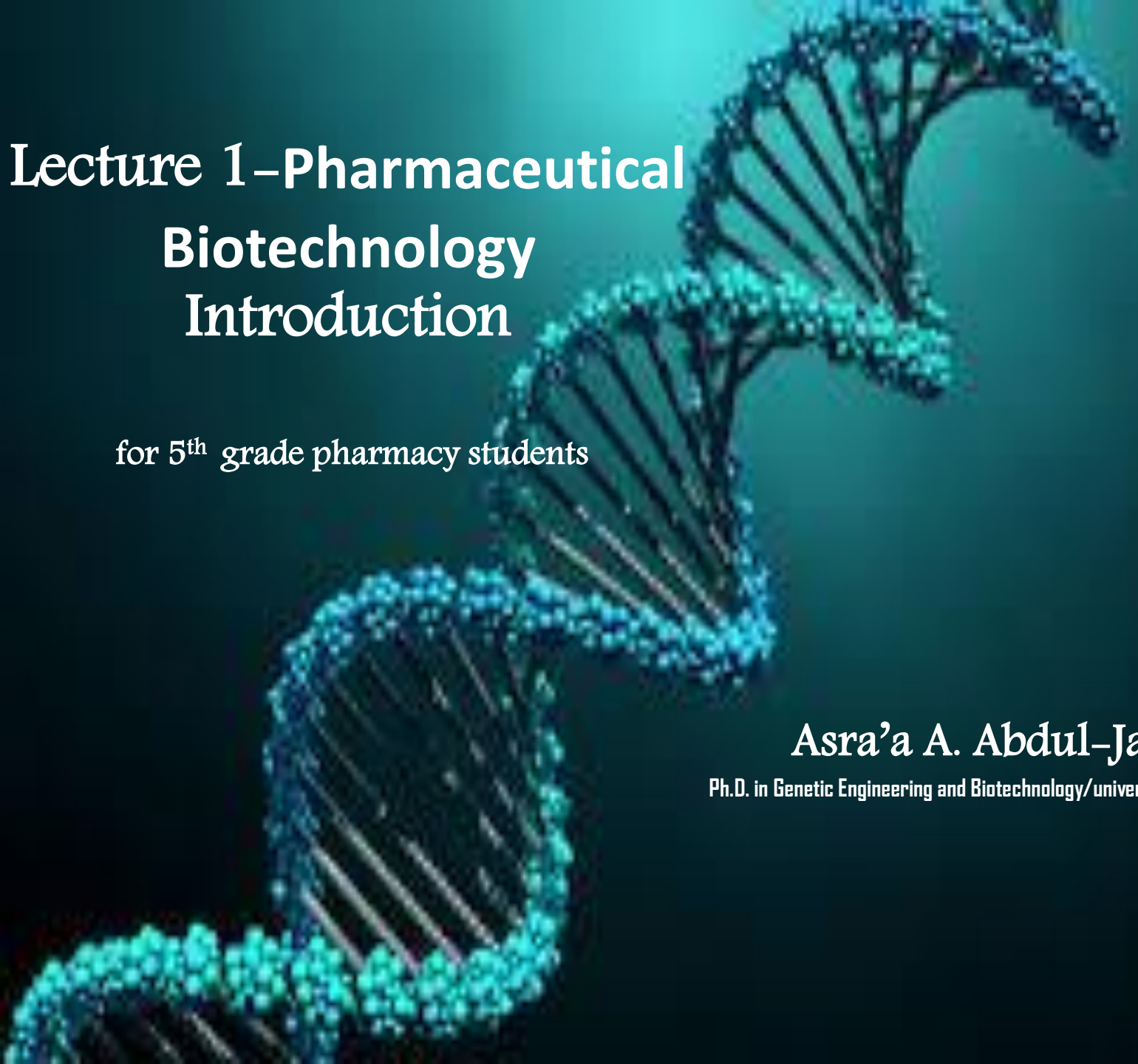
Lecture 1–Pharmaceutical Biotechnology Introduction

