



MECHANIZATION OF QUANTITY PRODUCTION

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CONTENTS



- ✘ Mechanization of quantity production
- ✘ Group technology
- ✘ Principle of GT in quantity production
- ✘ Application of GT in quantity production
- ✘ Inspection and quality control in quantity production
- ✘ Computerization and Robotization in quantity production



INTRODUCTION

- ✘ Mechanization is the process of changing from working largely or exclusively by hand or with animals to doing that work with machinery.
- ✘ It includes the use of hand tools.
- ✘ Nowadays mechanization implies machinery more complex than hand tools.
- ✘ Devices that cause speed changes or changes to or from reciprocating to rotary motion, using means such as gears, pulleys or sheaves and belts, shafts, cams and cranks, usually are considered machines.
- ✘ After electrification, most small machinery are no longer hand powered, mechanization was synonymous with motorized machines.

MECHANIZATION OF RICE PLANTATION



Manual Rice plantation

Mechanized Rice
Plantation



MECHANIZATION IN METALLURGY



- ✘ In metallurgy, mechanization of production is aimed at completion of mechanization of individual labor-intensive jobs and implementation of integrated mechanization of production in blast-furnace, steel-smelting, and rolling shops.
- ✘ The most difficult jobs near the hearths of blast furnaces, and also all essential operations with tap holes, have been mechanized.
- ✘ In steel production sophisticated filling machines are used, the processes of breaking and setting the lining of ladles and loading large-capacity electrical furnaces are mechanized, and automatic systems are coming into increasingly wide use to control the flow of oxygen in converters, to monitor the carbon content in the metal, and to control heat in open-hearth furnaces.

MECHANIZATION IN METALLURGY





MECHANIZATION IN MACHINE BUILDING

- ✘ In machine building, mechanization of production is primarily associated with the quantity and composition of the stock of metalworking equipment, since the machining operations are the most labor-intensive.
- ✘ In mass machine-building production, integrated mechanization of the machining processes is achieved by using unitized, special, and specialized semiautomatic and automatic machine tools.
- ✘ The stock of machine tools for electro-physical and electrochemical methods of machining perform many labor-intensive, fatiguing, and even unhealthful manual operations in the manufacture of dies, press molds, turbine vanes, hard-alloy tools, and parts with intricate shapes or are made of materials that are difficult to work with conventional tools.

MECHANIZATION IN MACHINE BUILDING



MECHANIZATION IN CONSTRUCTION



- ✘ In construction, mechanization of production is associated with the characteristic features of the technology of construction work, including high freight shipping and hauling intensity and the changeability of work sites.
- ✘ Mechanization of production in construction eases labor and reduces the time required to put units into operation.
- ✘ It is aimed mainly at the transformation of construction into a mechanized flow-line process of assembly and erection of buildings and structures from large-panel elements and assemblies manufactured at specialized plants.
- ✘ The increased production of construction machinery and widespread introduction of prefabricated reinforced-concrete structural members, new building materials, and highly productive work methods resulted in an increase in labor productivity.

MECHANIZATION IN CONSTRUCTION



MECHANIZATION IN AGRICULTURE



- ✘ In agriculture, mechanization of production is one of the most important problems in increasing production efficiency and improving working conditions.
- ✘ The level of mechanization of all types of agricultural work, together with selection, use of chemicals, and moisture regulation, determines the productivity of agriculture.
- ✘ Powerful tractors, highly productive grain combines, broad-swath and multi-row machines, and composite machines, which perform several operations in one pass.
- ✘ In animal husbandry and poultry farming the trend is toward the establishment of large specialized industrial-type farms, introduction of electrical machinery, and use of flow production lines (milking and primary milk processing, preparation and distribution of feeds, and so on).

MECHANIZATION IN AGRICULTURE



FURTHER DEVELOPMENT AND ADVANCEMENT



- ✘ The further development and advancement of equipment for mechanization of production are linked to the use of technical advances and scientific discoveries based on development of the natural sciences.
- ✘ The most important trends of scientific and technical progress and development of new means of labor are further development of synthesis, direct conversion of energy, the extent of processing of raw material, and protection of the environment.
- ✘ Under conditions of accelerating scientific and technical progress, the decisive factor in securing growth in labor productivity becomes the establishment of conditions for timely modernization of means of production, taking into account shortened periods for amortization and replacement of real fixed capital.
- ✘ An important role is played by solution of the problem of integrated mechanization of agricultural production and sectors related to it.
- ✘ Further expansion of the sphere of material production and foreign trade depends in large part on the development and operation of all types of transportation, and also on road construction; this requires improvement of the corresponding means of production.

