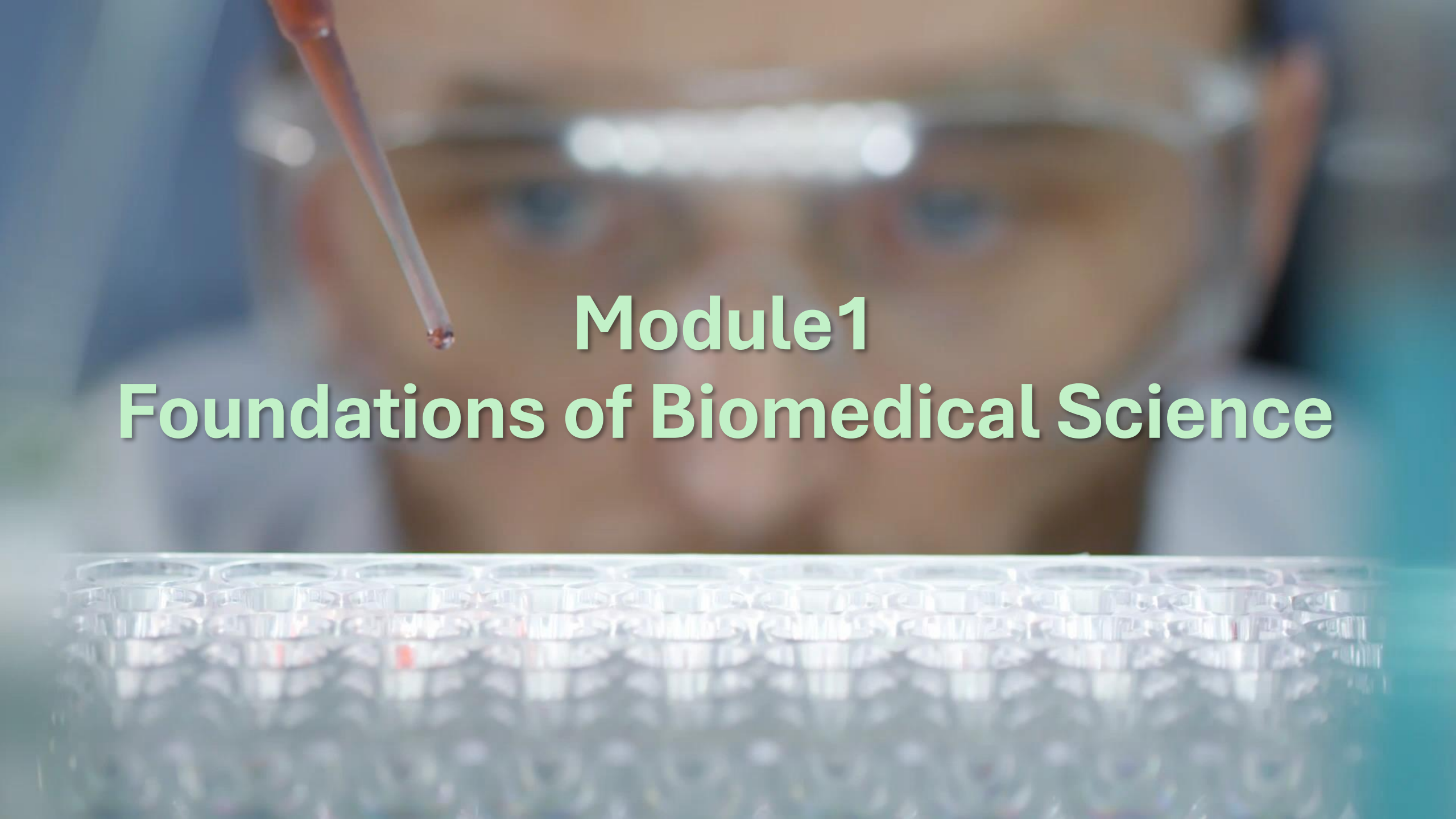
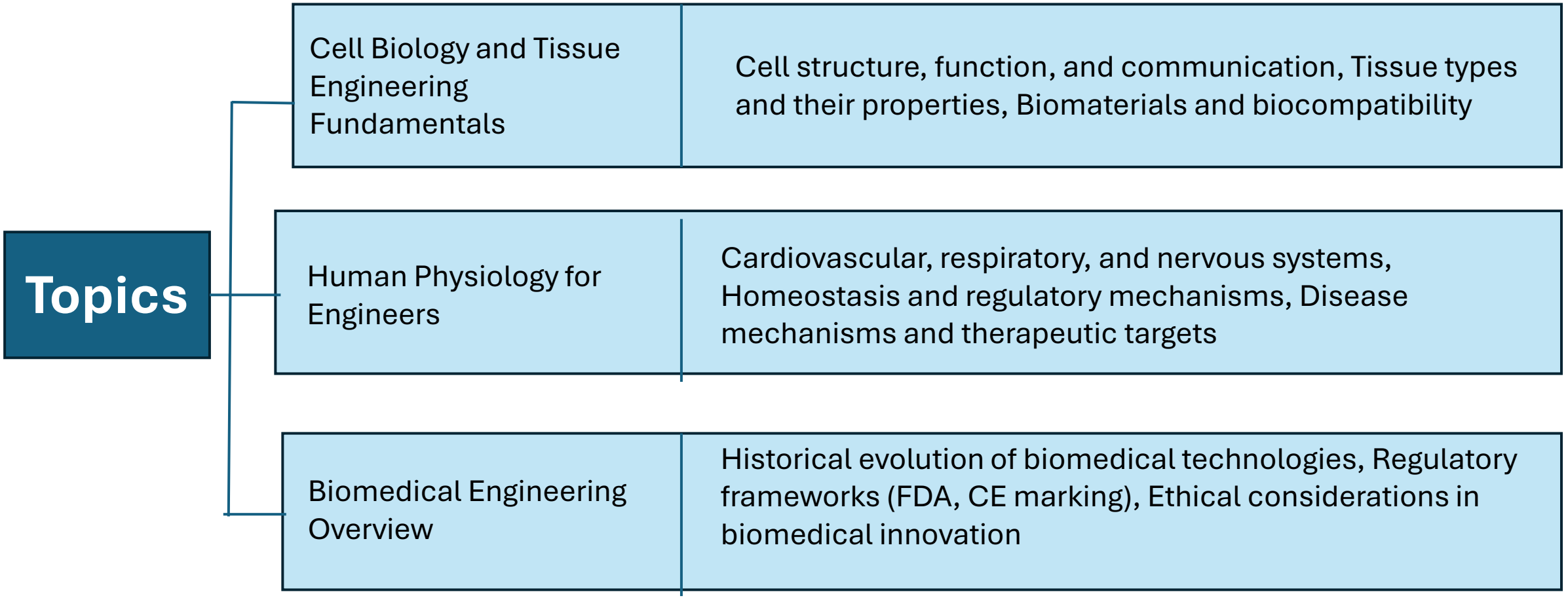


Module1
Foundations of Biomedical Science


Topics
Cell Biology and Tissue Engineering Fundamentals
Cell structure, function, and communication, Tissue types and their properties, Biomaterials and biocompatibility
Human Physiology for Engineers
Cardiovascular, respiratory, and nervous systems, Homeostasis and regulatory mechanisms, Disease mechanisms and therapeutic targets
Biomedical Engineering Overview
Historical evolution of biomedical technologies, Regulatory frameworks (FDA, CE marking), Ethical considerations in biomedical innovation

CELL

October 1837, Berlin

What is a Cell?

All plant parts (root, stem, leaves) have a common construction and organisation and is made up of same “thing”

Matthias Schleiden,
German Botanist

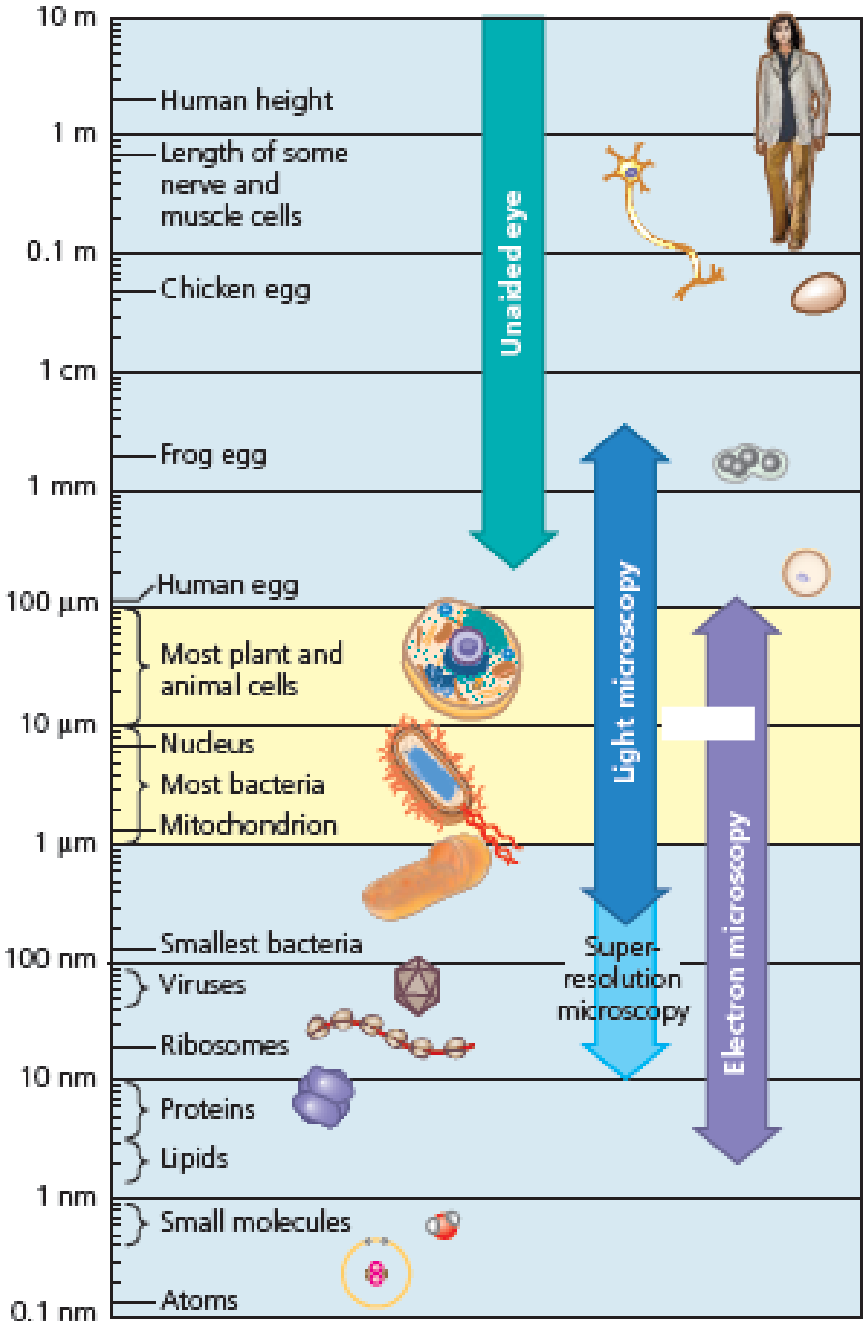
All Living Organisms are made up of simplest functional unit!!! CELLS!!

CELL THEORY

Even tadpoles are made up of a common construction and organisation and is made up of same “thing”

Theodor Schwann,
German Physiologist (Zoologist)

Cell Size and Shape



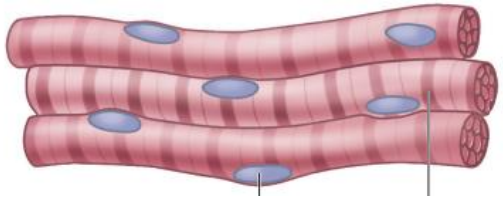

Coccus

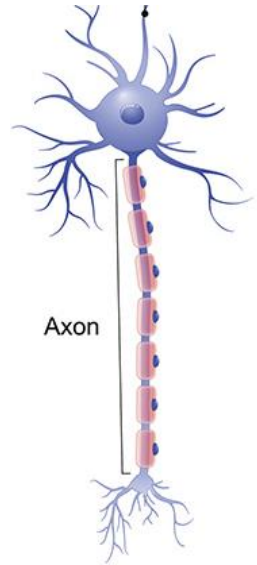

Streptococcus


Bacillus

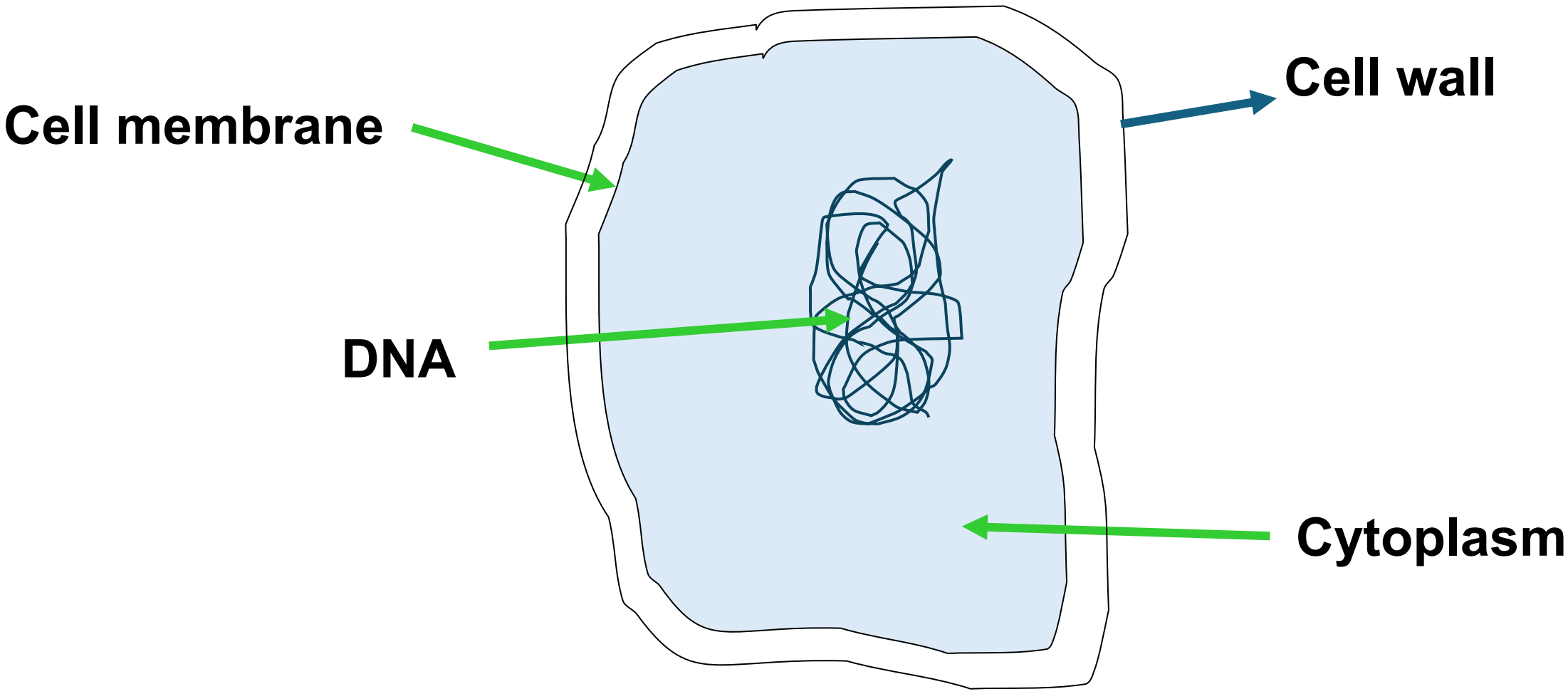
Amoeba

Paramecium



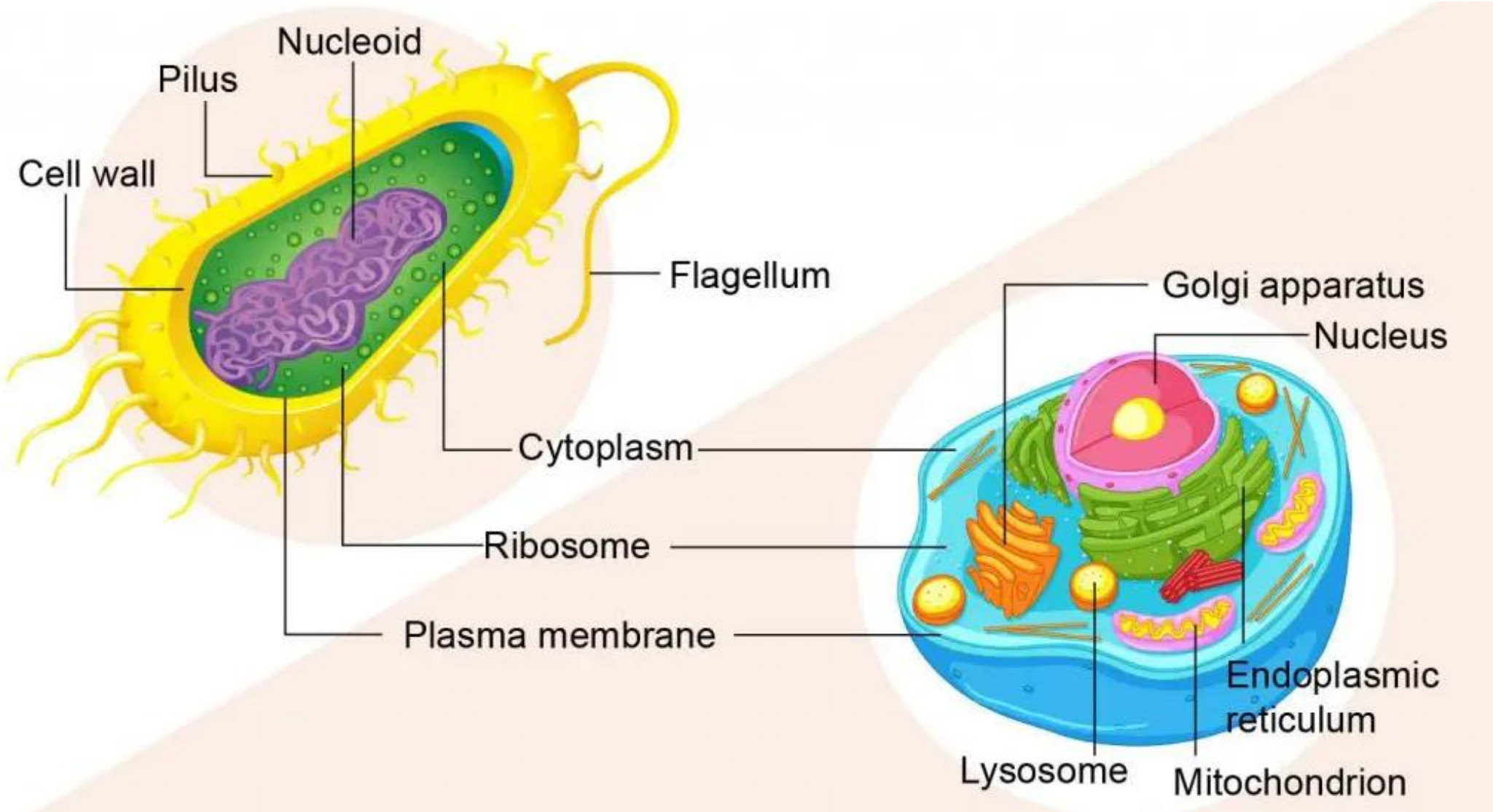


Basic components of Cell



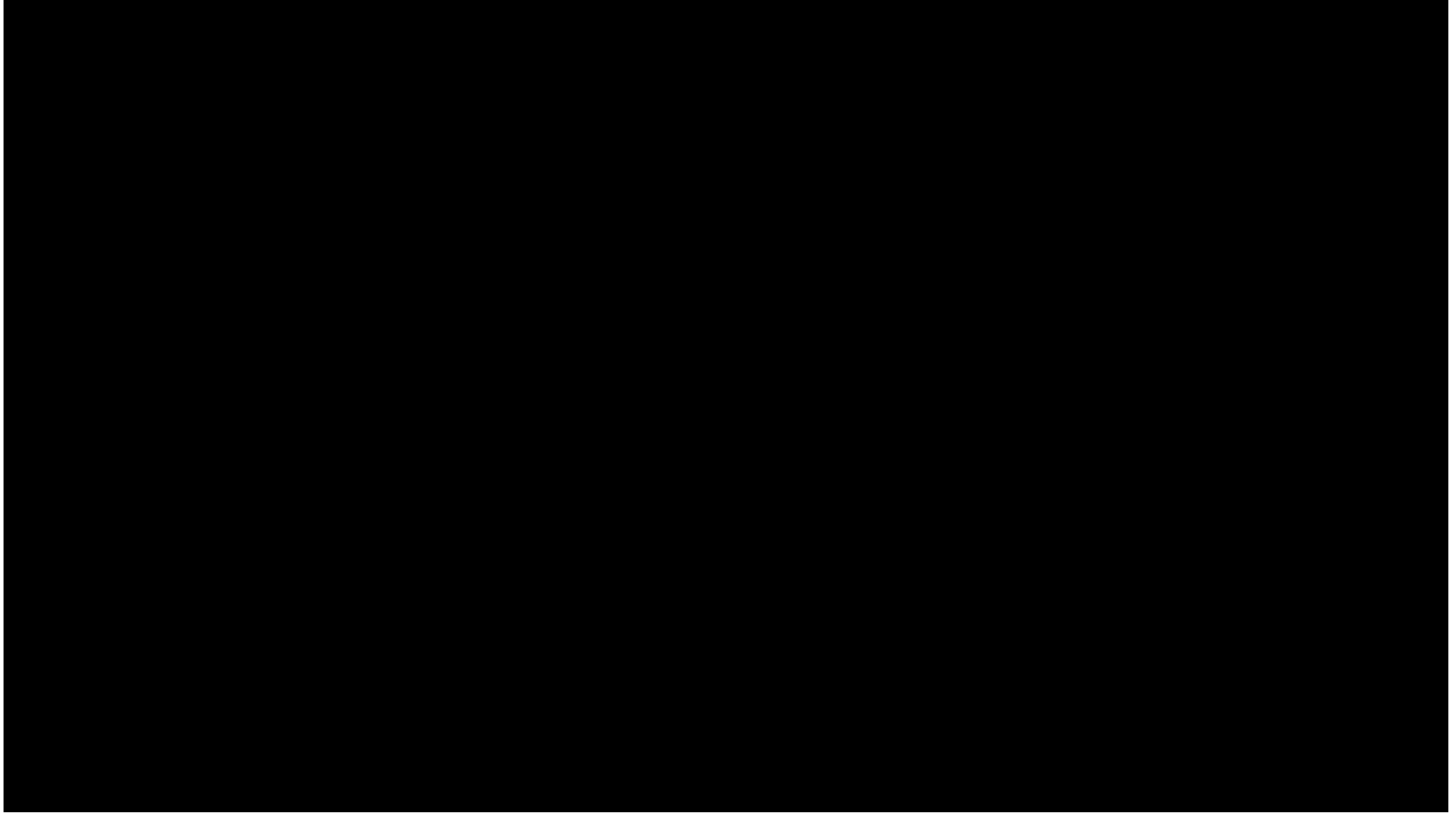
Prokaryotes (ex: bacteria)
(Pro=before; karyon=nucleus)

Eukaryotes (ex: human cell)
(Eu=true; karyon=nucleus)



(https://rsscience.com/eukaryote-prokaryote/)

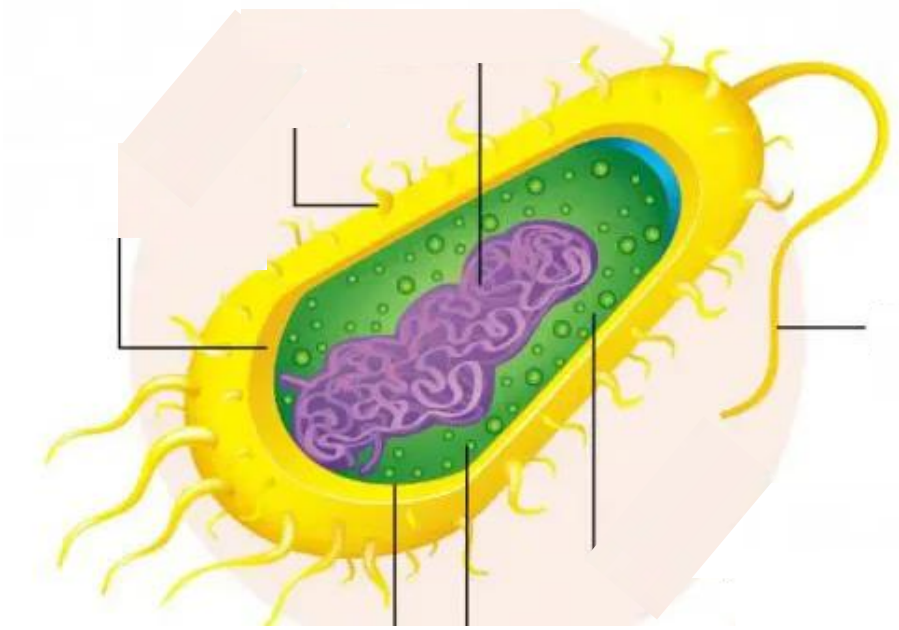
Feature	Prokaryotes	Eukaryotes
Size	Usually small (0.1 – 5.0 µm)	Comparatively larger (5 - 100 µm)
Cell wall	Cell wall present in all	Cell wall present in some absent in others
Nucleus	Nucleus is absent	Nucleus is present
DNA	DNA is circular, naked	Nuclear DNA is linear and is associated with proteins, extranuclear DNA is circular
Organelles	Cytoplasm lack membrane bound organelles	Cytoplasm possess membrane bound organelles
Ribosomes	Ribosomes are of 70 S type	Ribosomes are of 80 S type
Plasmid	Plasmids present	Plasmids absent
Examples	Bacteria	Plants, Animals

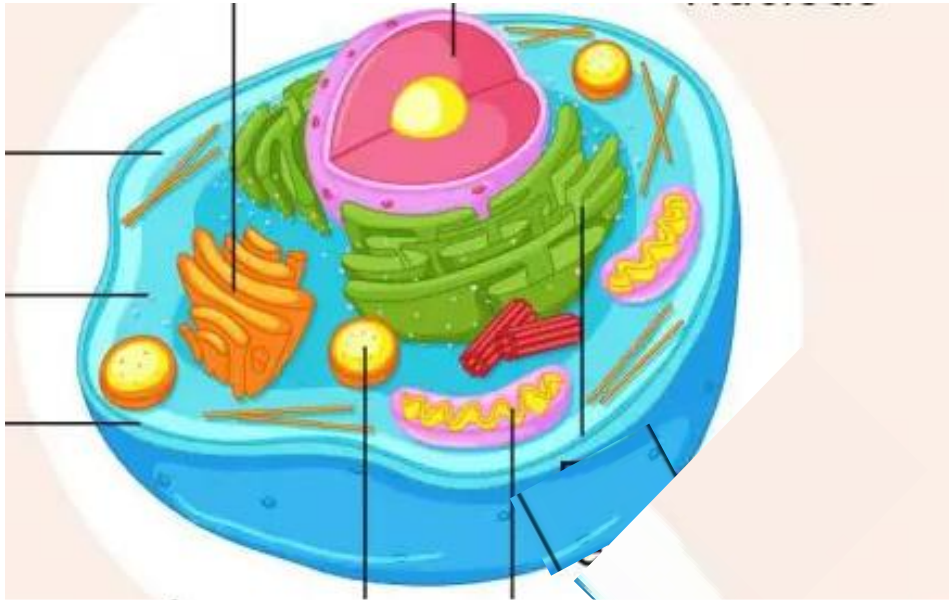


(https://www.youtube.com/watch?v=URUJD5NEXC8)

