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

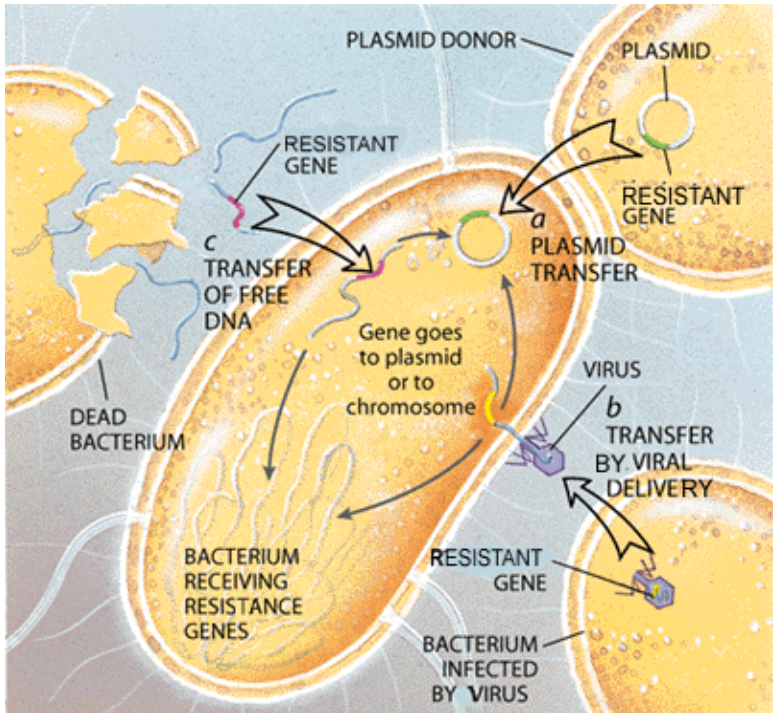
- Biotechnology has been in use for **centuries** to produce:
- Wine , Beer
- Cheese
- Antibiotics
- Bread
- Water treatment

Biotechnology Today

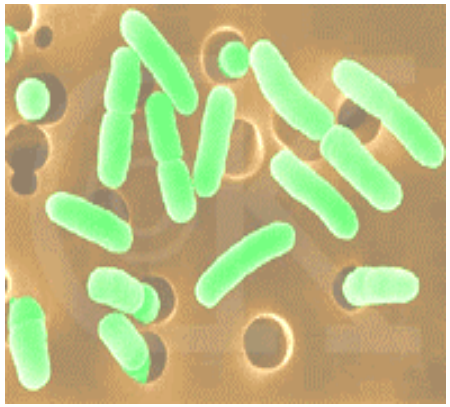
Modifying biological organisms to create

-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

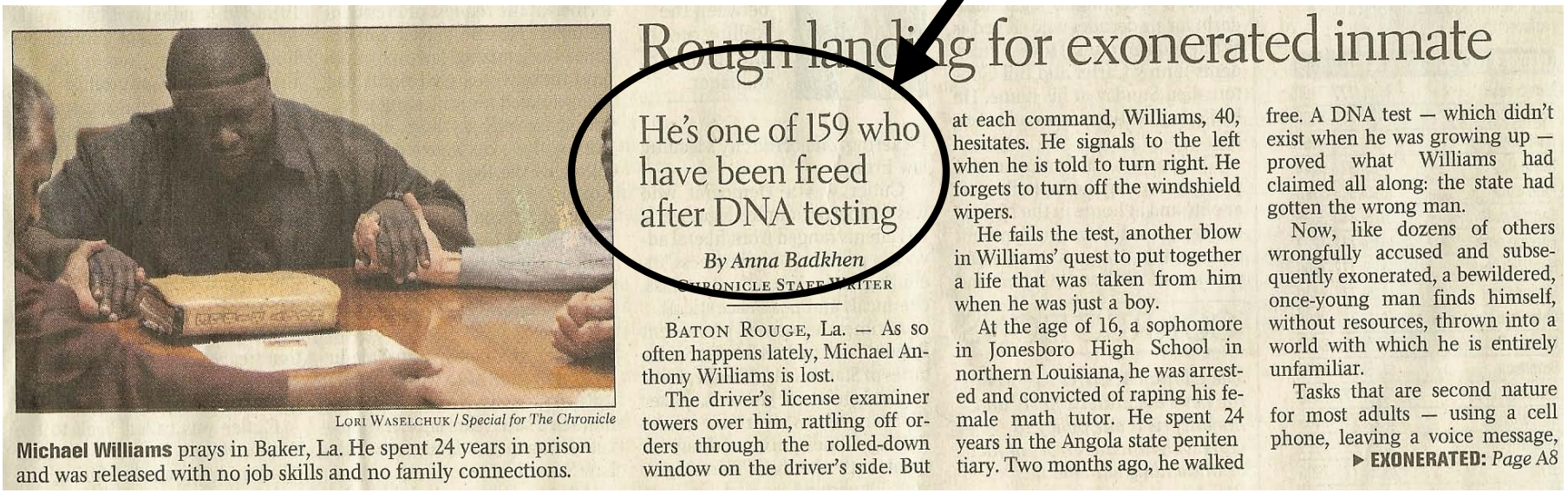
- How would you establish data to support your conclusion that it is safe, etc.?
- What is the name for this department?
- Are a second pair of unbiased eyes useful?
- What is the name for this department?