FURTHER DEVELOPMENT AND ADVANCEMENT



FACTORY OF THE FUTURE

IoT Sensors
for Supply Chain
Management

Modular
Equipment

Industrial
Augmented
Reality

Computer
Vision

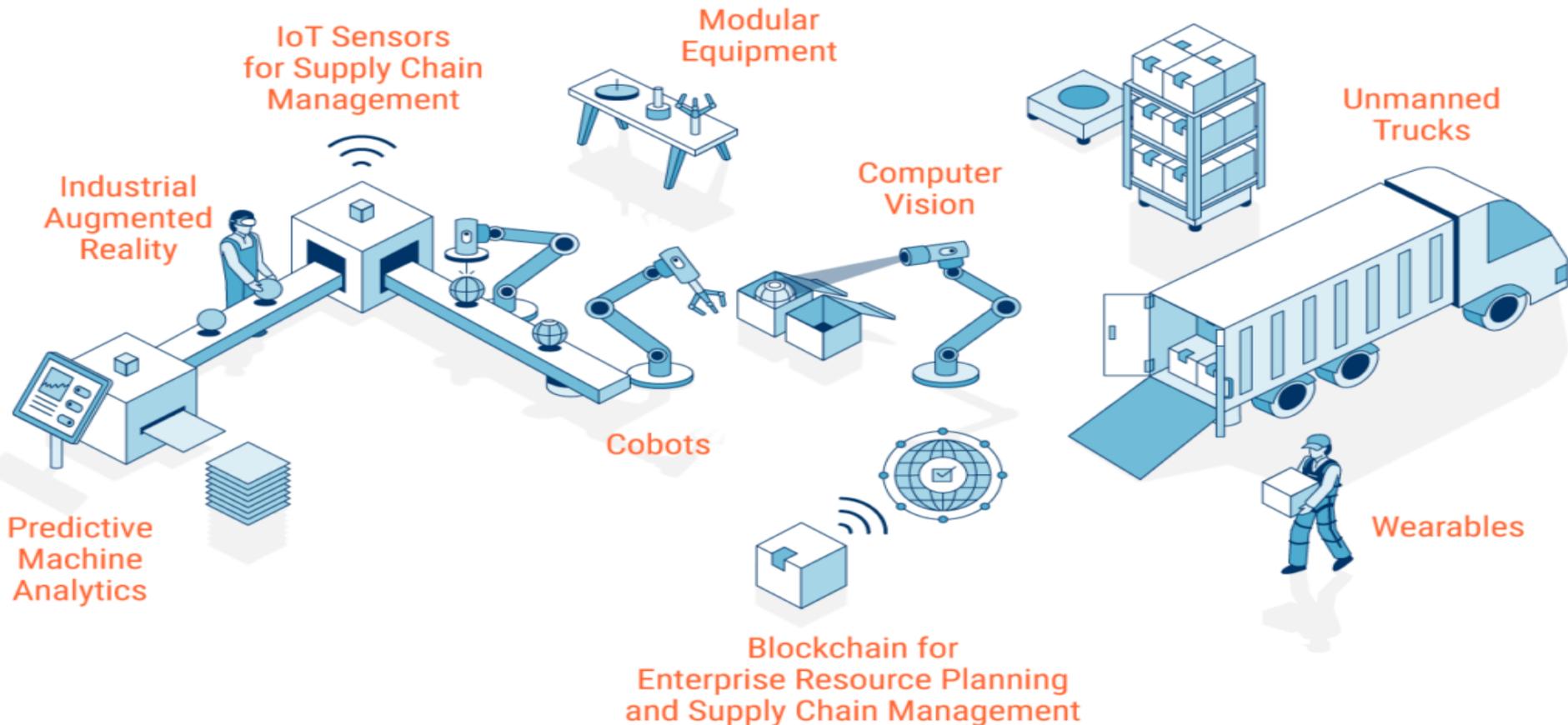
Unmanned
Trucks

Cobots

Predictive
Machine
Analytics

Wearables

Blockchain for
Enterprise Resource Planning
and Supply Chain Management





GROUP TECHNOLOGY

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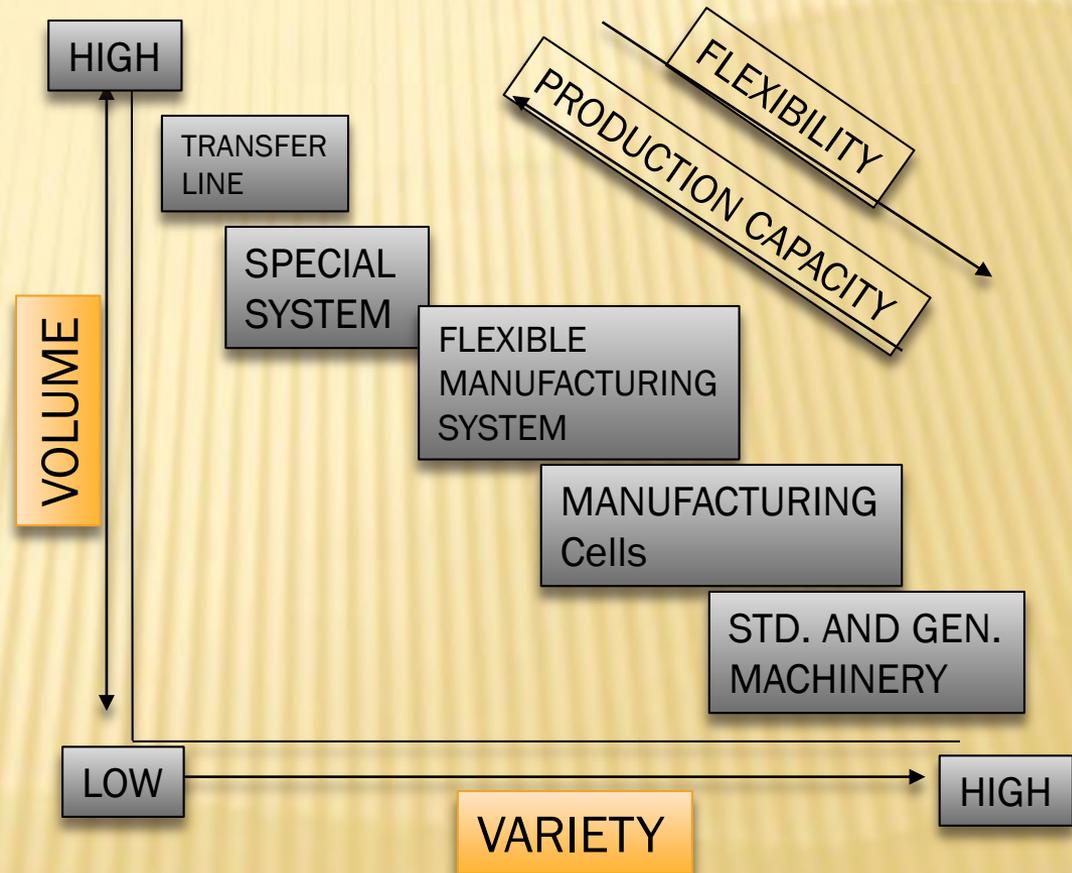
INTRODUCTION

- ✘ Group Technology is a manufacturing technique and philosophy to increase production efficiency by exploiting the “underlying sameness” of component shape, dimensions, process route, etc.
- ✘ Group Technology is the realization that many problems are similar, and that by grouping similar problems, a single solution can be found to a set of problems thus saving time and effort.

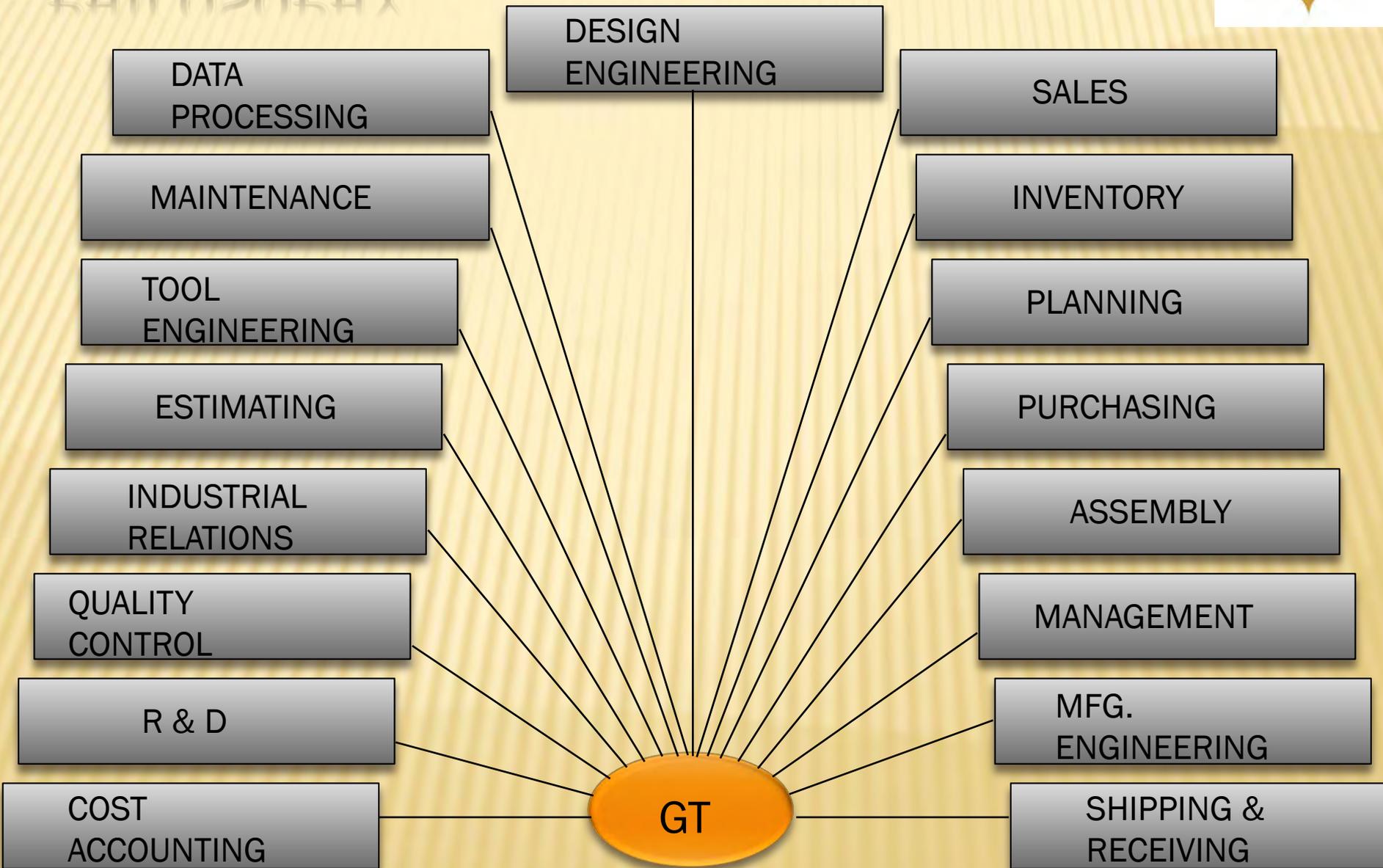
WHY GROUP TECHNOLOGY?



- ✗ Average lot size decreasing
- ✗ Part variety increasing
- ✗ Increased variety of materials
- ✗ With diverse properties
- ✗ Requirements for closer Tolerances
- ✗ Objectives of Group technology
 - + Reduce MLT
 - + Reduce WIP
 - + Improve scheduling
 - + Reduce tooling
 - + Increase equipment utilization



GROUP TECHNOLOGY MANUFACTURING PHILOSOPHY.



BENEFITS OF GROUP TECHNOLOGY



- ✘ Group technology promotes standardization of tooling, fixturing and setups.
- ✘ Material handling is reduced because the distances within a machine cell are much shorter than within the entire factory.
- ✘ Process planning and production scheduling are simplified.
- ✘ Setup times are reduced, resulting in lower manufacturing lead times.
- ✘ Work in process is reduced.
- ✘ Worker satisfaction usually improves when workers collaborate in a Group technology cell.
- ✘ Higher quality work is accomplished using group technology.



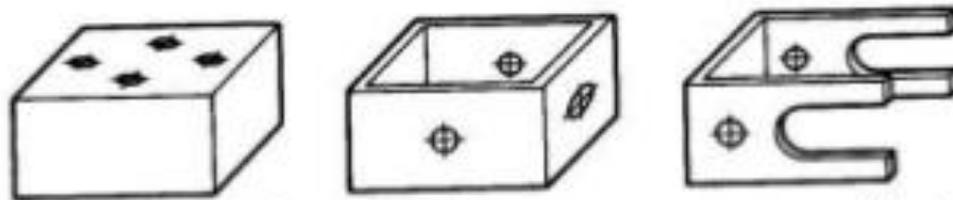
PART FAMILIES

- ✘ Part family is a collection of parts that are similar either because of geometric shape and size or because similar processing steps are required in their manufacture.
- ✘ The parts within a family are different, but their similarities are close enough to merit their inclusion as members of their part family.

PART FAMILIES



Similar prismatic parts requiring similar milling operations



Dissimilar parts requiring similar machining operations (hole drilling, surface milling)