Activity

Draw and label different component and organelles



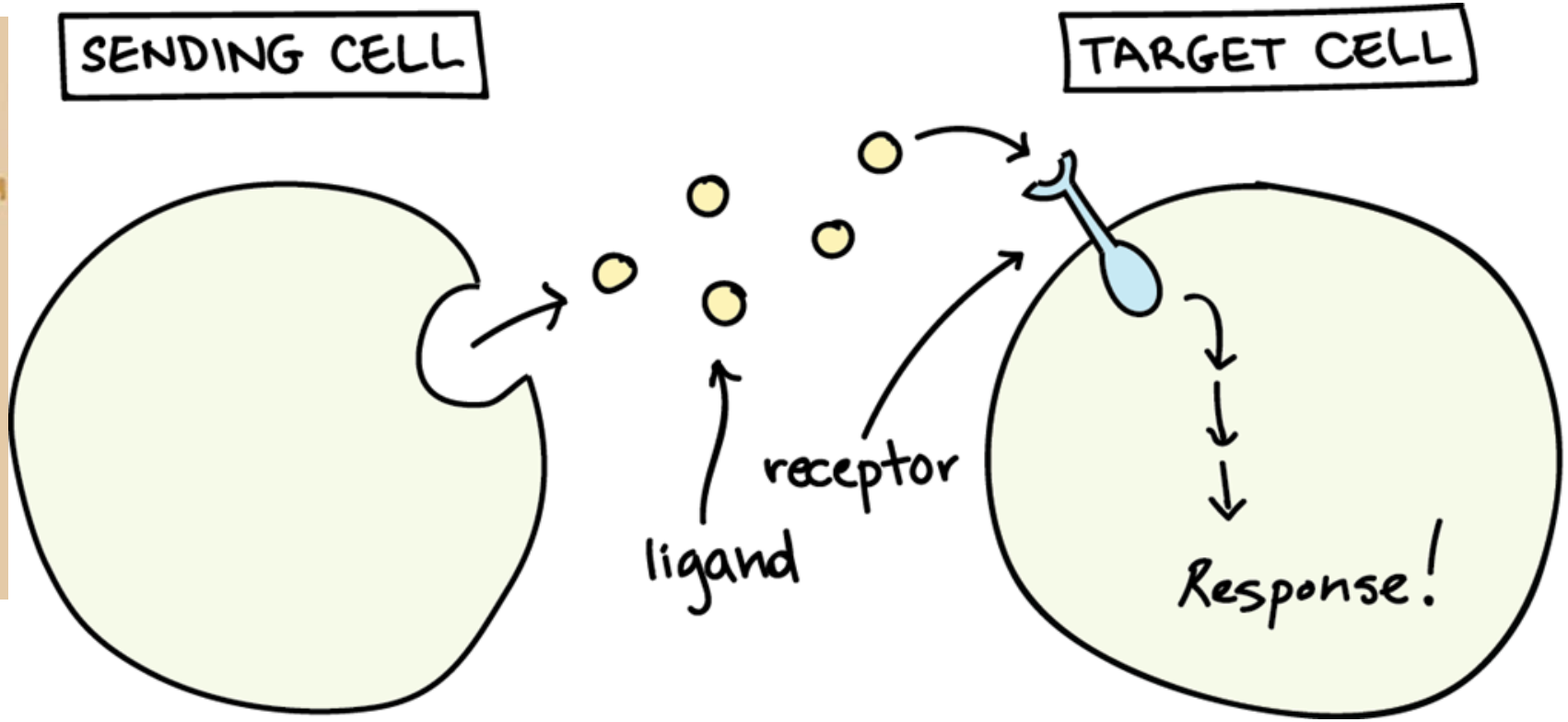


Activity

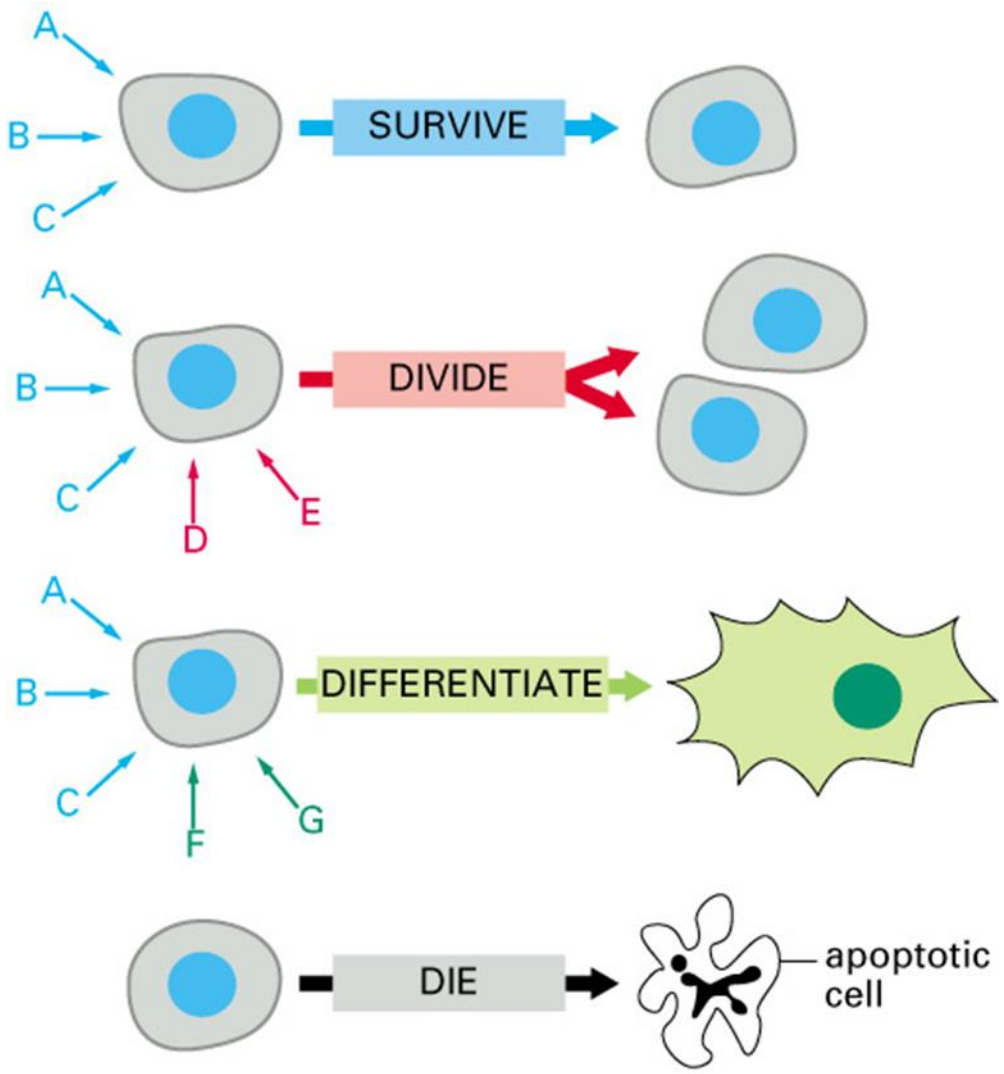
Write down the function of the organelles

Organelle	Function
Nucleus	Stores DNA; control center of the cell
Mitochondria	Produces energy (ATP) – "powerhouse"
Endoplasmic Reticulum (Rough/Smooth)	Protein and lipid synthesis
Golgi Apparatus	Protein packaging and transport
Lysosomes	Digestion and waste removal
Ribosomes	Protein synthesis (larger than in prokaryotes)
Plasma Membrane	Regulates what enters/leaves the cell
Chloroplasts (plant cells)	Photosynthesis
Cell wall (plant/fungal cells)	Structural support (not in animal cells)

Cells Communicate?



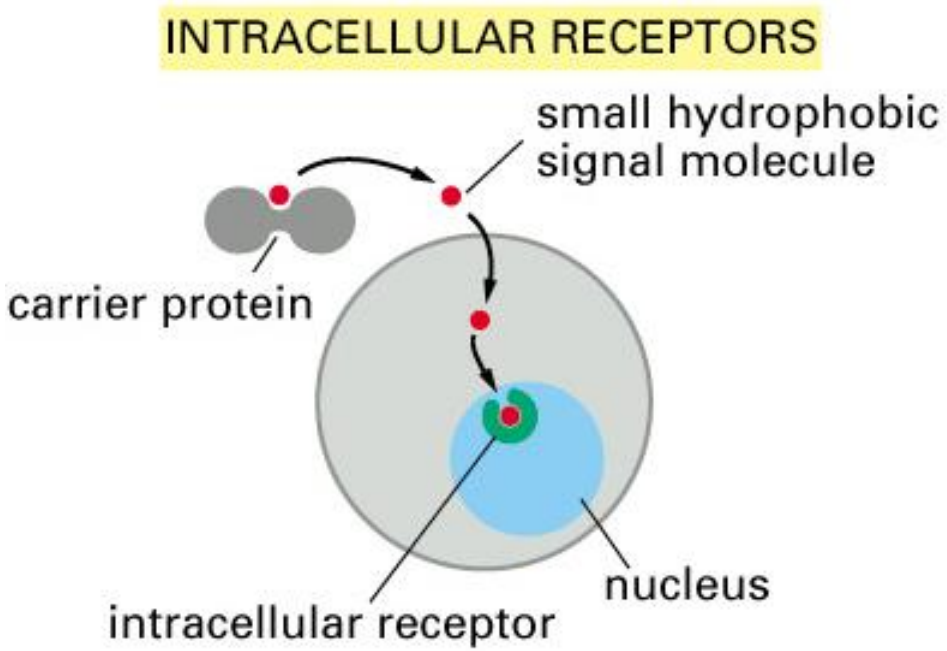
Cell signaling describes the ability of cells to respond to stimuli from their environment

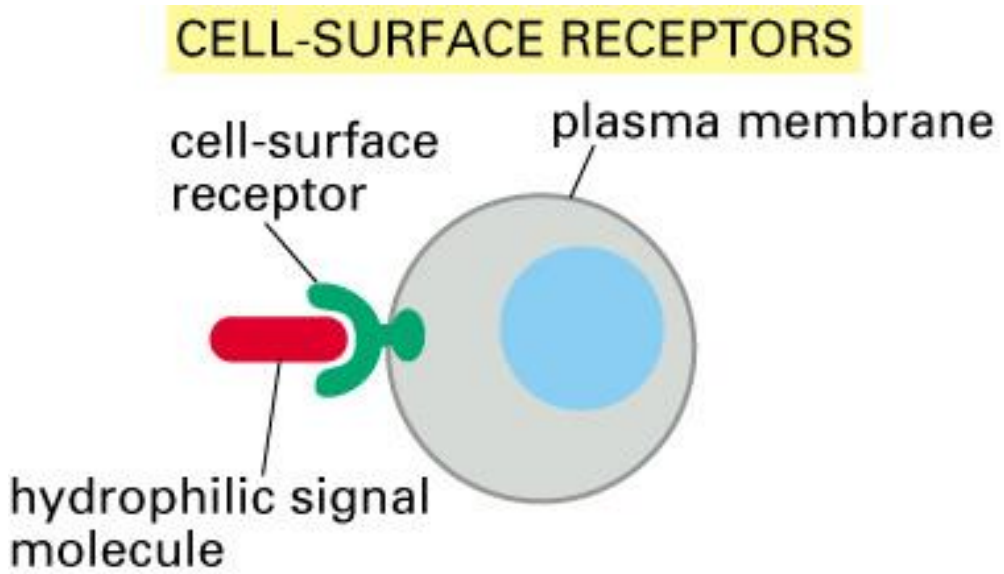


Signaling Process

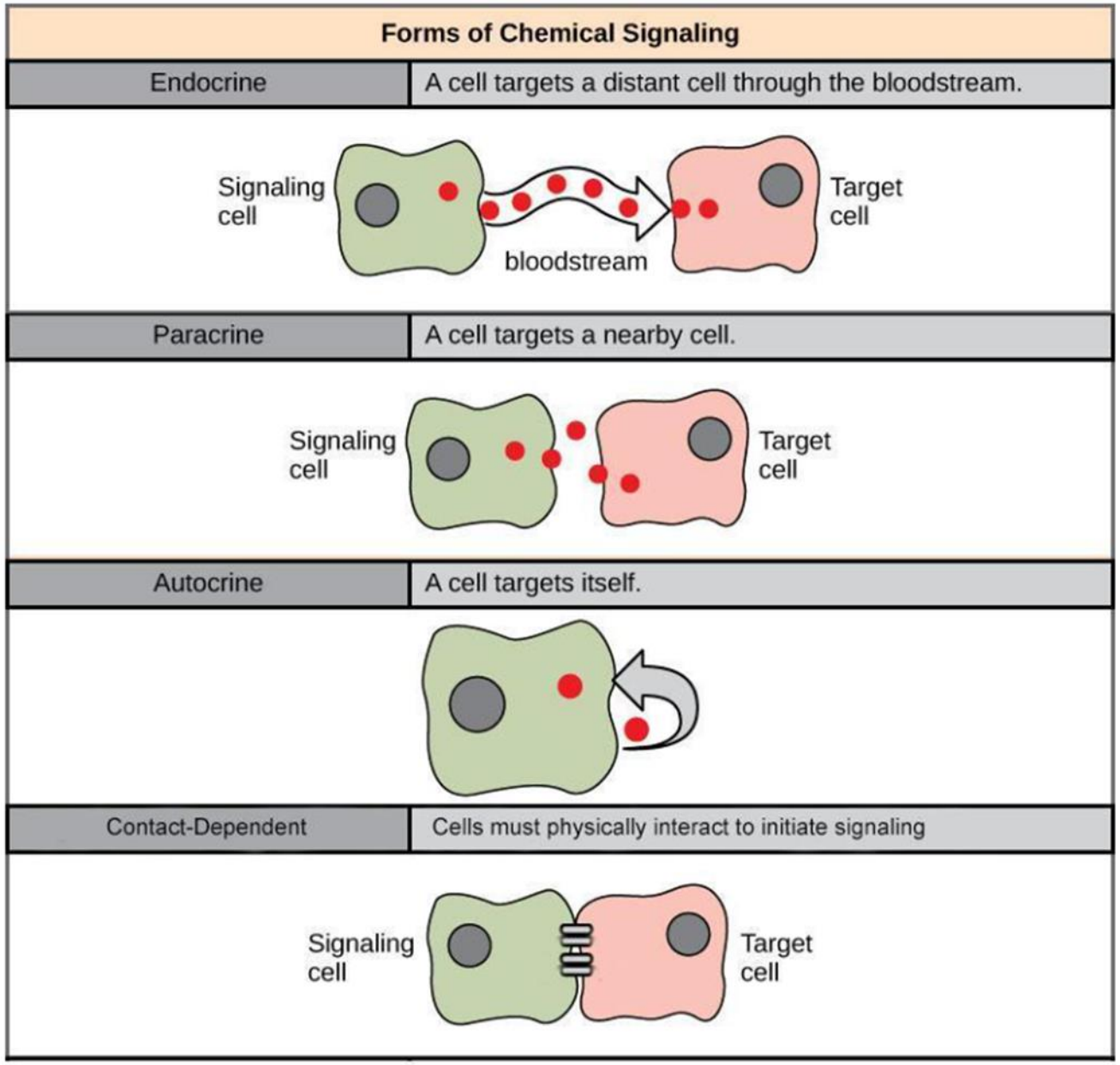
- **Recognition of signal**
  - Receptors
- **Transduction**
  - Change of external signal into intracellular message with amplification and formation of second messenger
- **Response**
  - Modification of cell metabolism and function

CELL Receptors





Types of cell signaling



Endocrine hormone signaling

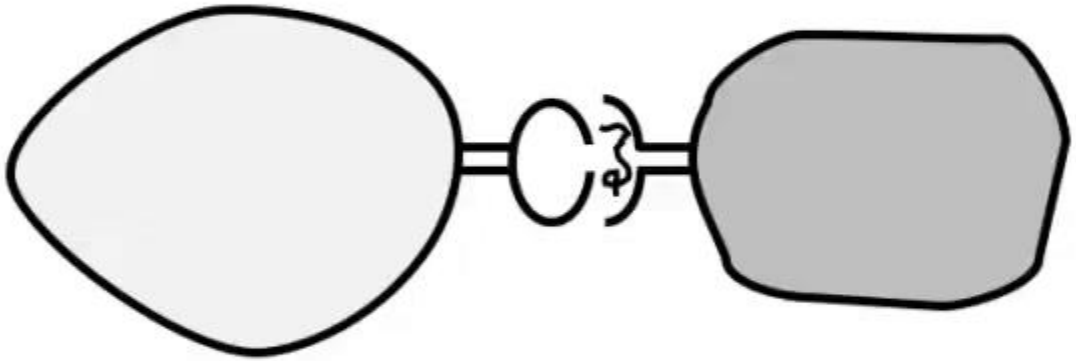
Thyroid gland
Pituitary gland

Neurotransmitter

Cell death

Calcium signaling

cell communication

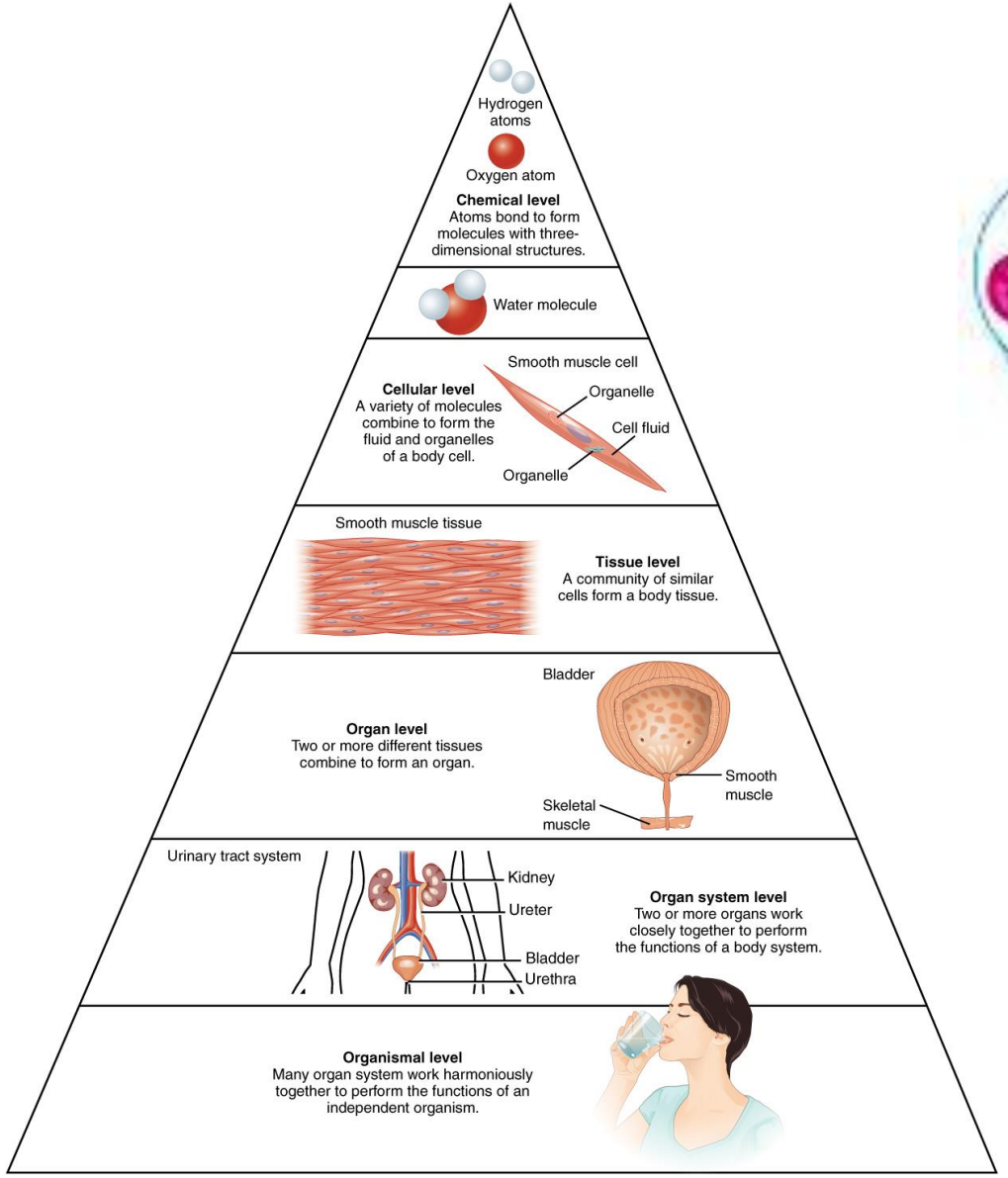


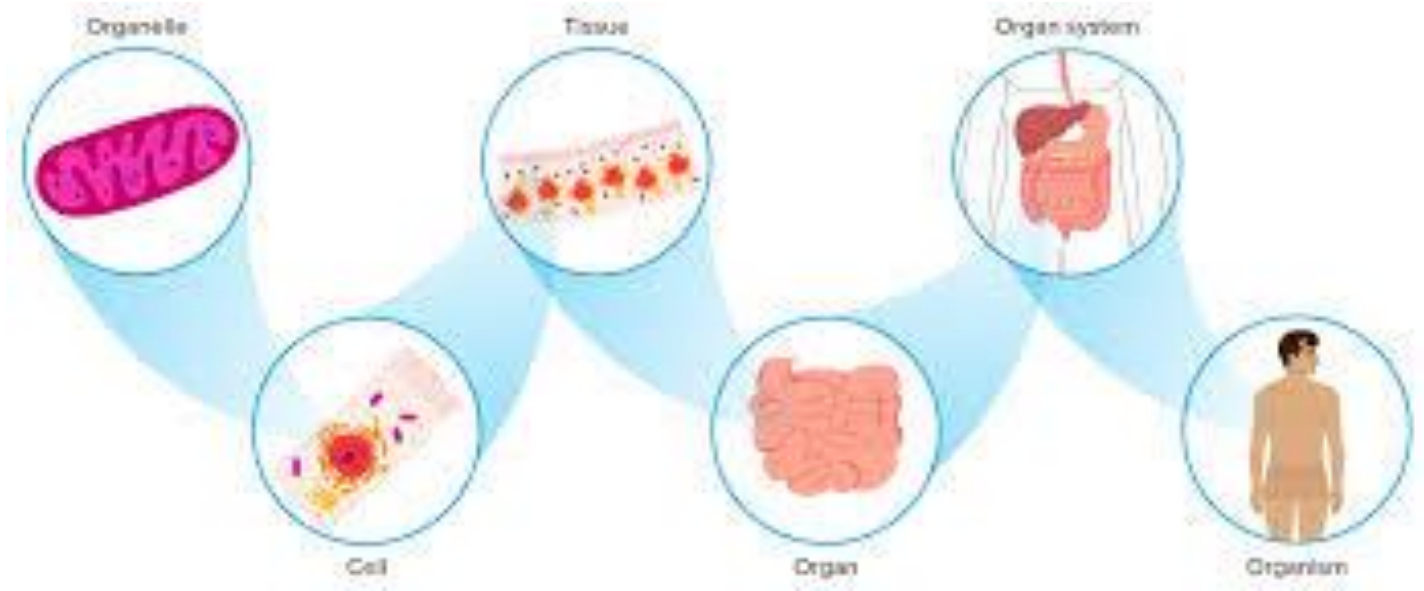
AP Biology

By: Rachel Taylor

Tissue types and their properties

Human body: Level of organization





What are tissues?

Tissues are a group of cells performing similar structure and function

CELLS Secrete and regulate → **EXTRACELLULAR MATERIAL AND FLUIDS**

Combine to form

TISSUES
with special functions

EPITHELIAL TISSUE

- Covers exposed surfaces
- Lines internal passageways and chambers
- Produces glandular secretions

CONNECTIVE TISSUE

- Fills internal spaces
- Provides structural support
- Stores energy

MUSCLE TISSUE

- Contracts to produce movement

NERVOUS TISSUE

- Propagates electrical impulses
- Carries information

Combine to form

ORGANS
with multiple functions

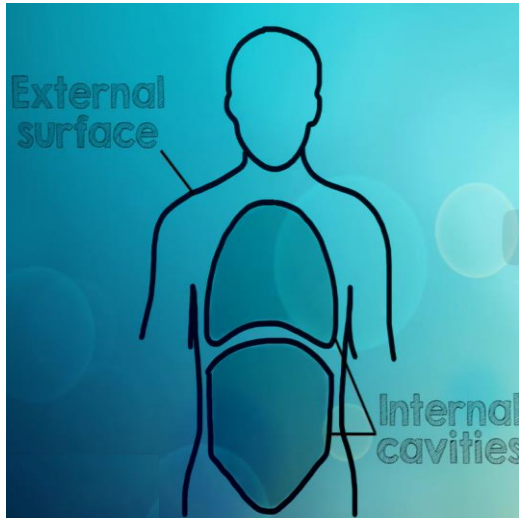
Interact in

ORGAN SYSTEMS

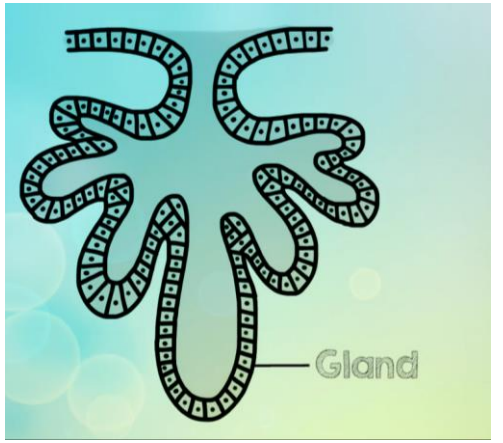
Epithelial tissue

Epithelial tissue

Epithelial tissue primarily appears as large sheets of cells covering all **surfaces** of the body exposed to the external environment and lining internal body cavities.



In addition, epithelial tissue is responsible for forming a majority of glandular tissue found in the human body.



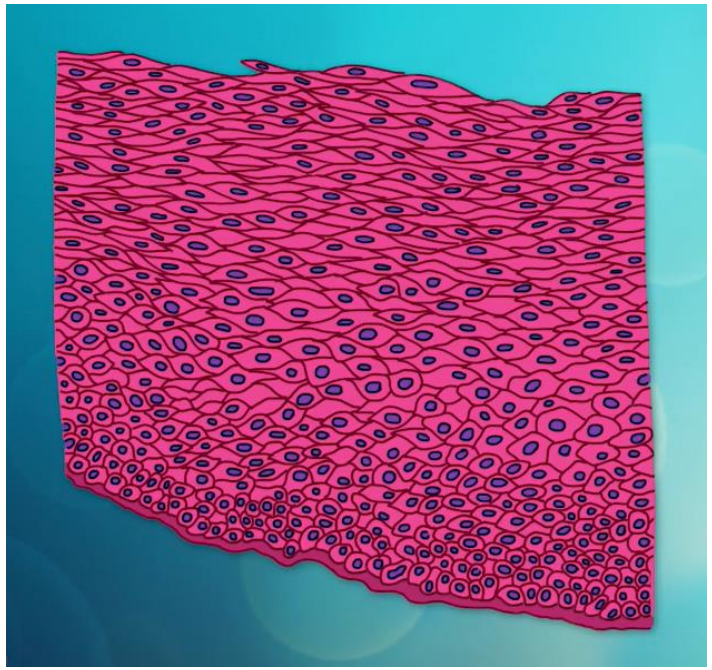
Characteristics of Epithelium

- Cellularity
- Polarity
- Attachment
- Avascularity
- Regeneration

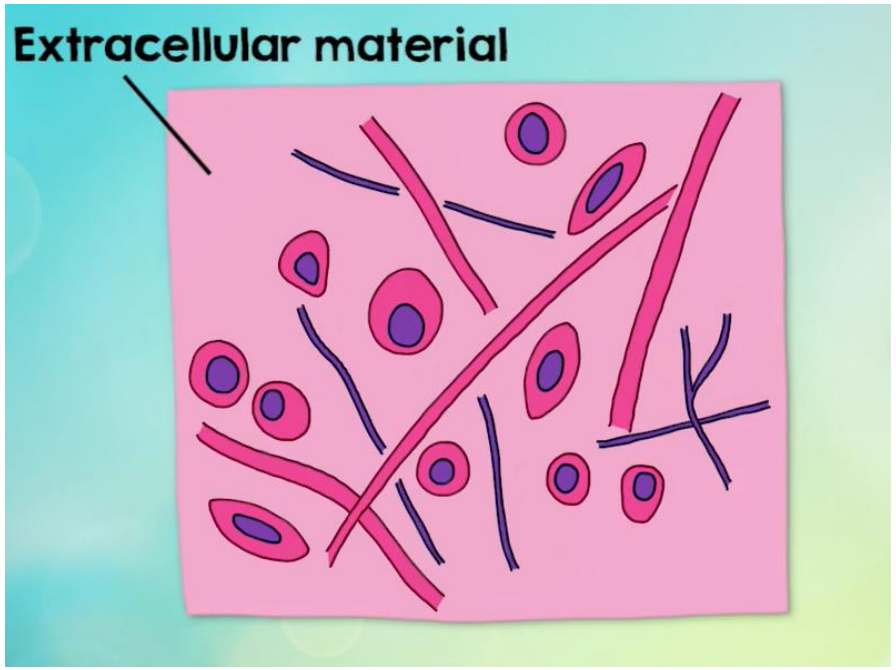
Characteristics of Epithelium

Cellularity – Epithelia are made almost entirely of cells with little or no extracellular material present between cells.

Epithelial tissue



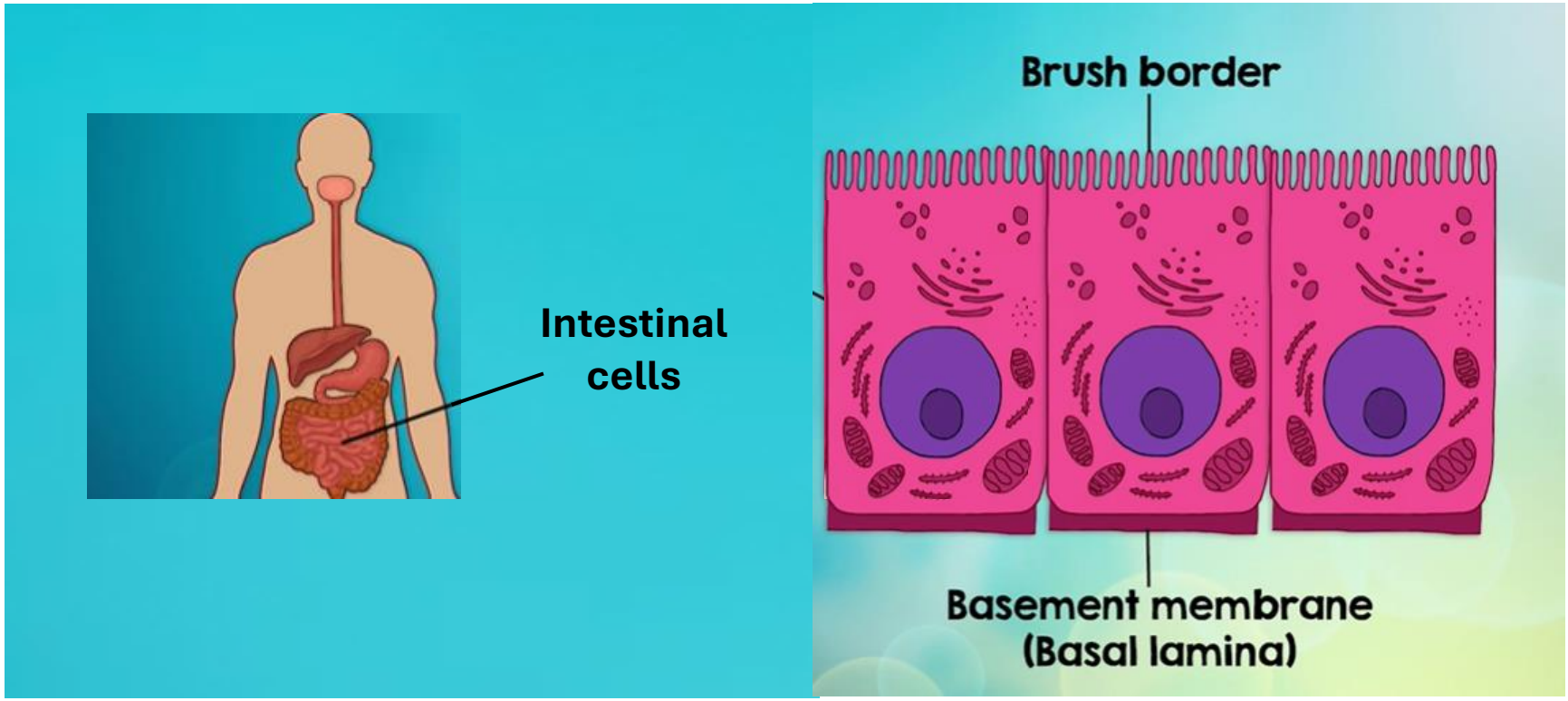
Other tissue



Characteristics of Epithelium

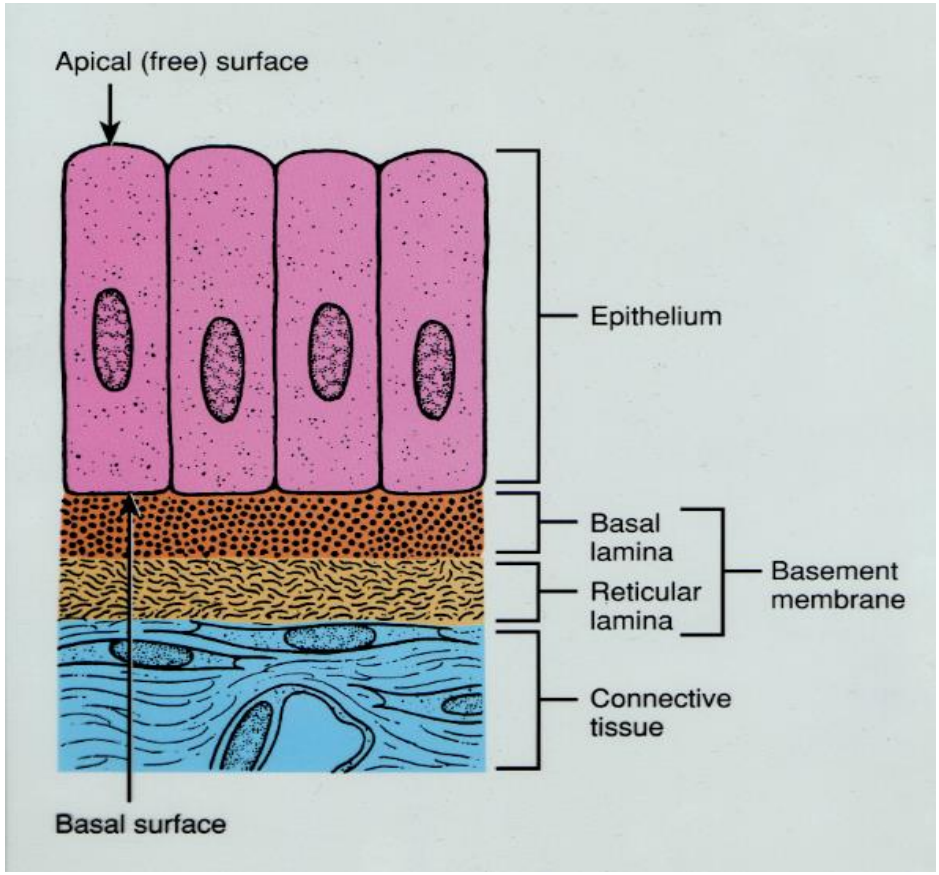
Polarity – The term polarity refers to the presence of structural and functional differences between the exposed and attached surfaces

An epithelium has an exposed surface, either facing the external environment or internal space, and a base, which is attached to underlying tissues.



