licensing agreements

# Prospect to Prescription

## How a drug comes to market

<p><b>Discovery</b> →</p> <ul style="list-style-type: none"> <li>● Genomics</li> <li>● Inpharmatics</li> <li>● Comb. Chem.</li> <li>● 2 – 10 Years</li> </ul>	<p><b>Pre Clinical</b> →</p> <ul style="list-style-type: none"> <li>● Lab &amp; Animal Testing to test efficacy and side effects</li> <li>● 1-4 Years</li> </ul>	<p><b>Phase I Trial</b> → (20 – 80 patients)</p> <ul style="list-style-type: none"> <li>● Study safe dosing in Humans</li> <li>● 1-2 Years</li> </ul>	<p><b>Phase II Trial</b> → (100-300 patients)</p> <ul style="list-style-type: none"> <li>● “Proof of Principal”</li> <li>● Test drug efficacy and safety (side effects) in Humans</li> <li>● 2 Years</li> </ul>
<p><b>Phase III Trial</b> → (350 – 5,000 patients)</p> <ul style="list-style-type: none"> <li>● Drug tested in larger, more diverse population</li> <li>● 2-3 Years</li> </ul>	<p><b>“NDA”</b> → (New Drug Application)</p> <ul style="list-style-type: none"> <li>● Submit all clinical data to FDA</li> </ul>	<p><b>FDA Review</b> →</p> <ul style="list-style-type: none"> <li>● FDA reviews NDA Assessing the quality of Research, Efficacy and Safety data</li> <li>● 1-2 Years</li> </ul>	<p><b>Approve/Reject/More Data</b></p> <ul style="list-style-type: none"> <li>● FDA Panel approves or rejects application. May also request more data or additional studies</li> </ul>

# Research Facilities

## The Shell Basics

- Minimum 14' floor to floor heights
- 125 lb/sf live floor loading
- 40 watts per square foot power
- Natural Gas
- Ample Water

# Research Facilities

## Generic Lab Space

- 100% outside air with a minimum of 6 air exchanges per hour
- Lab benches, Fume Hoods, Biosafety Cabinets
- Multiple Equipment Rooms
  - Tissue Culture, Cold & Warm Rooms, Vivarium, Chemistry labs, Dark rooms, Freezer room, incubators,
- Deionized Water systems, glass wash, autoclave, CO<sub>2</sub>, Gas, Vacuum
- Back up emergency power

# Research Facilities

## What does it cost?

- 50% Generic Lab / 50% Office
  - \$150 – 250/sf
  - 35% - 45% mechanical cost
  - 25% - 35% electrical cost
- GMP Manufacturing Space
  - \$250 – 650/sf
- Vivarium Space
  - \$250 – 450/sf

# Biosafety Levels

- The term “containment” is used in describing safe methods for managing the laboratory environment
- 3 elements of containment
  - Laboratory practice and technique – Good Laboratory Practices (GLP)
  - Safety Equipment
  - Facility design and construction
- Four Primary Biosafety Levels
  - BSL 1, BSL 2, BSL 3, BSL 4

# Biosafety Level 1 (BSL 1)

- Work with agents with little potential hazard to lab personnel and the environment
- Lab not generally separated from the general traffic patterns in the building
- Special containment not necessary
- Similar to a high school biology lab

# Biosafety Level 2 (BSL 2)

- Work with agents with moderate potential hazard to lab personnel and the environment
- Facility designed to enhance containment
  - 100% outside air handling with a minimum 6 air changes per hour
  - Fume hoods and Biosafety cabinets also used
  - Certain Systems and Equipment designed with redundancy
- Typical of approximately 90% of quality research labs in Puget Sound Region

# Biosafety Level 3 (BSL 3)

- BSL 3 space is required for companies working on infectious disease research
- 100% air exchange rate bumps to 15-20 per hour with full redundancy in mechanical equipment and power supply
- Usually hepafiltered, require gowning procedure prior to entry through and air locked facility

# Biosafety Level 4 (BSL 4)

- BSL 4 space is required for work with dangerous agents that pose a high risk of aerosol transmitted infections
- Examples of this space can be found at Centers for Disease Control
- None exists in WA

# Manufacturing Space

- Facilities built to meet all Good Manufacturing Practices (GMP) Guidelines and must be validated by the FDA
- Typically involve class 10k clean room environment, either BSL 2 or BSL 3
- Mechanical and Electrical Systems are typically designed with significant redundancy
- Facility failure can cost company millions in lost revenue

# Vivarium Space

- Animal Research Facility
- AAALAC Accreditation
  - "Association for Assessment and Accreditation of Laboratory Animal Care."
- Typically BSL 3 space with a minimum of 15 air exchanges per hour
- Requires significant redundancy
- [www.aaalac.org](http://www.aaalac.org)

# **7 X 24 Biotech**

## **Mission Critical Components**

- Lab space
  - GMP – FDA Validated Facilities
  - Vivarium Space
  - BSL 3 & BSL 4 Research Labs
  - Intensive Chemistry Lab

# **7 X 24 Biotech**

## **Mission Critical Components**

- **Equipment**
  - Fume Hoods
  - Biosafety Cabinets
  - Incubators
  - Freezers

# **7 X 24 Biotech**

## **Mission Critical Components**

- **Data**

- Genomics and Informatics Companies are relying more on data center reliability
- Still small scale users of rack space

# 7 X 24 Biotech

- The 7x24 Exchange Northwest Chapter's mission is to focus on the key disciplines of *design, construction, maintenance, security and management* with the goal of obtaining continuous data center operations.