Identical designed parts requiring completely different manufacturing processes

3/25/2016
Material: Plastic

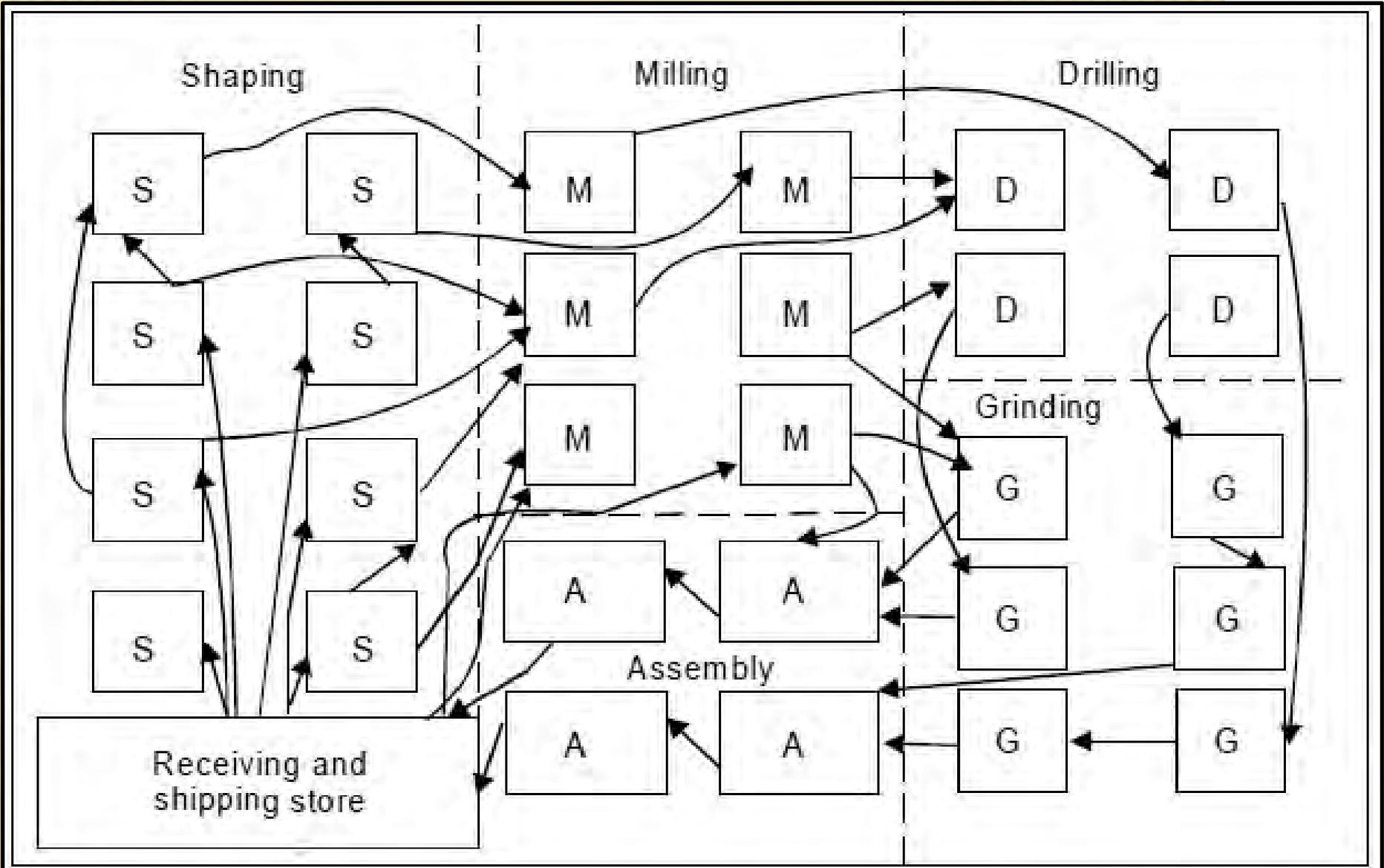
Material: Steel

PART FAMILIES



- ✘ One of the important manufacturing advantages of grouping work parts into families can be explained with reference to figures on next two slides.
- ✘ Figure on next slide shows a process type plant layout for batch production in a machine shop.
- ✘ The various machine tools are arranged by function.
- ✘ There is a lathe department, milling department, drill press Department and so on.
- ✘ To machine a given part, the work piece must be transported between departments.
- ✘ This results in work piece to visit the same department in several times.

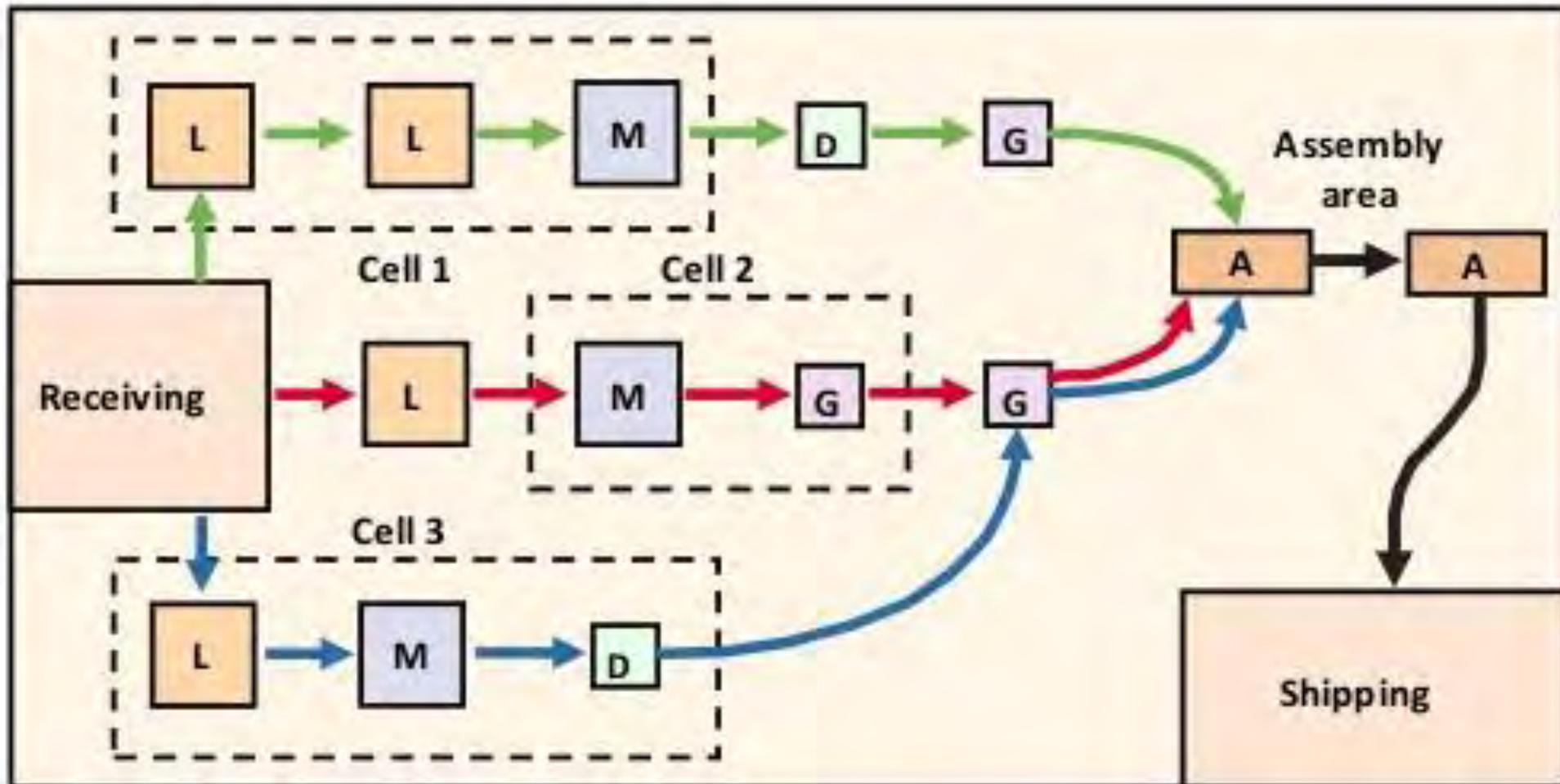
PROCESS TYPE PLANT LAYOUT



GROUP TECHNOLOGY LAYOUT



In the group technology layout machines are arranged into cells. Each cell is organized to specialize in the production of a particular part family.



PROCESS TYPE PLANT LAYOUT VS GROUP TECHNOLOGY LAYOUT



Process plant layout results in:

- ✘ Significant amount of material handling
- ✘ Work in process inventory
- ✘ More machine setups
- ✘ More lead time
- ✘ High cost

Group technology layout results in:

- ✘ Reduced material handling
- ✘ Lower setup time
- ✘ Less in process inventory
- ✘ Shorter lead time
- ✘ Low cost



PART FAMILY FORMATION IN GROUP TECHNOLOGY

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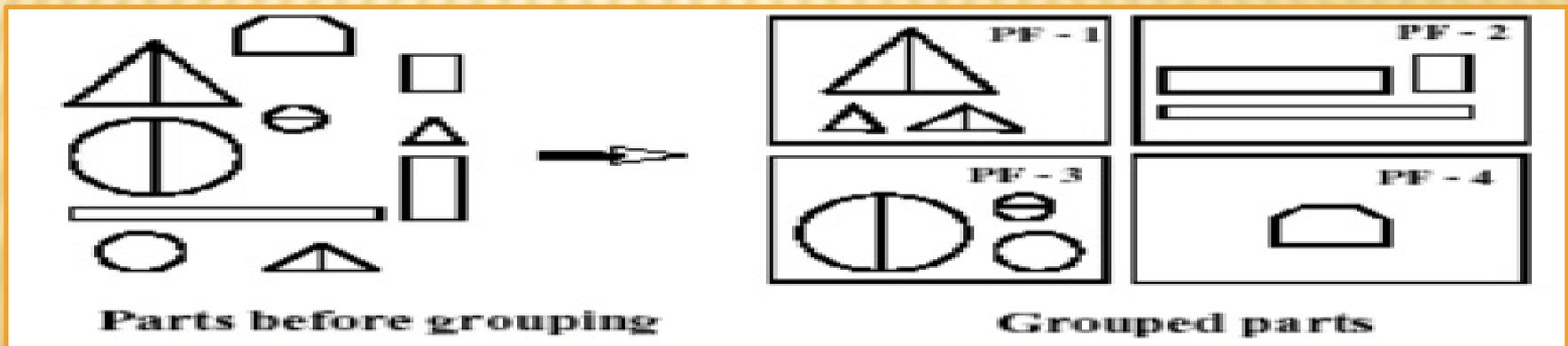
INTRODUCTION

- ✘ The biggest single obstacle in changing over to Group technology from conventional production shop is the problem of grouping the parts into families. There are three general methods for solving this problem.
 - + Visual Inspection
 - + Parts classification and coding
 - + Production flow analysis
- ✘ All the three methods are time consuming and involve the analysis of much data by properly trained personal.

VISUAL INSPECTION



- ✘ This method is the least sophisticated and least expensive method.
- ✘ It involves the classification of parts into families by looking at either the physical parts or their photographs and arranging them into groups having similar features.
- ✘ This method is generally considered to be the least accurate of the three, one of the first major success stories of Group technology is the change over using the visual inspection.
- ✘ This method is fast and simple and is useful when the part mix is not complex.



PARTS CLASSIFICATION AND CODING



- ✘ This method is the most time consuming of the three methods
- ✘ In parts classification and coding, similarities among parts are identified and these similarities are related in a coding system.
- ✘ Reasons for using a coding scheme include:
 - + **Design retrieval:** A designer faced with the task of developing a new part can use a design retrieval system to determine if a similar part already exists. Simply changing an existing part would take much less time than designing a whole new part from scratch.
 - + **Automated process planning:** The part code for a new part can be used to search for process plans for existing parts with similar or identical codes.
 - + **Machine cells design:** The part codes can be used to design machine cells capable of producing all members of a particular part family.
- ✘ Two categories of part similarities can be distinguished:
 - + **Design Attributes:** They are concerned with part characteristics such as geometry, size and material.
 - + **Manufacturing Attributes:** They are concerned with the processing steps required to make a part.