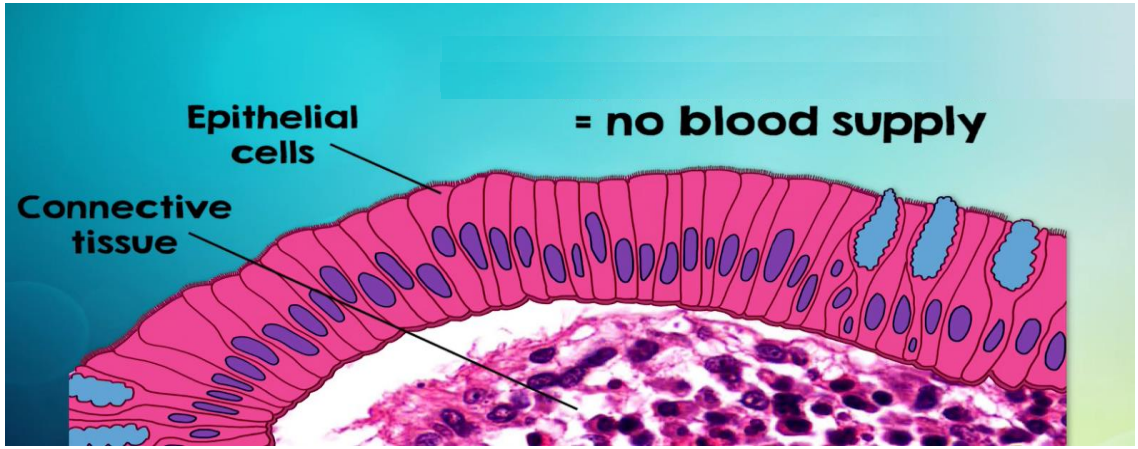
Characteristics of Epithelium

Attachment: basal surface against the basement membrane



Characteristics of Epithelium

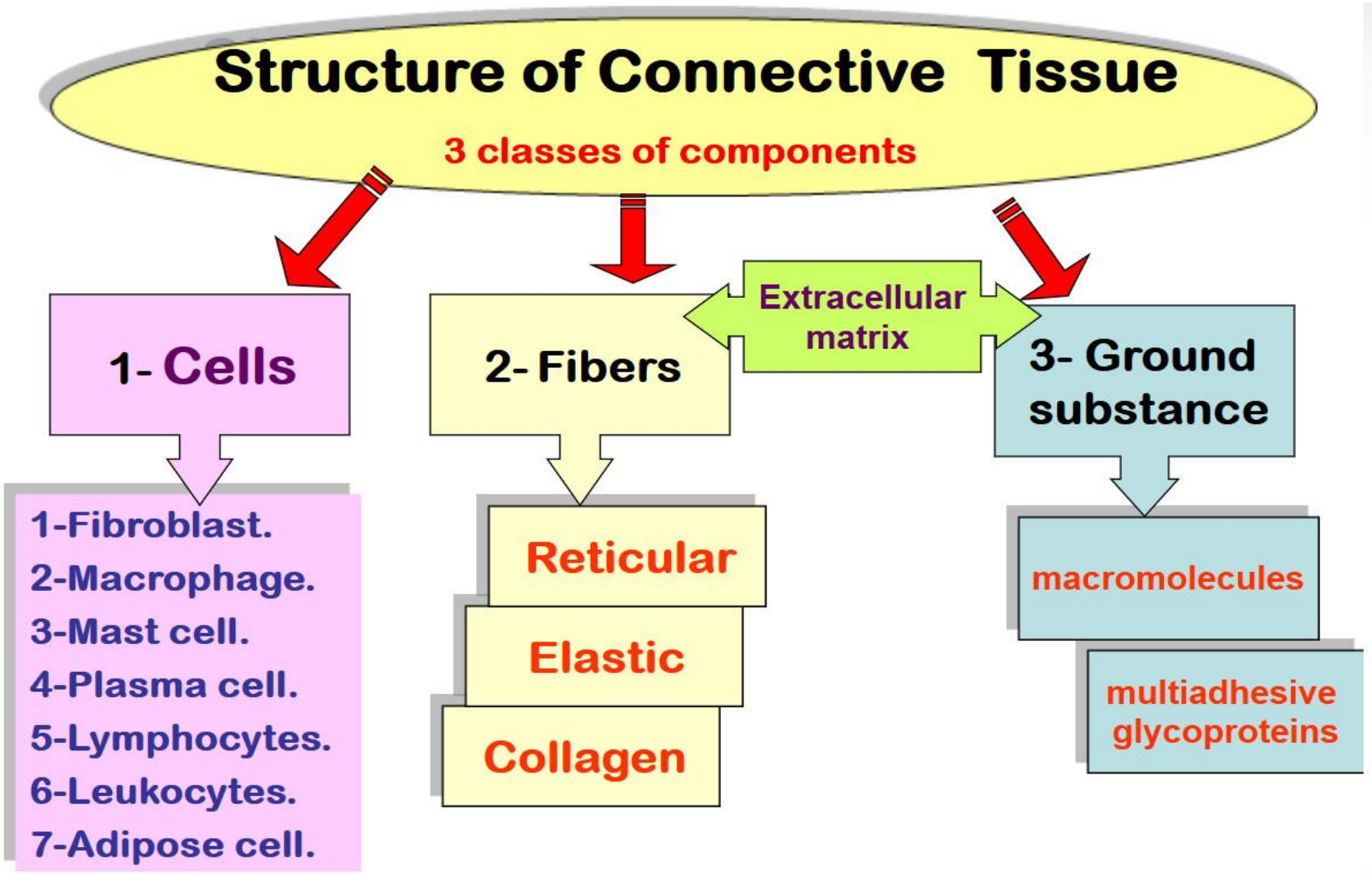
Avascular – contains no blood vessels but is supplied by nerve fibers (innervated)



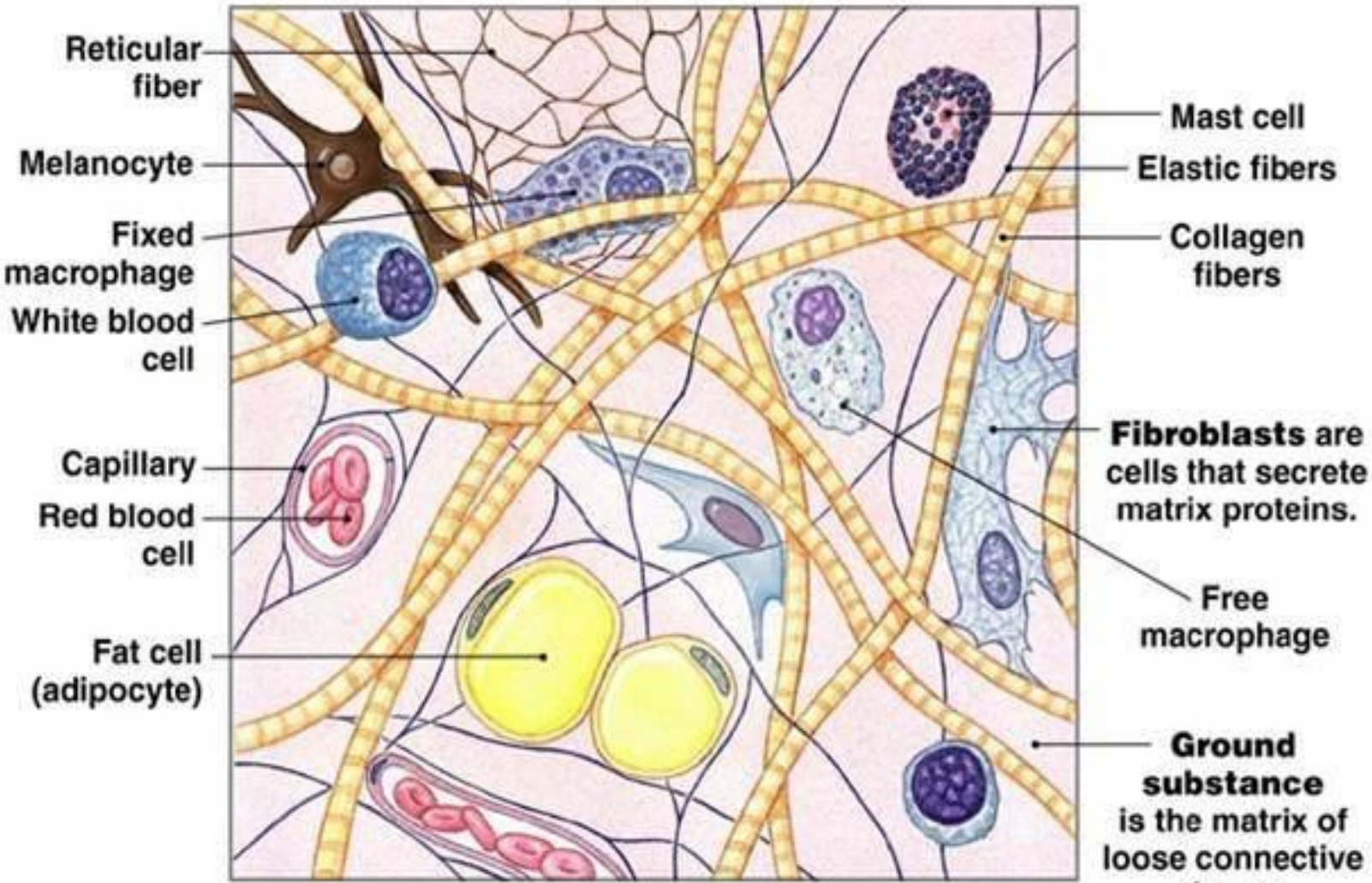
Regenerative – rapidly replaces lost cells by cell division. Regeneration is a characteristic of other tissues as well, but the rates of cell division and replacement are typically much higher in epithelia than in other tissues

Connective Tissue

Structural Elements of Connective Tissue



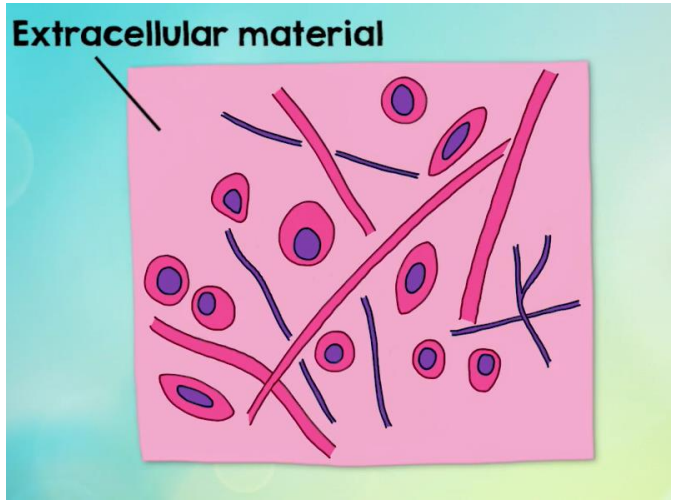
Connective Tissue

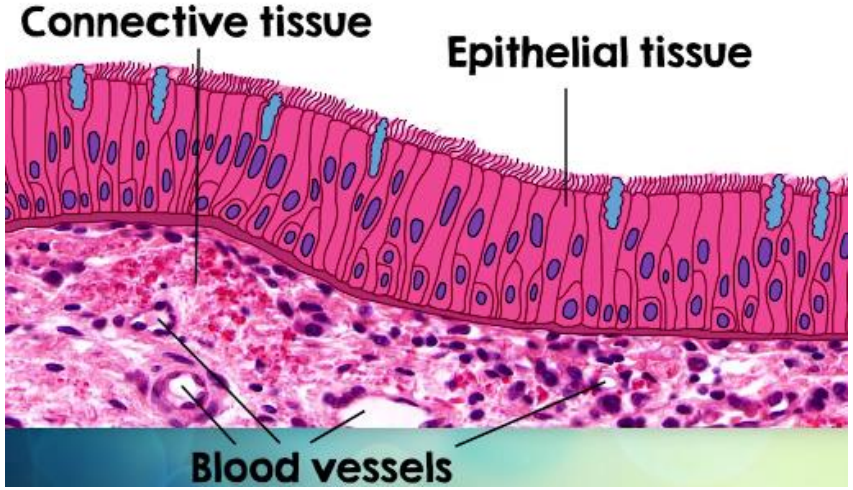


Loose connective tissue

Characteristics of Connective Tissue

- Most **abundant** type of tissue
- Cells are more **widely separated from each other** compared to the epithelial cells
- **Intercellular substance is present in considerably larger amounts**
- Connective Tissue is **vascular**





Muscle Tissue

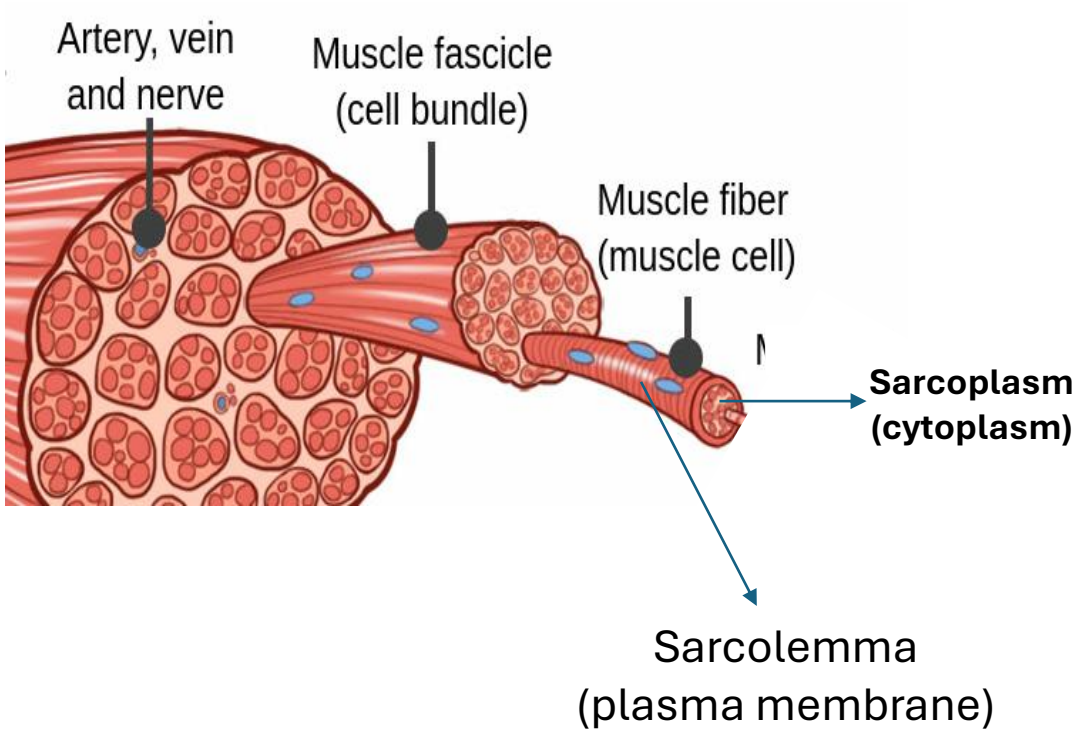
Muscle Tissue

Composed of specialized long cells having the ability to contract

- Since they are elongated in one direction hence called **muscle fibers** also known as **myocytes**

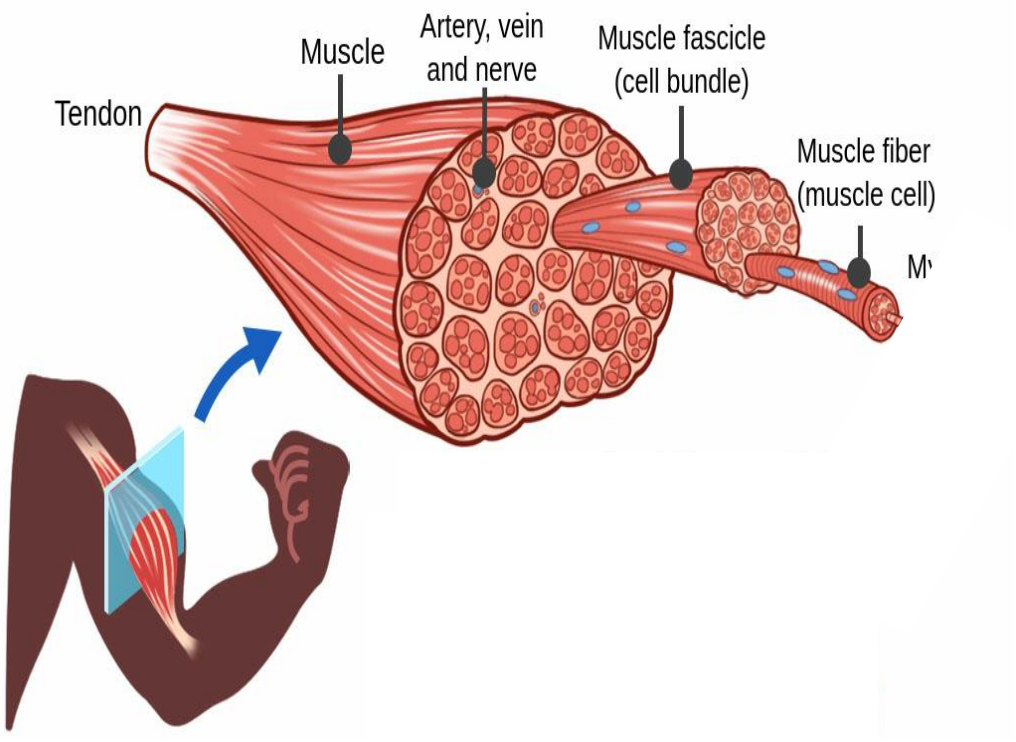
- Muscle tissue can **contract and relax** providing movement within the body and the body itself

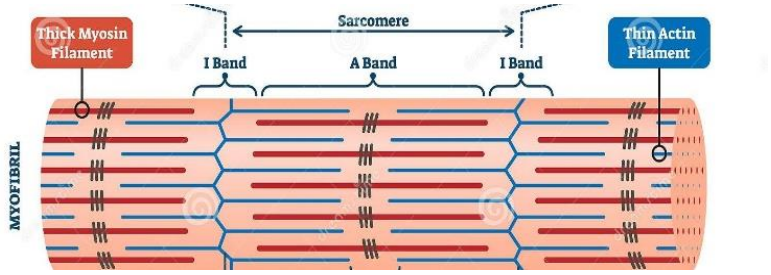
- Muscle contraction requires a **blood supply which provides oxygen and nutrients** and removes waste product

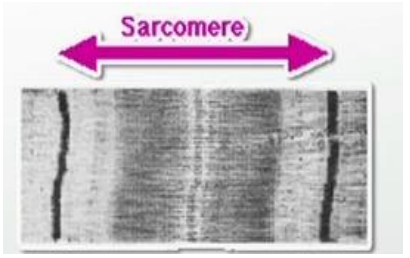


Sarcomere

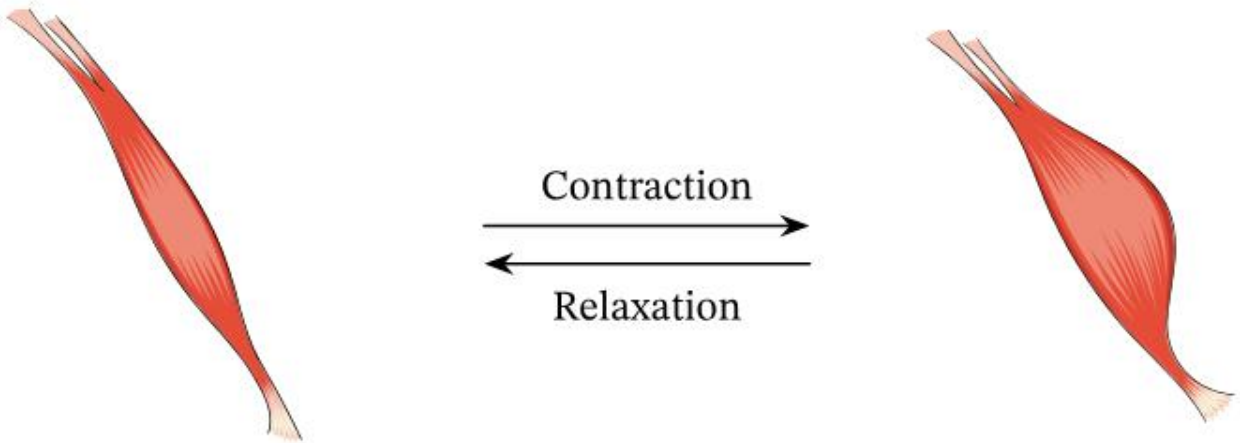
- **The sarcomere is the functional unit of the muscle tissue**
- Muscle fibers are elongated cells that contain **myo-contractile filaments** made of protein **actin and myosin.**
- Interaction between these proteins brings about contraction

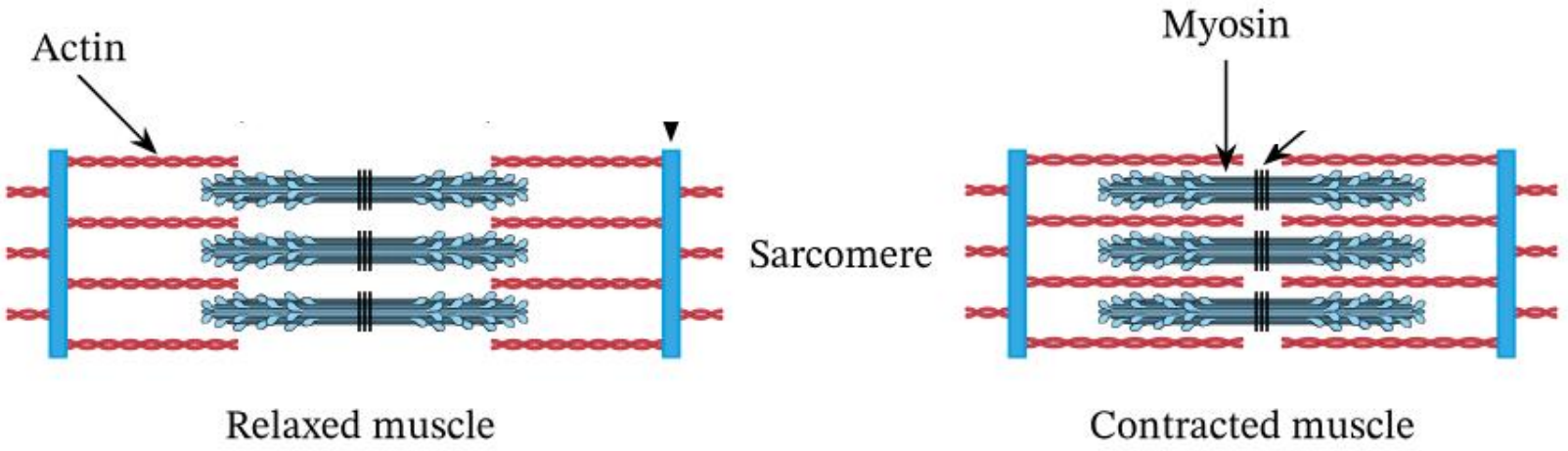






Contraction and Relaxation of muscles





Properties of muscular tissue

1. **Contractibility–** It is the ability of muscle cells to shorten forcefully.
2. **Extensibility–** A muscle has the ability to be stretched.
3. **Elasticity–** The muscles have the ability to recoil back to their original length after being stretched.
4. **Excitability–** The muscle tissue responds to a stimulus delivered from a motor neuron or hormone.

Nervous Tissue

Nervous Tissue

Nervous tissue is found in the central nervous system (CNS), and peripheral nervous system (PNS)

- It stimulates many **processes** in the body
- It is responsible for **coordinating and controlling** many body activities.
- **Sensing and responding**
- **Intellectual function:** memory, reasoning, emotions

To do all these things, cells in nervous tissue need to be able to communicate with each other by way of **electrical nerve impulses**

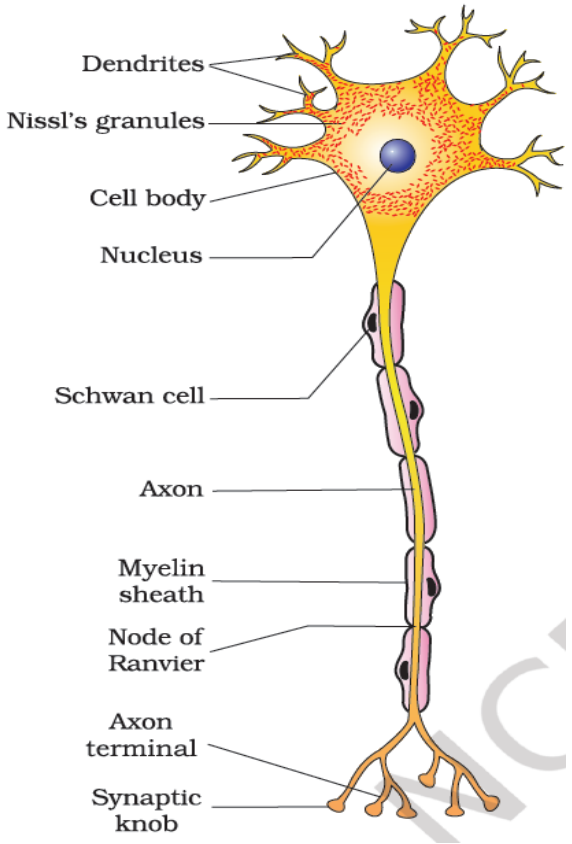
The cells in nervous tissue that generate and conduct impulses are called **neurons or nerve cells**

Cells of Nervous Tissue

Nervous tissue consists of two types of cells

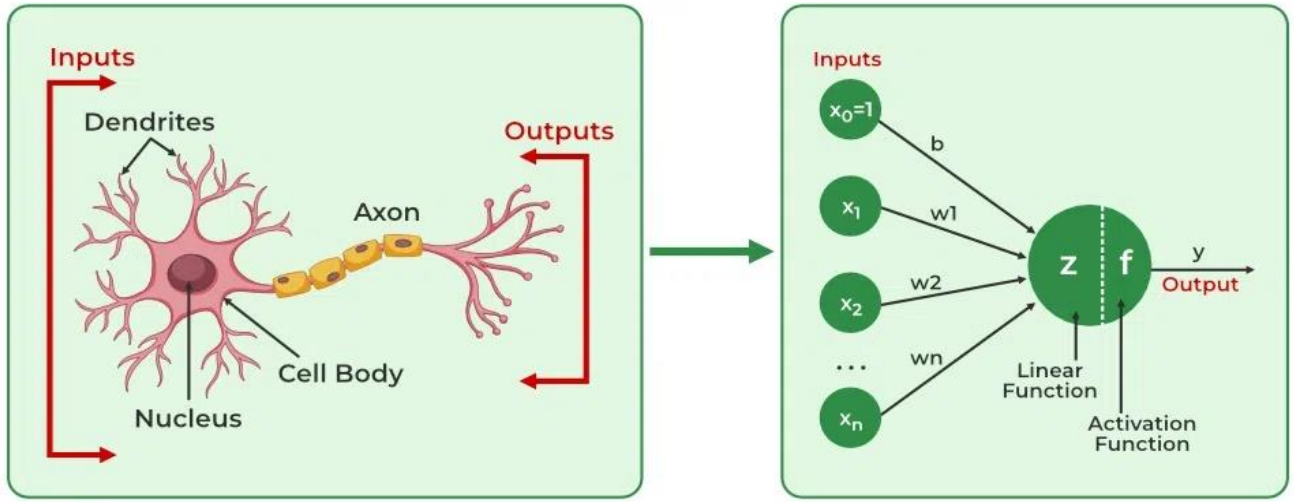
1 - **Neurons** – Neurons are defined as the basic structural and functional units of the nervous system.
   - **Excitable cells:** generate impulse
   - **Receive**
   - **Conduct**
   - **Transmission**

2 – **Neuroglia (Supporting cells)**
   - **Non excitable**
   - **They support**
   - **Nourish**
   - **Protect neurons**



Artificial Neural Networks and its Applications

- Computer systems designed to mimic how the human brain processes information.
- ANNs use artificial neurons to analyze data,
- ANNs can "learn" from the data they process, just as our brain learns from experience



Activity 1

Which tissue type has cells that are tightly packed with minimal extracellular material?
A. Connective tissue
B. Epithelial tissue
C. Muscular tissue
D. Nervous tissue

Epithelial tissue

Which tissue type is capable of generating electrical impulses and transmitting them?
A. Connective tissue
B. Epithelial tissue
C. Muscular tissue
D. Nervous tissue

Nervous tissue

Which tissue type can contract and produce movement?
A. Muscular tissue
B. Connective tissue
C. Nervous tissue
D. Epithelial tissue

Muscular tissue

Activity 1 (contd.)

