Biotechnology Industry

Which job will be yours?
Types of Companies

- Research and Development
- Full Service: single product line
- Full Service: diversified product lines
- Contract Manufacturers
Chief Executives

- CEO: Chief Executive Officer
- COO: Chief Operations Officer
- CIO: Chief Information Officer
- CFO: Chief Financial Officer
- VP Research and Development
- VP Medical or Medical Affairs
- VP Sales and Marketing
- General Counsel: Legal Department
Organizational Structure

CEO

VP R&D
- PhD scientists
- Research Assistants
- Lab Assistant

VP Medical
- Clinical Affairs
- Regulatory
- Medical Affairs
- Genetic Counselor
What does the Medical Dept. do?

- Oversee Medical Affairs
  - Patient data from clinical trials
  - Follow up on complaints especially if pt. dies

- Oversee Clinical Affairs
  - Authors and designs clinical trials
  - Compiles data and monitors clinical trials
  - Statisticians often times work in this group

- Oversee Regulatory Affairs
  - Primary liaison with FDA
  - Follows up on customer complaints
What do the folks in R&D do?

- VP: new product input and selection
- Scientists: design and direct experiments
- Research Assistants: execute experiments
- Lab Assistants: make reagents, clean glassware, run simple assays
Employment Opportunities

- Biotech offers something for everyone
  - High school diploma
  - Associates degree
  - Bachelors degree
  - Masters degree
  - Doctorate degree
Operations

- Manufacturing
  - Formulate, fill, finish
  - Group who makes the product, fills the product, labels and gets it packed for shipping
  - This area may involve a variety of different manufacturing techniques such as chromatography, fermentation, formulation of bulk liquids or powders, etc.

- Quality Control
  - Inspect materials at all stages
  - Tests materials at all stages
  - Stability studies on finish goods
Operations

- Quality Assurance
  - Document Control
  - Audits (internal and external)
  - Batch Record Review

- Materials
  - Group who receives raw materials and ships finished goods
  - Warehouse personnel
Engineering

- **Bio-process Engineer**
  - Helps to design, purchase, install, and validate new equipment and processes
  - Will work with manufacturing to optimize processes to improve yields and efficiency

- **Metrology**
  - This group will calibrate and inspect equipment such as balances, centrifuges, etc.
Finance and Accounting

- Accounts payable: pay for inventory
- Accounts receivable: collect cash for sales
- Finance: balance the books
Information Technology

- All networking and database management
- Help desk calls
- All employee computer issues
- Software for all functions
- Audit trails of users and transactions
General Counsel

- Almost all biotech companies have a legal department.
- They handle lawsuits, SEC filings, patent filings, etc.
- Often times a lawyer will be the Compliance officer for the company.
Matching the degree to the job

- What type of jobs require a high school diploma?
- Which ones require a BS degree?
- Which ones require a Masters degree?

- Fill and labeling
- Testing finished products
- Water testing
- Follow up on clinical trial
- Receiving incoming materials
- Lawyer
- Accountant
- Typist for documents
- Auditor
Matching the degree to the job

- What type of jobs require a high school diploma?
  - Fill and labeling: HS/AS
  - Testing finished products: AS/BS
  - Water testing: HS/AS
  - Follow up on clinical trial: BS/Masters
  - Receiving incoming materials: HS/AS
  - Lawyer: BS and then Law degree (MS)
  - Accountant: AS/BS
  - Typist for documents: HS/AS
  - Auditor: AS/BS/MS

- Which ones require a BS degree?

- Which ones require a Masters degree?
Matching the degree to the job

- Which jobs require a BS?
  - Genetic counselor
  - Medical Affairs director

- Which job requires a Masters?
  - CEO
  - Vice President of R&D
  - QC Supervisor

- Which job requires a PhD?
  - Sales and Marketing Manager
Matching the degree to the job

- Which jobs require a BS?
- Which job requires a Masters?
- Which job requires a PhD?

- Genetic counselor: BS
- Medical Affairs director: MS or PhD
- CEO: MS or PhD
- Vice President of R&D: PhD
- QC Supervisor: BS or MS
- Sales and Marketing Manager: BS or higher
Skills Required

- The following skills are required for ALL jobs in biotechnology
  - Safety skills and awareness
  - Basic lab skills and familiarity w/lab
  - Knowledge of cGMP