for 5th grade pharmacy students



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References

1. **Pharmaceutical biotechnology**

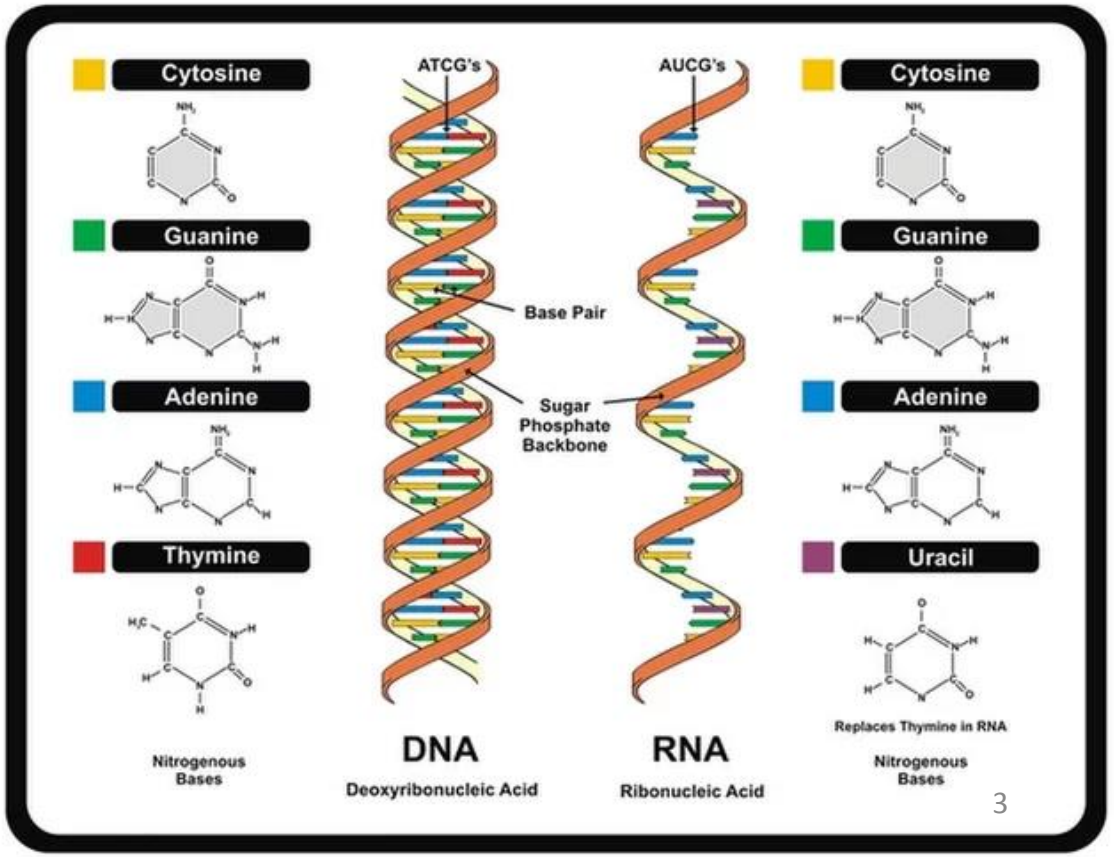
J . A . Crommelin , Robert D. Syinder

2. **Biophrmaceuticals**

Walsh G.

