Biotechnology
Quality Assurance & Quality Control
Formal Definitions of Biotechnology

1. The use of microorganisms, such as bacteria or yeasts, or biological substances, such as enzymes, to perform specific industrial or manufacturing processes.

2. The application of the principles of engineering and technology to the life sciences; bioengineering.
Biotechnology is Not New

- Biotechnology has been in use for **centuries** to produce:
  - Wine, Beer
  - Cheese
  - Antibiotics
  - Bread
  - Water treatment
Biotechnology Today

Modifying biological organisms to create
- new **products**
- organisms with new **functions**
What does that mean?

- Bacteria usually make proteins useful for bacteria
- If you provide it *human* genetic information it will make *human* proteins
- The same with Sheep, provided with Human genetic information they can make Human proteins
  - Dolly made human factor IX a human protein used as medicine for Hemophilia A
Human Medicine

Human Growth Hormone

In 1983 scientists at the Universities of Pennsylvania and Washington inserted human growth-hormone genes into mouse embryos, producing a giant mouse (right). This was the first time that a human gene functioned in another animal.

Eyes of hope. Ten-year-old Tracy Moreno of California (above), born with a growth-hormone deficiency, grew five inches in one year of treatment with a man-made hormone.
What do Biotech companies make?

- **Drug**
  - A substance used in the diagnosis, treatment, or prevention of a disease or as a component of a medication. b. Such a substance as recognized or defined by the FD&C Act

- **Biologic**
  - Derived from living material--human, plant, animal, or microorganism--and they're used for the treatment, prevention or cure of disease in humans.
Goal of the FDA cGMPs

3-fold goal of the cGMPs is to provide a product:
- which is safe and meets the purity that it is stated to possess
- which meets the same specifications at the expiration date as when packaged
- for use in human clinical studies that is identical to the marketed product
Assuring the FDA that your Drug is Safe, Pure, & Meets Specifications

- How would you establish data to support your conclusion that it is safe, etc.?
- What is the name for this department?
- Are a second pair of unbiased eyes useful?
- What is the name for this department?
Biotechnology Sectors

- Human Health - pharmaceuticals, biotech companies
- Medical Devices, Equipment/Supplies, Bioengineering
- Food Production and Processing
- Nanotechnology
- Ag-Bio (BT & Potato examples)
- Aquaculture/Marine Biotechnology (Salmon)
- Environment
- Forest Products
- Industrial Biotechnology
- Mining/Energy/Petroleum/Chemicals
- Forensics
Forensics

- CSI fact or Fiction?

Rough landing for exonerated inmate

He’s one of 159 who have been freed after DNA testing

By Anna Badkhen

Baton Rouge, La. — As so often happens lately, Michael Anthony Williams is lost.

The driver’s license examiner towers over him, rattling off orders through the rolled-down window on the driver’s side. But at each command, Williams, 40, hesitates. He signals to the left when he is told to turn right. He forgets to turn off the windshield wipers.

He fails the test, another blow in Williams’ quest to put together a life that was taken from him when he was just a boy.

At the age of 16, a sophomore in Jonesboro High School in northern Louisiana, he was arrested and convicted of raping his female math tutor. He spent 24 years in the Angola state penitentiary. Two months ago, he walked free. A DNA test — which didn’t exist when he was growing up — proved what Williams had claimed all along: the state had gotten the wrong man.

Now, like dozens of others wrongly accused and subsequently exonerated, a bewildered, once-young man finds himself, without resources, thrown into a world with which he is entirely unfamiliar.

Tasks that are second nature for most adults — using a cell phone, leaving a voice message, — EXONERATED: Page A8
Biotech started in San Francisco

- It started with Dr. Herbert Boyer at UCSF and Dr. Stanley Cohen at Stanford discovering they could make **bacteria** express **human proteins**.
- Based upon that discovery they started...
Genentech : a new company

It began in a warehouse in South San Francisco
And turned into…..
Genentech (Roche): Today

- 100 acre So. SF campus employing >8000 people
Today the Bay Area is the world’s Hot spot of Biotechnology with over 700 companies connected to Biotech!
Drug Development

- Basic research “formation of the idea, concept”
- Developmental research “How do you make the idea practical?”
- Commercial development” How do you make it economically & production feasible?”
- Product lifetime development “Are there other applications?”
Manufacturing from Door to Door:

- Receiving/warehousing
- Inspection
- Quality Assurance
- Reagent Prep
- Manufacturing
- Formulation
- Filling / Finishing
- Inspection
- Quality testing
- QA review /release
- Shipping
Manufacturing

Raw Materials

Fermentation

Production

Packaging and Labeling

Holding and distribution

Shipping

Stores/pharmacies/doctors

Patient/customer With drug

Quality Control

Quality Assurance

Management

Janitorial

Regulatory Affairs

Records Department

Components, Containers, Closures

Quarantine

test

Release/reject
Inspection / Quality Assurance

What testing would be performed here?
Manufacture / Fermentation

What testing would be performed here?
Purification

What testing would be performed here?
Quality Control Testing

What testing would be performed here?
On average _______ compounds in 1000 make it to clinical (human) trials?
FDA obligations

**Discovery/Preclinical Testing - 6.5 Years**
Laboratory and animal studies to assess safety, biological activity and formulations
5,000 compounds evaluated

**Phase I - 1.5 Years**
20-100 healthy volunteers
Scientists study how the drug works and whether it is safe
5 compounds enter clinical trials

**Phase II - 2 Years**
100-500 patient volunteers
Drug is tested to evaluate effectiveness, look for side effects

**Phase III - 3.5 Years**
1,000-5,000 patient volunteers
Drug is tested to confirm effectiveness, monitor adverse reactions from long-term use

**FDA Review - 1.5 Years**
Drug review process and approval
NDAs typically run 100,000 pages or more
1 compound is approved

**Phase IV**
Additional post-marketing testing required by FDA
Current Example of Quality Control
Non-compliance
Current Example of Quality Assurance Non-compliance