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?



LORI WASELCHUK / *Special for The Chronicle*

Michael Williams prays in Baker, La. He spent 24 years in prison and was released with no job skills and no family connections.

Rough landing for exonerated inmate

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

By Anna Badkhen

CHRONICLE STAFF WRITER

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 wrongfully 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

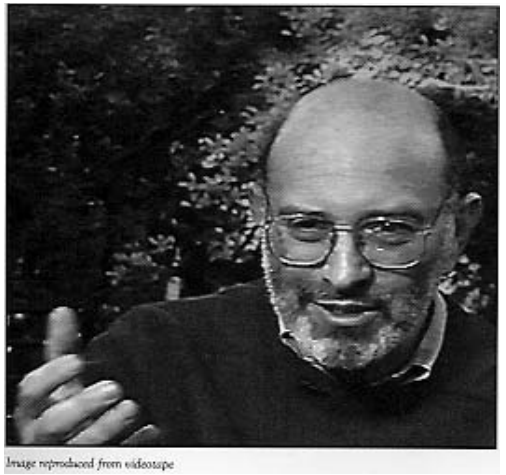


Image reproduced from videotape

- 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

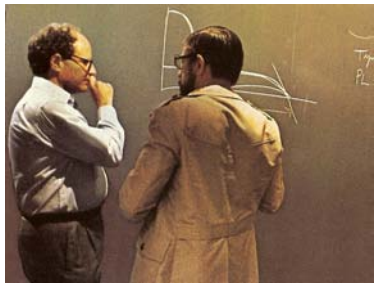
And turned into…..

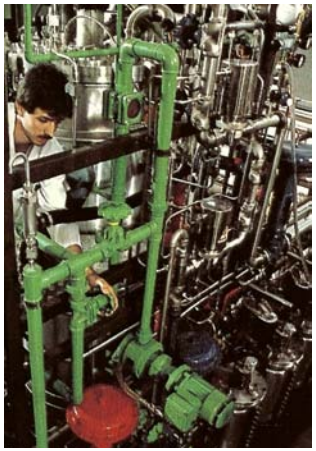
Genentech (Roche): Today

- 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

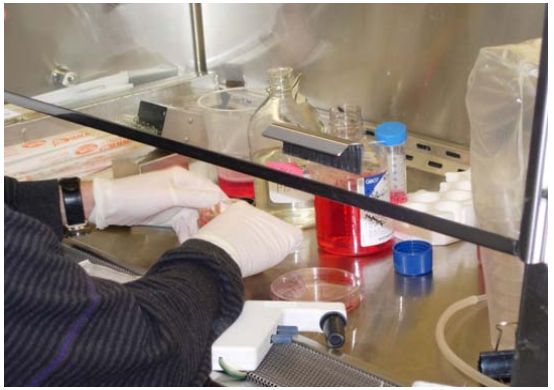




- Basic research “formation of the idea, concept”
- Developmental research “How do you make the idea practical?”
- Commercial development” How do you make it economically & production feasible?”
- Product lifetime development “Are there other applications?”

