

The Journey to Biopharma– Get Ready for Change.



Biologics can be costly therapeutics

While a small-molecule drug is priced at US\$1 per day on average, a biological drug costs an average of US\$22 per day. Biologics are often used to treat chronic illnesses, increasing their typical expense.

Source: gabionline.net

Cumulative sales in first 10 years Cumulative sales in the subsequent 5 years

Million

Humira, a monoclonal antibody-based drug, was the world's best-selling drug in 2020. However, the all-time most successful drug is Lipitor, a small-molecule drug.

Source: spglobal.com



Biologics compared with small molecules





| Produced by living cell or organism in reactor | Predictable chemical reaction, synthesized in lab |
|---|--|
| High molecular weight | Low molecular weight |
| Complex, heterogeneous structure | Well defined structure |
| Strongly process dependent | Mostly process independent |
| Not entirely characterizable | Completely characterizable |
| Unstable | Stable |
| Immunogenic | Non immunogenic |

Source: technologynetworks.com





Proteins can be large

Titin's chemical name, arguably the longest word in the English language, features 189,819 letters and can take around 3.5 hours to say.

Source: washingtonpost.com



The majority of biopharma molecules are monoclonal antibodies



A total of 175 new drugs approved by the FDA from 2016 to 2019. Source: *Pharmaceuticals* 2020, 13(3), 40

Different physicochemical properties

Biologics and small molecules vary from each other physicochemically, which influences:

Pharmacological aspects of the drug*

Classes of biologics



Antibody therapeutics

Antibodies can be adapted to target certain proteins with high specificity and potency. Monoclonal antibodies, antibody drug conjugates, bispecific antibodies, and fragment antibodies are examples



*e.g., mechanism of action, pharmacodynamics (PD), pharmacokinetics (PK)



of antibody-based therapeutics.

Peptide or protein therapeutics

Because of their large size, proteins are often directed at extracellular targets. Example therapeutics are fusion proteins, created by joining two or more genes that encode for separate proteins. Peptides are smaller molecules that can be engineered to be very selective and specific.

Nucleotide-based therapeutics

Progress in genomics research has both revealed several new drug targets and opened the way for therapeutics based on nucleotides. These include antisense oligonucleotides, messenger RNA, small interfering RNA, and therapeutic gene editing.



DNA can store a lot of data

Up to 700 TB of data can be stored on 1g of DNA, and readwrite DNA technology can be developed. It's estimated that, if stored on DNA, all the world's information could fit into a van.

Source: usatoday.com



Interested in biopharma-specific LC systems? Find out more about the new Agilent InfinityLab Bio LC Solutions portfolio. www.agilent.com/chem/complete-bio-lc

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