General concepts

- **Genetic material!!!**
- **Building Blocks!!**
- **Gene expression**
- **Codons**



Abbreviations

AA	amino acid(s)
Ab	Antibody
Ag	Antigen
BRCA1	breast cancer gene 1
cDNA	copy DNA/ complementary deoxyribonucleic acid
EDTA	Ethylene di amine tetra acetic acid
EMBL	European Molecular Biology Laboratory
FDA	Food and Drug Administration
DDBJ	DNA Data Bank of Japan
FSH	follicle-stimulating hormone
GF	Growth Factor
HPLC	high-performance liquid chromatography
IV	intravenous
Kb	thousand base pairs of DNA
HIV	Human immunodeficiency virus
EMEA	European Agency for the Evaluation of Medicinal Products

PHARMACEUTICAL BIOTECHNOLOGY

INTRODUTION:

Pharmaceutical biotechnology consist of the combination of two branches which Are "PHARMACEUTICAL SCIENCE" AND "BIOTECHNOLOGY".

DEFINATION:

PHARMACEUTICAL SCIENCE: Can simply be define as the branch of science that deals with the formulation and dispensing of drugs

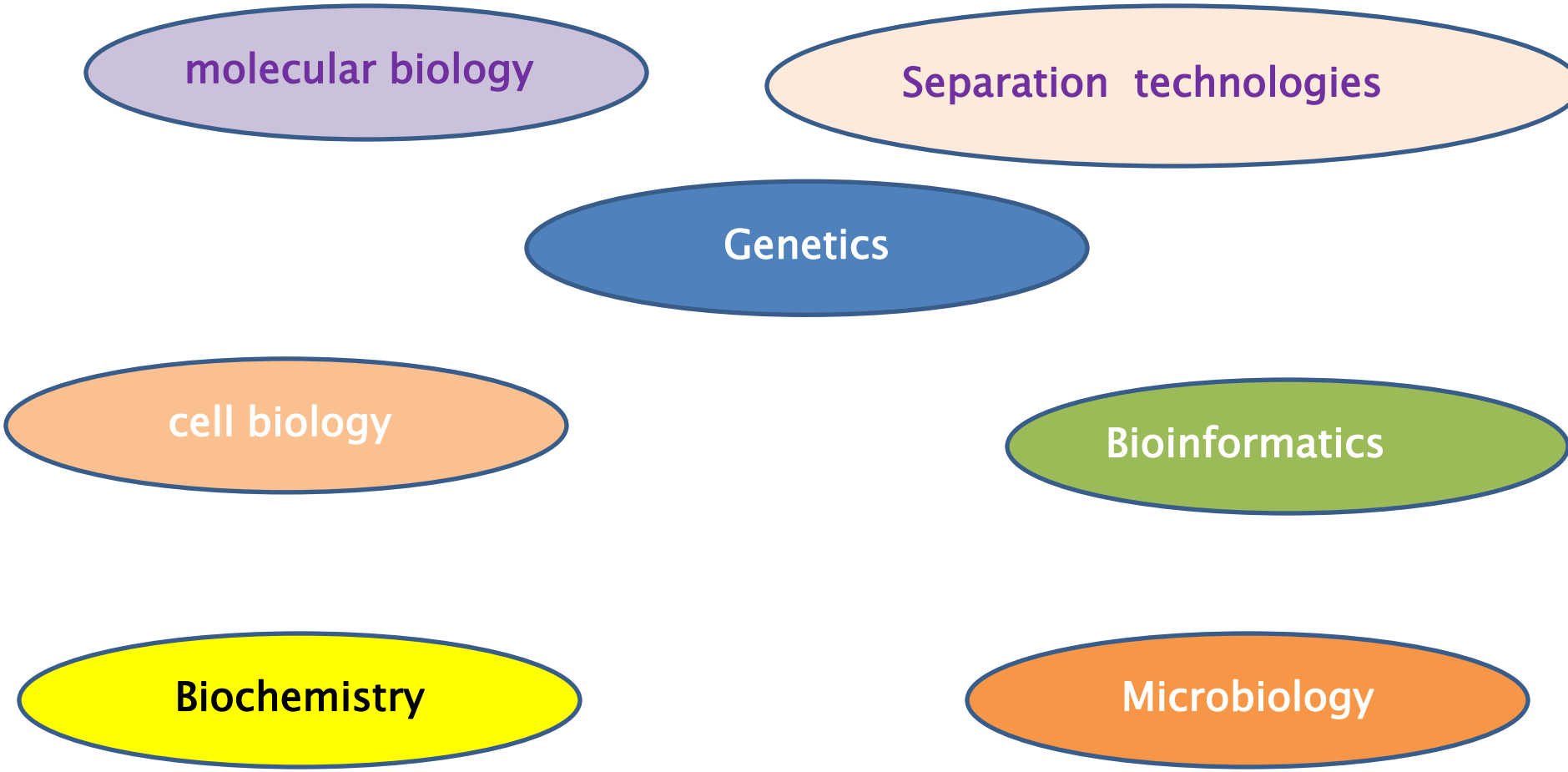
BIOTECHNOLOGY: Can simply be define as the application of biological system, living organisms, or their derivatives in making or modifying products or processes for specific use.