PARTS CLASSIFICATION AND CODING

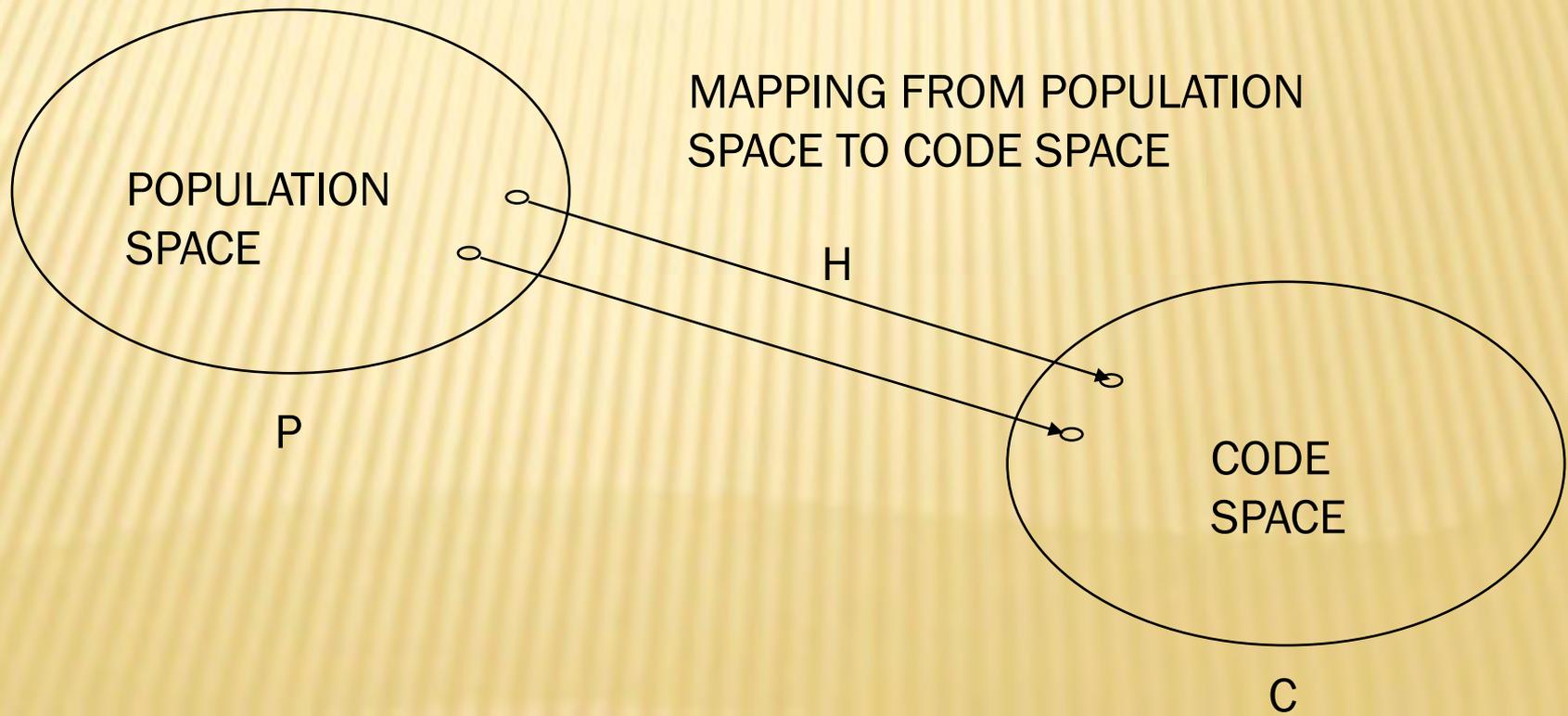


- ✘ To accomplish parts classification and coding requires examination and analysis of the design and/or manufacturing attributes of each part. The examination is sometimes done by looking in tables.
- ✘ An alternative and more productive approach involves interaction with a computerized classification and coding system, in which the user responds to questions asked by the computer.
- ✘ On the basis of the responses, the computer assigns the code number to part. Whichever method is used, the classification results in a code number that uniquely identifies the part's attributes.
- ✘ A number of classifications and coding systems are available and there are a number of commercially available coding packages. However, none of the systems has been universally adopted. One of the reasons for this is that a classification and coding system should be customized for a given company or industry. A system that is best for one company may not be best for another company.



TYPES OF CLASSIFICATION AND CODING SYSTEMS

- ✘ Group Technology coding can benefit many facets of the firm and fall into one of 3 categories:
 - + Systems based on part design attributes
 - + Systems based on part manufacturing attributes
 - + Systems based on design and manufacturing attributes