1. **A researcher observes a tissue sample with cells arranged in continuous sheets and no blood vessels, relying on diffusion for nutrients. Which tissue and which property are reflected here?**

2. A slide shows a tissue with widely scattered cells and a lot of intercellular space filled with fibers and fluid. Which tissue and which property?

3. During a lab experiment, a tissue sample is observed to shorten when stimulated electrically, pulling on a slide cover slip. **Which functional characteristic is being demonstrated?**

Biomaterials and Biocompatibility

Can you think of a situation where your body rejected something??

- Ever worn an earring or a necklace that left your skin red, itchy, or blistered?
- Have you ever had red marks or rashes after wearing a band-aid for too long?
- Some people get **inflammation or even pus** around stitches

If a part of your body—say a bone, tooth, or even your heart—gets damaged or needs replacement

- **what would you put inside?**
- **And how would you know if your body accepts it?**

Definition:

A **biomaterial** is any natural or synthetic substance that can **interact with biological systems** for a **medical purpose**—such as **treatment, re**

Fun Fact:

"Did you know some contact lenses are made of silicone-based polymers that were originally developed for **spacecraft insulation**?"

- **Examples:**
- **Metals:** Titanium (implants), stainless steel (surgical tools)
- **Polymers:** Silicone (catheters), PLA/PEG (drug delivery)
- **Ceramics:** Hydroxyapatite (bone grafts), alumina (dental implants)
- **Natural materials:** Collagen, chitosan, alginate


Medical devices
Bone in
Nerve Implants
Suture
Suture
Polymer nerve conduit
Polymeric biomaterial
Ocular implants
Breast Implant
Drug delivery
Radiotherapy
Biosensor
COFs
TMDCs
Metals
LDHs
MOFs
C_3N_4
MXenes
BN
Xenes
Immunotherapy
Bioimaging
Antibacteria
Phototherapy
Nanodynamic therapy
Tissue engineering

What is Biocompatibility?

Will the Body Accept It?

Biocompatibility is the ability of a biomaterial to perform its function in the body **without causing harm**, while supporting the desired biological response.

Key Factors:

- **Non-toxicity** (doesn't kill cells)
- **Non-immunogenicity** (doesn't trigger the immune system)
- **Stability** (doesn't degrade too quickly)
- **Integration** (supports healing or tissue bonding)

Example:

1. A **pacemaker** casing made of titanium is **biocompatible** because it doesn't corrode or irritate tissues.
2. **Dental Implants** (Titanium)
3. **Intraocular Lenses** (PMMA, Silicone) in cataract surgery

Engineering Design Considerations: Factors to consider while designing

Choosing the Right Biomaterial:

- Must match **mechanical properties** of tissue (e.g., bone vs. blood vessel)
- Must resist **corrosion**, **degradation**, or **wear**
- Should promote **cell attachment**, **healing**, or **drug release** as needed

Applications:

- **Orthopedics:** Bone plates, joint replacements
- **Cardiology:** Stents, heart valves
- **Tissue Engineering:** Scaffolds for growing new organs

Activity Title: “Quick Class Poll"

1. Which of these materials is considered most biocompatible for bone implants?

- A) Teflon
- B) Stainless Steel
- C) Wood
- D) Rubber

✅ **Answer: B) Stainless Steel**

2. Which material naturally integrates with bone tissue due to osseointegration?

- A) Titanium
- B) Nylon
- C) PVC
- D) Silver

✅ **Answer: A) Titanium**

3. Which material is commonly used in dental implants due to its corrosion resistance and compatibility?

- A) Copper
- B) Titanium
- C) Zinc
- D) Acrylic

✅ **Answer: B) Titanium**

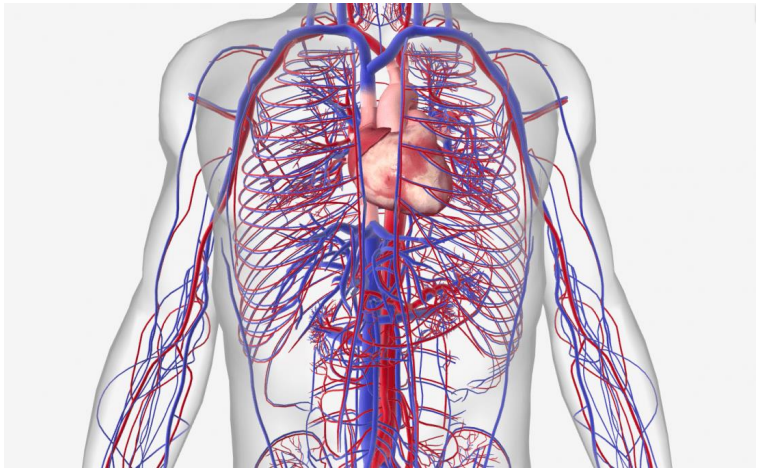
Which of the following is a natural biomaterial widely used in wound dressings and tissue scaffolds?

- A) Chitosan
- B) Nylon
- C) Acrylic
- D) Teflon

✅ **Answer: A) Chitosan**

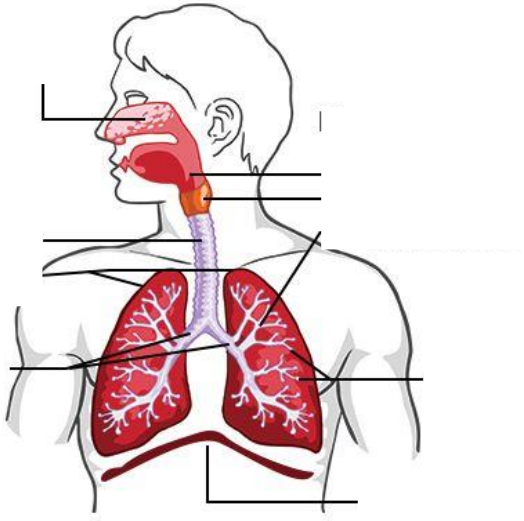
Cardiovascular, respiratory, and nervous systems

Cardiovascular system



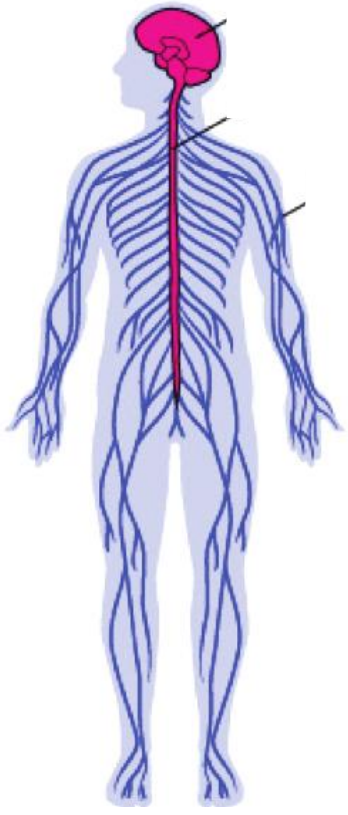
Principal functions:
Distribution of nutrients, oxygen, wastes, hormones, electrolytes,
heat, immune cells, and antibodies; fluid, electrolyte, and
acid-base balance

Respiratory system



Principal functions:
Absorption of oxygen, discharge of carbon dioxide, acid–base balance, speech

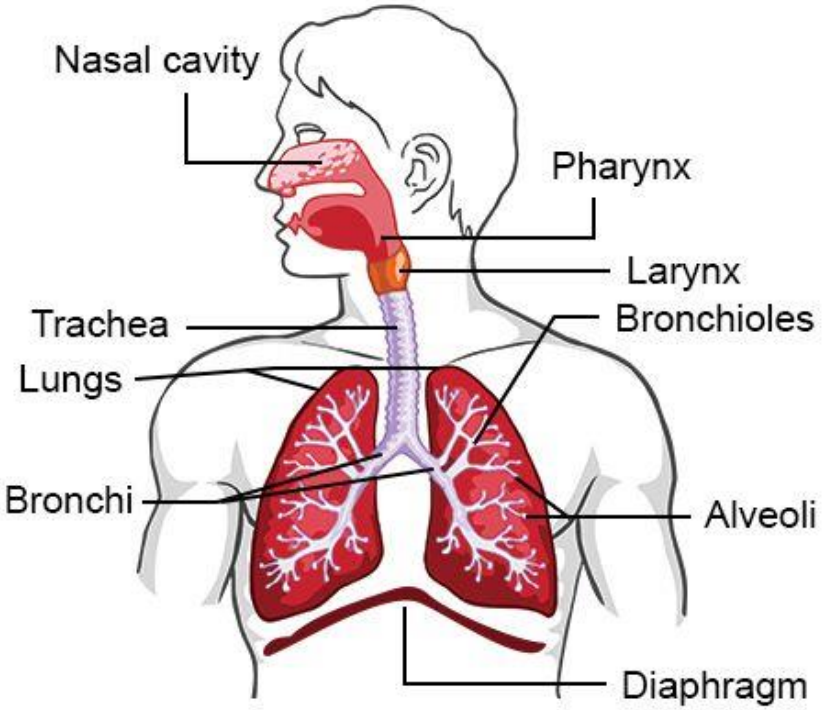
Nervous system



Principal functions:
Rapid internal communication, coordination, motor control
and sensation

Human Respiratory System

- A pair of external **nostrils** open out above the upper lips.
- It leads to a **nasal cavity** through the nasal passage.
- The nasal cavity opens to **pharynx**
- **Pharynx – Larynx – Trachea – Bronchi – Lungs**



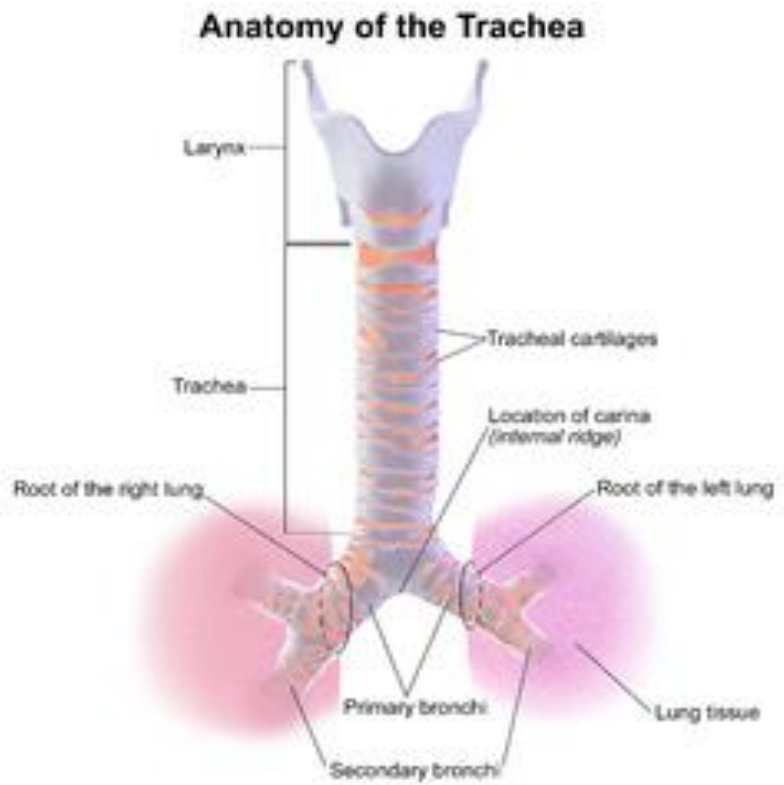
<u>Upper respiratory tract</u>

Nose
Nasal cavity
Pharynx

<u>Lower respiratory tract</u>

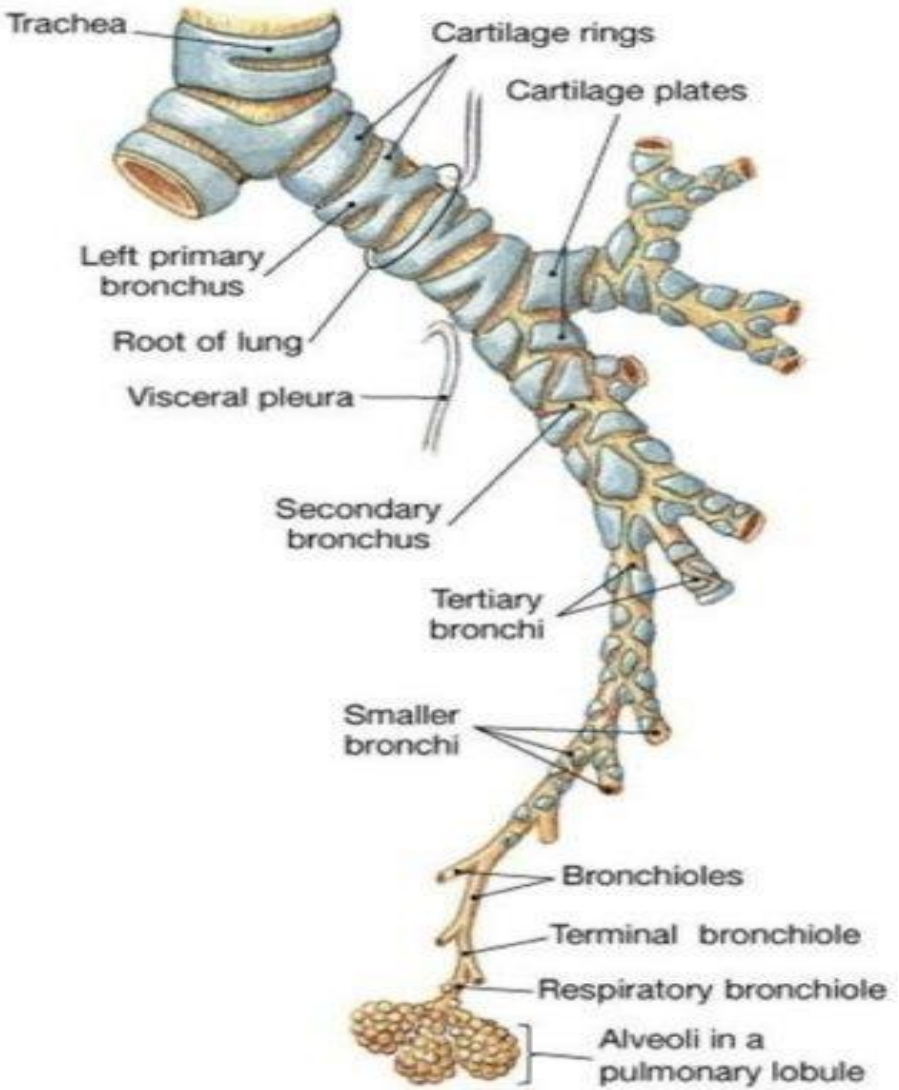
Larynx
Trachea
Bronchi
Lungs

Human respiratory system -Trachea



- **The trachea** or **windpipe** is a straight tube extending up to the mid-thoracic cavity
- It divides into the right and left primary bronchi. Right bronchus go into the right lung and the left bronchus which goes into the left lung
- They are **C-shaped** rings of **hyaline cartilage** to protect and support the trachea and bronchi from collapsing

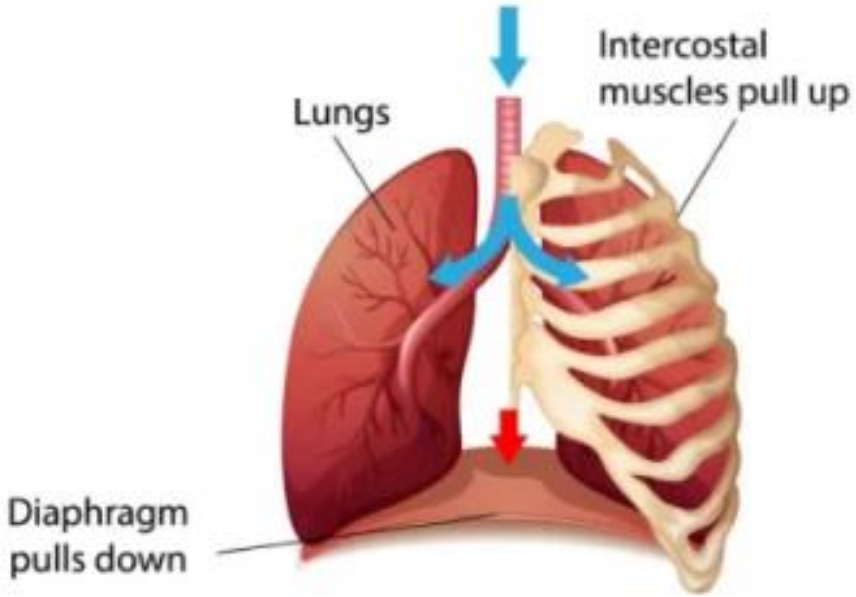
Trachea, Bronchi and Bronchioles

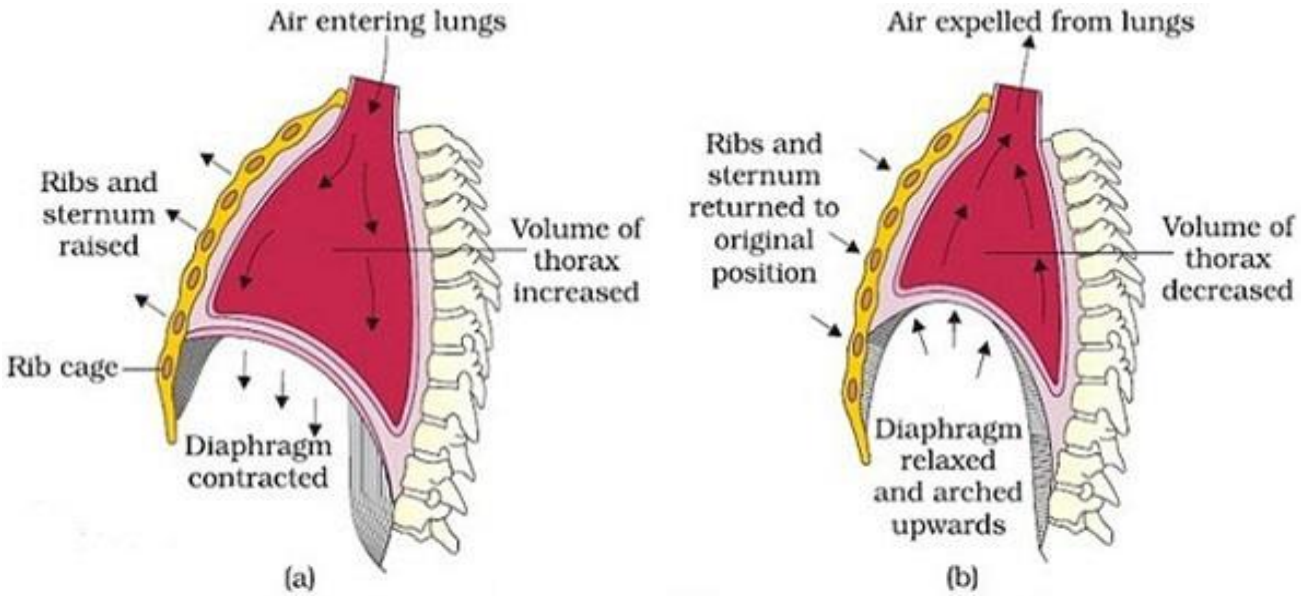


- On entering the lungs, the primary bronchi divide to form smaller bronchi the **secondary bronchi**
- The secondary bronchi continue to branch, forming still smaller **bronchi called tertiary bronchi** that divide into **bronchioles**.
- Bronchioles terminate with air-sacs called as **Alveoli**

Breathing

The process of exchange of oxygen from the environment with carbon dioxide produced by the cells is termed breathing



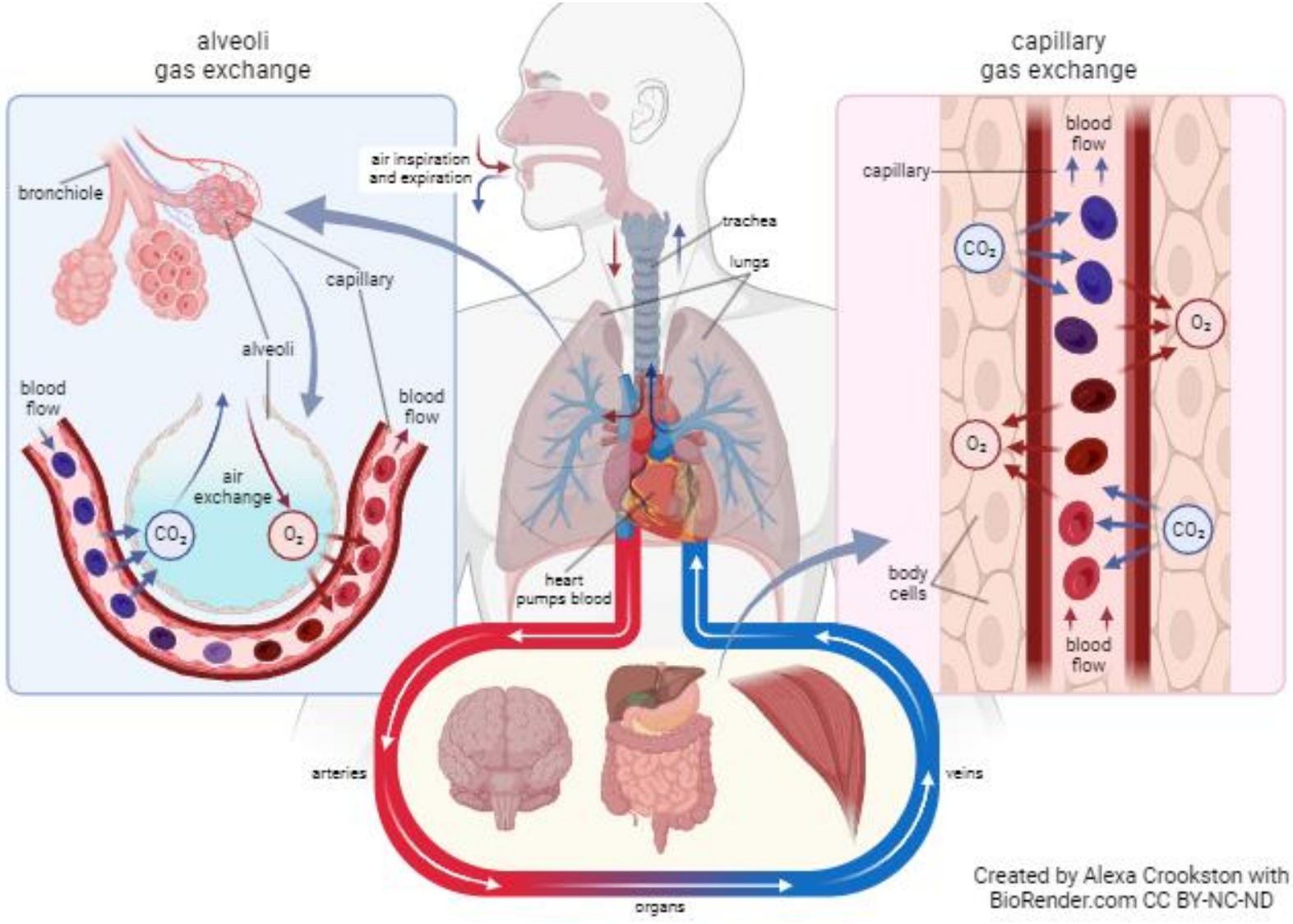


Mechanism of Breathing
a. Inspiration
b. Expiration

Respiration

External Respiration: Exchanges Gases Between the Lungs and the Bloodstream

Internal Respiration: Exchanges Gases Between the Bloodstream and Body Tissues

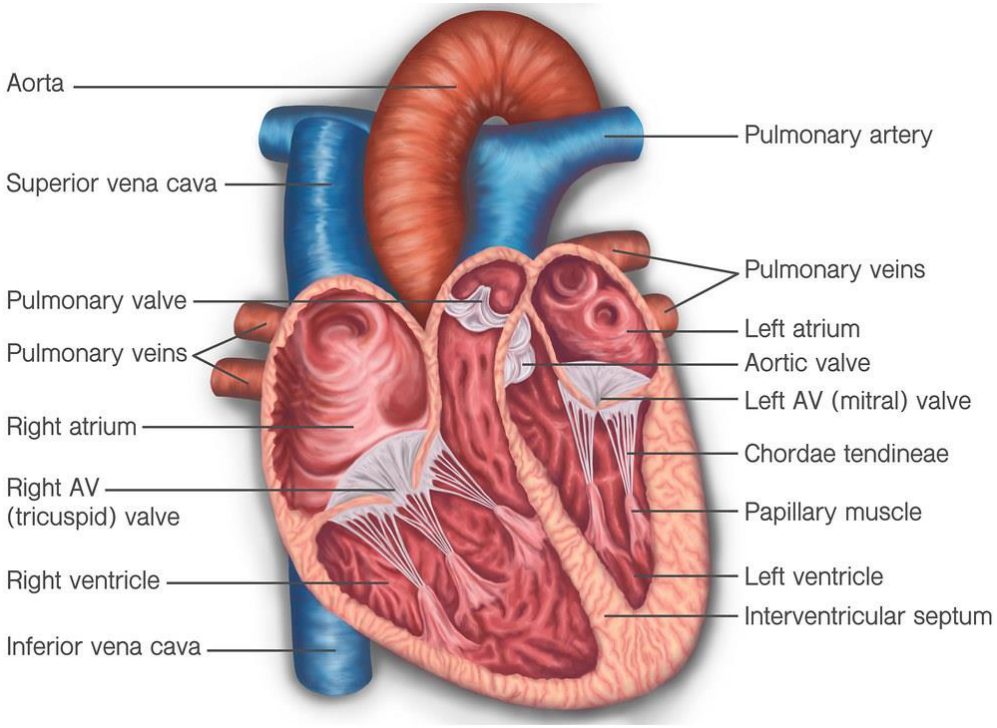


Video showing the function of respiratory system

https://www.youtube.com/watch?v=BSskr1IkeW8&t=9s

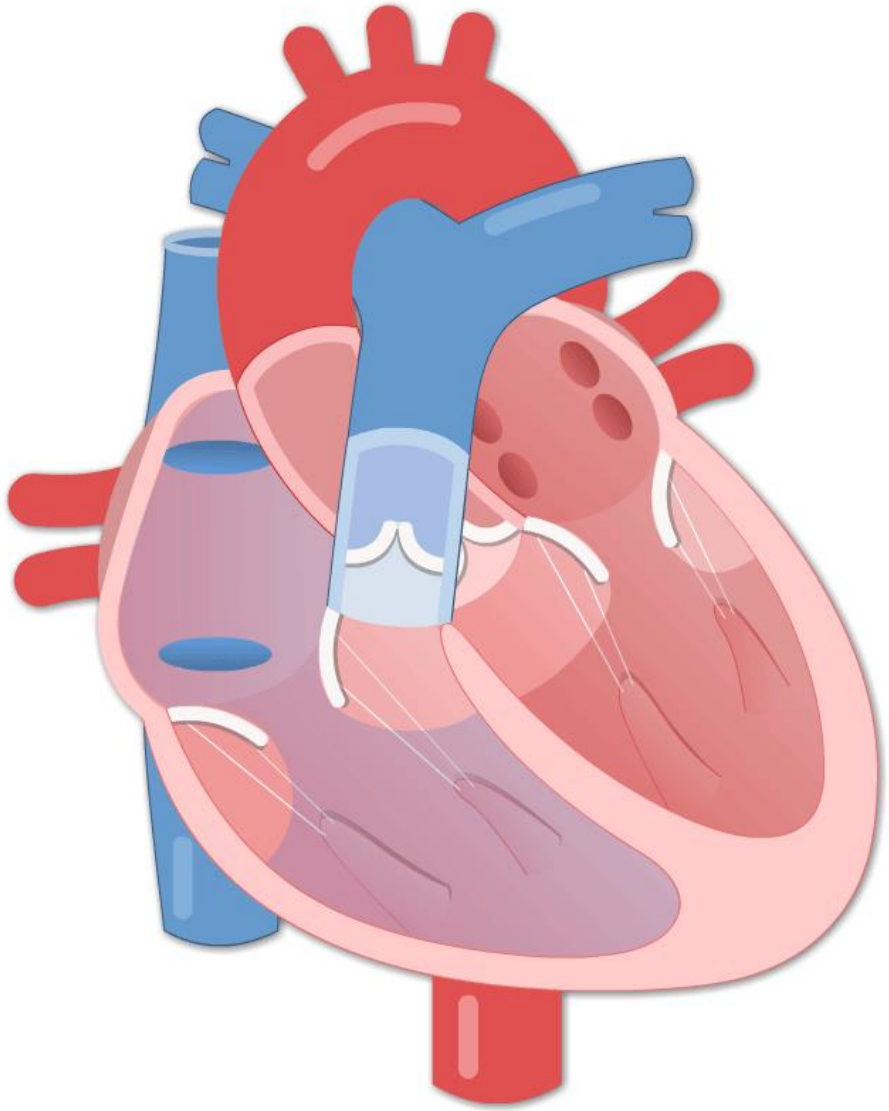
Structure of heart

- Human heart has four chambers, two relatively **small upper chambers called atria** and **two larger lower chambers called ventricles**
- Muscular wall called the **interatrial septum** separates the **right and the left atria**, whereas **the inter-ventricular septum**, separates the left and the right ventricle
- The atrium and the ventricle on the same side are also separated by a thick fibrous tissue called the **atrioventricular septum**