PHARMACEUTICAL BIOTECHNOLOGY : **Can simply be define as the science that covers all technologies required for the production, manufacturing and registration of biological drugs.**

The aim of this pharmaceutical biotechnology is to design, produce drugs that are adapted to each persons genetic make up, which can give the maximum therapeutic effect.

Biotechnology plays an important role in pharmaceutical science most especially in the pharmaceutical industries by creation of genetically modified organisms that can be used in industrial production.

Biotechnology makes use of findings from various research areas, such as:



Development of Biotechnology

- 1953: Discovering the double helical structure of DNA by(----------&----------).
- 1971: Restriction enzymes (H.W.) discovered
- 1975: Production of monoclonal antibodies by hybridoma technology
- 1982: recombinant human insulin approved by the FDA .(sequence??).

In 1978, the first recombinant DNA human insulin was prepared by David Goeddel and his colleagues (of Genentech) by utilizing and combining the insulin A- and B- chains expressed in *Escherichia coli* .Thereafter, Genentech and Lilly signed an agreement to commercialize rDNA insulin. In 1982, the first insulin utilizing rDNA technology, Humulin® R (rapid) and N (NPH, intermediate-acting), were marketed

Biopharmaceuticals vs. small molecule(traditional) drugs

Since then (insulin production) a large number of biopharmaceuticals (biotechnology drugs) have been developed.

Until now biopharmaceuticals are primarily proteins

Therapeutic proteins differ in many aspects from classical, small molecule drugs. They differ in size, composition, production, purification, contaminations, side effects, stability, formulation, regulatory aspects, etc.

The main differences between Biopharmaceuticals and small drug molecules

Biopharmaceuticals	Small molecule drugs
Produced by living cell cultures	Produce by chemical synthesis
High molecular weight	Low molecular weight
Complex, heterogeneous structure	Well-defined structure
Strongly process–dependent	Mostly process–independent
Impossible to fully characterize the molecular composition and heterogeneity	Completely characterized
Unstable, sensitive to external conditions	Stable
Often injected or infused	Mostly oral route
Example: trastuzumab (m.wt = 145531 Da)	Example: atorvastatin (m.wt = 558 Da)

Trastuzumab

Targets (13)

IDENTIFICATION

Name	Trastuzumab
Accession Number	DB00072 (BTD00098, BIOD00098)
Type	Biotech
Groups	Approved, Investigational
Biologic Classification	Protein Based Therapies Monoclonal antibody (mAb)
Description	Produced in CHO cell cultures, trastuzumab is a recombinant IgG1 kappa, humanized monoclonal antibody [6] that selectively binds with high affinity in a cell-based assay (Kd = 5 nM) to the extracellular domain of the human epidermal growth factor receptor protein (HER2) [Label]. It is used as