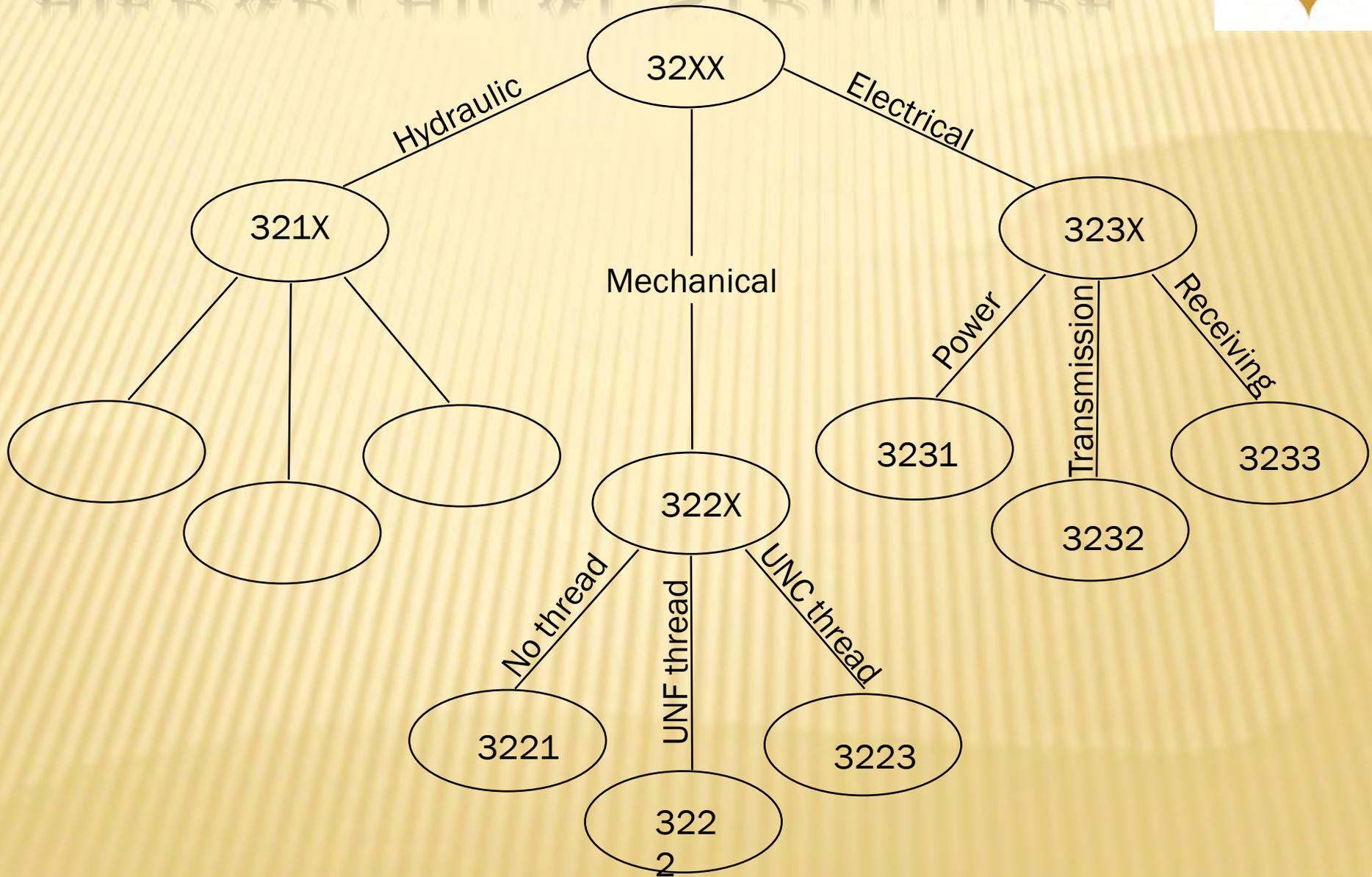




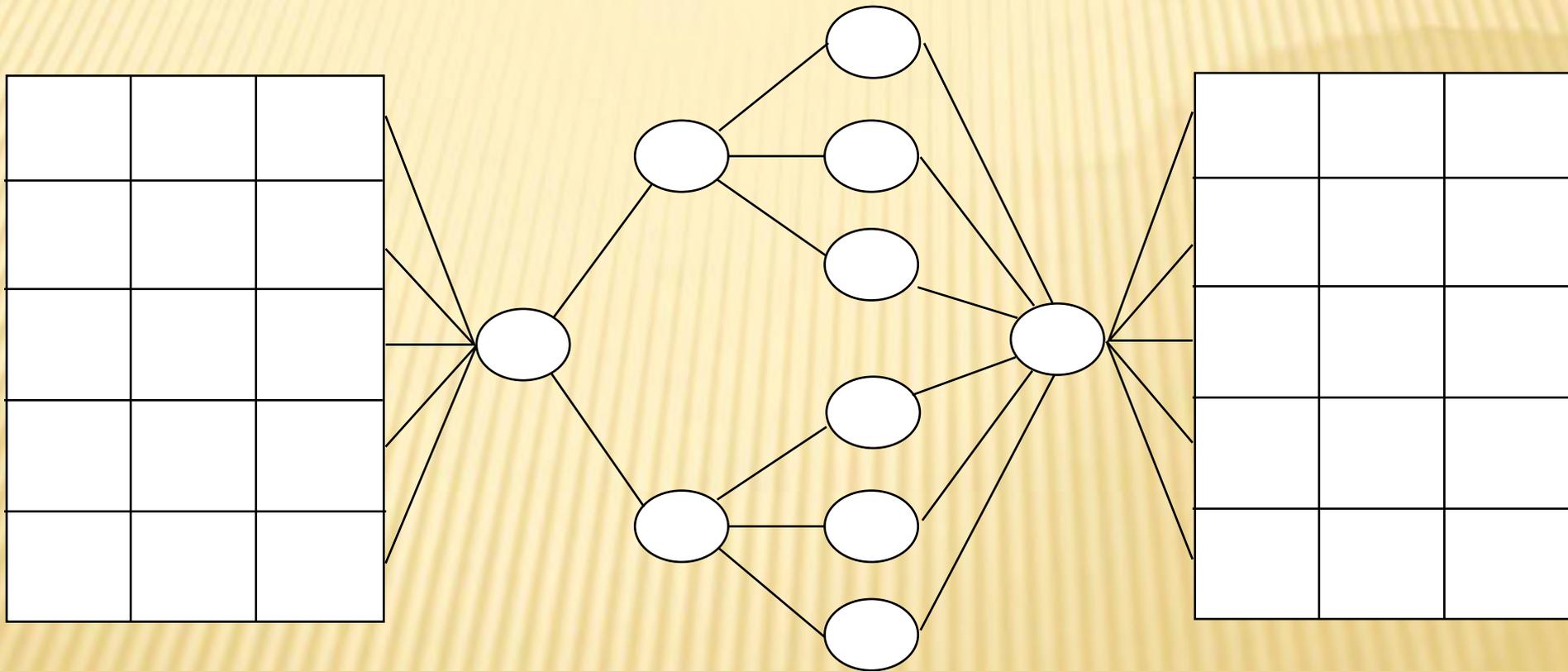
GT CODE--A SEQUENCE OF NUMERICAL DIGITS

- ✘ In terms of the meaning of the symbols in the code, there are three structures used in the classification and coding scheme.
 - + **Hierarchical structure or monocode:** A code in which each digit amplifies the information given in the previous digit.
 - + **Chain type structure or polycode:** Each digit is independent of all others, presents information that is not dependent on previous ones
 - + **Hybrid or mixed:** Has some digits forming monocodes, but strings them together in the generate arrangement of a polycode

HIERARCHICAL STRUCTURE



HYBRID STRUCTURE



Polycode

Monocode

Polycode



PRODUCTION FLOW ANALYSIS IN GROUP TECHNOLOGY

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INTRODUCTION

“Method for identifying part families and associated machine groupings based on production route sheets rather than part design data”

- ✘ Work parts with identical or similar route sheets are classified into part families.
- ✘ Advantages of using route sheet data
 - + *Parts with different geometries may nevertheless require the same or similar processing*
 - + *Parts with nearly the same geometries may nevertheless require different processing*

STEPS IN PRODUCTION FLOW ANALYSIS



1. Data collection – operation sequence and machine routing for each part (number)
2. Sortation of process routings – parts with same sequences and routings are arranged into “packs”
3. PFA chart – each pack is displayed on a PFA chart.
 - + Also called a *part-machine incidence matrix* .
4. Cluster analysis – purpose is to collect packs with similar routings into groups.
 - + Each machine group = a machine cell

CELLULAR MANUFACTURING



“Application of group technology in which dissimilar machines or processes are aggregated into cells, each of which is dedicated to the production of a part family or limited group of families”

- ✘ Typical objectives of cellular manufacturing:
 - + To shorten manufacturing lead times and material handling
 - + To reduce WIP
 - + To improve quality
 - + To simplify production scheduling and process planning
 - + To reduce setup times

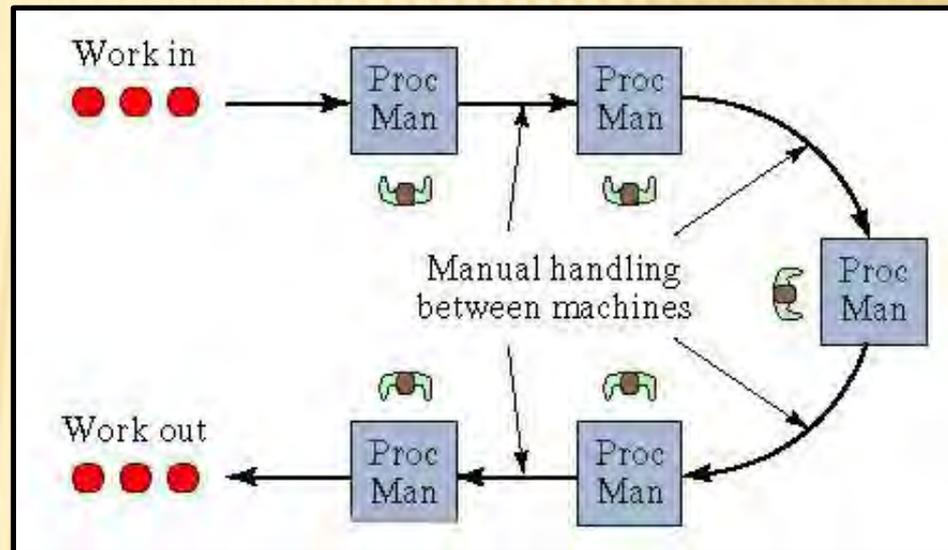
MACHINE CELL DESIGNS



- ✘ Single machine
 - + Consists of one machine plus supporting fixtures and tooling
- ✘ Multiple machines with manual handling
 - + Often organized into U-shaped layout
- ✘ Multiple machines with semi-integrated handling
- ✘ Automated cell – automated processing and integrated handling
 - + *Flexible manufacturing cell*
 - + *Flexible manufacturing system*

MACHINE CELL WITH MANUAL HANDLING

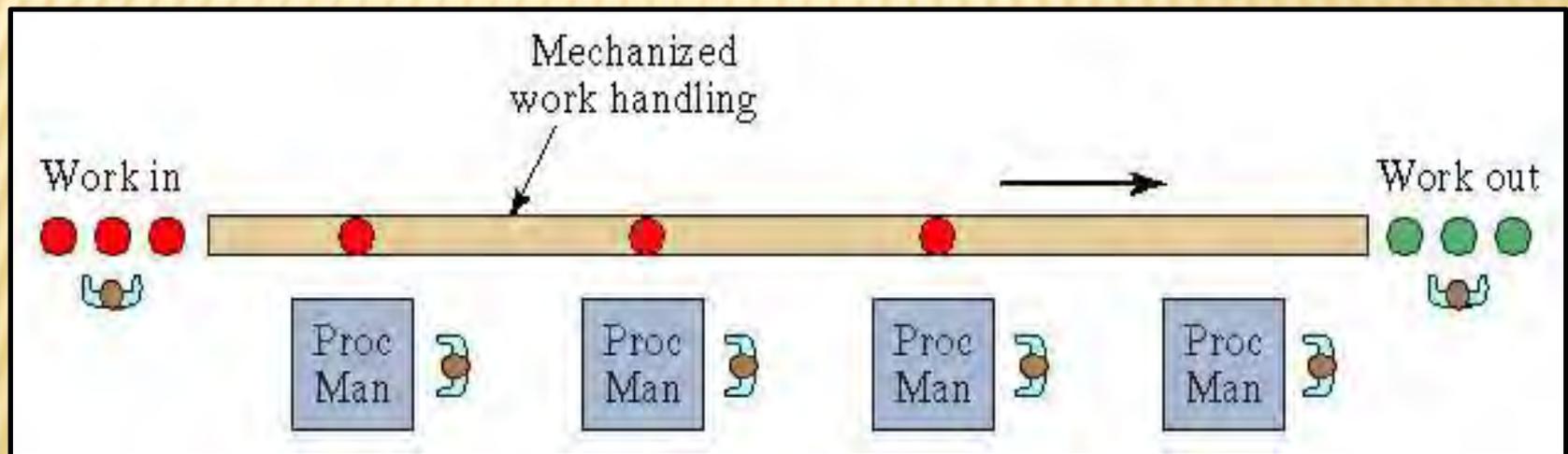
- ✘ The group machine cell with manual handling is an arrangement of more than one machine used collectively to produce one or more part families.
- + Appropriate when there is a variation in the workflow among the parts made in the cell
- + Allow multifunctional workers in the cell to move easily between machines
- + Easier changeover of models
- + Visual control of WIP
- + More flexibility to adjust to increased demand