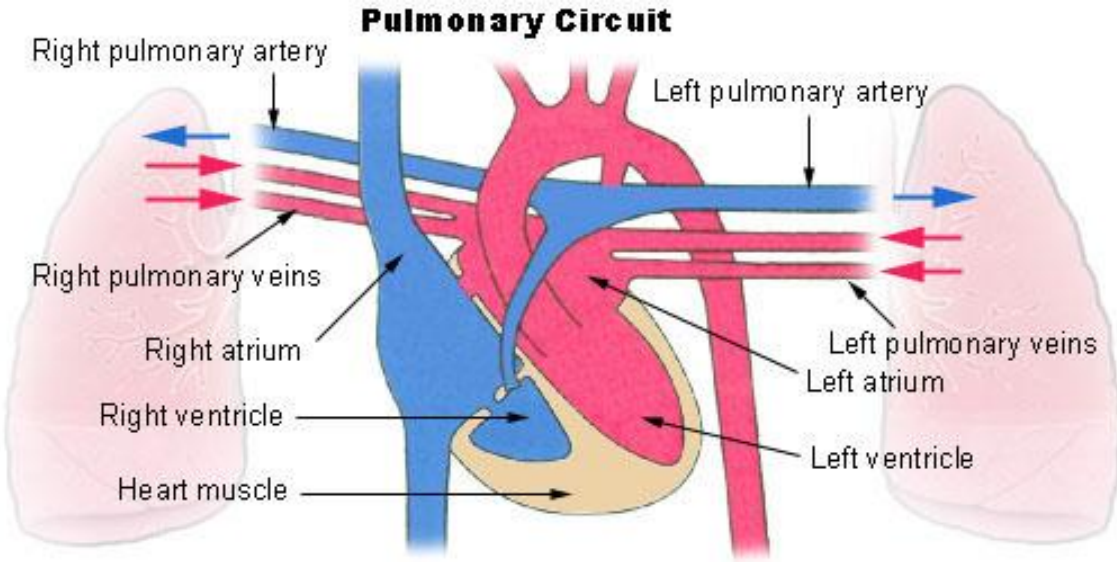
Cardiac cycle

This sequential event in the heart which is cyclically repeated is called the cardiac cycle and it consists of systole and diastole of both the atria and ventricles



Pulmonary circulation

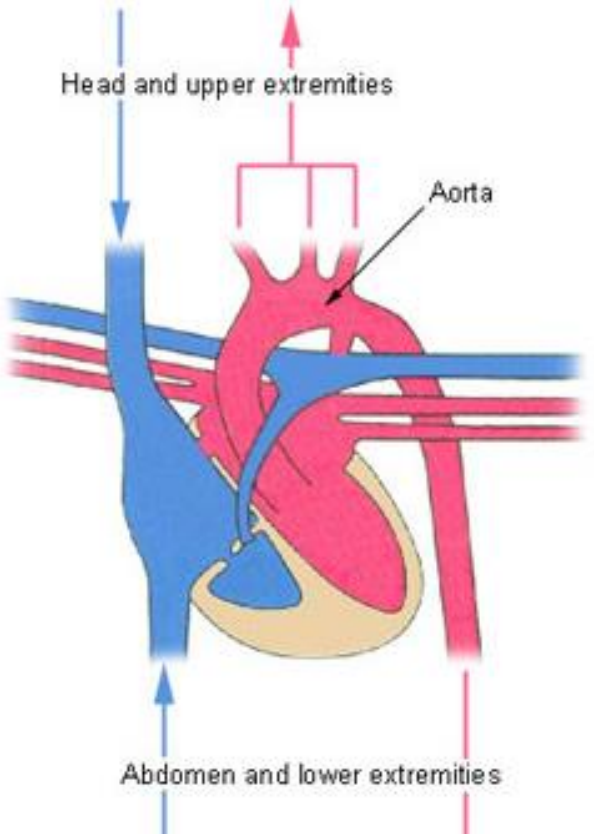
- The right side of the heart pumps deoxygenated blood from **right ventricles** to the lungs
- Gas exchange occurs i. e. the blood collects oxygen (O_2) from the air sacs and carbon (CO_2) dioxide diffuses into the air sacs for exhalation
- From the lungs the oxygenated blood flows to the **left Atrium**



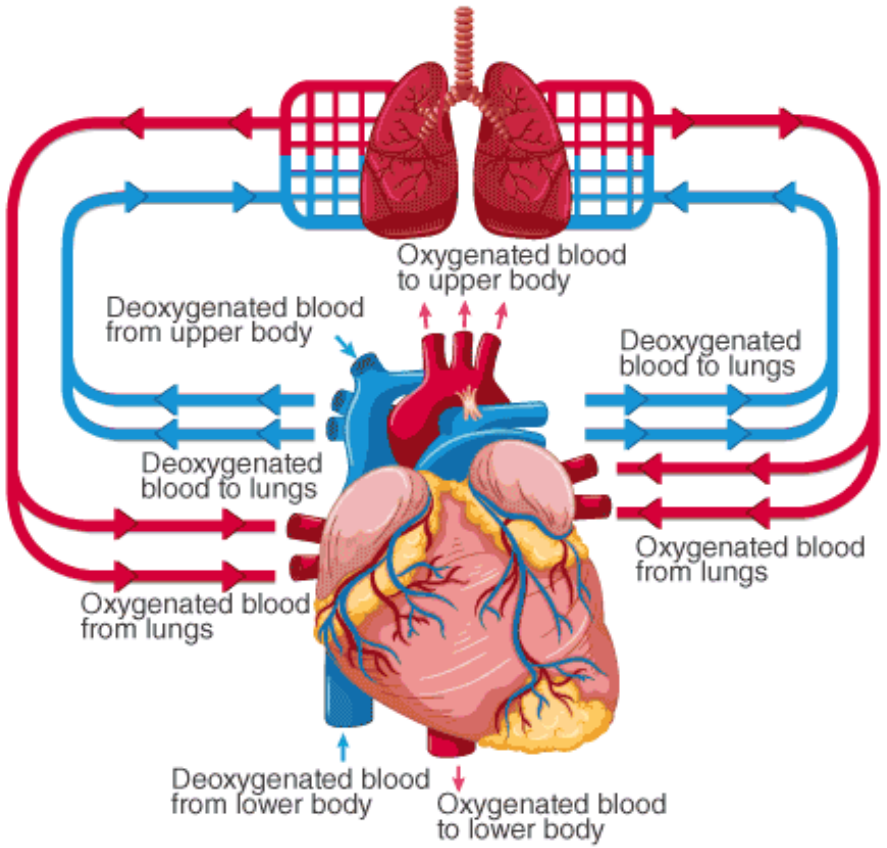
Systemic circulation

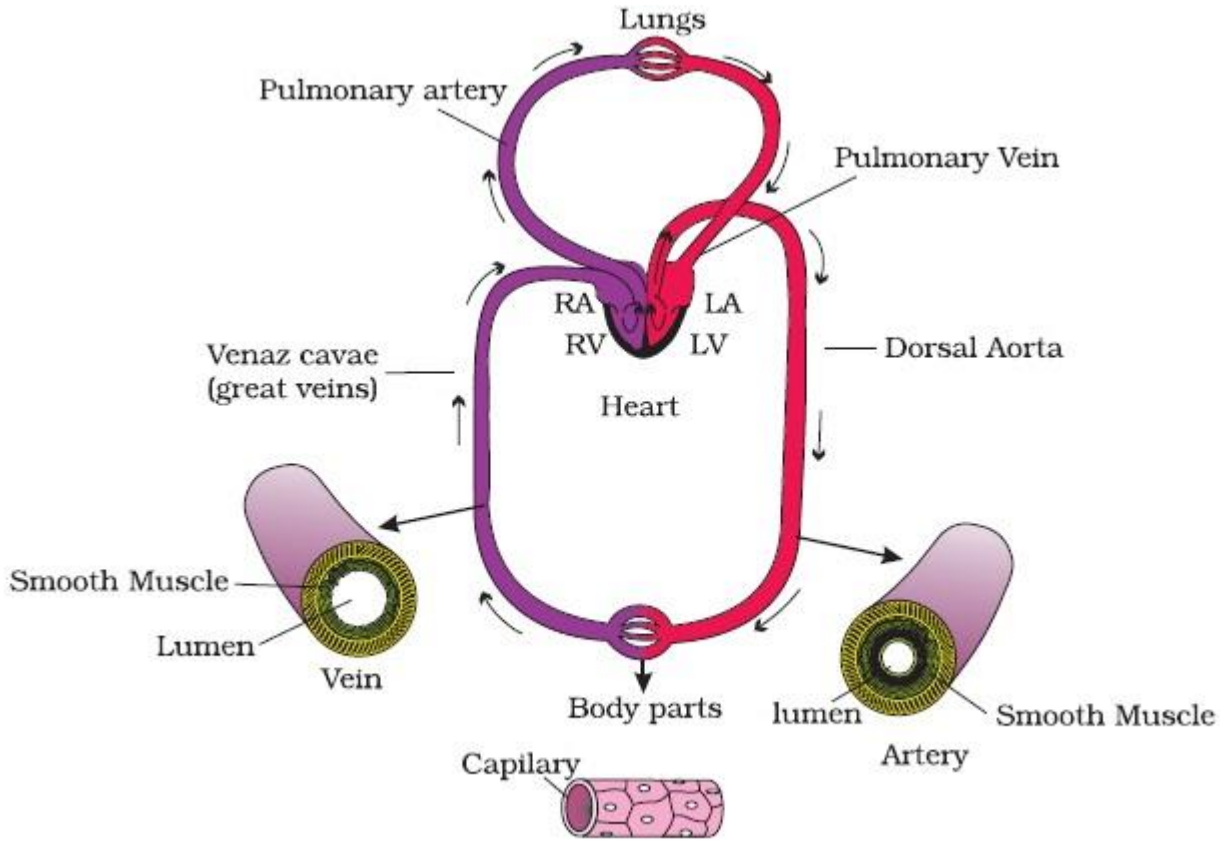
- The left side of the heart pumps blood to systemic circulation which supplies the blood to rest of the body

- Body cells extract nutrients and oxygen from the oxygenated blood and tissue wastes are passed into the blood for excretion



Blood circulatory system

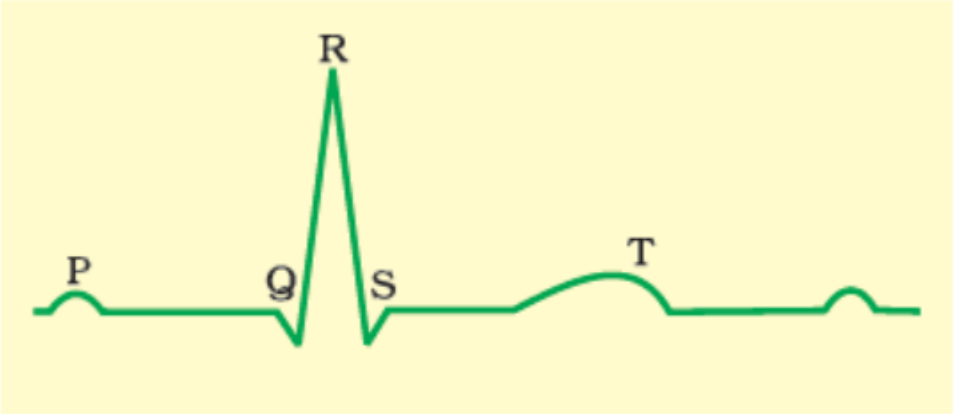




Electrocardiogram/ Electrocardiography (ECG)

Electrocardiography (ECG) is a graphical representation of the electrical activity of the heart during a cardiac cycle. The main goal of electrocardiography is to obtain information regarding the pattern of cardiac cycle

- **The P-wave** represents the **electrical excitation (or depolarisation) of the atria**, which leads to the contraction of both the atria.
- **The QRS complex** represents the depolarisation of the ventricles, which initiates the ventricular contraction. The contraction starts shortly after **Q and marks the beginning of the systole.**
- **The T-wave** represents the return of the ventricles from an excited to **normal state (repolarisation). The end of the T-wave**



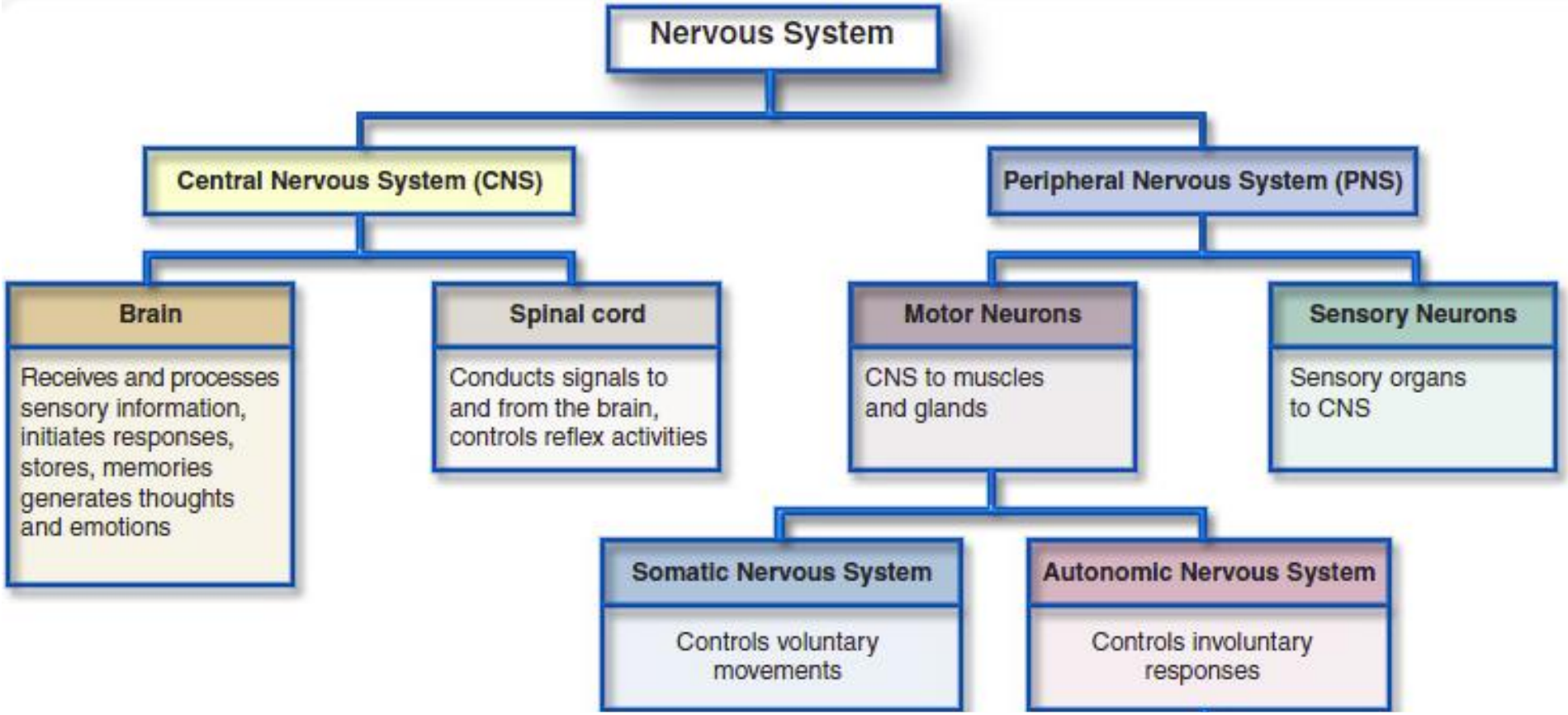
Cardiovascular diseases

- **Coronary Artery Disease (CAD)** : Blood Vessel Diseases
- **Cardiomyopathy**: Heart Muscle Disease
- **Heart Valve Disease**: Problems with the heart valves
- **Arrhythmias**: Abnormal Heart Rhythms
- **Congenital Heart Defects**

Structural Classification of the Nervous System

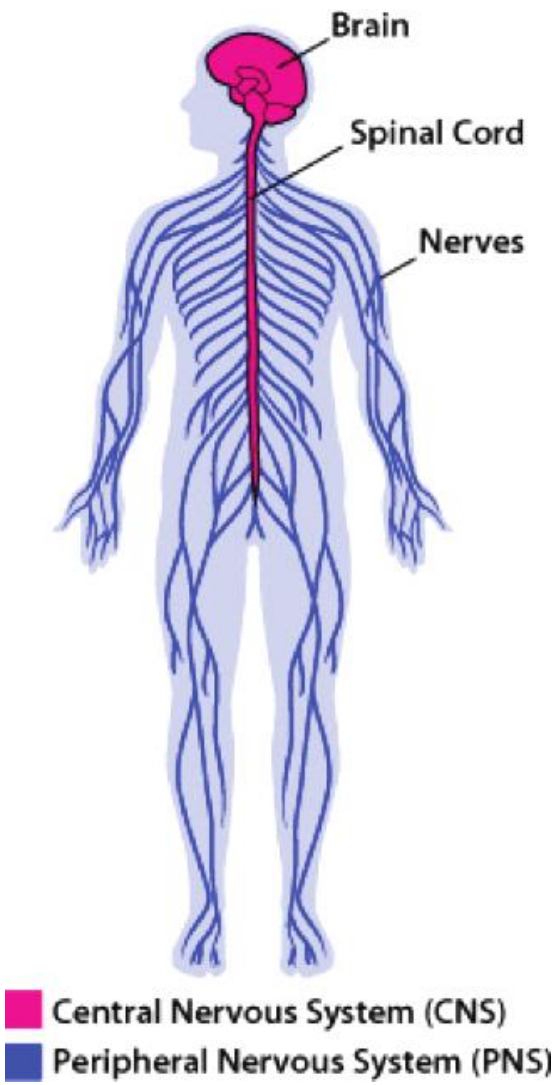
1. Central nervous system (CNS)

2. Peripheral nervous system (PNS)

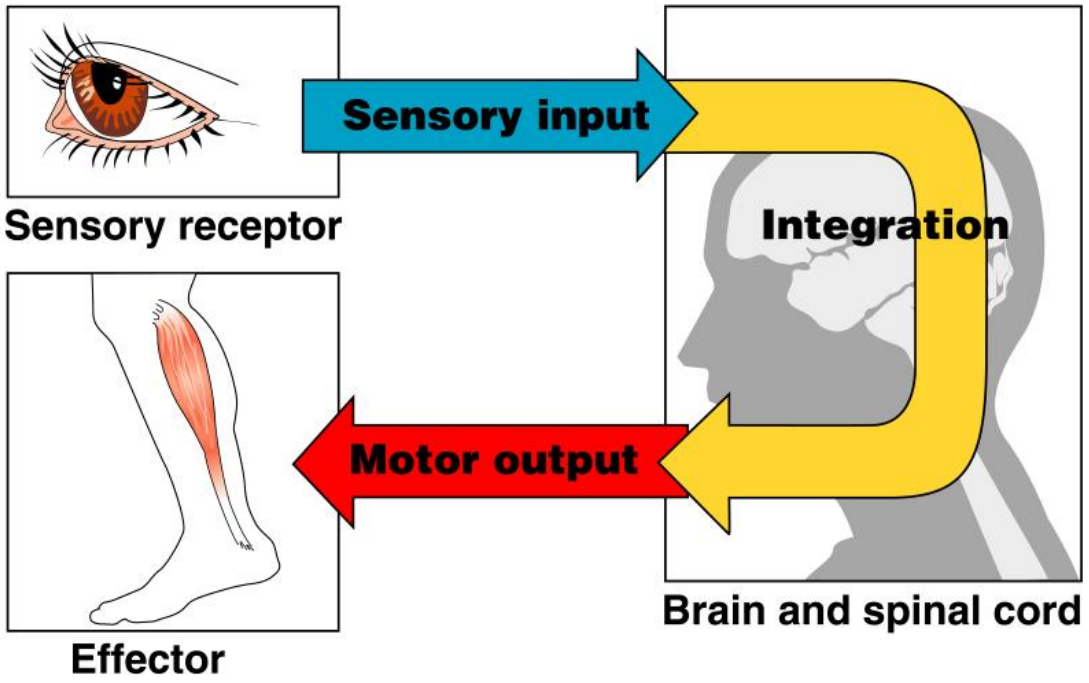


skeletal muscle

Smooth muscle
cardiac muscle
glandular tissue

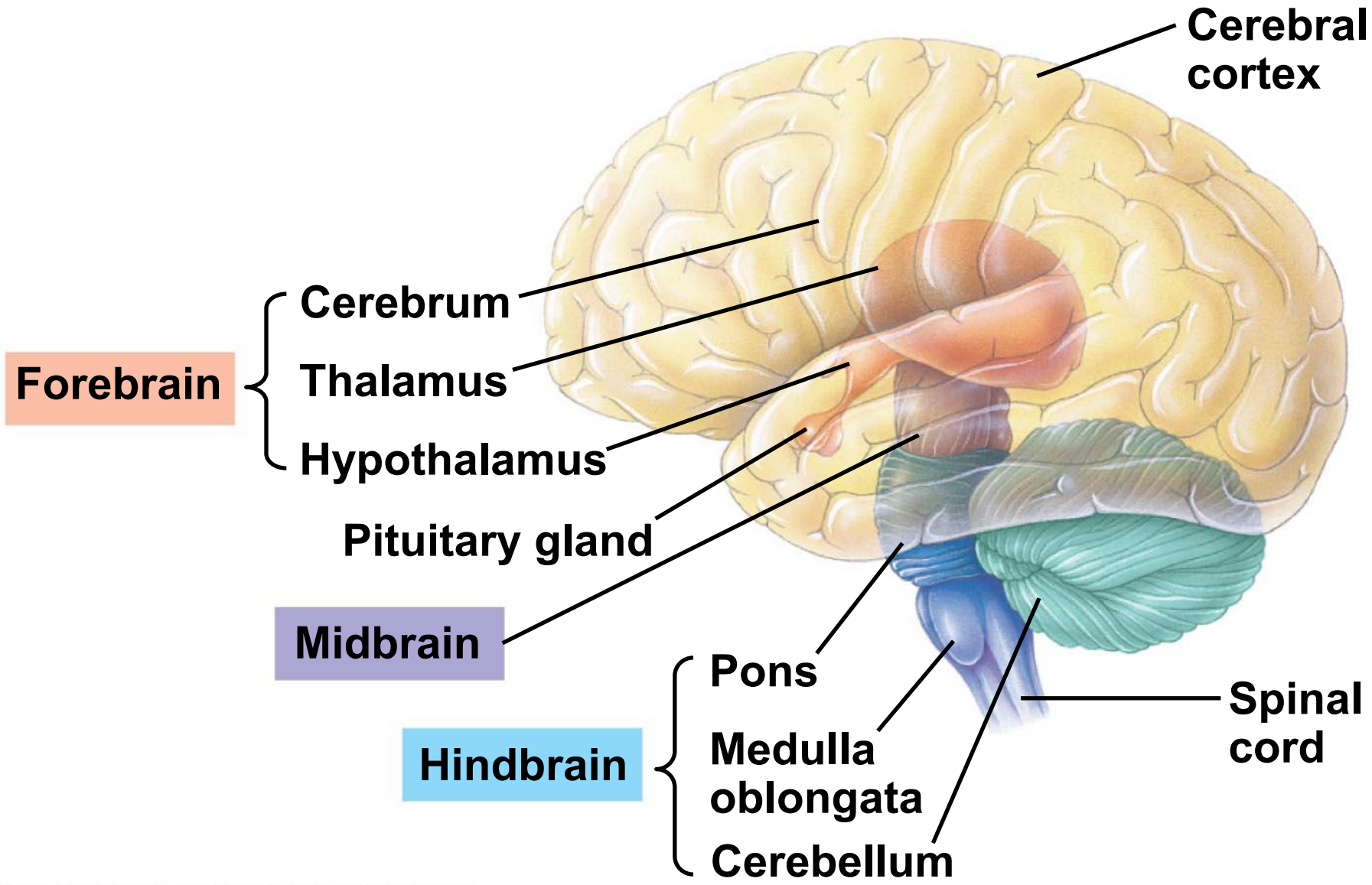


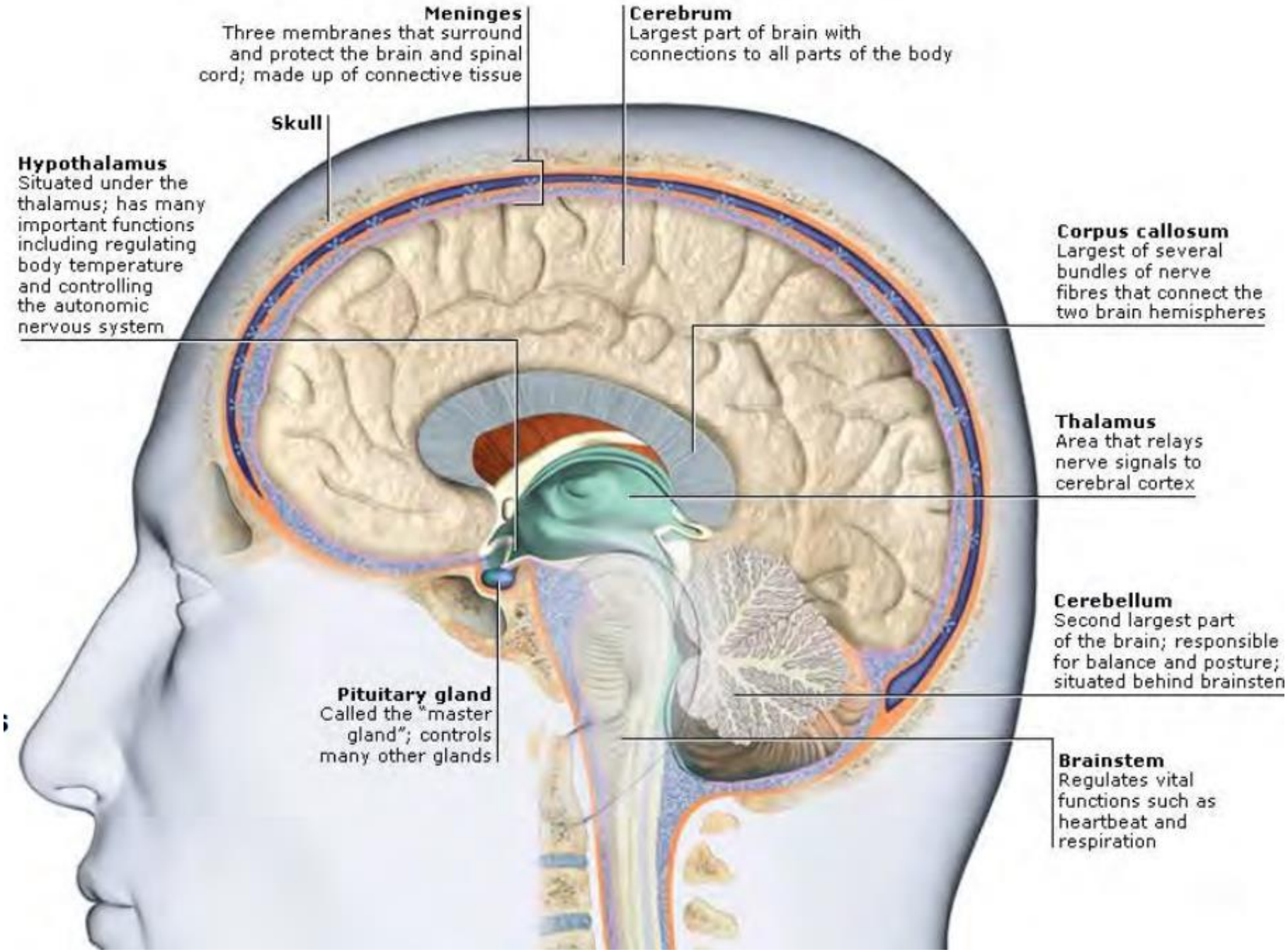
Functions of the Nervous System

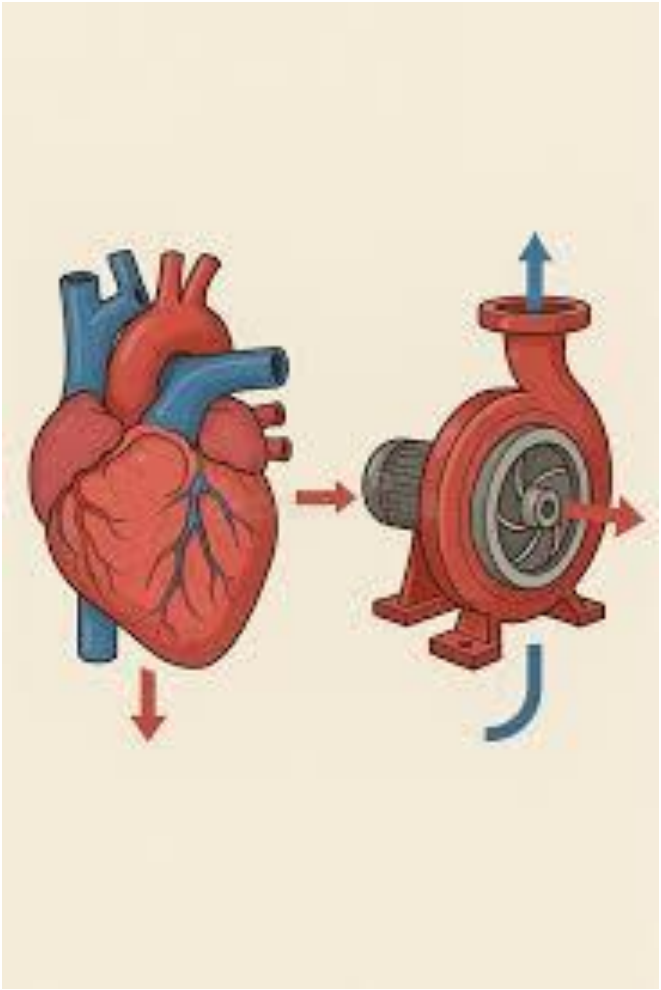


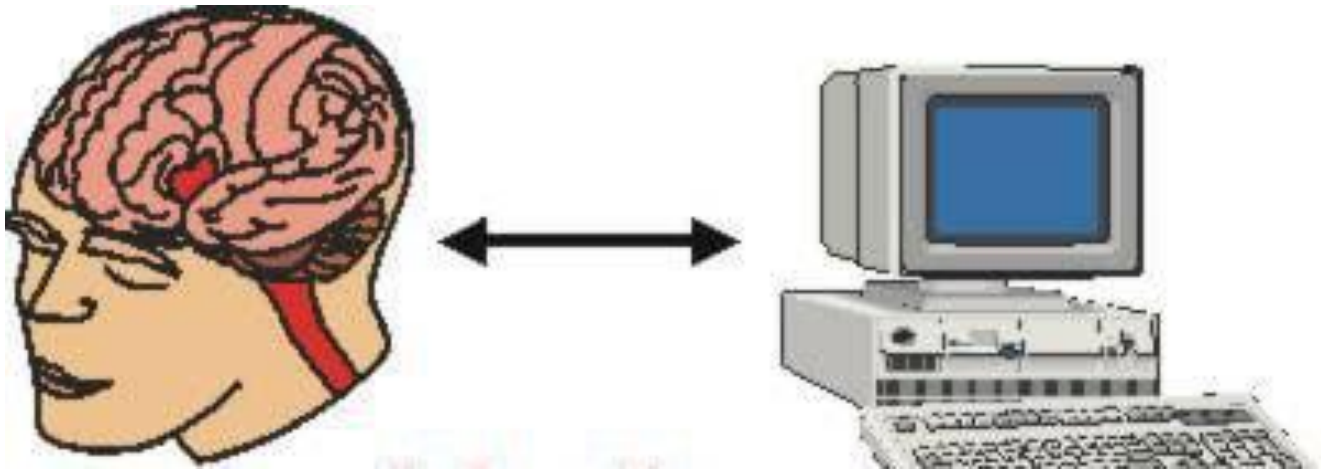
- Sensory input – gathering information
- Transmission
- Integration
- Motor output

