

Drug Chemistry and Technology Basics,
Cleaner Production and Mega-Trends in Pharmaceutical Industry

Trends in Pharmaceutical Industry

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Questions

1. What are pharmacopoeias?
2. What are their functions?
3. Tell about the International Pharmacopoeia
4. Tell about the European Pharmacopoeia
5. Describe the overall structure of any Pharmacopoeia



LECTURES

- 1. Introduction**
- 2. Terminology of Drugs**
- 3. Drug Design and Quality standards**
- 4. Falsification of Medicines**
- 5. Quality Assurance in Medicines**
- 6. Control by Pharmacopeias**
- 7.  Trends in Pharmaceutical Industry**

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The fight against new and existing threats

Newer diseases or old diseases in newer forms emerge periodically:

- ✓ severe acute respiratory syndrome (SARS)
- ✓ multi-drug resistant tuberculosis
- ✓ Ebola fever
- ✓ hepatitis C etc.

No anticancer drug yet exists that acts as a magic bullet – as is the case with penicillin and infectious diseases – although drugs are used to treat cancer patients, and in some cases lives have been extended through their use

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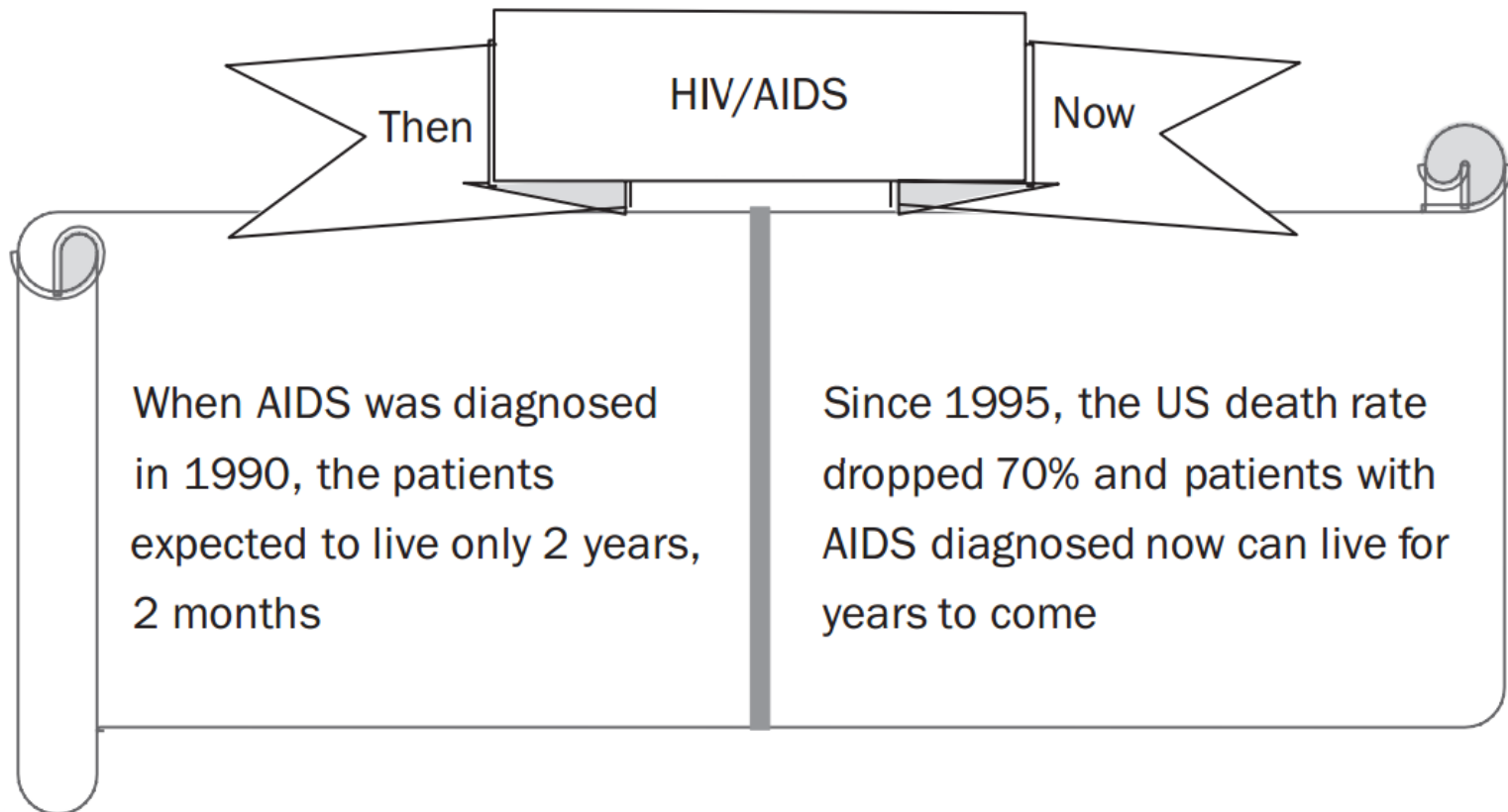
Increasing longevity of life