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Drugs

Atorvastatin

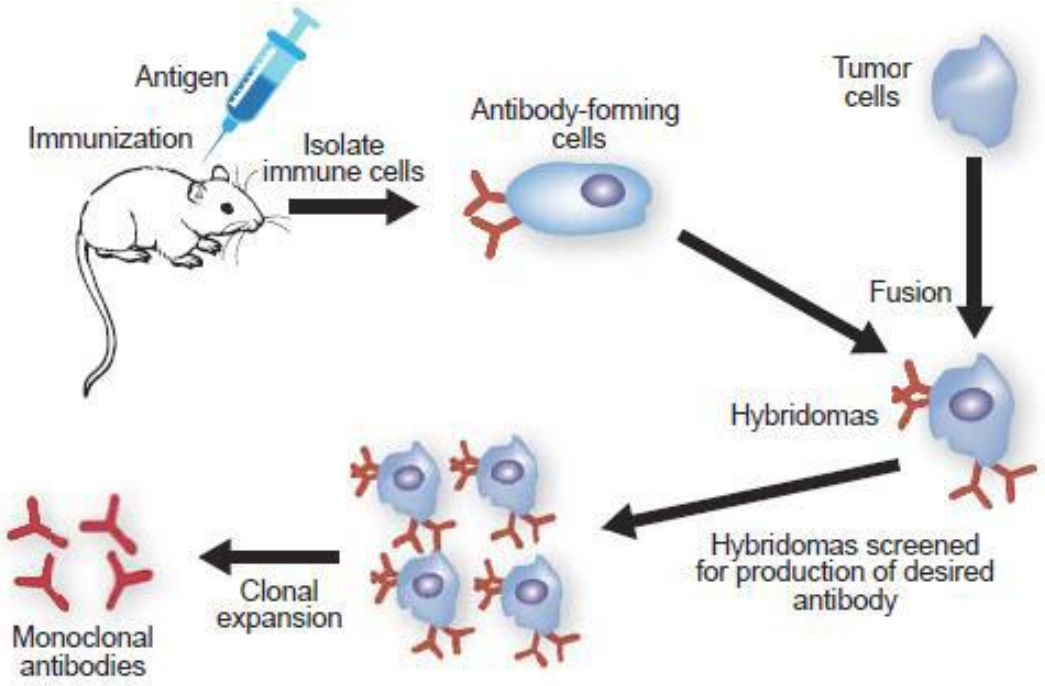
Targets (5) Enzymes (10) Carriers (1) Transporters (10) Biointeractions (28)