U-shaped machine cell with manual part handling between machines

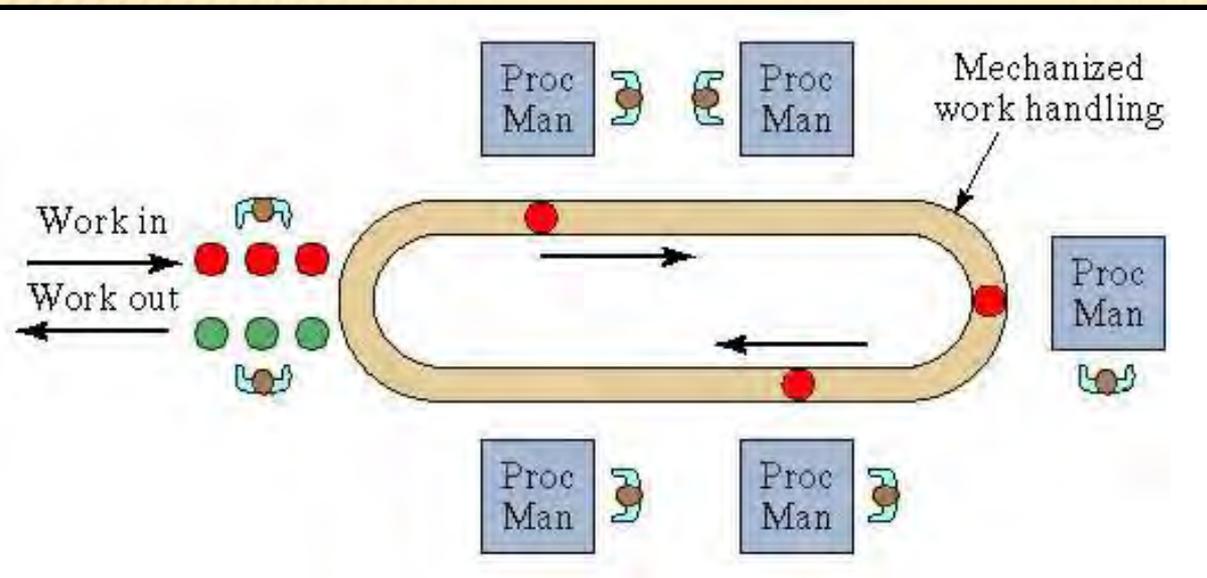
CELL WITH SEMI-INTEGRATED HANDLING

- ✘ The group machine cell with semi-integrated handling uses a mechanized handling system, i.e. conveyor, to move parts between machines in the cell.
- ✘ The Flexible Manufacturing System (FMS) combines a fully integrated material handling system with automated processing stations. ©



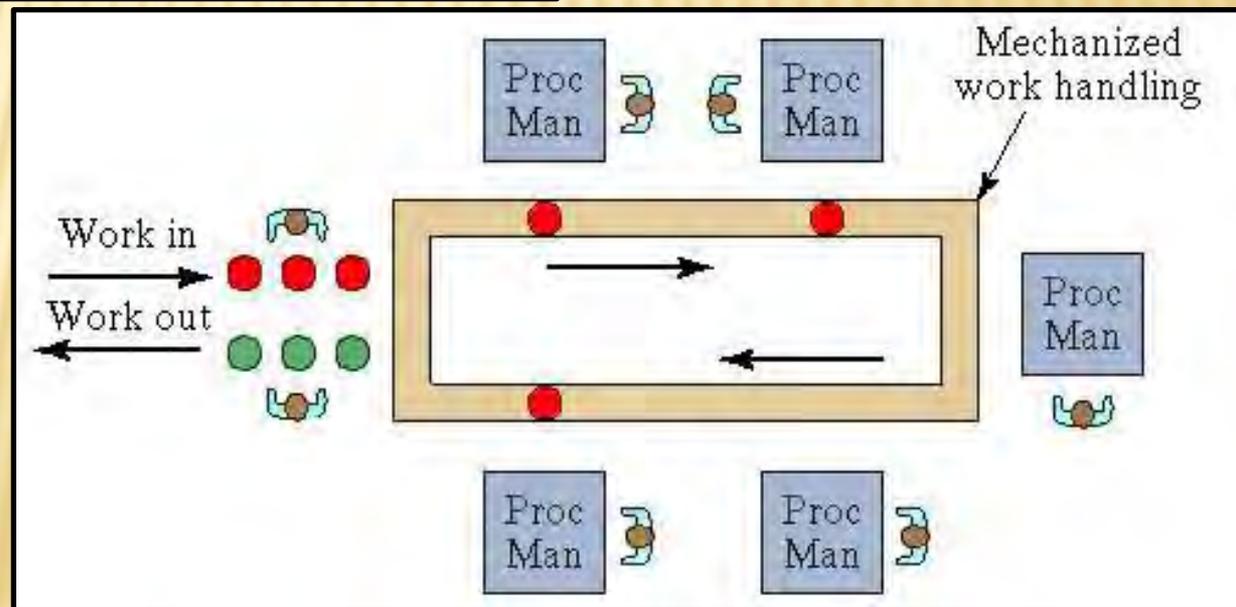
In-line layout using mechanized work handling between machines

CELL WITH SEMI-INTEGRATED HANDLING



Loop layout allows variations in part routing between machines.

Rectangular layout also allows variations in part routing and allows for return of work carriers if they are used.

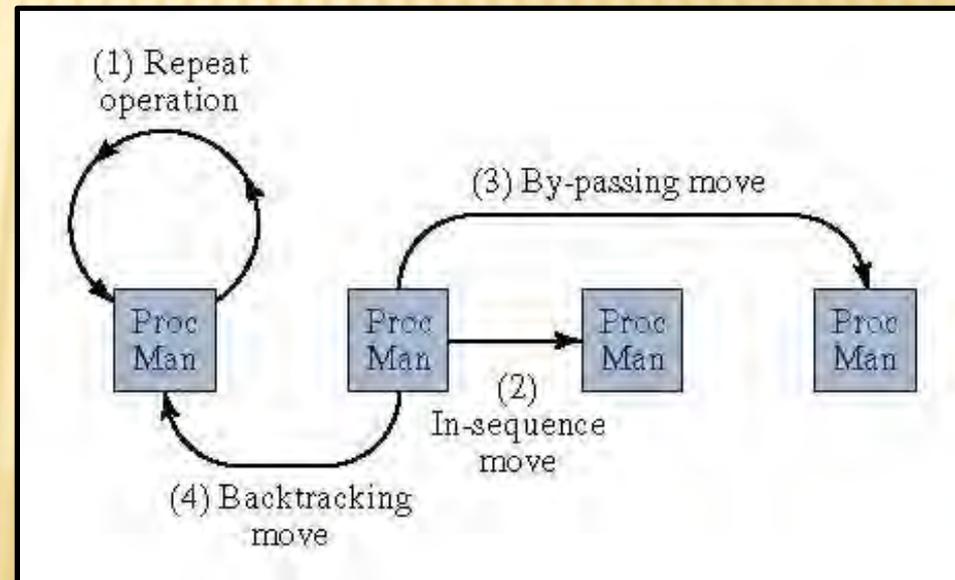


MOST APPROPRIATE CELL LAYOUT



Determining the most appropriate cell layout depends on the routings of parts produced in the cell.

- ✘ **Repeat operation:** a consecutive operation is carried out on the same machine (Multiple stations)
- ✘ **In-sequence move:** the part moves forward from the current machine to an immediate neighbor (In-line or U-shaped layout)
- ✘ **Bypassing move:** the part moves forward from the current machine to another machine that is two or more machines ahead (U-shaped layout)
- ✘ **Backtracking move:** the part moves backward from the current machine to another machine (Loop or Rectangular layout)





APPLICATIONS OF GROUP TECHNOLOGY

Manufacturing Applications

- ✘ Different ways of forming machine cells:
 - + *Informal scheduling and routing of similar parts through selected machines to minimize setups*
 - + *Virtual machine cells – dedication of certain machines in the factory to produce part families, but no physical relocation of machines*
 - + *Formal machine cells – machines are physically relocated to form the cells.*
 - + Automated process planning
 - + Modular fixtures
 - + Parametric programming in NC

Product Design Applications

- ✘ Design retrieval systems
 - + Industry survey: For new part designs,
 - ✘ Existing part design could be used - 20%
 - ✘ Existing part design with modifications – 40%
 - ✘ New part design required – 40%
- ✘ Simplification and standardization of design parameters such as tolerances, chamfers, hole sizes, thread sizes, etc.
 - + Reduces tooling and fastener requirements in manufacturing

QUANTITATIVE ANALYSIS IN CELLULAR MANUFACTURING



Grouping parts and machines by Rank Order Clustering: Determining how machines in an existing plant should be grouped into machine cells. Start with the initial part-machine incidence matrix.

- + In each row of the matrix, read the series of 1's and 0's from left to right as a binary number. Rank the rows in order of decreasing value. In case of tie, rank the rows in the same order.
- + Numbering from top to bottom, is the current order of rows the same as the rank order determined in the previous step? If yes, go to Step 7. If no, go to the following step.
- + Reorder the rows in the part-machine incidence matrix by listing them in decreasing rank order starting from the top.
- + In each column of the matrix, read the series of 1's and 0's from top to bottom as a binary number. Rank the columns in order of decreasing value. In case of a tie, rank the columns in the same order.
- + Numbering from left to right, is the current order of columns the same as the rank order determined in the previous step? If yes, go to Step 7. If no, go to the following step.
- + Reorders the columns in the part-machine incidence matrix by listing them in decreasing rank order, starting with the left column. Go to Step 1.
- + Stop.