Human Brain


Cerebral cortex
Forebrain
Cerebrum
Thalamus
Hypothalamus
Pituitary gland
Midbrain
Pons
Hindbrain
Medulla oblongata
Cerebellum
Spinal cord


Meninges
Three membranes that surround and protect the brain and spinal cord; made up of connective tissue
Cerebrum
Largest part of brain with connections to all parts of the body
Skull
Hypothalamus
Situated under the thalamus; has many important functions including regulating body temperature and controlling the autonomic nervous system
Corpus callosum
Largest of several bundles of nerve fibres that connect the two brain hemispheres
Thalamus
Area that relays nerve signals to cerebral cortex
Cerebellum
Second largest part of the brain; responsible for balance and posture; situated behind brainsten
Pituitary gland
Called the "master gland"; controls many other glands
Brainstem
Regulates vital functions such as heartbeat and respiration





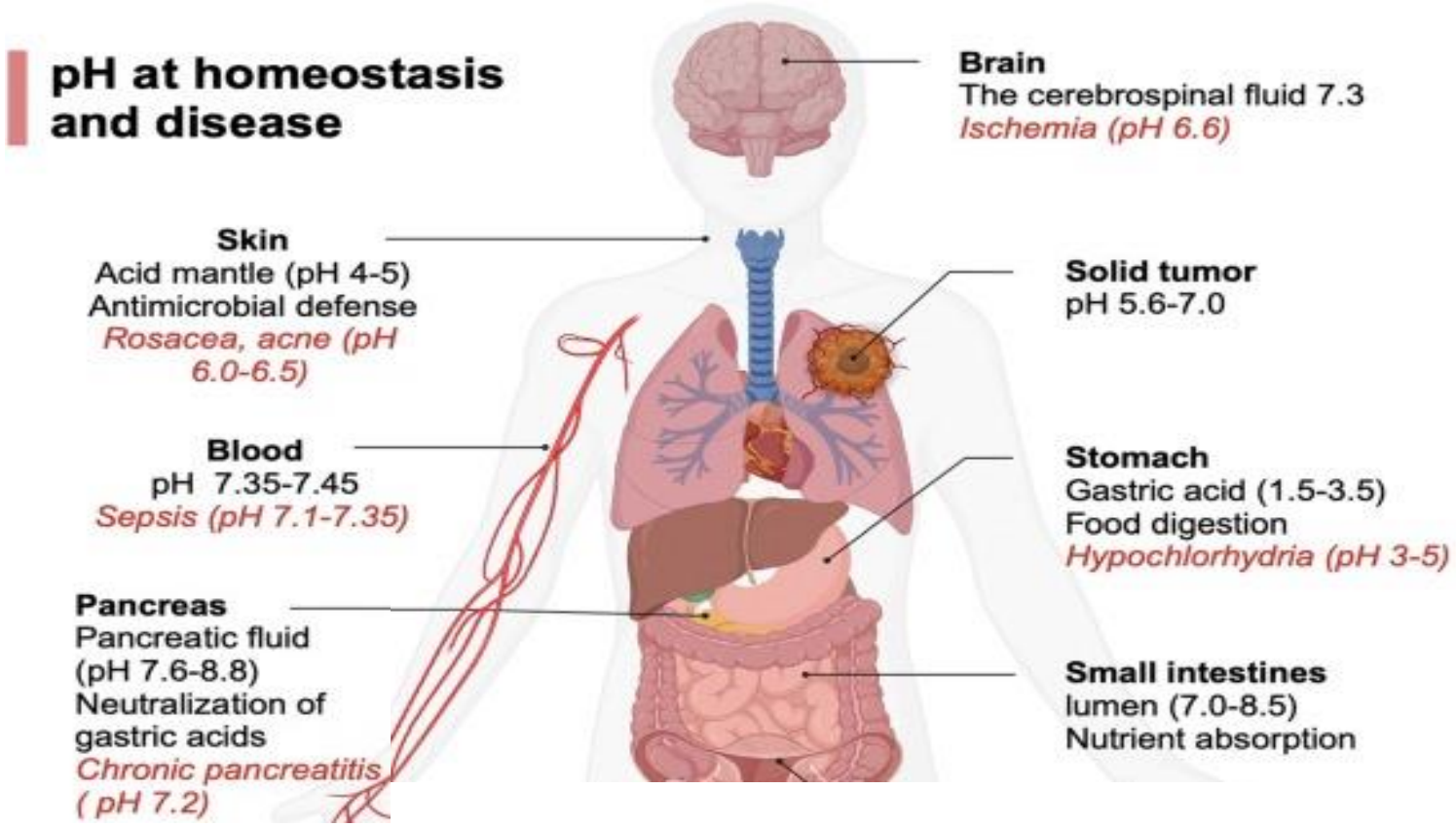
Homeostasis and Regulatory Mechanisms

Understanding the Engineering of Body Balance

Homeostasis

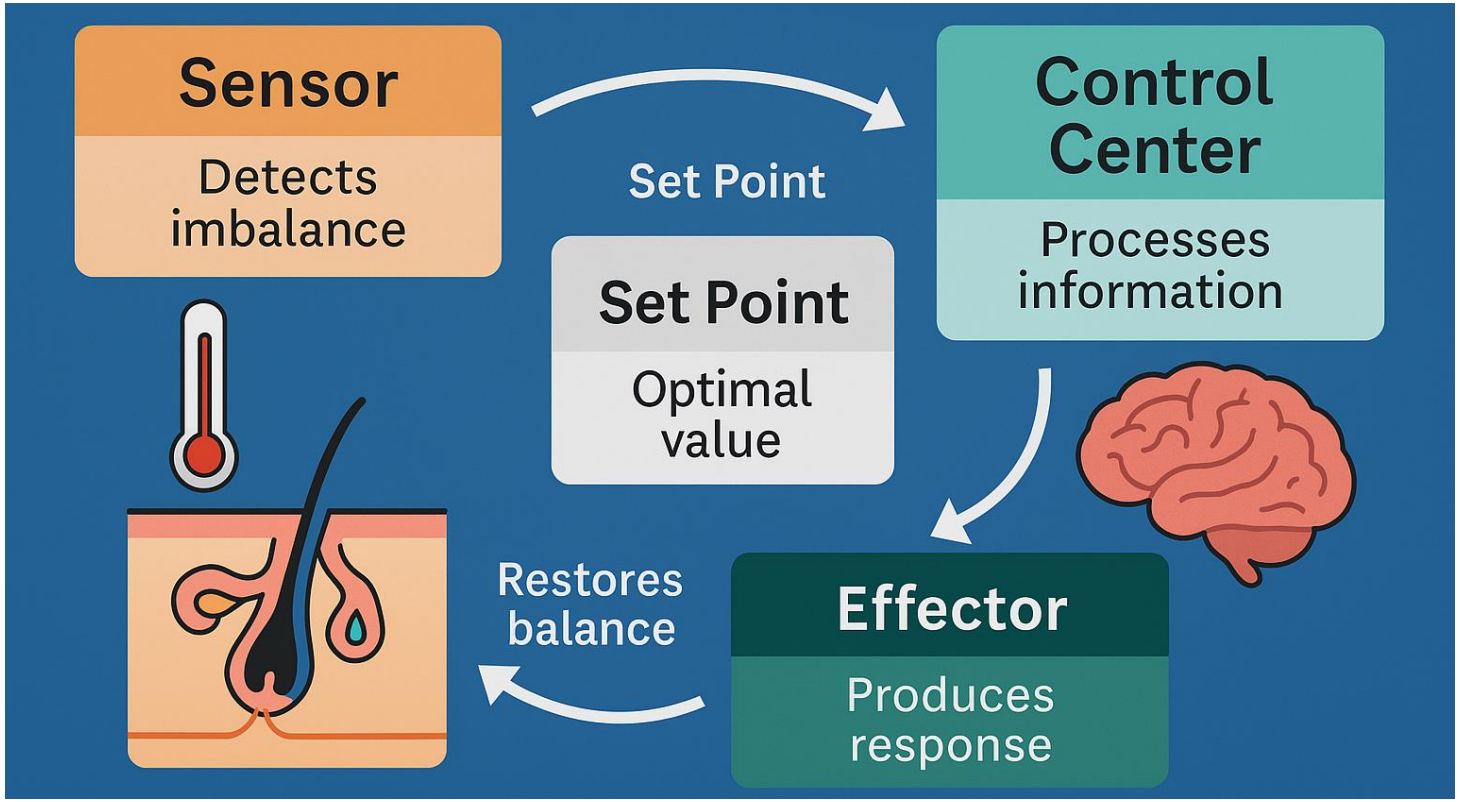
Homeostasis involves maintaining a stable internal environment

Examples: Temperature, pH, glucose



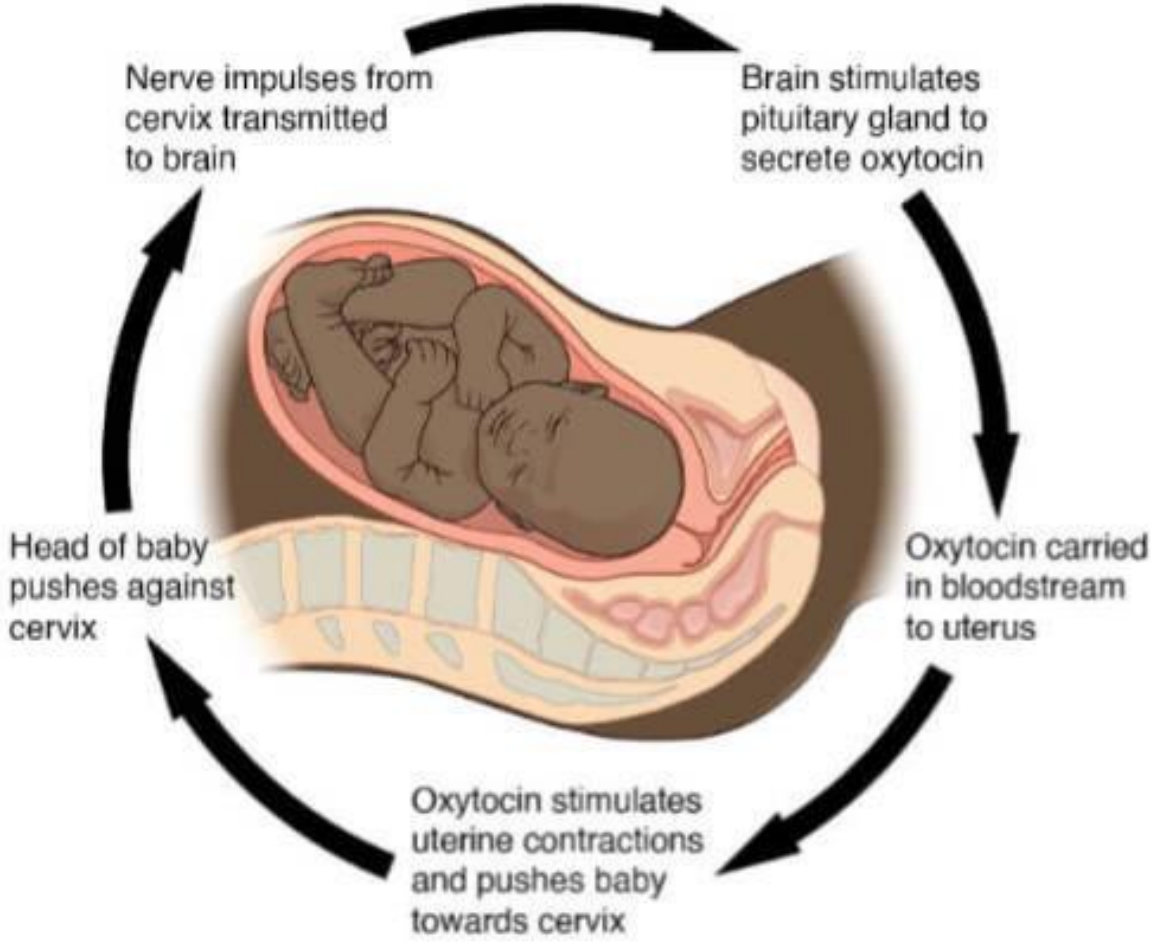
Components of a Regulatory Mechanism

Stimulus → Sensor → Control centre → Effector → Response



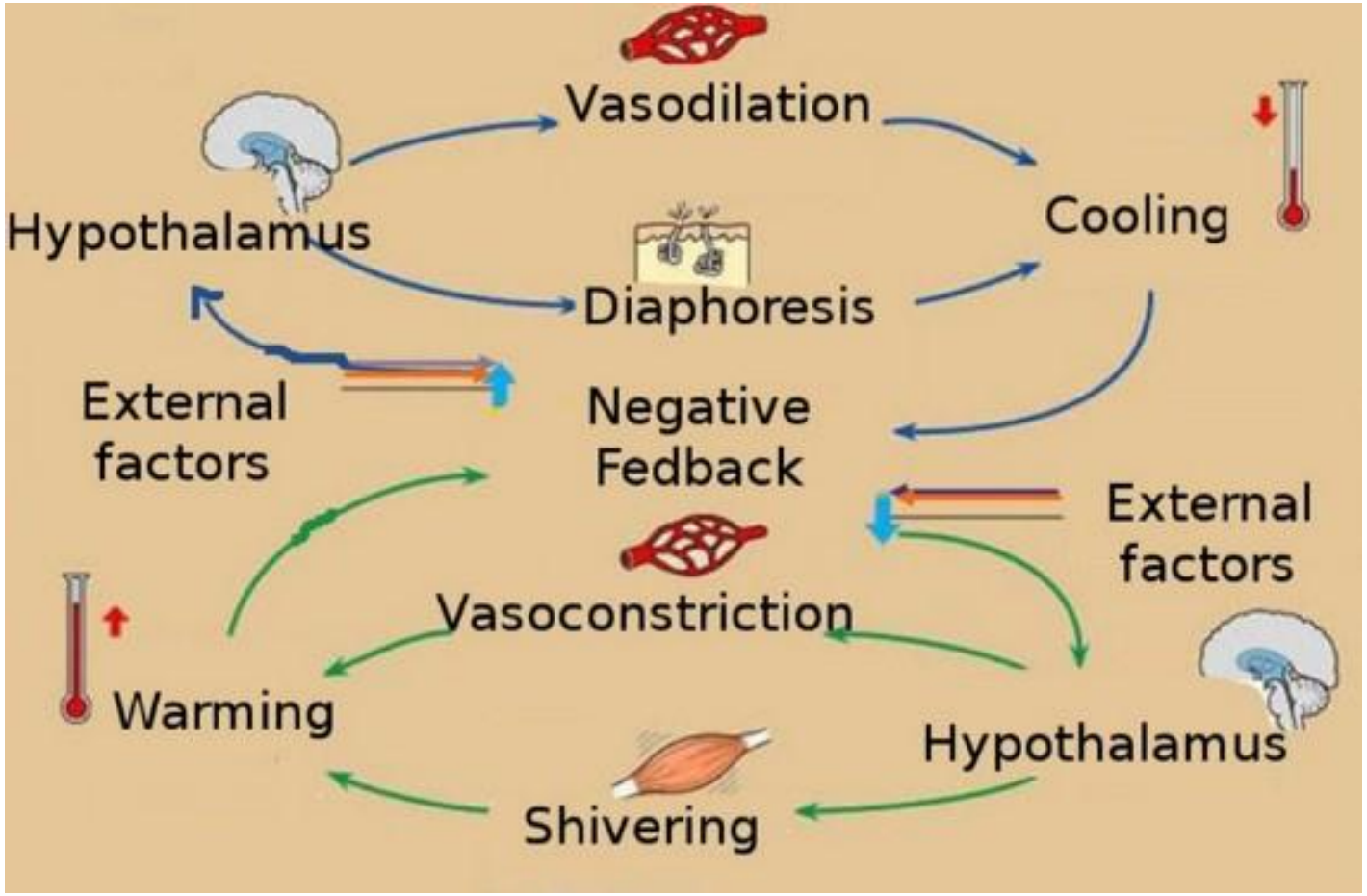
Positive Feedback Mechanism

A positive feedback mechanism is a process where a change in a system is amplified, leading to further change in the same direction.



Negative Feedback Mechanism

A negative feedback mechanism is a regulatory process where the output of a system reduces the initial stimulus or input, thus maintaining stability and equilibrium.



POSITIVE FEEDBACK

VERSUS

NEGATIVE FEEDBACK

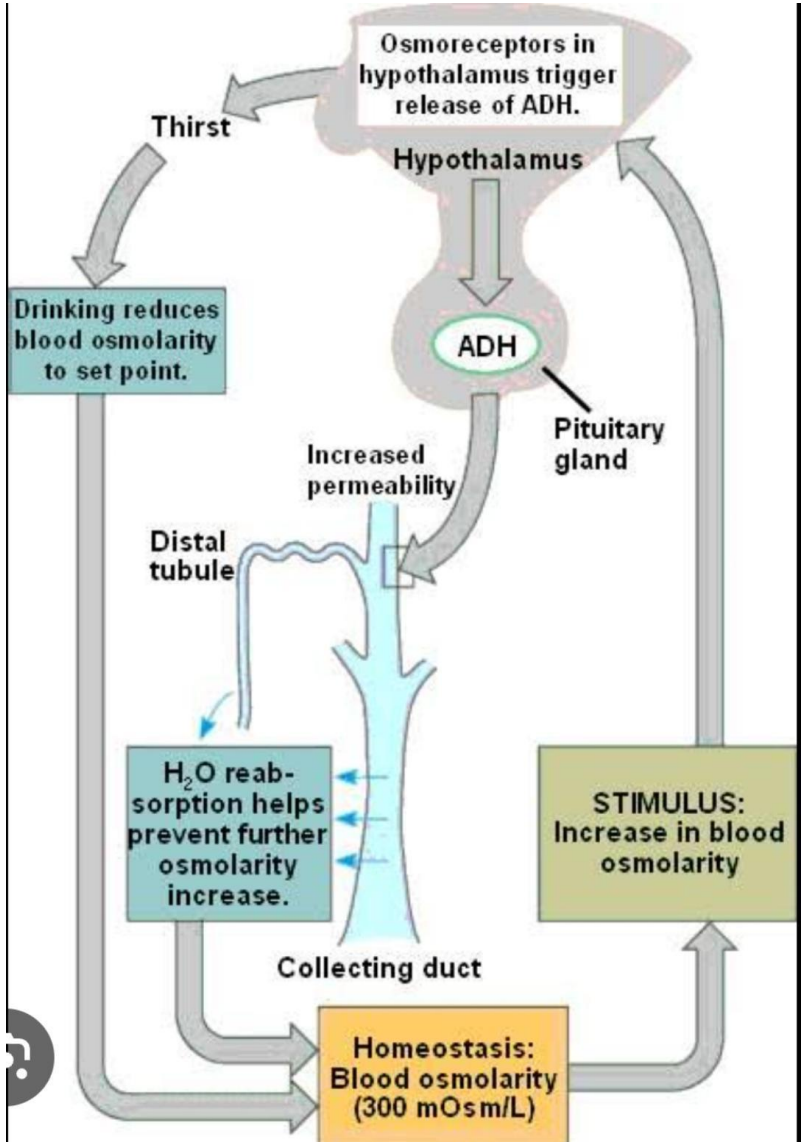
Positive Feedback	Negative Feedback
Less frequent mechanism	More frequent mechanism
Exhibits positive correlation between stimulus and product or process	Exhibits negative correlation between stimulus and product or process
Less associated with stability	Closely associated with stability
Enhances change	Resists change
Wider range	Narrower range
May be associated with vicious cycles and even death	Most often associated with restoring homeostasis
May require external interruption	Does not require external interruption

Think-Pair-Share Act

- “Which is more common: positive or negative feedback? Why?”

Dehydration

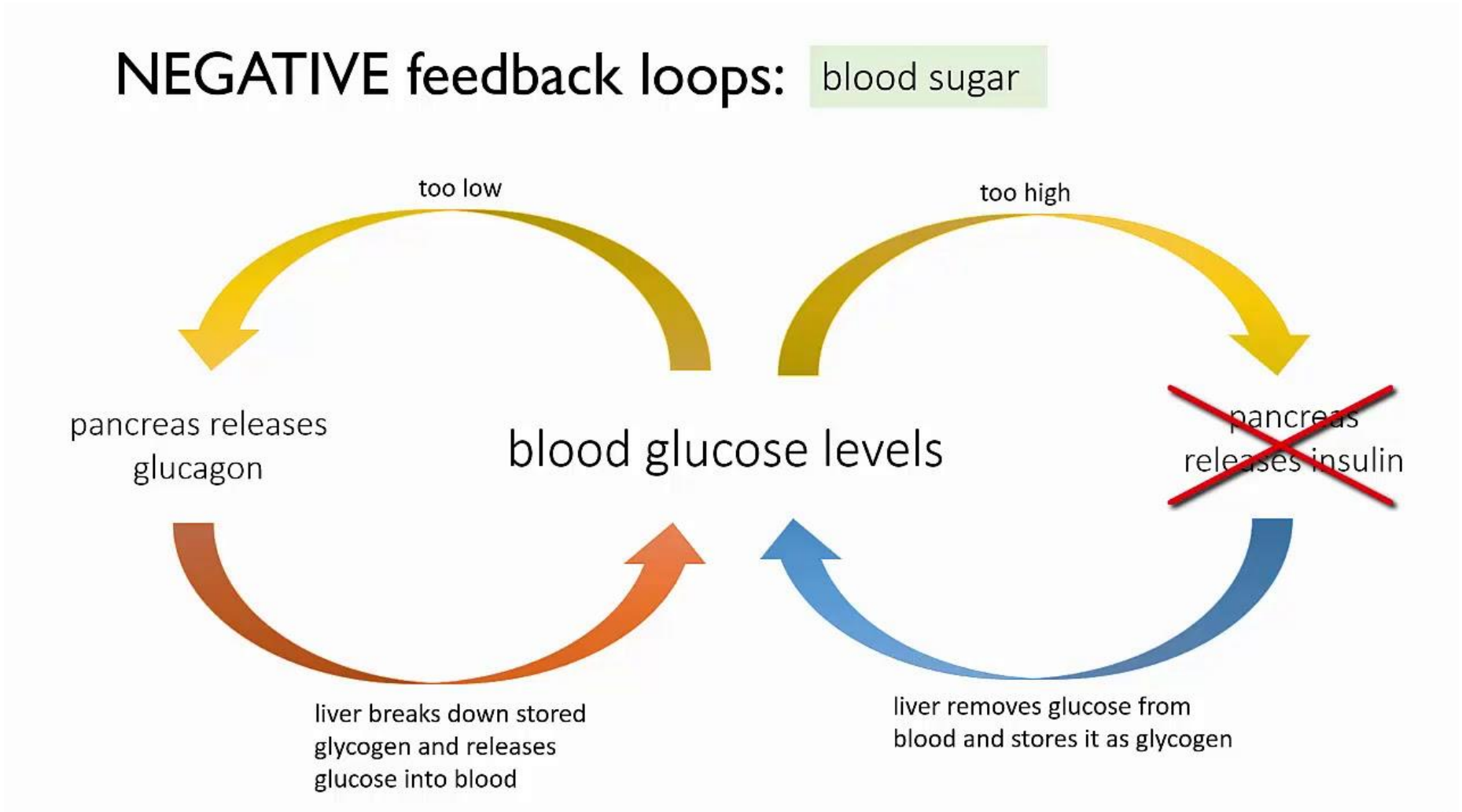
- Scenario: Hot day, no water
- What kind of feedback is this?



Video feedback mechanism

https://www.youtube.com/watch?v=14SQT97EE4c&list=PPSV&t=47s

NEGATIVE feedback loops: blood sugar

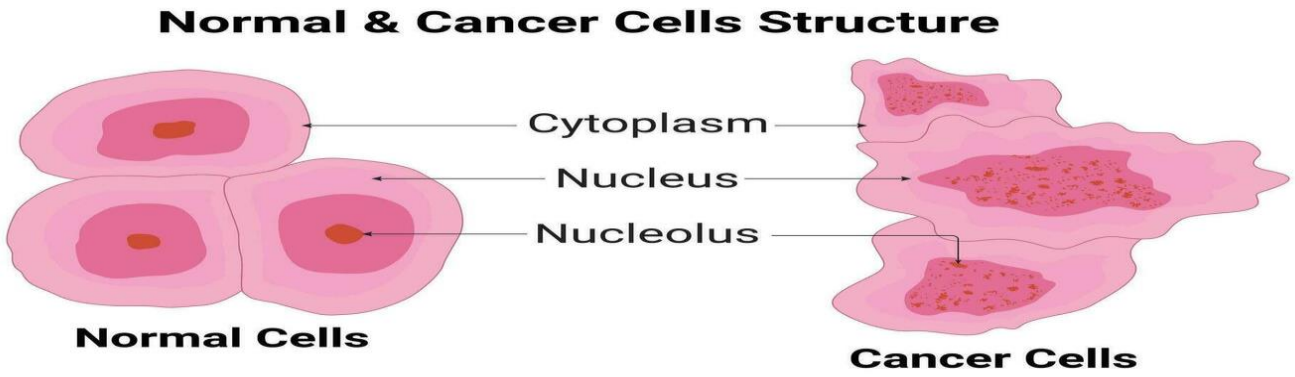


Summary

- Homeostasis: balance via feedback
- Sensors and effectors maintain internal conditions
- Most feedback is negative and stabilizing

Disease Mechanisms and Therapeutic Targets

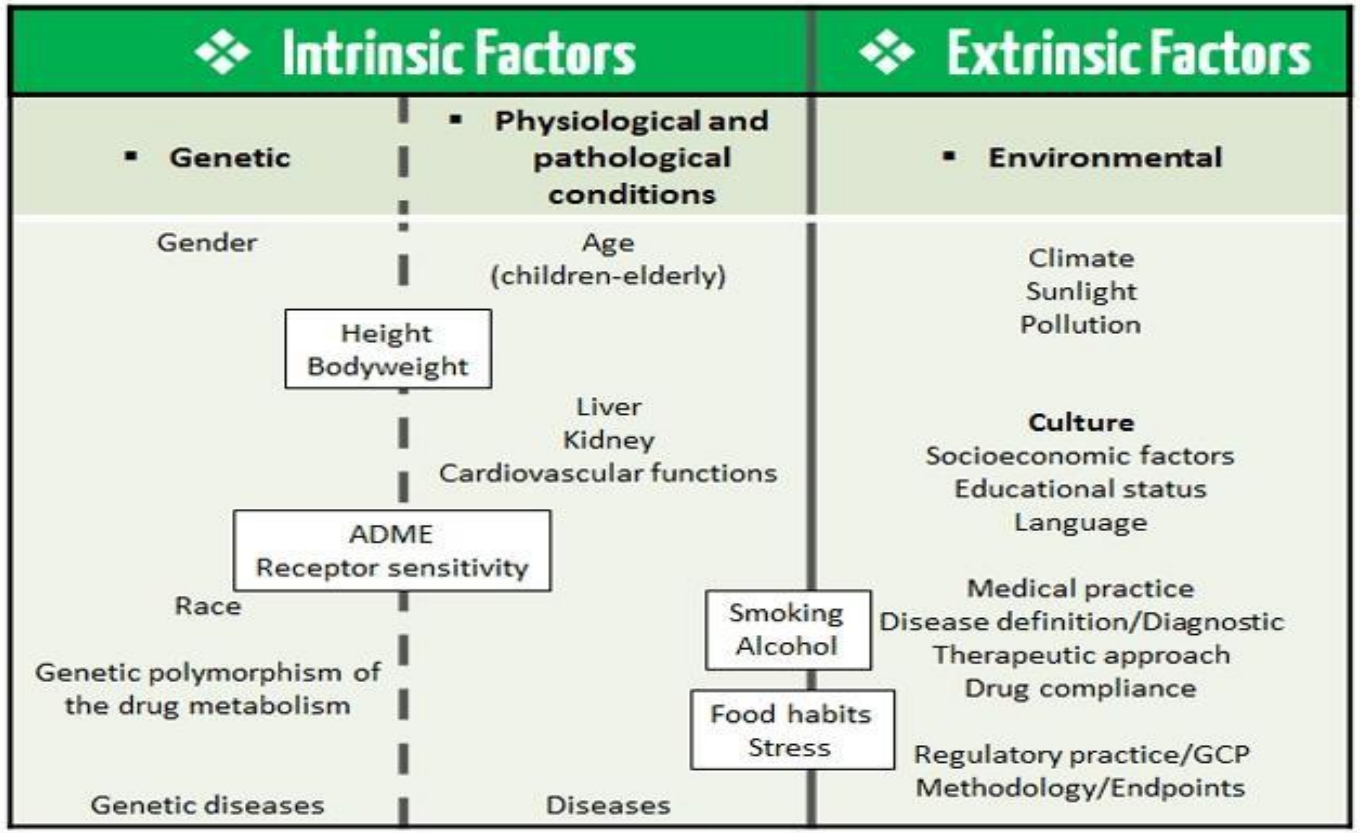
From Cellular Dysfunction to Targeted Therapy



What Causes Disease?