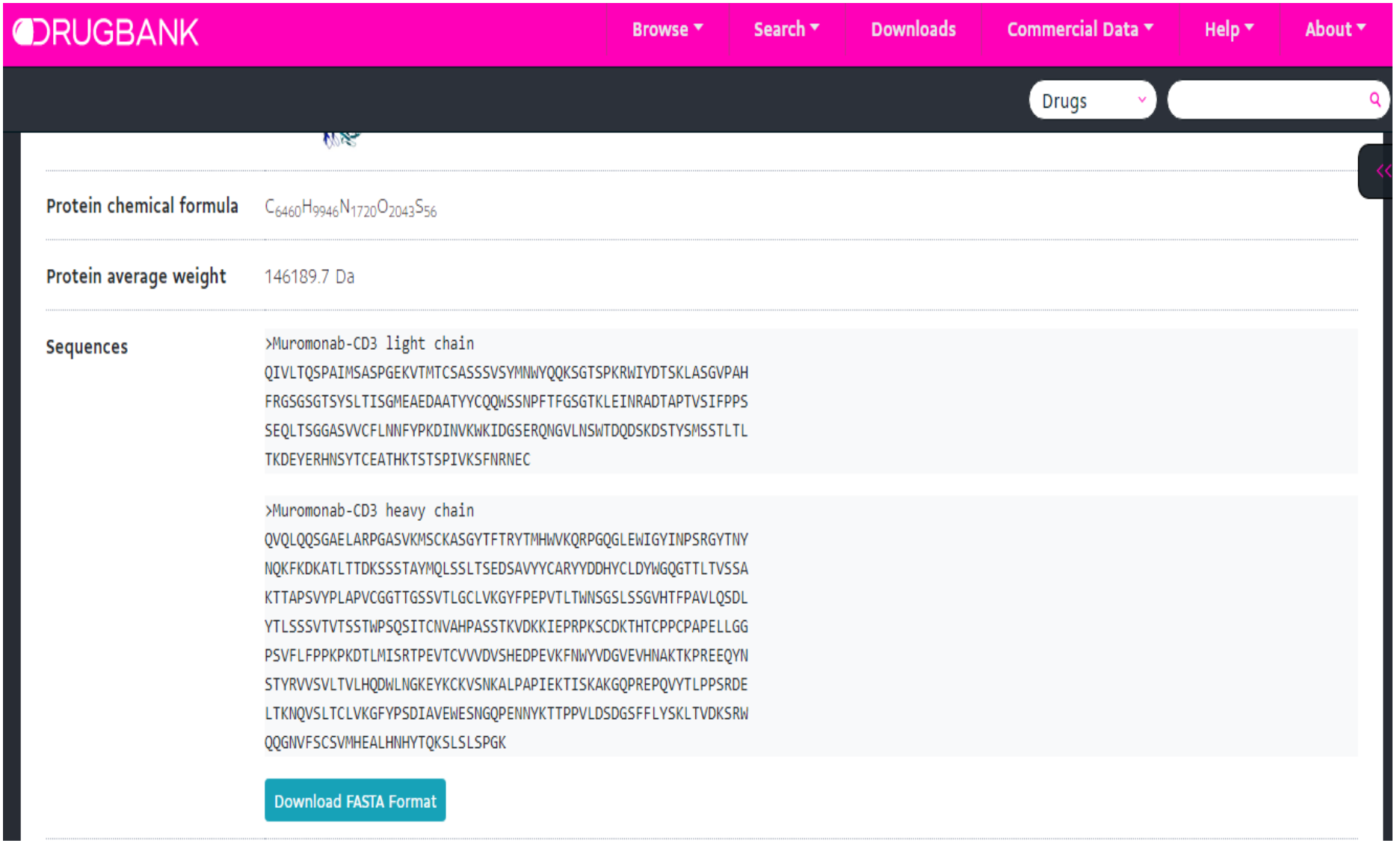
IDENTIFICATION

Name	Atorvastatin
Accession Number	DB01076 (APRD00055)
Type	Small Molecule
Groups	Approved
Description	Atorvastatin, also known as the brand name product Lipitor, is a lipid-lowering drug belonging to the statin class of medications. By inhibiting the endogenous production of cholesterol in the liver, statins lower abnormal cholesterol and lipid levels and ultimately reduce the risk of cardiovascular disease. More specifically, statin medications competitively inhibit the enzyme hydroxymethylglutaryl-coenzyme A (HMG-CoA) Reductase,[8] which catalyzes the conversion of HMG-CoA to mevalonic acid. This conversion is a critical metabolic reaction involved in the

Hybridoma Technology

- First therapeutic mAb was produced by hybridoma technology! (H.W)
- Muromonab-CD3 (1985): immunosuppressant in organ transplants

