



EUROPA<sup>B</sup>BIO<sup>TM</sup>

The European Association for Bioindustries

## Healthcare Biotechnology: Using the human body's own tools and weapons to fight diseases

**Biotechnology aims to target the causes of diseases and not the symptoms. And that's why biotechnology offers one of the strongest hopes for patients to treat diseases. Biotechnology offers patients a variety of new solutions such as:**

- **Unique, targeted and personalized therapeutic and diagnostic solutions for particular diseases or illnesses**
- **An unlimited amount of potentially safer products**
- **Superior therapeutic and diagnostic approaches**
- **Higher clinical effectiveness because of the biological basis of the disease being known**

### Introduction

- Biotechnology medicines and therapies use proteins, enzymes, antibodies and other substances naturally produced in the human body to treat diseases, including genetic disorders. Biotechnology also uses other living organisms - plant and animal cells, bacteria, viruses and yeasts – in the large-scale production of medicines for human use.
- Biotechnology produces information that is used to alter and improve cell behaviour. Many biotech companies specialise in finding ways to deliver and apply biotechnology information to cells to aid in identifying, preventing and treating disease. Representative applications include diagnostic tests that use biotechnology materials to detect the presence or risk of disease such as cancer, genetic diseases or pollution of a cell or material
- There are three primary areas in healthcare in which biotechnology is currently being used: medicines (also including advanced therapies such as cell and gene therapy), vaccines and diagnostics

### So why do they cost so much?

- Many years can be spent in identifying the therapeutic molecule, determining its genetic sequence and working out a process to make the treatment stable, biologically active and reproducible. As a result, the biotech industry spends more on research and development (about 20-25% of revenue) compared to the mainstream pharmaceutical industry (about 15% of revenue).
- A biotech treatment requires specialised and complex manufacturing techniques and distribution processes; making the mass handling of therapies very difficult. Since biotech drugs are derived from natural sources, they are often less stable than synthetic molecules and necessitate special handling and distribution.
- Most biotech treatments can not be administered orally, but need to be injected or infused. This requires a high purity and sterility for biologic medicines, adding to their cost.
- One of the main benefits of biotech treatments is that they often target patients with relatively uncommon diseases or those who constitute a small subset of patients with a highly prevalent condition such as asthma. However, the development and approvals process costs the same as a more widely applicable treatment, but with a smaller patient basis that can take advantage of the treatment.

**EuropaBio is bound to the highest ethical values and has developed its Core Ethical Values available here**  
[http://www.europabio.org/ethics\\_and\\_dialogue.htm](http://www.europabio.org/ethics_and_dialogue.htm)



## What is different about biotech treatments?

Conventional drugs	Biotech drugs
Normally made by mixing chemicals in a factory	Far more complex, mimicking substances produced by the human body such as enzymes, insulin, and antibodies
They are mostly small, relatively simple molecules and can usually be shaped into a pill and swallowed	Instead of mixing chemicals, biotech drugs are grown in live cells in a bioreactor and then purified. The resulting drugs are almost always administered by injection or infusion
There are around 50 monitoring and quality tests for a traditional (chemical) medicine	Because biotechnology drugs are so complex, the manufacturing of biotechnology-based medicines requires a high level of monitoring and quality testing - typically, around 250 in-process tests are conducted for a biological medicine
Conventional drugs, based on relatively simple molecules, are easy to copy	The unique starting material and the complex manufacturing processes mean that it is more difficult to exactly reproduce a biological molecule in a copy

## Biotech drugs – already making a difference

- By 2007, **more than 325 million patients had benefited from biotech medicines** (including gene technology) to treat or prevent heart attacks, stroke, multiple sclerosis, breast cancer, cystic fibrosis, leukemia, rare genetic diseases, hepatitis, diabetes and other diseases.
- Biological products currently represent 40% of the total registered products\*.
- An estimated 50% of all new medicines originate from biotechnologies, and the proportion grows when it comes to the most innovative treatments such as: growth hormones, recombinant growth factors, vaccinations, monoclonal antibodies for the treatment of cancers and inflammatory and infectious diseases, cell therapy etc.
- Healthcare biotechnology continues to grow annually at a rate of 15% - more than double that of traditional pharma – and is now 7 times larger than it was 10 years ago

The most recent report from PhRMA\* reported that more than 600 biotech medicines were being tested to treat more than 100 diseases. Among these 600 biotechnology medicines are:

- 210 medicines to treat cancer
- 50 medicines to treat infectious disease
- 44 to treat autoimmune disorder
- 22 to treat HIV infection and related conditions
- And 22 to treat cardiovascular diseases

\*The Pharmaceutical Research and Manufacturers of America

**For more information:** [www.europabio.org](http://www.europabio.org)

\*taking into account chemical medicines developed with biotechnologies.

EuropaBio's mission is to promote an innovative and dynamic biotechnology-based industry in Europe. EuropaBio, (the European Association for Bioindustries), has 68 corporate and 7 associate members operating worldwide, 4 Bioregions and 25 national biotechnology associations representing some 1800 small and medium sized enterprises.

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