

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

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, CO₂, 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

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Mission Critical Components

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

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Mission Critical Components

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

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Mission Critical Components

- **Data**

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

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- 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.