The pharmaceutical industry developed a number of medicines and antiretroviral drugs against Acquired Immune Deficiency Syndrome (AIDS), such as tenofovir, atazanavir, AZT, which can prolong lives of AIDS patients when are taken in combination

It is expected that there will be an **AIDS vaccine** on the market within the next few years (Currently, there is no effective HIV vaccine but many research projects managing clinical trials seek to create one)

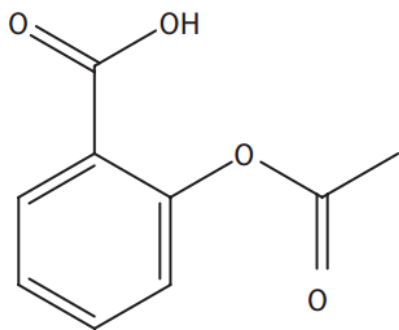
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Increasing longevity of life

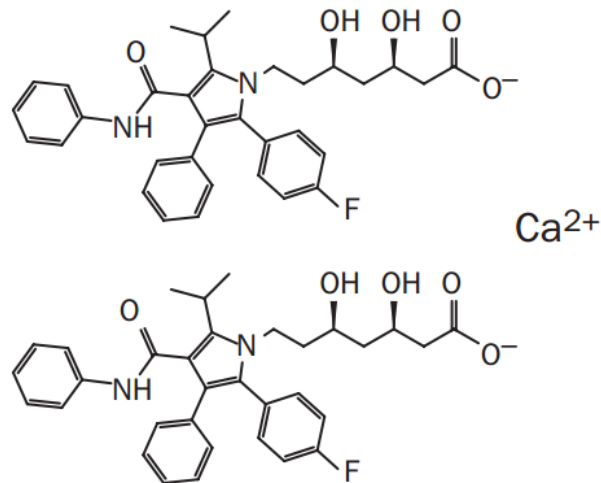


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Complexity of drugs



Acetylsalicylic acid
(aspirin), Bayer, 1899



Atorvastatin (Lipitor),
Pfizer, 1996



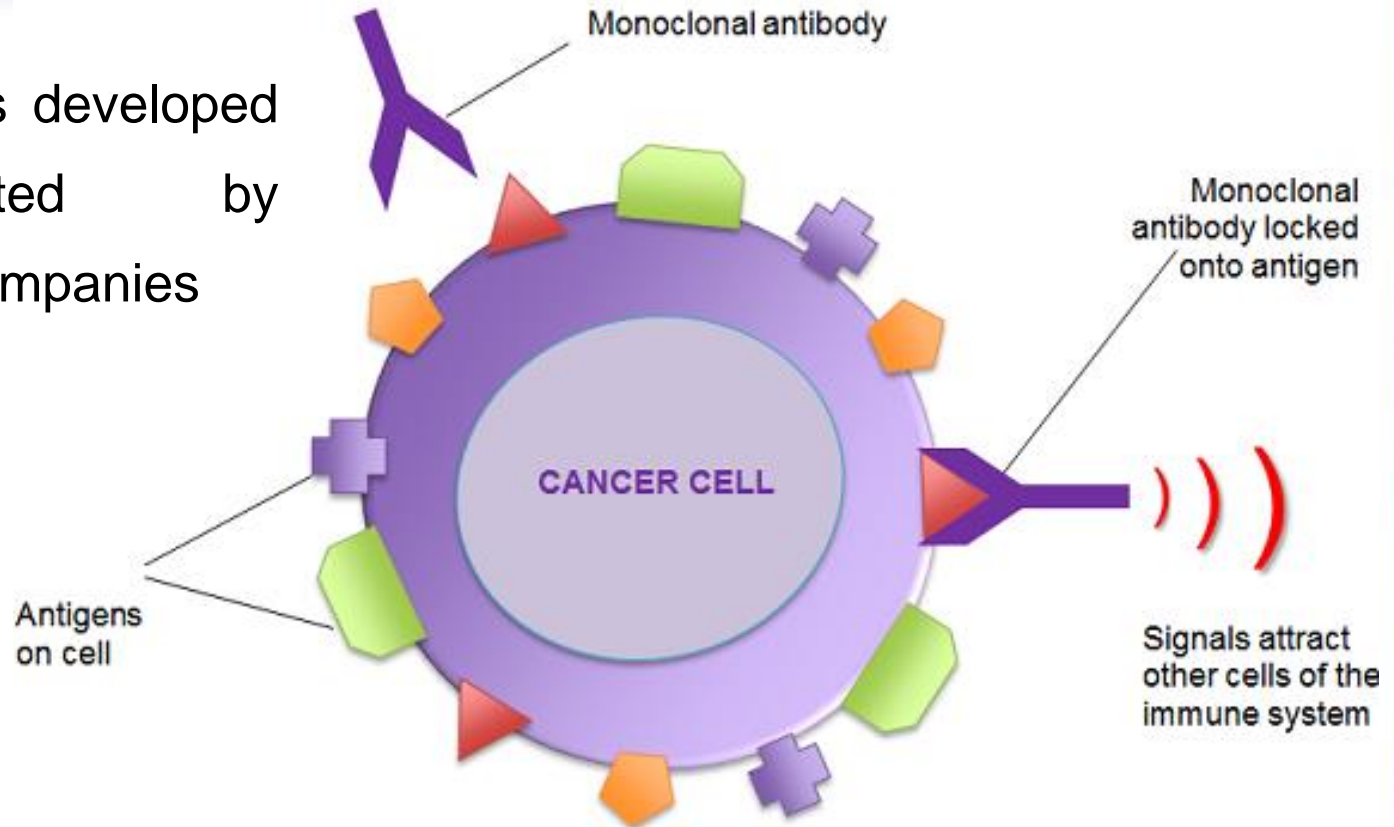
Bevacizumab (Avastin),
Genentech/Roche, 2004