Idea or research interest

Academic Research ← Research → Company R&D



DISCOVERY!!

In vitro
cell lines
Tissues
Animal studies

Clinical Trials
Phase I
Phase II
Phase III

Manufacturing

Manufacturing from Door to Door:

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

Quality Control

Quality Assurance

Management

Janitorial

Regulatory Affairs

Records Department

Components, Containers, Closures

Manufacturing

Raw Materials

Quarantine

test

Release/reject

Fermentation

Production

Packaging and Labeling

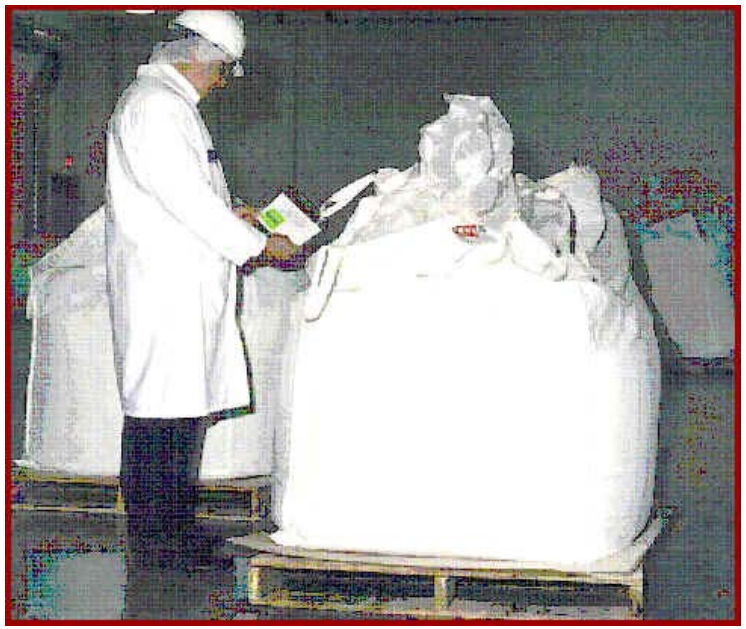
Holding and distribution

Shipping

Stores/pharmacies/doctors

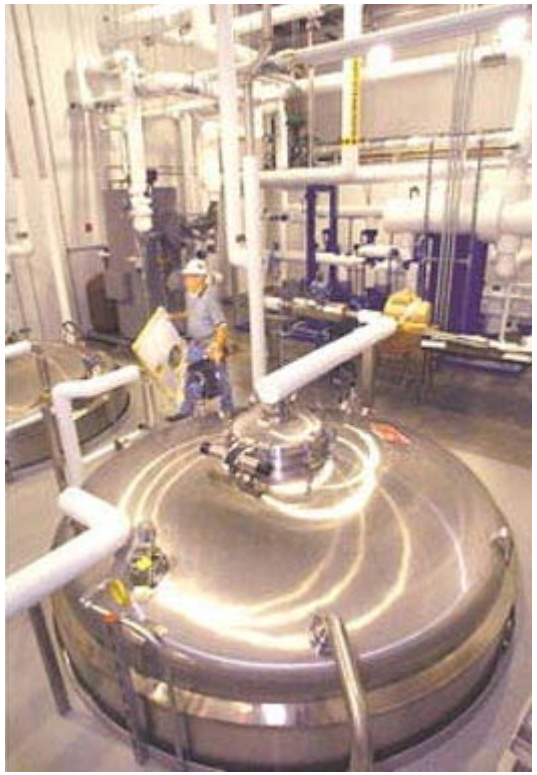
Patient/customer
With drug

Inspection / Quality Assurance



What testing would be performed here?

Manufacture / Fermentation



What testing would be performed here?