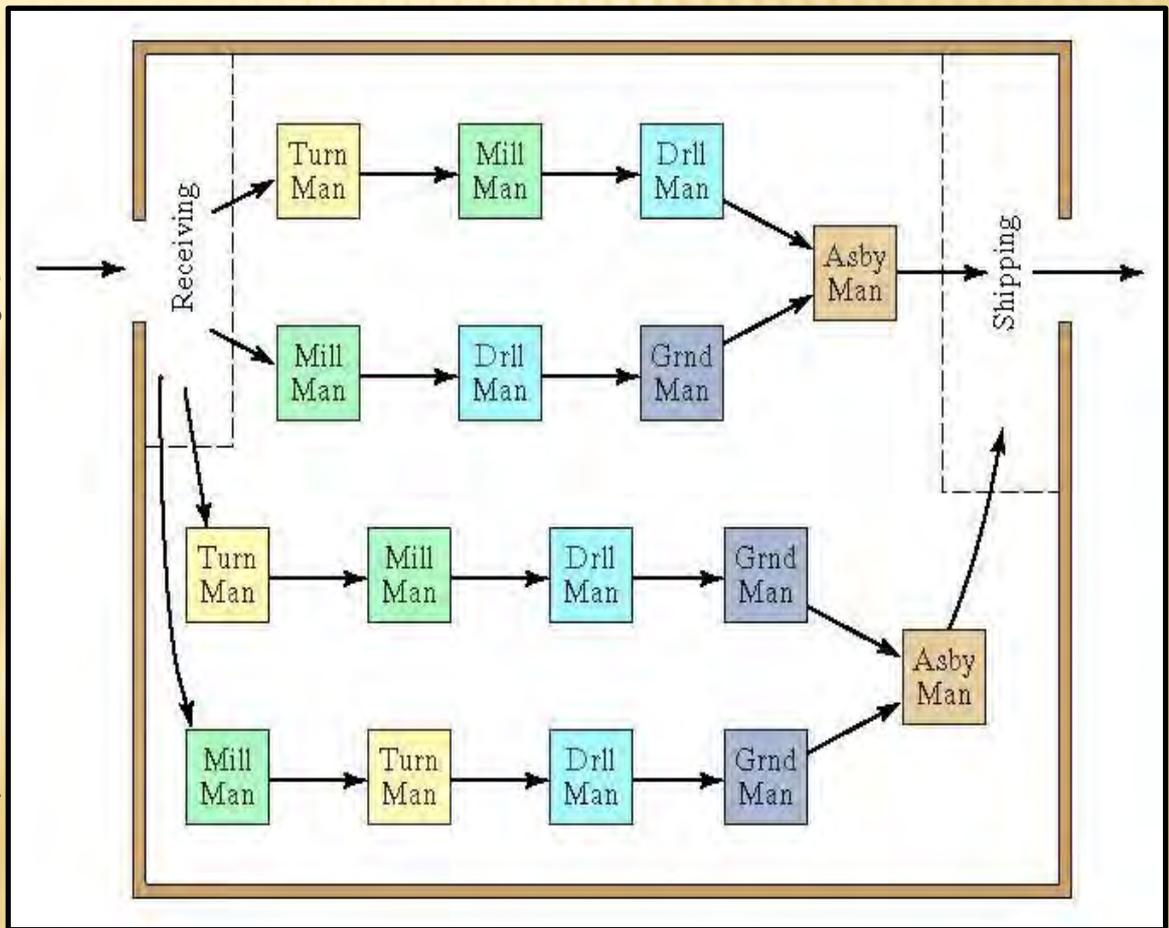
QUANTITATIVE ANALYSIS IN CELLULAR MANUFACTURING

If there is overlapping of machines

- + Place the machines in both cells.
- + Change the routing of the part.
- + Redesign the part.
- + Purchase the part.

Arranging machines in a GT Cell: This is done using Hollier's Method as follows

- + Develop From/To chart: indicate numbers of part moves between the machines in the cell.
- + Determine the From/To ratio for each machine.
- + Arrange machines in order of decreasing From/To ratio.





QUALITY CONTROL AND INSPECTION

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INTRODUCTION

“Quality is not an accident; But it is the result of intelligent efforts”

✘ WHAT IS QUALITY?

- ✘ “Quality is fitness for use. ”
- ✘ “The totality of features and characteristics of a product or service that bear on its ability to satisfy a given need.”
- ✘ “Quality involves meeting customers need, preferences and exceeding it.”
- ✘ “Quality also encompasses people, process and environment.”

WHY QUALITY CONTROL?



- ✘ Manufacturing process is a repetitive process depending on both controllable and non-controllable factors.
- ✘ This produces deviation in the quality of the product.
- ✘ Quality Control is the process of verification, or correction of the quality of the product when deviations are found to be more than expected.

WHAT IS QUALITY CONTROL?

“Those planned and systematic actions which provides a mean to control and measure the characteristics of a product, process or a service to established requirements.”

QUALITY CONTROL AS PER ISO



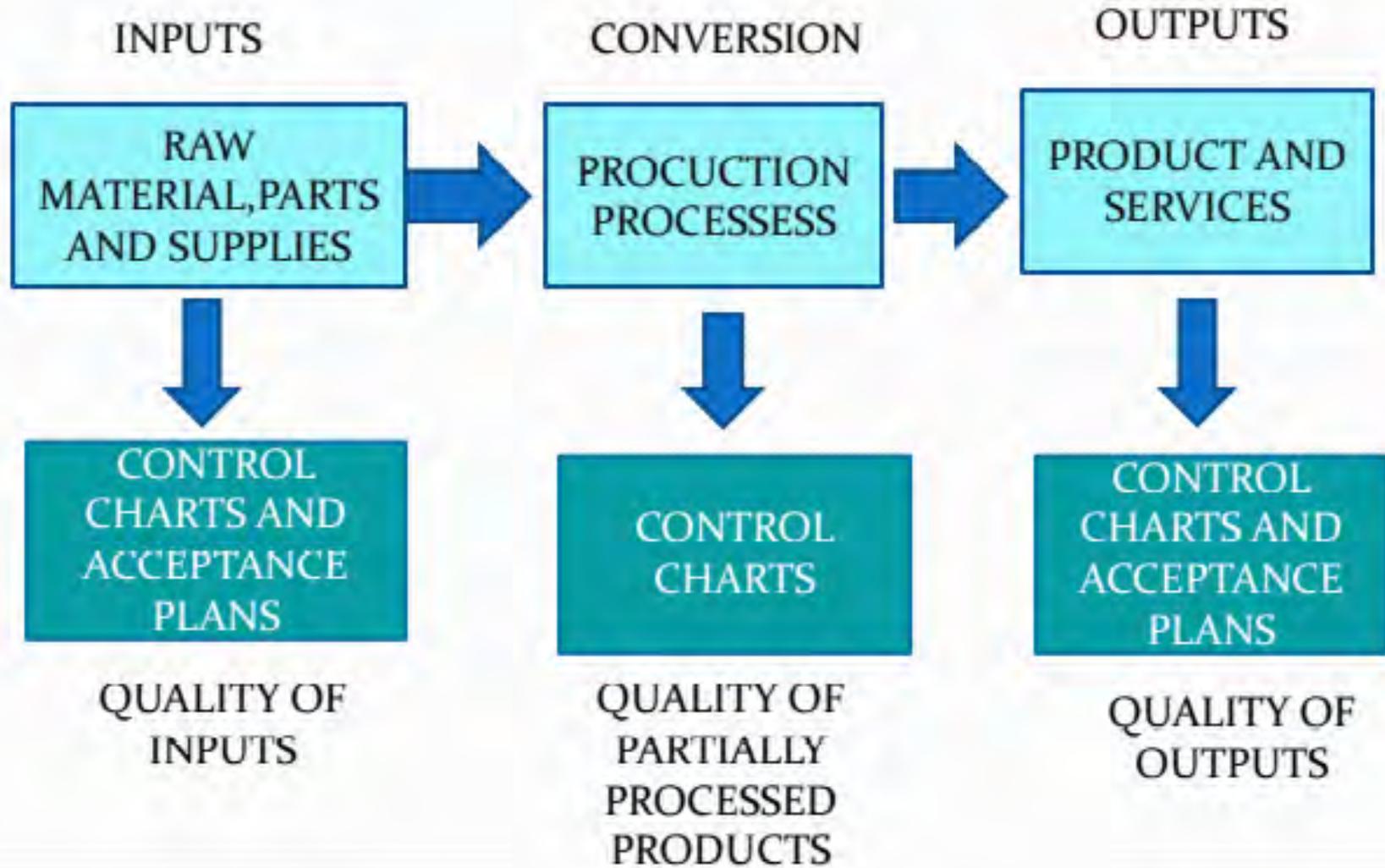
- ✘ “The operational techniques and activities that are used to satisfy quality requirements.”
- ✘ The quality control system verifies and maintains desired level of quality in an existing product or service by careful planning, use of proper equipments and continued inspection and corrective action as required.

WHAT IS QC INSPECTION?

The ISO standard defines inspection as “activity of measuring, examining, testing one or more characteristics of a product or service and comparing the results with specified requirements in order to establish whether conformity is achieved for each characteristic.”



QUALITY CONTROL THROUGH PRODUCTION SYSTEM



PRE PRODUCTION QC INSPECTION



- ✘ The safety and efficacy of the finished dosage form is largely dependent on the purity and quality of the bulk active drug substance.
- ✘ Physical tests such as particle size for raw materials flow properties etc. are essential tests to assure consistent operation of the production and control system and to assure quality and efficacy.
- ✘ To decrease quality risk, the inputs can be inspected prior to production.
- ✘ Samples are randomly taken and checked.
- ✘ An experienced inspector examines the sample/prototype to make sure that:
 - + The raw materials meet the specified standards
 - + Whether development team has clearly communicated the requirements to the manufacturing team.
 - + Whether equipments for mass production is similar to that for making prototypes

IN PROCESS QC INSPECTION



- ✘ The first products that got out of the line are inspected for conformity.
- ✘ If issues are raised at this stage, the factory can immediately take actions and avoid delays.
- ✘ In-process products are rarely checked as it takes technician to reliably detect errors on unfinished products.
- ✘ Inspect the test results from in-process tests performed for conformance with established sampling and testing protocols, analytical methods, and specifications.
- ✘ For example, evaluate the tests for weight variation, hardness, and friability. All testing must comply with cGMP.
- ✘ The inspection must confirm that the in-process tests were done, as described in the plan, and ascertain that the results are within specifications.

CLASSIFICATION OF IN-PROCESS INSPECTION



- ✘ **Trial run inspection:** Tools and machines are checked before operation.
- ✘ **First-off inspection:** The items produced in the first production run are inspected and examined with respect to specifications.
- ✘ **Inspection by self control:** Done by operators, controlling operations at different levels of production process.
- ✘ **Decentralized inspection:** Semi finished goods are inspected either on machines or in the production line.
- ✘ **Centralized inspection:**
 - + There can be single inspection unit for whole plant or each section can have inspection unit to inspect the items.
 - + The inspection staff is more experienced and skilled in this case.
 - + Sophisticated and reliable instruments and techniques are use to measure the quality.
 - + Hence centralized inspection is reliable and accurate.