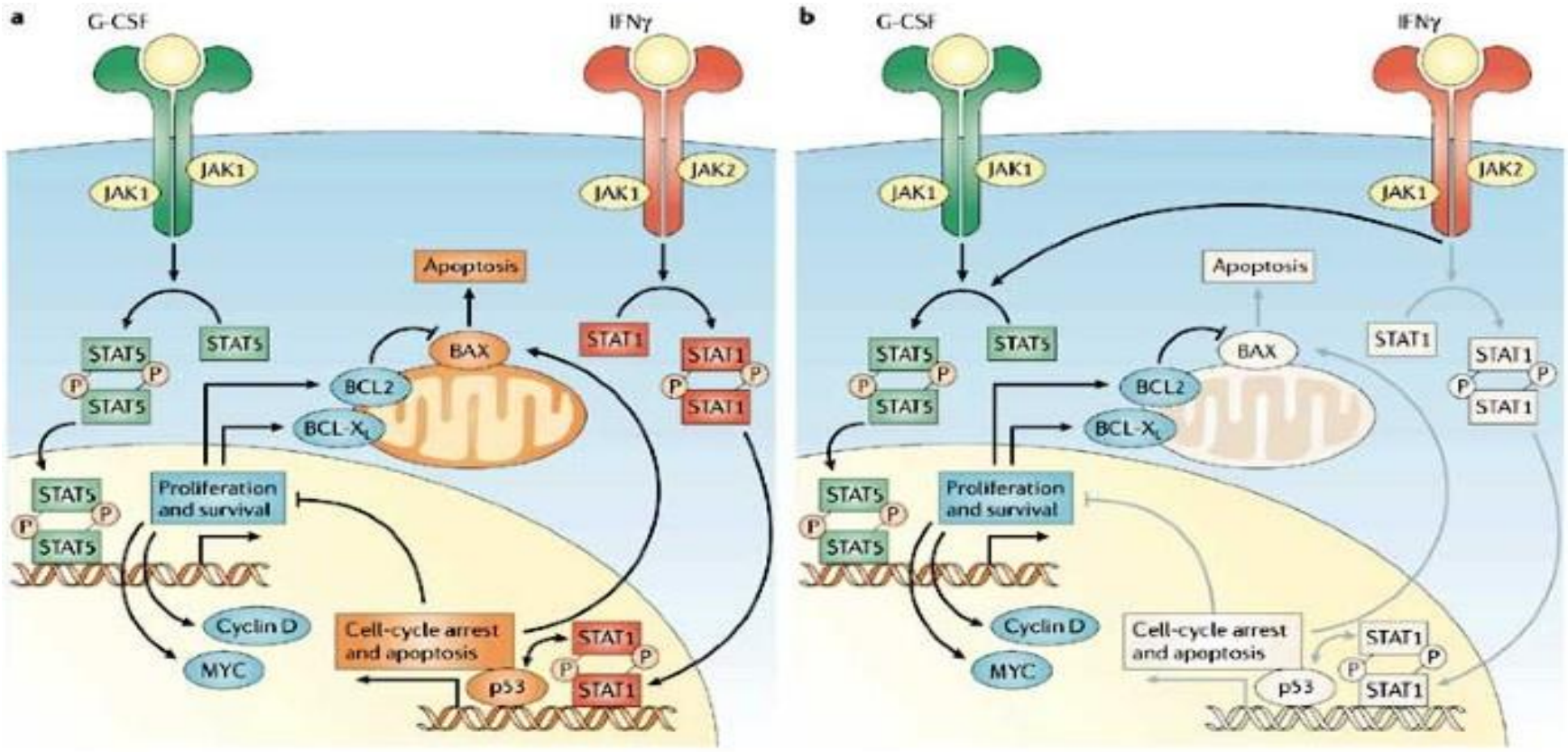
- Intrinsic (genetic, autoimmune) and extrinsic (infection, toxins) factors

  Examples: Sickle cell anemia (mutation), Tuberculosis (infection)



Disease Pathways and Dysregulation

- In biology, dysregulation refers to an impairment or disruption in the normal regulatory mechanisms of a biological system.
- Pathways affected: Inflammation, apoptosis, signaling



Engineering Analogy: Malfunctioning Circuits

- Faulty wiring = Faulty cell signaling
- Overcurrent = Overactive inflammation

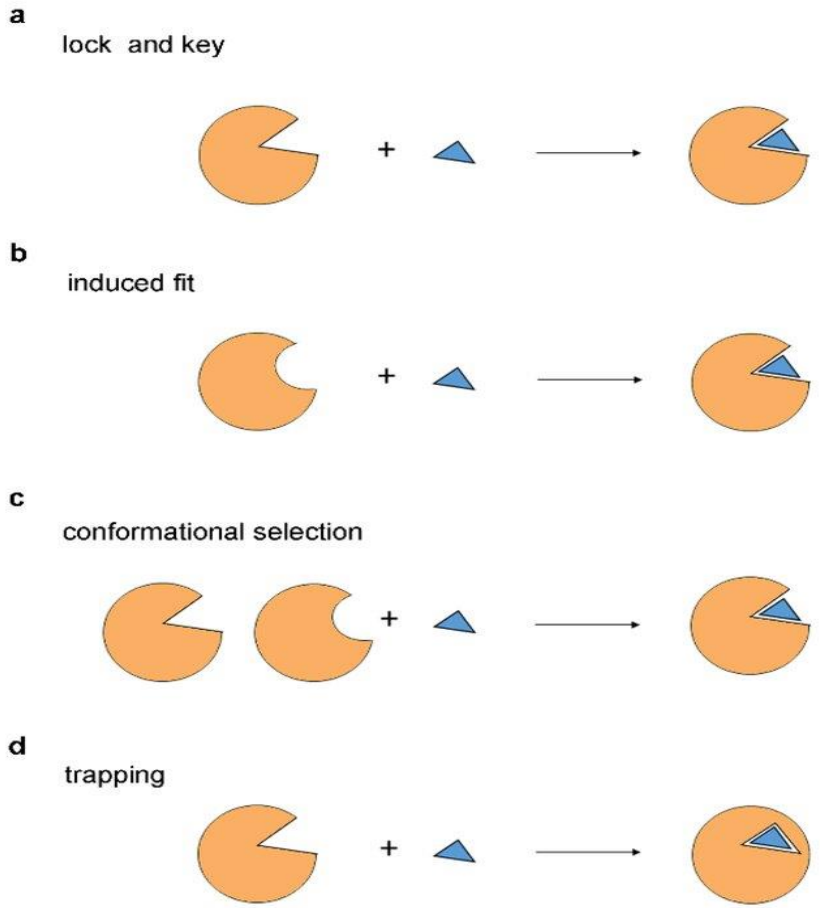
Think-Pair-Share Activity

- How is cancer like a machine stuck in ON mode?

Therapeutic Targets

- Types: Enzymes, receptors, proteins, nucleic acids

Example: HER2 in breast cancer, HIV protease



Jigsaw Activity

- Groups of 4: Each group reads a short summary of a different disease (e.g., Diabetes, Alzheimer’s, Asthma, Cancer)
- Identify:
- Disease cause
- Affected pathway
- Targeted therapy example
- Regroup and teach peers

Targeted Therapy in Cancer

- Concept: Precision medicine

Example: Imatinib for CML (targets BCR-ABL)

	How does it work?	Side Effects	Limitations
 Chemotherapy	Targets rapidly dividing cells (mostly cancer cells)	Hair loss, intestinal damage, nausea	Cancer cells develop resistance to chemotherapy, not specific
 Targeted Therapy	Targets Proteins required for cancer growth	Liver problems, diarrhea, skin rash	Cancer cells develop resistance

How Targeted Therapies Work Video

- https://youtu.be/0EHBE6k0H7o?si=ra4mnq7wZyxCB-rY

Current Challenges and Future Trends

- Resistance to drugs
- Personalized medicine
- Use of nanotechnology

Summary

- Disease = Dysfunctional systems
- Therapeutics = Restoration or control
- Future = Smarter, targeted therapies

Historical Evolution of Biomedical Technologies

Introduction

Biomedical technologies refer to any tools, equipment, techniques, or systems that are developed and applied to support healthcare.

They play a vital role in

- Diagnosing
- Monitoring
- Treating diseases

Advancement in medicine (3000- 300 BC)

(Source: Bronzino, 2005; https://www.1001inventions.com/; https://www.smithsonianmag.com/)

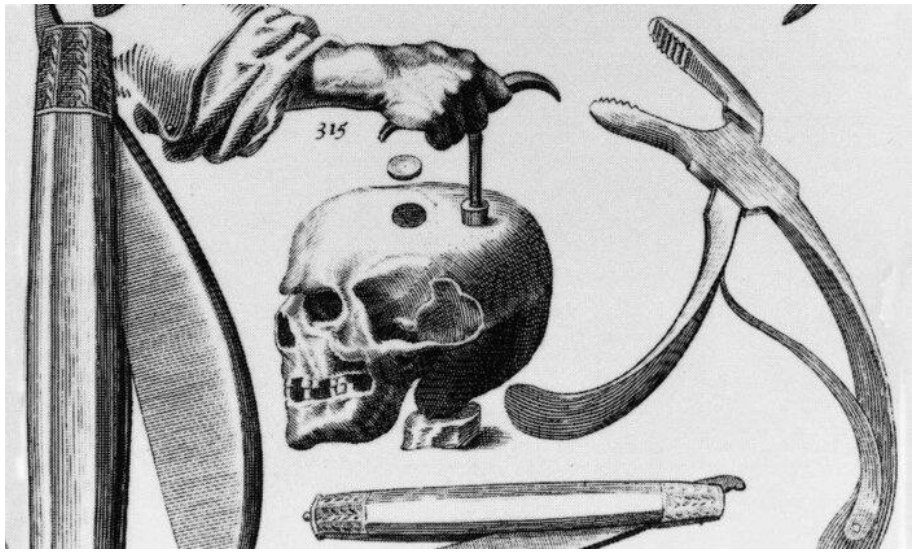
Ancient and Traditional Practices

Egypt, China, India, Greece

Herbal remedies

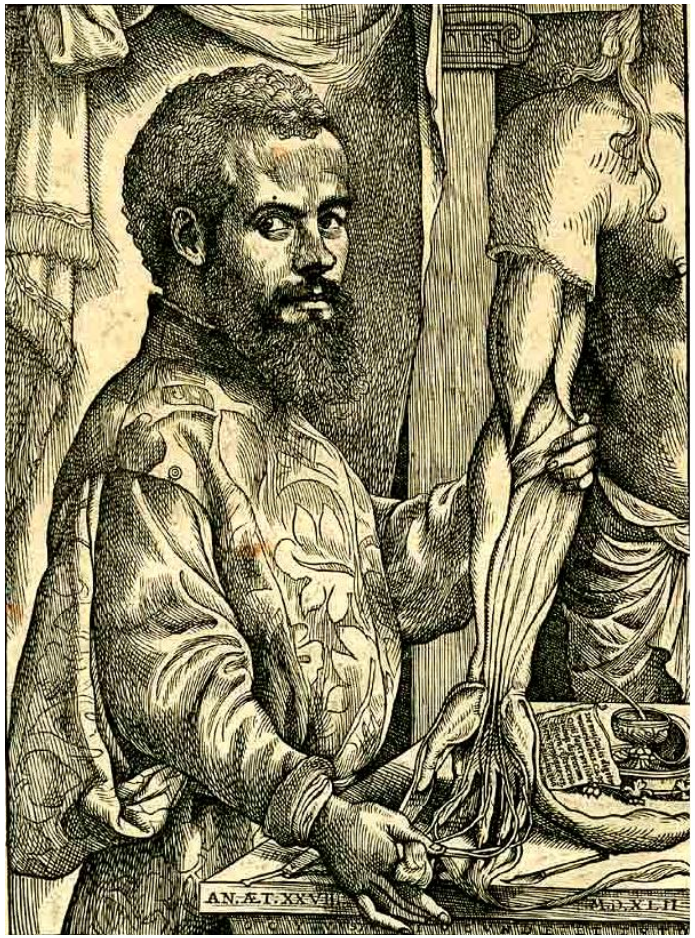
acupuncture

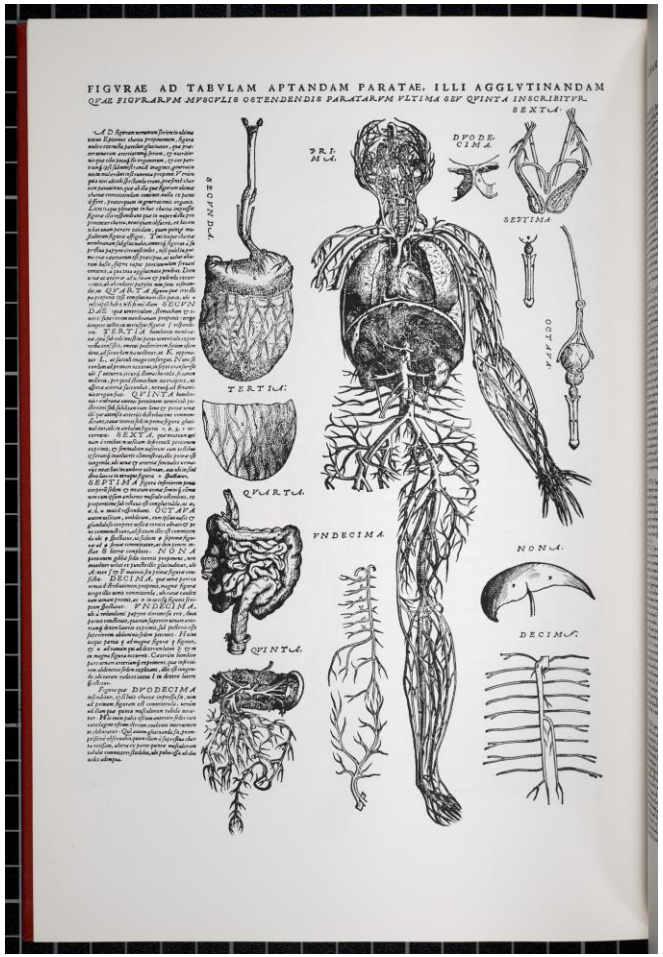
trepanation



Developments during 1500s–1800s

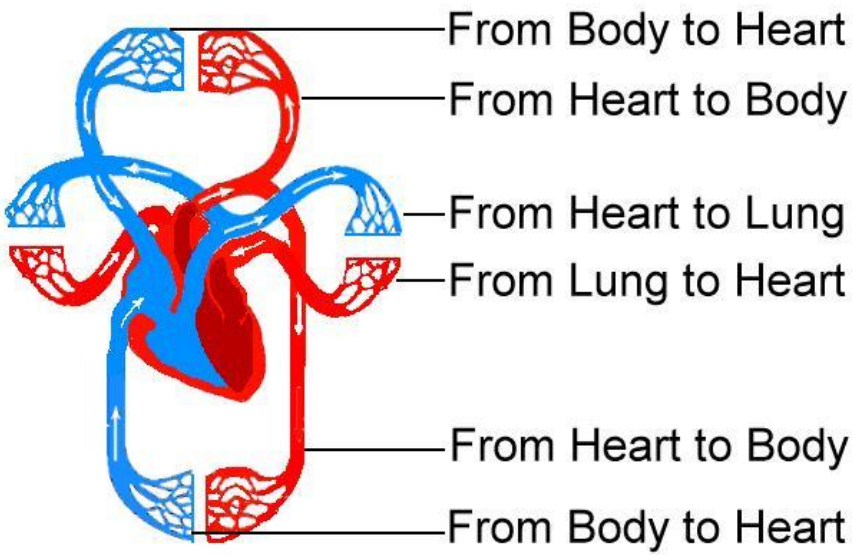
Human anatomy: Andreas Vesalius

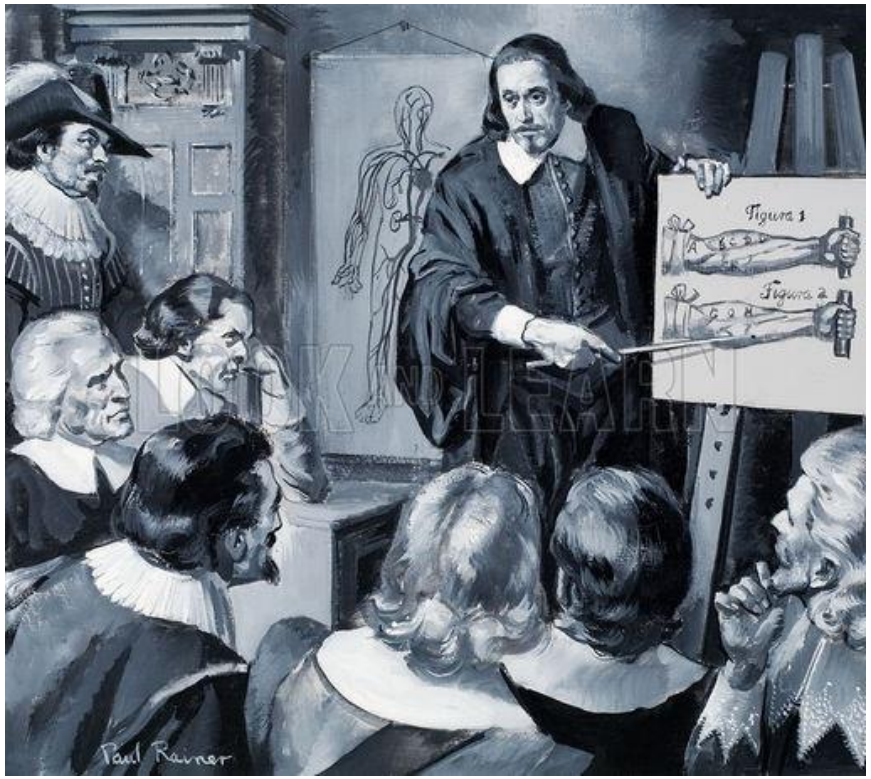




Developments during 1500s–1800s

William Harvey's discovery of blood circulation: Human physiology

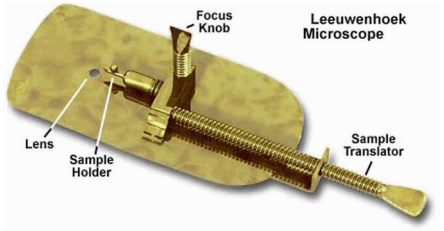


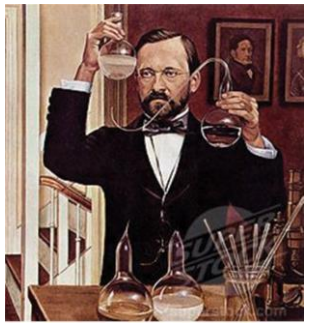


Advancement in medicine

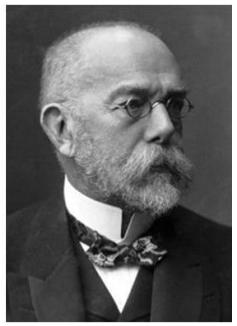
Anton Van Leeuwenhoek

1673





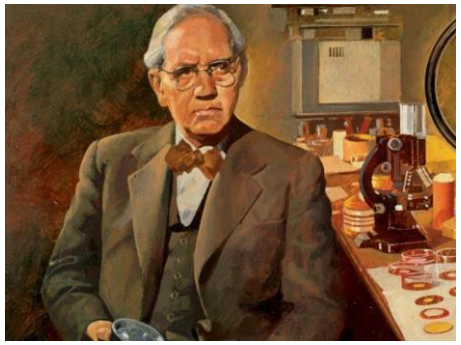
Louis Pasteur



Robert Koch

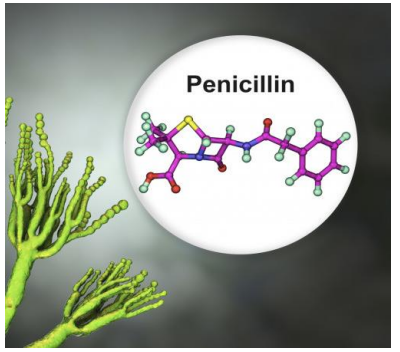
1850 - 1890

Germ Theory of disease



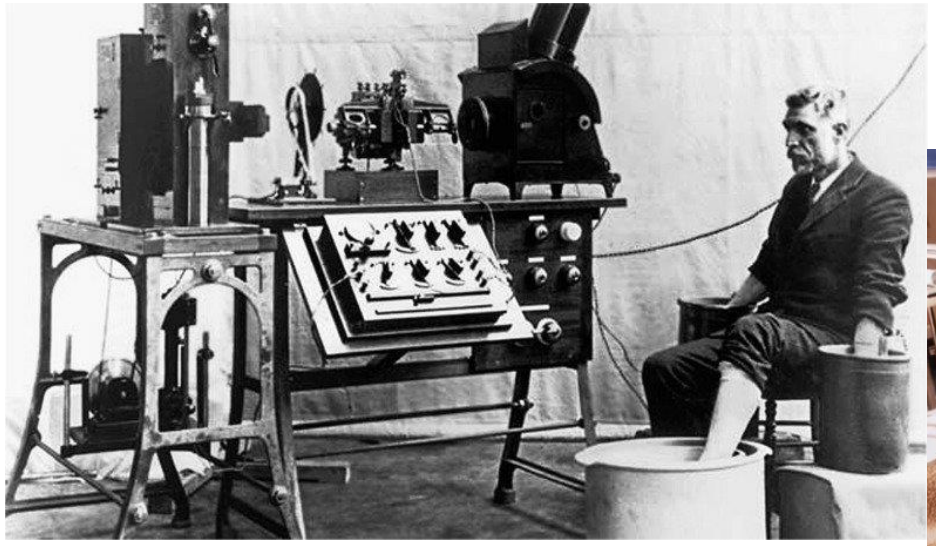
Alexander Fleming

1928

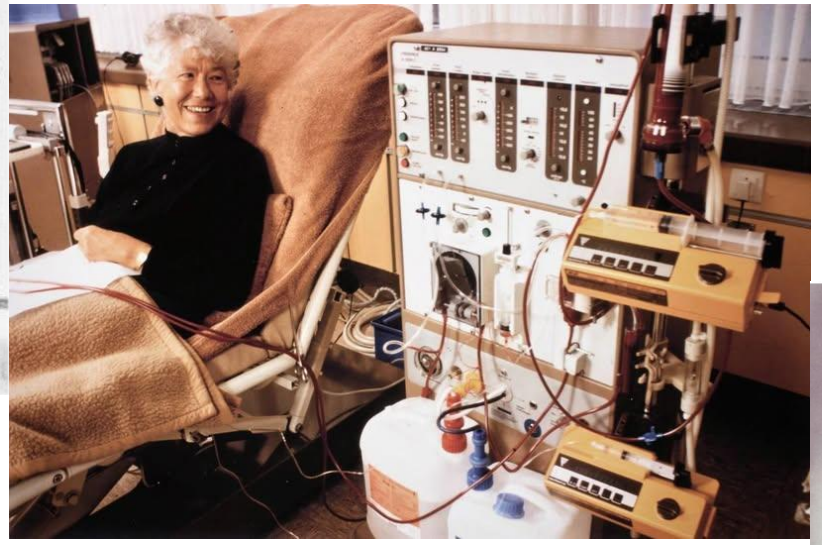


Early 20th Century Advances

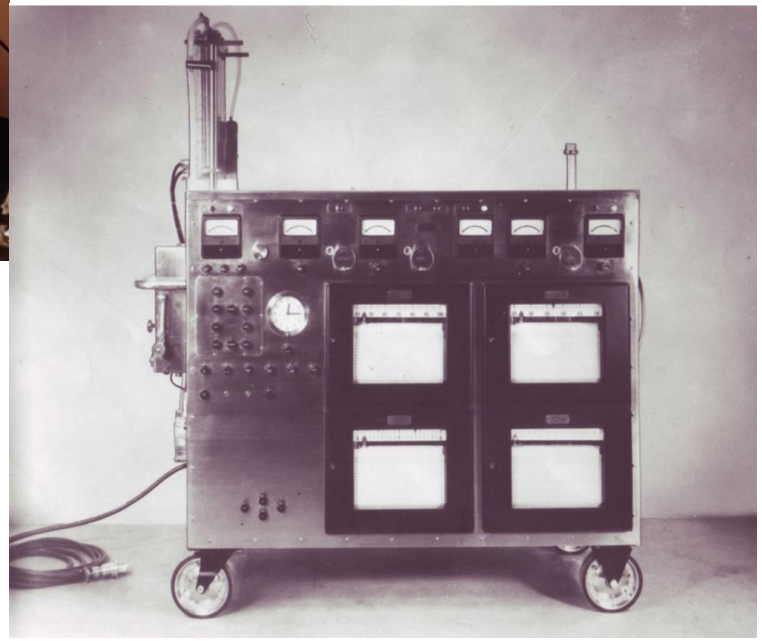
Electrocardiogram (ECG)



Dialysis machine

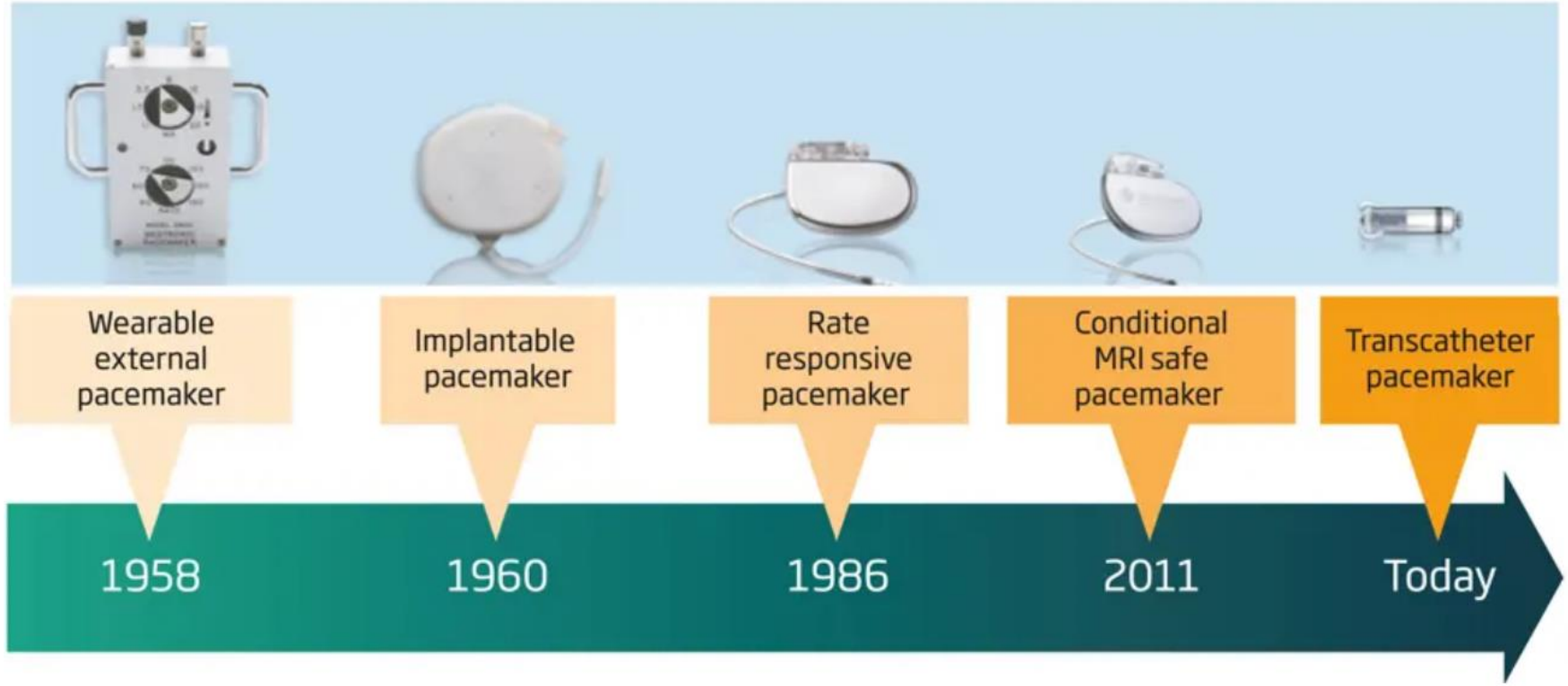


Heart-lung machine



Mid-20th Century (Post-War Boom)

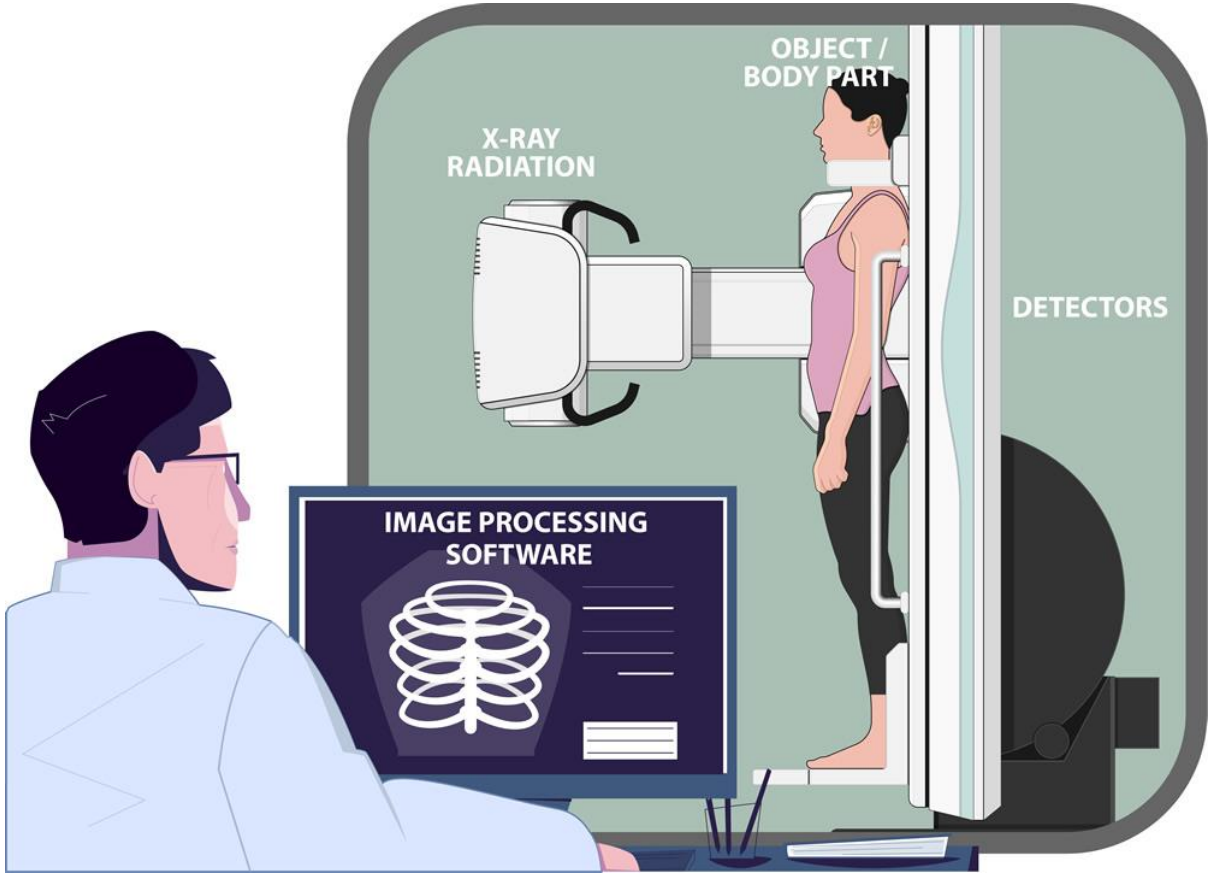
Cardiac pacemaker

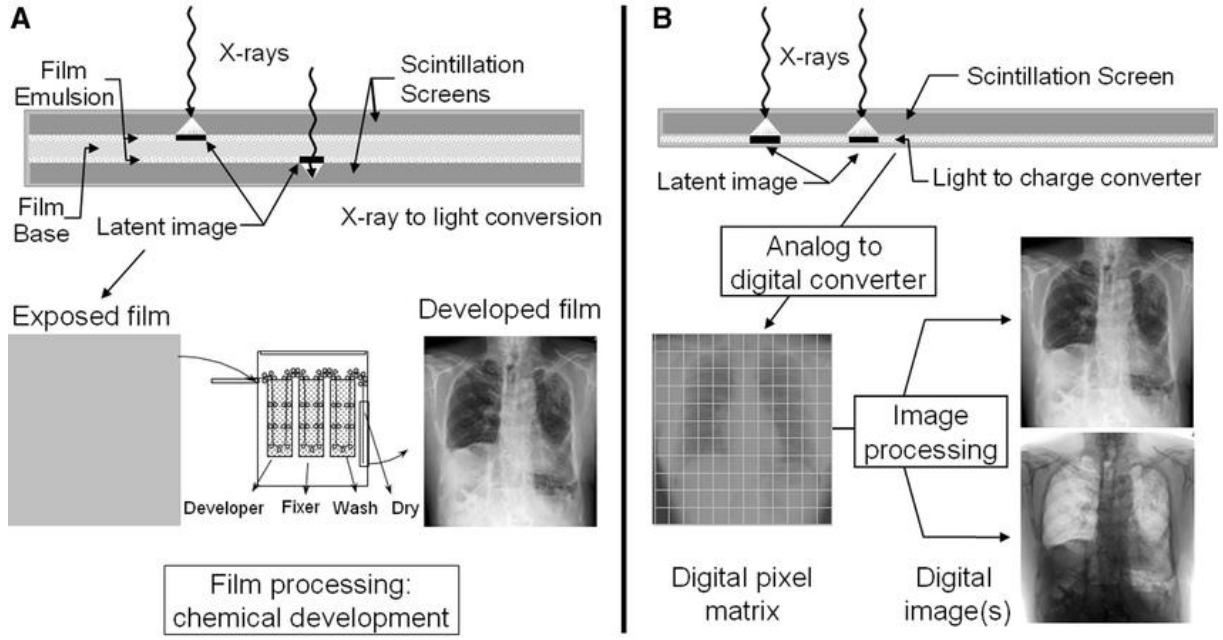


Technological Developments of Biomedical Science

- Biomedical Imaging
- AI And ML In Disease Diagnosis
- Biomaterials And Tissue Engineering
- Brain Computer Interface
- Robotic Surgery