Structural complexity with time; evidence of technological advancement

Monoclonal antibody (mAb) drugs

Anticancer drugs developed and marketed by biotechnology companies

(alemtuzumab, bevacizumab, trastuzumab etc.)



One innovative idea is to use them to **make cancer cells more recognizable as foreign** by our bodies' immune systems, so they can fight against the cancer cells

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Personalized medicine

One drug does not fit **everyone**

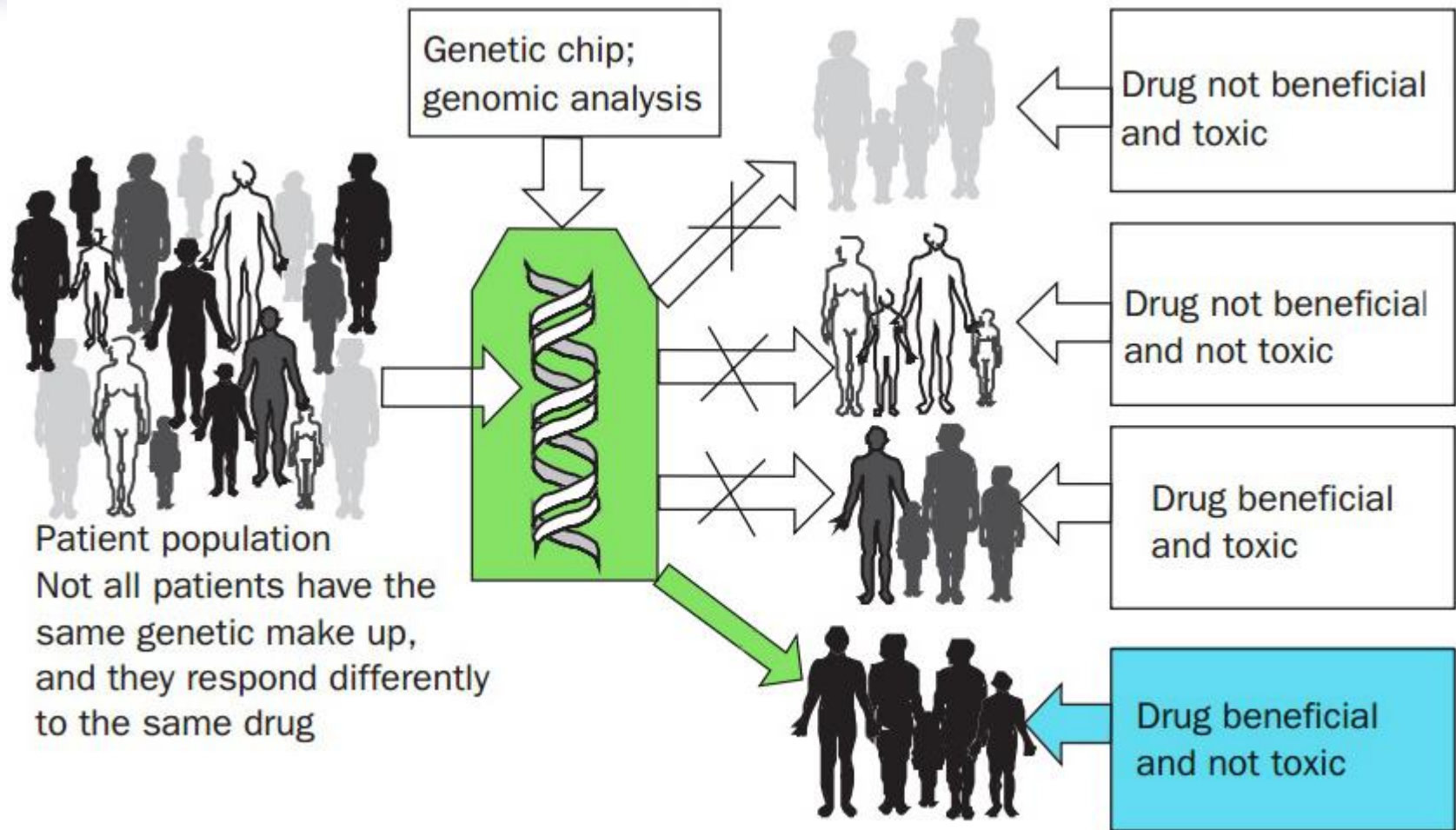
*In 2010 the US FDA announced a new boxed warning on the anticlotting drug **clopidogrel (Plavix)**, explaining that it can be less effective in people who cannot metabolize the drug to convert it to its active form. So this drug is less effective for people with a variant gene for a liver enzyme, which catalyzes clopidogrel to its active form*