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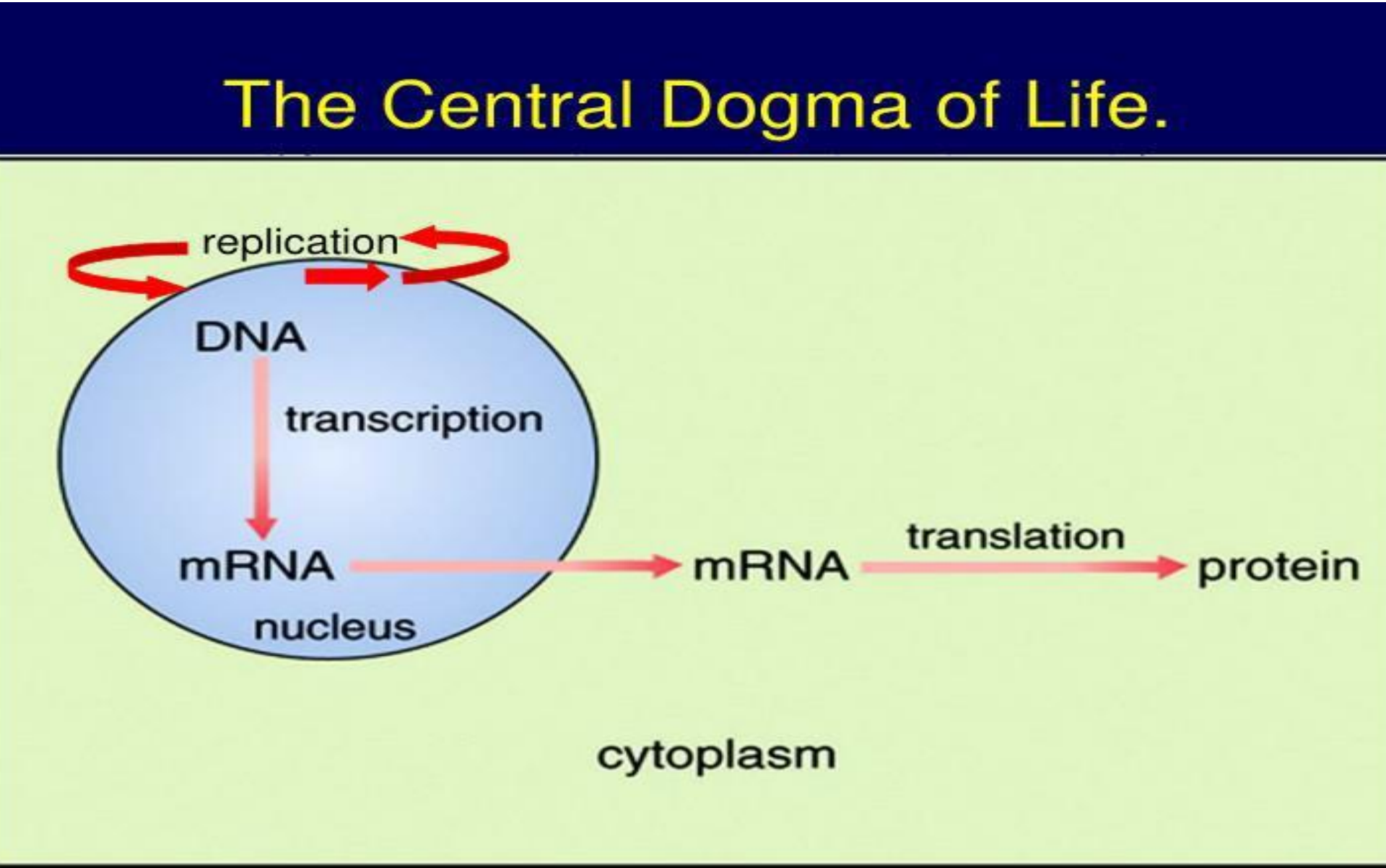
❖ Most common biotech drugs are listed below:

- **Hormones (insulin, glucagon, growth hormone, gonadotrophins)**
- **Monoclonal antibodies (mAbs)**
- **Blood factors (Factor VIII and Factor IX)**
- **Thrombolytic agents (tissue plasminogen activator)**
- **Haematopoietic growth factors (Erythropoietin, colony stimulating factors)**
- **Interferons (Interferons-α, -β, -γ)**
- **Interleukin-based products (Interleukin-2)**
- **Vaccines (Hepatitis B surface antigen)**
- **Additional products (tumour necrosis factor, therapeutic enzymes)**

The central dogma of Molecular Biology




THANK YOU