Biomedical Imaging: X-ray imaging technique

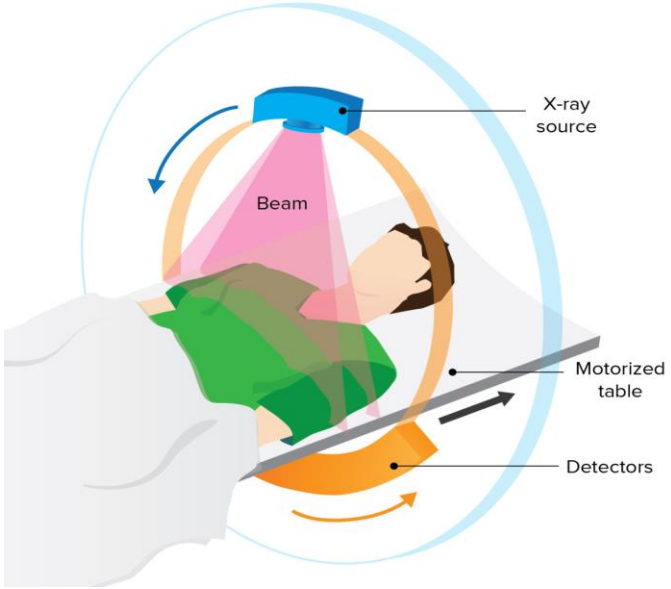


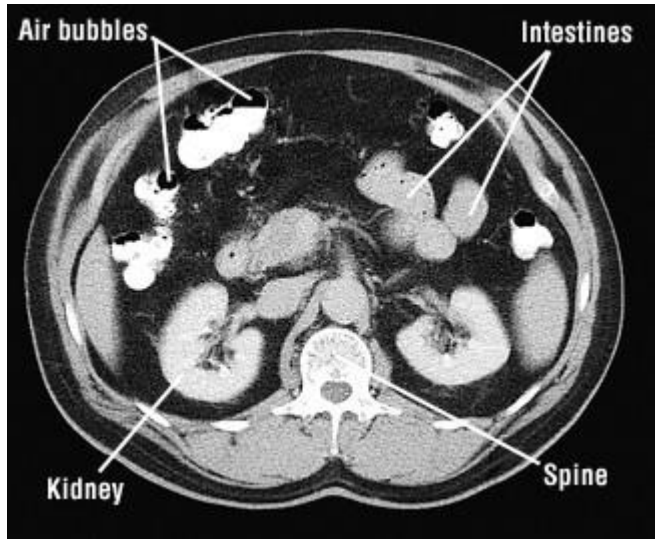


(https://www.chemtronics.com/)

Biomedical Imaging: CT (Computed Tomography) Scan

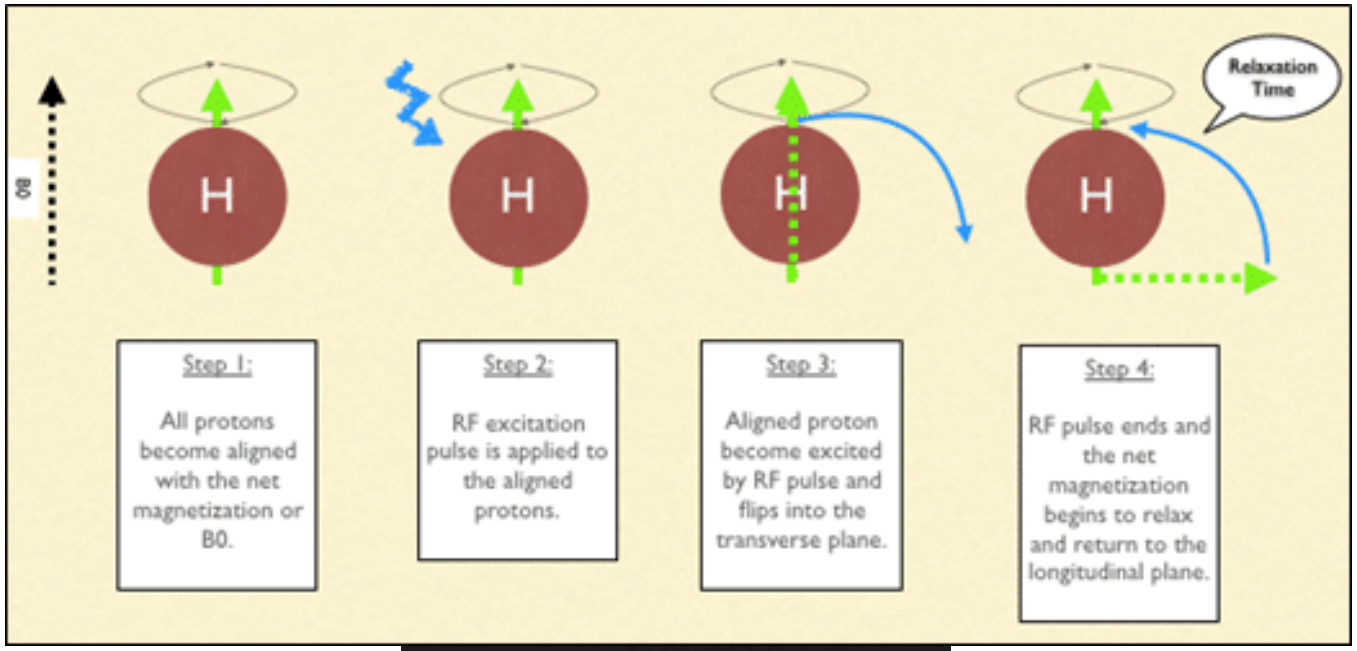
Source:





Source:

Biomedical Imaging: MRI Scanning

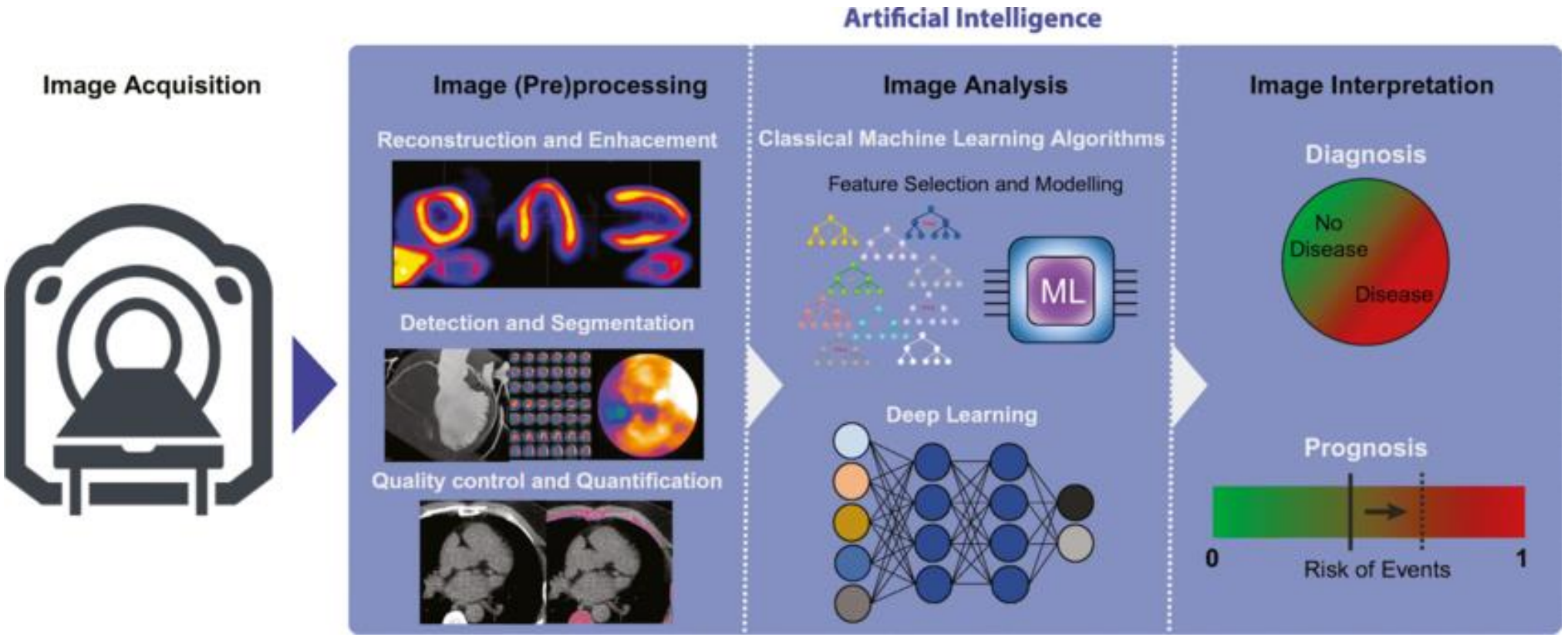


Source:

AI And ML In Disease Diagnosis

Traditional way

Radiologist identifies patterns	Subjective interpretation	Diagnostic report



Quantitative scores + visual heatmaps

(Slart et al. 2021)

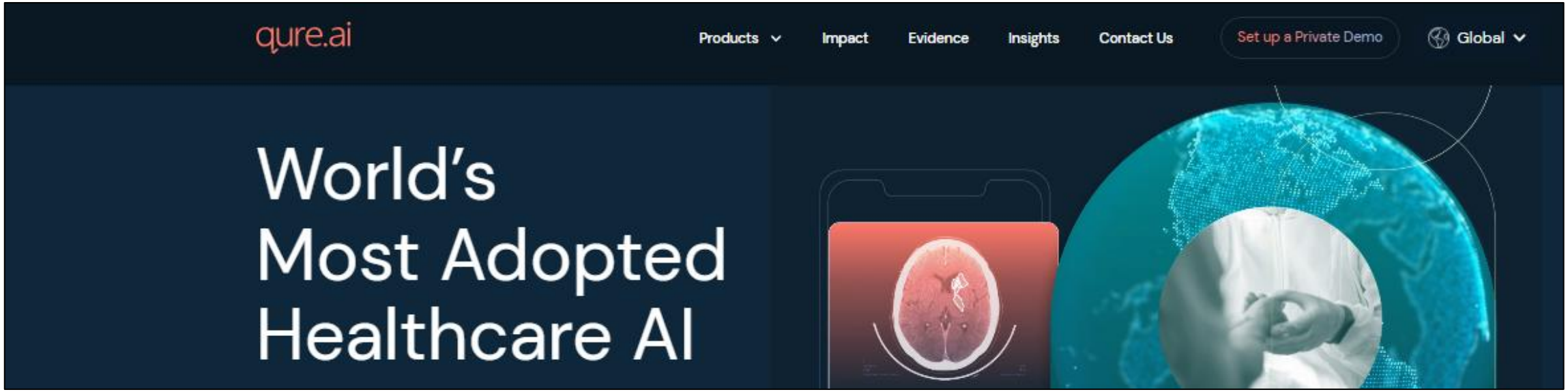
Real-World Implementations

Google DeepMind

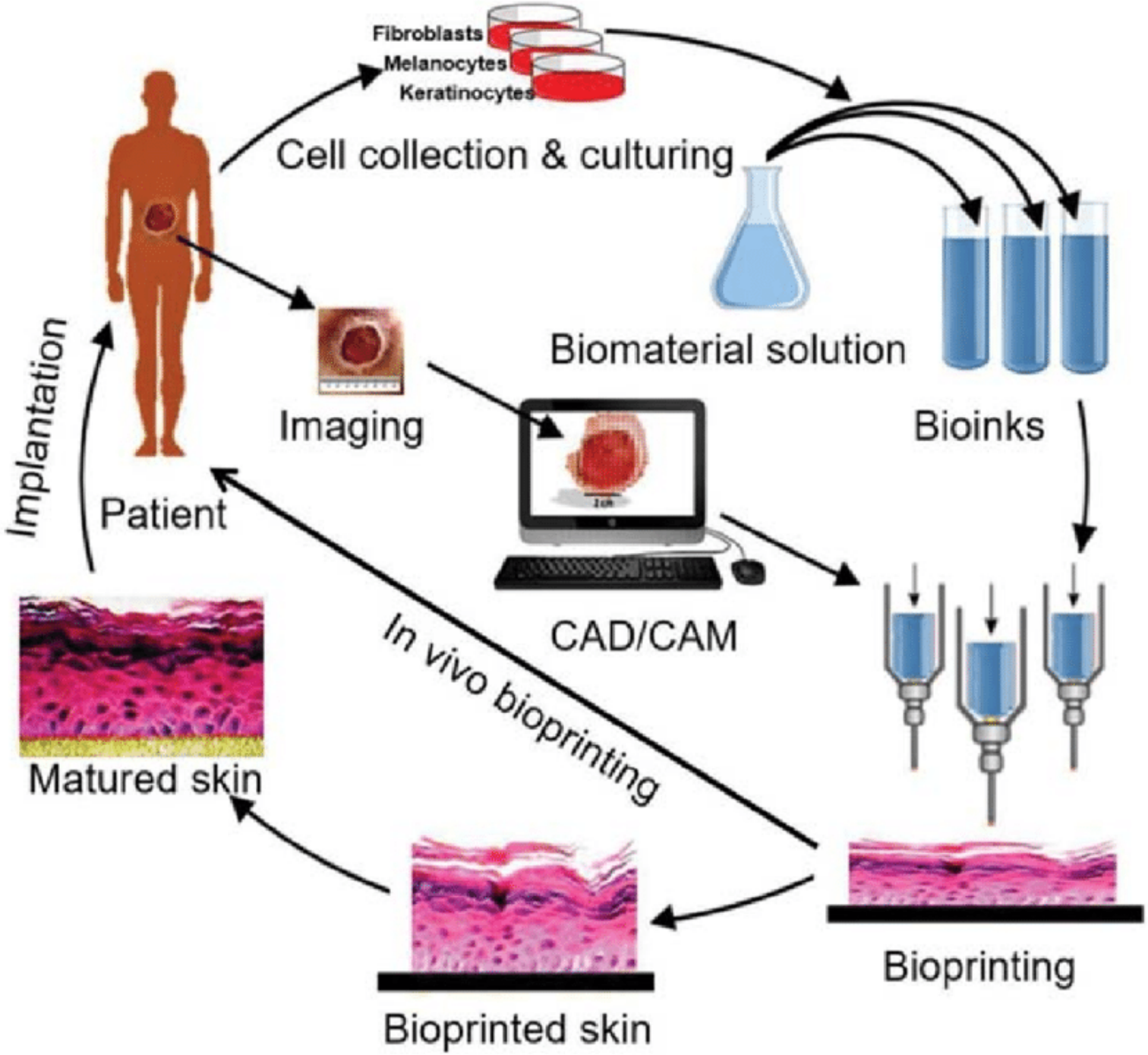
Try Google AI Studio | Try Gemini

RESEARCH

Using AI to predict retinal disease progression



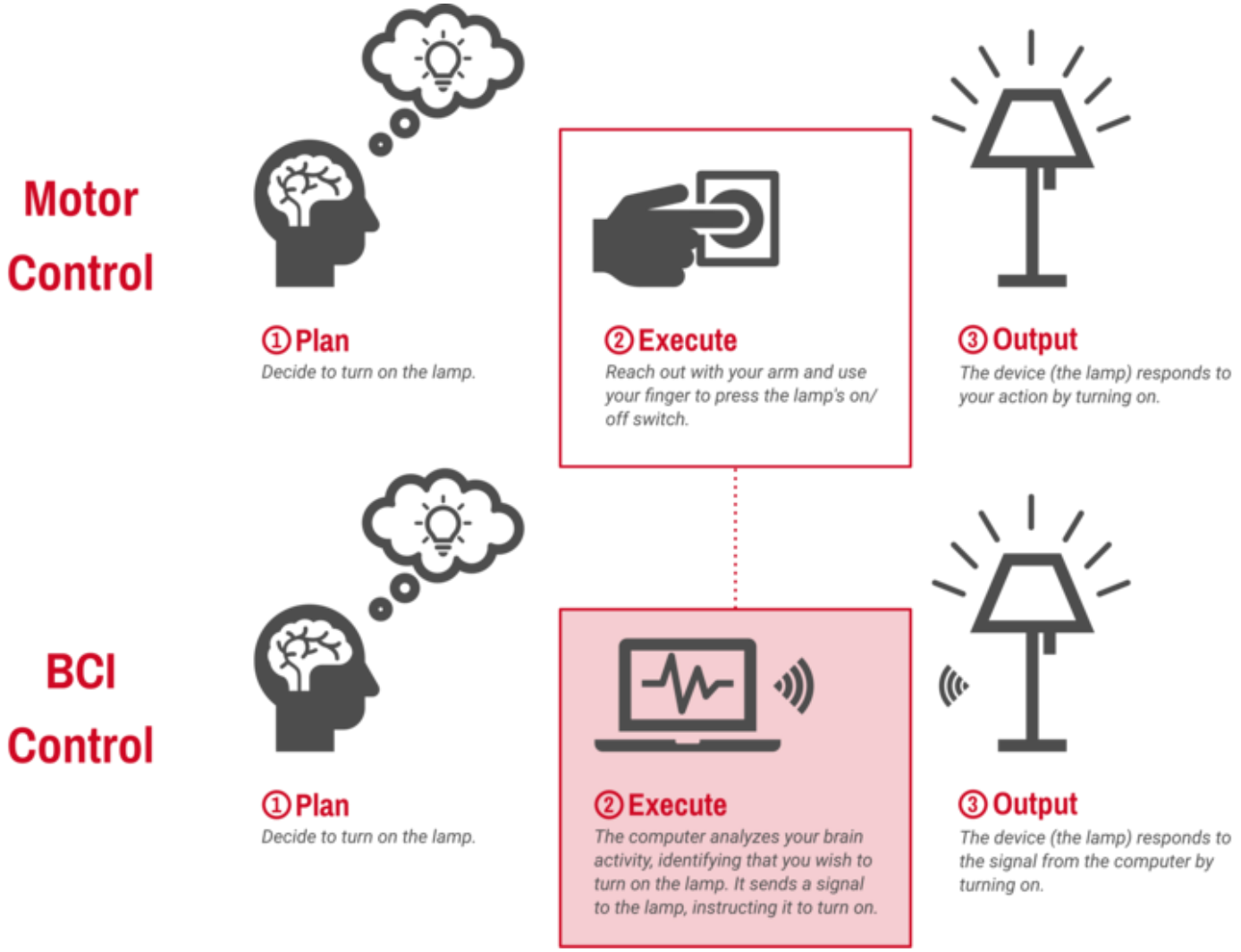
The 3D-bioprinting



(Source: Ulucan-Karnak, 2021)

Brain computer interface

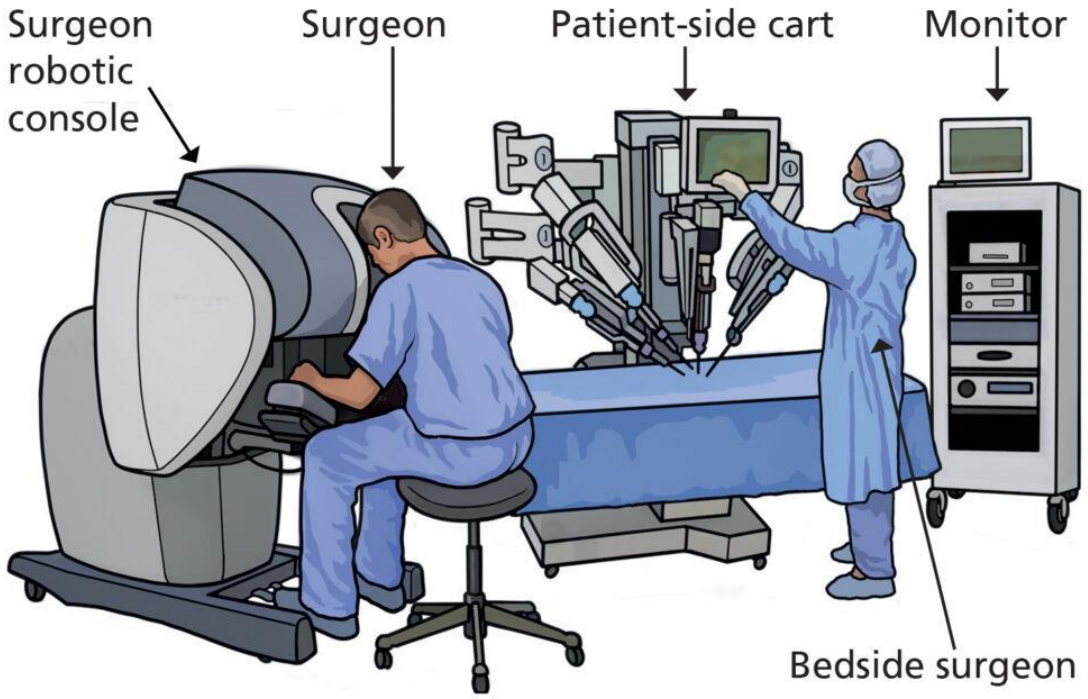
BCIs create **direct communication pathways** between biological systems and computers



Source: https://cumming.ucalgary.ca/research/pediatric-bci/bci-program/what-

Robotic Surgery

Robotic surgery is a type of **minimally invasive surgery** that uses robotic systems to enhance the precision, flexibility, and control of surgical procedures.



The *da Vinci* Surgical System

(Source: https://www.leedsth.nhs.uk/)

Regulatory Frameworks (FDA & CE Marking)

Questions:

Would you use a medicine that hasn’t been tested?

or

Who makes sure medical devices are safe?

Guidelines:


FDA


EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

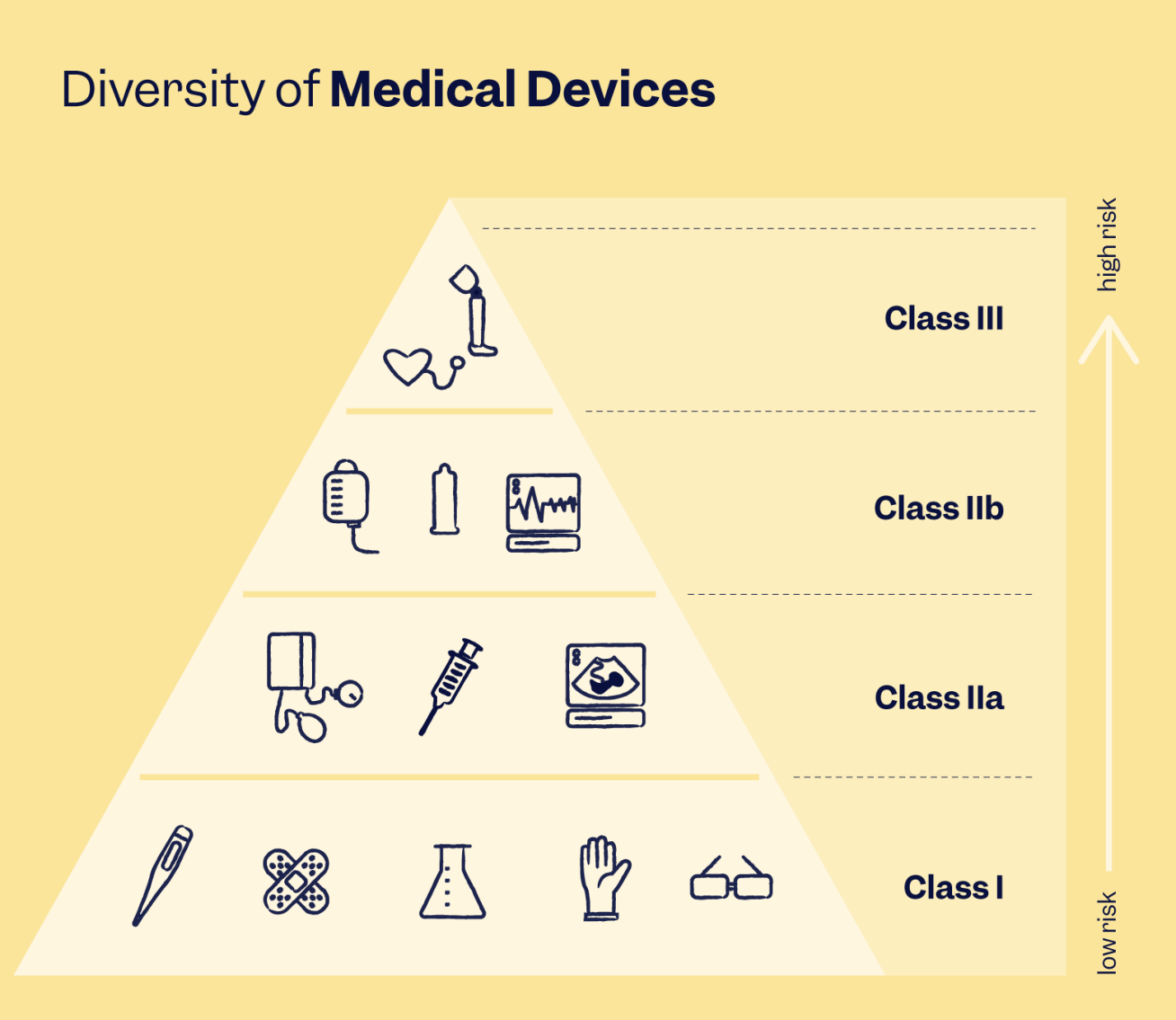

INDIAN COUNCIL OF MEDICAL RESEARCH
NEW DELHI
icmr
INDIAN COUNCIL OF MEDICAL RESEARCH
Serving the nation since 1911


NCCN
National Comprehensive Cancer Network®


World Health Organization (WHO)
International Guidelines Series


invideo/imran
iStock
by Getty Images

CE marking in Europe



The CE certification mark, often referred to as the CE mark, is a symbol that indicates a product complies with the essential health, safety, and environmental protection requirements established by European legislation

Examples of devices requiring CE marking:

- **Implantable contraceptives:**
- **Absorbable implants (e.g., skin or GI):**
- **Total and partial joint replacements:**
- **Implants in contact with the spinal column:**
- **Devices incorporating nanomaterials:**
- **Software with potential for serious health impact:**
- **Non-invasive devices in contact with cells for IVF:**
- **Devices incorporating human-derived substances:**

Design a medical instrument/ Drug. Choose the FDA steps/ Choose the CE steps. What criteria is considered to get the product passed?

Group A

A. A. Drug for migraine
B. B. Drug for cancer
C. Drug for heart attack
D. New antibiotics

Group B

A. New device for controlling of heart beat (implantable)
B. Understanding neurological functioning of the brain
C. Artificial kidneys in body
D. Prosthetic limb

Ethical Considerations in Biomedical Innovation

Some Open Questions..

- Would you use a medicine that hasn’t been tested?
- Who makes sure medical devices are safe?

Tuskeejee Syphilis Study, 1932-72, USA

Henrietta Lacks, 1945, USA

Ethical Guidelines

FDA (U.S. Food and Drug Administration)

1. **Informed Consent** is mandatory for all human participants, ensuring they understand the risks, benefits, and can withdraw at any time.
2. **IRB (Institutional Review Board) Oversight** is required to protect participants' rights, safety, and well-being throughout the trial.

EMA (European Medicines Agency)

1. **Ethics Committee Approval** is required before any trial begins in EU countries, in line with the EU Clinical Trials Regulation.
2. **Data Transparency and Protection** are key—participant data must be anonymized and handled under GDPR regulations.

ICMR (Indian Council of Medical Research)

1. **Informed Consent + Audio-Visual Recording** is compulsory for vulnerable populations, ensuring transparency and protection.
2. **Ethics Committee Registration** with CDSCO is mandatory, and all trials must follow ICMR's 2017 National Ethical Guidelines.

Think and Share your IDEAS!!

Sec 8 (1-6): CRISPR and Gene Editing in Babies

Scenario: Scientists now have the ability to edit genes in embryos to remove diseases—or even change traits like eye colour.

Discussion Points: Is it ethical to edit unborn babies? Where should we draw the line? Who decides?

Sec 8 (7-12): Use of Patient Data in Health Apps

Scenario: A popular fitness app tracks user heart rate and sleep. The company shares this data with researchers without asking users.

Discussion Points: Is this okay if it helps science? What about privacy? Should users give consent?

Sec 12 (1-6): Artificial Intelligence for Diagnosing Diseases

Scenario: Hospitals are using AI to read X-rays and predict illnesses. But the AI sometimes makes mistakes, and no one knows exactly how it works.

Discussion Points: Who is responsible for wrong diagnoses? Should patients be told when AI is used?

Sec 12 (7-12): Animal Testing for Biomedical Research

Scenario: A new drug to treat cancer must be tested on animals before human trials. The animals may suffer side effects.

Discussion Points: Is it fair to test on animals to save humans? Are there alternatives?