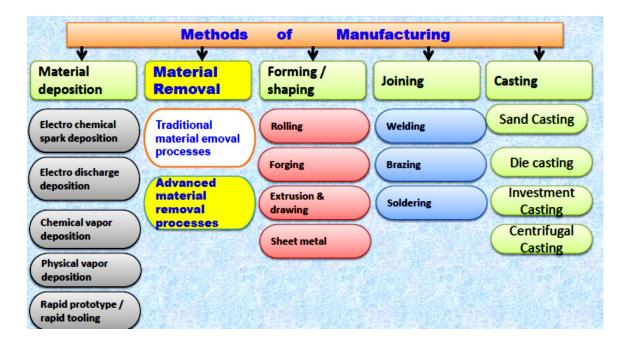
#### 1.1 INTRODUCTION

#### Why is Manufacturing Important?

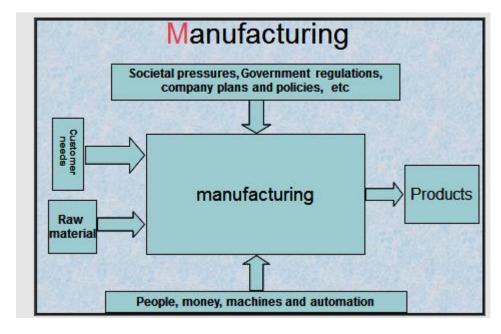
- Impact on economy
  - Major wealth creation engines
  - Manufacturing backbone of any industrialized nation.
  - Related to the economic health of a country.
  - Higher the level of manufacturing activity: higher the standard of living (Japan, U.K, China, etc.)
  - Gross Domestic Product
  - Jobs
- Most decisions made during design are impacted by production/manufacturing processes
- Critical Decisions/Trade-offs
- Choose materials
- Choose process(es)
  - Cost determined by the material and the processes used to create the shape

Basic manufacturing industries and processes including casting, forging, assembling, inspection/attesting and certification; packaging, warehousing and forwarding. Metalworking operations; shaping, planning, milling, drilling, turning, reaming, broaching, abrasive machining, chip-less machine processes. Metal cutting tools and cutting fluids; cutting forces and power requirement for cutting. Threads, gears, selection of materials; processing methods and equipment for manufacturing. Fabrication methods including welding, soldering, brazing adhesive bonding and

mechanical fastening. Heat treatment. Tools for wood-working. Quality control in manufacturing.



Manufacturing was derived from two Latin words namely *manus* (hand) and *factus* (made). Therefore, manufacturing literally means "made with hand" of "hand made".



Manufacturing engineering can be defined as "the study of the processes required to produce parts and assemble them into machines and mechanisms". Manufacturing engineering produces various machines for the use of a nation and thus, the economic and industrial growth of a nation is dependent on the development of engineering industries. The living condition of the people in terms of shelter, clothing and food is determined by how much they produce and the level of production is dependent on manufacturing capability.

## **1.2 Basic Manufacturing Systems**

Manufacturing systems may be classified into four based of the scale of production as follows:

#### (a) Piece or Job or Lot Production:

- Small quantities of products to satisfy a specific demand.
- Use mainly general purpose equipment, standard cutting tools and universal measuring facilities.
- Use skilled labour for the manufacturing of lots.
- Large variety of products
- Products move through the shop to various machines

**Examples** include manufacture giant hydro- and steam-turbines aeroplanes, rolling mills, refineries etc.



#### (b) Project Shop

- Product being manufactured **cannot** be easily moved during production
- Production processes are brought to the product

Examples: Bridges, ships, large airplanes, locomotives, large machinery



- **(c) Medium or Batch Production:** This is concerned with the manufacture of parts in repeated lots or batches and to a specific order.
  - Requires special production facilities and storage space for stock.
  - The equipment used is general purpose type equipped with universal, adjustable and sectional built-up jigs, fixtures and tools.
  - Cost of production substantially.
    Examples include manufacture machine tools, compressors and print books.

#### (d) Mass or Flow Production:

- Larger quantities of products
- Production line
- Use of specialized and single purpose machine tools
- Reduces the time required for assembly operations.
- Semi-skilled or unskilled workers are required
- The setting up the company requires a high capital
- The unit cost of production is low.

*Examples* are manufacture or produce bolts, nuts, washers, automobiles, biros, pencils, matches.. etc.



- **(e) Continuous Process Production:** Involves the manufacture of bulk quantities of material
- Large plants
  Examples include the products of refineries, oil plant, liquids, gases, powders, continuous chemical plant etc.



## 1.2 Classification of Manufacturing Processes

Manufacturing processes may be grouped into the following main categories:

**1- Casting Processes:** This is a process whereby molten metal is poured into a prepared temporary or permanent mould and is allowed to solidify and take the shape of the mould.

*Examples* include sand casting, permanent mould casting, centrifugal casting etc.

- **2- Machining processes:** This is also known as metal cutting and is the removal of metal in the form of chips from a work piece to get the required shape.
  - *Examples* of machining processes include the conventional methods such as milling, drilling, turning, broaching and nonconventional methods such as Electro-Discharge Machining (EDM), Abrasive Jet Machining (AJM) and Water Jet Machining (WJM).
- **3- Powder Metallurgy:** This involves the pressing and sintering of various sizes of particles of ceramics, polymers, glass, etc. to obtain the final product.
- **4- Plastic Materials/Polymers Processing Methods:** This include various methods for processing plastic materials /polymers and various moulding processes (compression moulding, injection moulding, thermoforming, etc)
- 5- Deformation Processes: These operations induce shape changes on the work piece by plastic deformation under the action of forces applied by various tools and dies to produce a required shape. The deformation may be hot or cold. During this process, there is no removal of material but displacement to get the final shape. Deformation processes include metal working/forming processes such as forging, rolling, extrusion, drawing; sheet metal working processes such as deep drawing and bending etc; unconventional forming processes such as High Energy Rate Forming (HERF) and High Velocity Forming (HVF) are part of these processes.

- **6- Joining Processes:** These are the joining of two or more components to produce a required product. It includes welding, brazing, soldering, diffusion, bonding, riveting, bolting and adhesive bonding.
- **7- Heat Treatment and Surface Treatment Processes:** These are the processes employed to improve the properties of a work piece. The processes include annealing, normalising, hardening, and tempering methods. Surface treatment methods include electro-plating and painting etc.
- **8- Assembly Processes:** The assembly processes for machines and mechanisms are the parts of manufacturing process concerned with the consecutive joining of the finished parts into assembly units and complete machines of a quality that meets the manufacturing specifications.
- **9- Inspection and Certification:** Inspection of assembled parts is done to ensure that the products certify the quality requirements. Quality products are then certified OK for packaging.
- **10-** Packaging, Warehousing and Forwarding Processes: Packaging involves putting the products into cartons for onward transfer to warehouse (warehousing) and for delivery to the consumers/customers.

#### 1.3 Steps for manufacturing of a Medical Device

- 1. Materials selection;
- 2. Types of tests required for evaluation depend on the physical and chemical nature of its materials and the nature of the device's exposure to the body;
- 3.Its physical properties, cost, and availability may be acceptable, but might contain toxic chemical components;

- 4. Screen the candidate materials at an early stage to eliminate those that are toxic, and select those that are sufficiently biocompatible or nontoxic for their intended use.
- 5. Chemical constituents and potential extractable should be identified and quantitated for overall safety assessment of the device.