An analysis of an individual's genomic data can show possible responses to a particular drug

The future of the pharmaceutical industry depends on who can provide personalized medicine:

- ✓ early diagnosis of certain chronic diseases
- ✓ better diagnosis and choosing the best course of treatment

Personalized medicine



Personalized medicine



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Treatment of the increasing ageing population

(treating of age-related chronic illness, such as Alzheimer's disease, Parkinson's disease, dementia, arthritis, cancer, a destructive eye disease, or type II diabetes)

Controlled-release drugs

(using biodegradable polymers, dendrimers, electroactive polymers, modified C-60 fullerenes)



3 Phase Tablets

Concerta® XL is a convenient once daily formulation using a sophisticated **3-phase delivery system** that allows 12 hour symptom control to cover the full active day

The immediate release component provides effective relief from symptoms in the first one to two hours after taking

The extended release components gradually release the remaining MPH (methylphenidate), providing ADHD (Attention Deficit/Hyperactivity Disorder) symptom control for school and home

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Biopharmaceuticals or biologics market potential

Biologics are pharmaceutical drug product manufactured in, extracted from or semisynthesized from **biological sources** (*different from chemically synthesized pharmaceuticals*)

They include **vaccines, blood, blood components, allergenics, somatic cells, gene therapies, tissues, recombinant therapeutic protein**, and living cells used in **cell therapy**

They are isolated from natural sources – human, animal, or microorganism (*not well defined structure and very difficult to characterize*)

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Biotechnology – a way forward

Modern **biotechnology** has widespread applications in the production of biopharmaceuticals, vaccines, and diagnostics

*Human insulin was the first biotechnologically produced medicine, developed and produced by Genentech and marketed by Eli Lilly. The first modern biotechnology company, **Genentech** (acquired by **Roche** in 1999), had great success in producing a number of biopharmaceutical products*

Stem cell therapy – hope for the future

Every cell in the body originates or stems from **stem cells**. After receiving instructions from the body, stem cells start to divide to make certain genes or new proteins

Medical and pharmaceutical researchers believe that stem cell therapy has **the potential to cure chronic diseases**. Current stem cell therapies include bone marrow transplants to treat leukemia and other cancers

What are stem cells and How can they be used for medical benefit



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A graphic showing a molecular structure with blue and white spheres connected by lines, set against a light blue background.

Technology and automation

The introduction of **automation** and **robotics** with the ability to identify new drug candidates out of millions of compounds. In addition, the use of advanced **bioinformatics** helps scientists create computer-aided design of new drugs, and understand the molecular pathways of diseases and the three-dimensional structure of proteins

The future pharmaceutical R&D work force

R&D has always been a primary sector in the development of the pharmaceutical industry and will remain so. The future pharmaceutical R&D work force will remain **multidisciplinary** but more inclined towards areas related to **molecular genetics**

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Stronger generics markets in future

Once the patent is off, generic companies launch generic equivalents

Two factors gain generic drugs immediate access to the market:

- ✓ reduced cost for consumers
- ✓ guarantee by a drug control authority of their safety, quality, and efficacy

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Emerging new markets

For many years, the **USA**, European countries such as **Germany, UK, France, Italy**, and **Spain**, and **Japan** were the leading global pharmaceutical markets

But more recently countries from **Asia** and **Latin America** have emerged with remarkable market growths

China, Brazil, Russia, and **India** in particular have emerging new markets



Thank You !

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