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Manufacturing Process Overview (adapted from Salt Lake Community College BMAN 1110)

- Prototyping/Pilot Plant Phase = product transfers from R & D to production
- Biomanufacturing can begin during this transfer phase
- Scale up issues must be resovled during transfer phase
  Idea → R & D (proof of concept) → prototyping/pilot plant (validation & smaller scale production) →manufacturing (mass produce/large scale) → consumer

- Identify required
  - resources
    - Materials
    - People
    - Equipment & tools
    - Facilities
    - $$$
  - Processes
    - Process = any operation or tecxhnique used to transform materials into products
    - Involves technology: engineering and science considerations
  - Work Flow & Facilities
    - Work flow is impacted by facility layout
      - Typical layouts: product vs. process
      - Cellular layout: newer, lean philosophy
        - Work cell= combination of process and product layout
        - Flexible, can be customized as needed
        - Typically 3-12 workers per cell, cross trained
        - Cell is responbible for all aspects of product-output & quality
      - Line balancing: assignment of tasks at a station/cell to maximize efficient output
- Raw Material Acquisition
  - Identify source(s)
  - Qualify Vendor
    - Regulatory compliance
  - Purchase raw materials
  - Inspect incoming raw materials
    - Released for use if meets specifications
    - Quarantined/rejected if not
  - Add to inventory: traceability!

- Production Run

    - Verify all raw material availablility
    - Schedule production run
    - Line clearance before starting
    - Follow appropriate work instructions
        - Approved
        - Most current
    - Manage resources throughout
    - Product must meet desired specifications/requirements
    - Monitor/control production to ensure quality
    - Complete batch record with production run
    - Entire run = one “lot” or “batch”
    - Deviations? Get approval & document
- Product Complexity
    - Some products are made from smaller parts/subassemblies
        - May be made in-house or by a supplier/vendor
        - Finished product company has overall responsibility over parts/subassemblies used
            - importance of vendor qualification
    - Subassemblies can be made
        - Prior to final product and ‘stocked’
        - “Just in Time” for use in final product
    - Traceability is critical!
- Packaging and labeling
    - Maximize product stability
    - Sterility concerns?
- Label product appropriately (labels & products inserts)
    - Must follow federal regulations
    - All claims must have supporting data
- Inspection and release
    - Finished product inspected to ensure quality and consistency
        - Various levels of visual checks- cross-referenced with documentation
        - May include testing: sampling vs. 100% testing
        - Verify product meets desired specifications/requirements
- Distribution and Customer Support
    - Sales and marketing
        - -ties to R & D
        - Warehousing
        - Shipping
        - Customer service/technical support
- Continuous Improvement
    - Can always improve on any and all phases of manufacturing

        - Resource scheduling
            - Shifts
            - Equipment maintenance
        - Production
            - Supply chain management
            - Inventory: transit, material, work-in-progress, buffer, finished goods
            - Lean manufacturing
            - "Just-in-Time" manufacturing
        - Quality Assurance
- Materials Inventory
    - Types of Inventory
        - Transit
        - Raw materials/parts
        - Work-in-progress
        - Buffer = safety stock
        - Maintenance repair and oerations (MRO) = machine parts & tools
        - Finished goods (FG) = final product
    - Inventory costs $: carrying costs vs. shortage costs
- Supply Chain
    - Supply chain management = coordination of supply chain elements to maximize efficiency and profit
    - Effective management results in:
        - Shorter lead times
        - Reduced inventory costs
        - Faster response to demand changes
        - Supplier → storage (raw materials) →production →storage (finished goods) →distributor → delivery/retail → customer
- Time Costs $$
    - Time includes
        - Supplier lead times
        - Equipment set-up
        - Scheduled maintenance
        - Production
        - Unexpected events: breakdowns, repairs, delivery delays
    - Minimize down-time = minimize costs
        - Preventative maintenance vs. repairs
        - Maximize use of production equipment
        - Maximize quality
- Productionv Systems
    - Two main types
        - PUSH system

- Forecasted demand
    - Accurate prediction: errors cause shortage or excess
    - Hard to change once production begins
    - Larger WIP inventory
- PULL System
    - Made to order
    - Only necessary materials moved downstream
        - Signaled by *kanban* (Japanese- a visual sign)
        - Works best if stations are close and workers cross trained
        - Small WIP inventory so material delays affect production

	PUSH	PULL
Production Trigger	Predicted demand	Customer demand
Buffer/WIP inventory	Large	Small
Production run length	Long	short
Product changeover speed	Slow	fast
Effect of supply disruption	Can continue until no more WIP	Stops until supply is replenished
Speed to demand change	Slow	fast
Scheduled maintenance effect	Depends on WIP inventory	Production stops
uses		▪ Agile manufacturing- flexible automation- rapid new product development ▪ Just in Time production- low inventory and waste ▪ Biggest risk if material flow interrupted

- Documentation
    - Critical to production process
    - Puropose is to
        - Reference every action
        - Reference results
        - Ensure all procedures and regulation were followed
        - Help worker understand process
        - communicate between teams
        - Identify necessary improvements
        - justify changes
        - trace materials
    - Can be written or electronic

- Types
  - SOP
  - WID
  - Work Order
  - Batch record
  - Maintenance record
  - Testing record
  - Shipping record
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