Purification

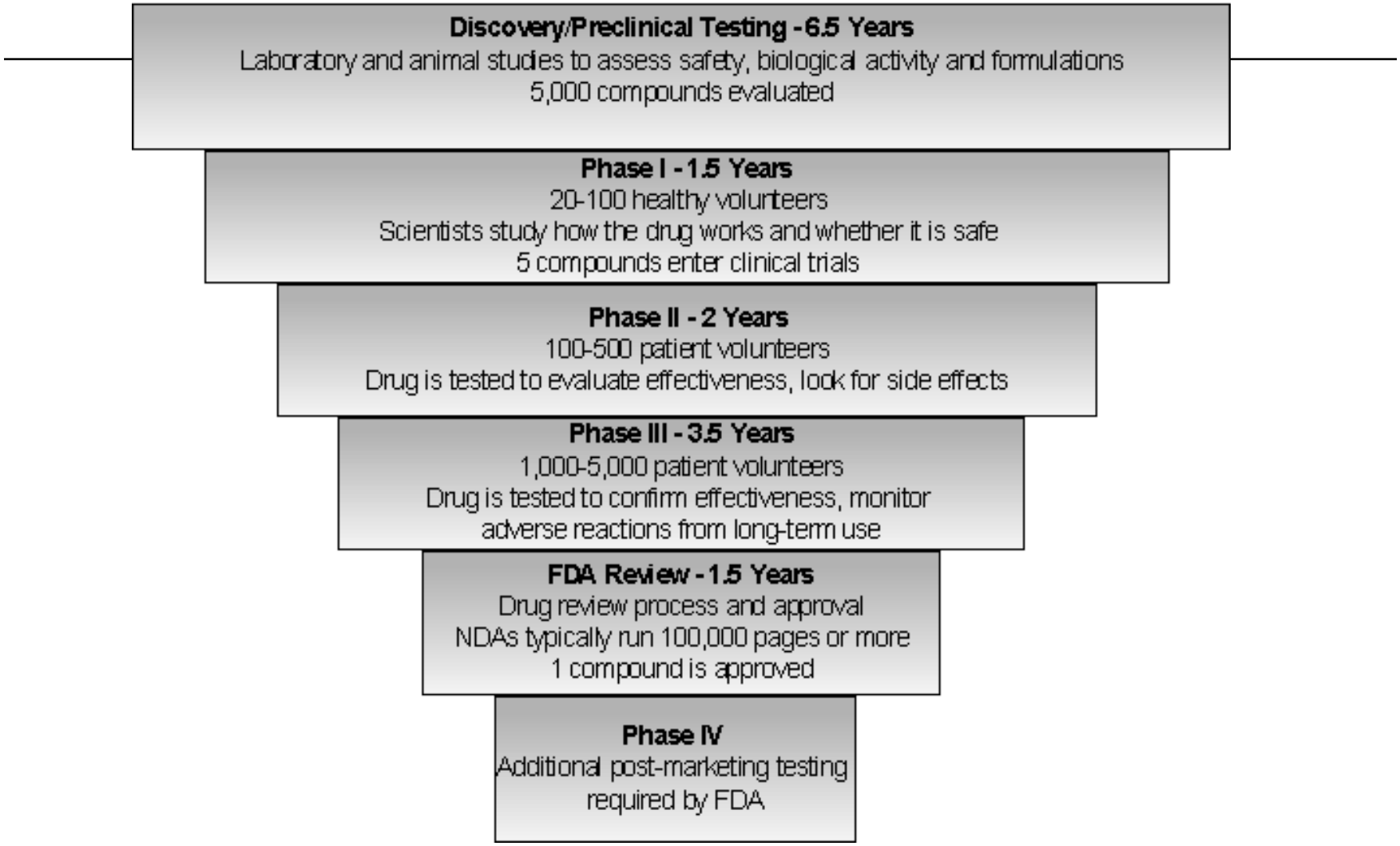
What testing would be performed here?

Quality Control Testing

What testing would be performed here?

On average _____ compounds in 1000 make it to clinical (human) trials?

FDA obligations



Current Example of Quality Control Non-compliance

Current Example of Quality Assurance Non-compliance