QC INSPECTION IN PRODUCTION



- ✘ **Component dominant:** Incoming material must be checked for required specifications.
- ✘ **Set-up dominant:** An operation once set at a level, remains at that level for long. Hence products produced initially if found free from defects and conforming to specifications, then the operation can be cleared for continuous operation.
- ✘ **Machine dominant:** Operation drift away from initial set-up level as operation proceeds. Hence needs periodic inspection for correcting set up.
- ✘ **Operator dominant:** A certain portion of job is entirely influenced by operator's skill.
- ✘ **Information dominant:** All the information including the SOP's, nature of job is given to concerned person.
- ✘ **Record dominant:** The written records and documentation of every process and test conducted should be maintained.



QUALITY CONTROL INSPECTION ANALYTICALLY AND STATICALLY

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QUALITY CONTROL INSPECTION ANALYTICALLY



In general, these inspections include:

- ✘ The specific methodology which will be used to test a new drug product.
- ✘ A complete assessment of laboratories conformance with GMP'S.
- ✘ A specific aspect of laboratory operations.
- ✘ Laboratory records and logs represent a vital source of information that allows a complete overview of the technical ability of the staff and of overall quality control procedures.
- ✘ SOPs should be complete and adequate and the operations of the laboratories should conform to the written procedures.
- ✘ Specifications and analytical procedures should be suitable and, as applicable, in conformance with application commitments and compendia requirements.
- ✘ Documents relating to the formulation of the product, synthesis of the bulk drug substance, product specifications, analysis of the product, and others are examined during the review process in headquarter.
- ✘ Inspections are designed to determine if the data submitted in an application are authentic and accurate and if the procedures listed in the application were actually used to produce the data contained in the application.
- ✘ Additionally, they are designed to confirm that plants (including QC laboratory) are in compliance with CGMP regulations.

FDA INSPECTION



- ✘ Based on team inspection approach.
- ✘ Highly technical and specialized testing equipments, procedures, data manipulations as well scientific laboratory operations will be evaluated.
- ✘ The inspection of a laboratory requires the use of observations of the laboratory in operation and of the raw laboratory data to evaluate compliance with CGMP's.
- ✘ FDA INSPECTION- 4M's
- ✘ MACHINE:
 - + Inspection should confirm that preventive maintenance, cleaning, adjustment etc are performed.
 - + Machine usage, maintenance, calibration logs, repair records should be examined.
 - + Verify that the equipments were in good working order at the time the batches were analyzed.
- ✘ METHOD/PROCESS:
 - + Information regarding validation of methods should be carefully evaluated.
 - + All processes that may cause deviation to a device's specification and all validated process must be monitored and controlled.
 - + If the process is software controlled, confirm that the software was validated.
 - + Review the software documents, software validation activities, software change controls and software validation results to confirm that software will meet user need

FDA INSPECTION



✘ MATERIALS:

- + Raw material testing is of utmost importance as it directly affects the quality of final product.
- + Hence inspection should examine the analysis of materials including purity test, quality, charts etc.
- + Inspect if the methods for analyzing the purity were validated.
- + The manufacturer must have complete knowledge of manufacturing process and the potential impurities that may appear in materials.
- + These impurities cannot be evaluated by without a suitable method and one that has been validated.

✘ MAN:

- + Verify that personnel have been qualified to implement validated processes.
- + Appropriately trained to implement processes which yield results that can be fully verified.
- + Confirm that the employees have complete knowledge of the devices, processes.
- + Confirm that employees are aware of the device defects that may occur as a result of improper performances.
- + Confirm that the employees conducting QC tests are aware of the defects and errors that may be encountered while performing their responsibilities.

FINAL INSPECTION



- ✘ It is also known pre-shipment inspection.
- ✘ This is the most popular type of QC inspection or importers.
- ✘ It takes place once all the products are finished and ready for shipment.
- ✘ The samples are drawn in a random manner and thus can be representative of the whole batch.

STATISTICAL QUALITY CONTROL



- ✘ It is a technique for controlling quality of product using a set of statistical tools.
- ✘ It involves two elements:
 - + Statistical process control: This summarizes collection of data , makes use of control charts.
 - + Acceptance sampling
- ✘ CONTROL CHARTS
 - + Primary purpose of control charts is to indicate when production processes might have changed sufficiently to affect product quality.
 - + If the indication is that product quality has deteriorated, corrective is taken.
 - + Compare attributes (No. of defectives in a sample) or variables (characteristics that can be measured on a continuous scale (weight, length, etc.) of the sample with that of the standard
- ✘ ACCEPTANCE SAMPLING OR SAMPLING INSPECTION
 - + It is process of evaluating portion of the product material in a lot for the purpose of accepting or rejecting the lot as either conforming or not conforming to quality specifications.
 - + The acceptance plan identifies the:
 - ✘ Size of samples, n .
 - ✘ Type of samples .
 - ✘ Decision criterion, c , used to either accept or reject the lot .
 - ✘ the Samples may be either single, double, or sequential.



SINGLE SAMPLING PLAN

Draw random sample (n) from the lot

Determine number of defection in the sample

If total no. of defects does not exceed c , accept the lot

If defection exceed c , reject the lot

DOUBLE SAMPLING PLAN



Determine no. of defectives in the sample(n)

Defectives do not exceed c_1 , accept the lot

Defectives equal or exceed r_1 , reject the lot

Defectives exceed c_1 but less than r_1 , draw another sample(n_2)

Determine no. of defectives in second sample

Total no. of defectives does not exceed c_2 . accept the lot

Total no. of defectives equals or exceeds c_2 , reject the lot

SEQUENTIAL/MULTIPLE SAMPLING



- ✘ This is extension of double sampling plan.
- ✘ At each stage of sampling the cumulated results are analyzed to take decision of accepting/rejecting the lot.
- ✘ If no final decision can be taken at any stage, then another sample is drawn to take further decision.

QUALITY AUDIT AND FOLLOW UP



- ✘ ISO defines audit as systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these are implemented effectively and are suitable to achieve objectives.
- ✘ It checks if quality system and procedures are
 - + Free from congenital defects.
 - + Capable of achieving and maintaining standards of quality chosen by enterprise or costumers.
 - + Being adhered to and compiled with, in day to day work.
- ✘ Prior to writing auditing report, auditor explains the observations to audited.
- ✘ Corrective actions to be taken are proposed.
- ✘ Audit report are written in standard format which contain area audited, dates of audit, persons contacted, commendable features and recommendations.
- ✘ The report must contain status of implementation of pending corrective measures as per previous audit.

QC INSPECTION IN DISTRIBUTION AND STORAGE



- ✘ GMP summarizes following principles with respect to distribution:
 - + Only authorized products are distributed.
 - + Premises are suitable for their intended use and kept on good sanitary condition.
 - + All products are received, stored and handled carefully.
 - + All operations are performed according to written procedure, supervised and documented.
 - + Adequate provision exist to handle complaints, recalls and return goods
- ✘ **Storage:** Warehouse should be clean, inaccessible for unauthorized persons, temperature and humidity control, adequate shelving, free from insects and vermin.
- ✘ **Special storage:**
 - + Availability of cold room/refrigerator for vaccines and biological products.
 - + Special storage areas for controlled drugs and other prescription drugs.
 - + Suitable and secure storage facility for controlled drugs and poisons



COMPUTERIZATION AND ROBOTIZATION IN QUANTITY PRODUCTION

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INTRODUCTION



Cheaper, more capable, and more flexible technologies are accelerating the growth of fully automated production facilities. The key challenge for companies will be deciding how best to harness their power.

- ✘ This “lights out” production concept—where manufacturing activities and material flows are handled entirely automatically—is becoming an increasingly common attribute of modern manufacturing.
- ✘ In part, the new wave of automation will be driven by the same things that first brought robotics and automation into the workplace: to free human workers from dirty, dull, or dangerous jobs; to improve quality by eliminating errors and reducing variability; and to cut manufacturing costs by replacing increasingly expensive people with ever-cheaper machines.
- ✘ Today’s most advanced automation systems have additional capabilities, however, enabling their use in environments that have not been suitable for automation up to now and allowing the capture of entirely new sources of value in manufacturing.
- ✘ As robot production has increased, costs have gone down. Over the past 30 years, the average robot price has fallen by half in real terms, and even further relative to labor costs. As demand from emerging economies encourages the production of robots to shift to lower-cost regions, they are likely to become cheaper still.

ACCESSIBLE TALENT



- ✘ People with the skills required to design, install, operate, and maintain robotic production systems are becoming more widely available, too.
- ✘ Robotics engineers were once rare and expensive specialists.
- ✘ Today, these subjects are widely taught in schools and colleges around the world, either in dedicated courses or as part of more general education on manufacturing technologies or engineering design for manufacture.
- ✘ The availability of software, such as simulation packages and offline programming systems that can test robotic applications, has reduced engineering time and risk.
- ✘ It's also made the task of programming robots easier and cheaper.



EASE OF INTEGRATION

- ✘ Advances in computing power, software-development techniques, and networking technologies have made assembling, installing, and maintaining robots faster and less costly than before
- ✘ For example, while sensors and actuators once had to be individually connected to robot controllers with dedicated wiring through terminal racks, connectors, and junction boxes, they now use plug-and-play technologies in which components can be connected using simpler network wiring.
- ✘ The components will identify themselves automatically to the control system, greatly reducing setup time.
- ✘ These sensors and actuators can also monitor themselves and report their status to the control system, to aid process control and collect data for maintenance, and for continuous improvement and troubleshooting purposes.
- ✘ Other standards and network technologies make it similarly straightforward to link robots to wider production systems.



NEW CAPABILITIES

- ✘ Robots are getting smarter, too. Where early robots blindly followed the same path, and later iterations used lasers or vision systems to detect the orientation of parts and materials, the latest generations of robots can integrate information from multiple sensors and adapt their movements in real time.
- ✘ This allows them, for example, to use force feedback to mimic the skill of a craftsman in grinding, deburring, or polishing applications.
- ✘ They can also make use of more powerful computer technology and big data–style analysis.
- ✘ For instance, they can use spectral analysis to check the quality of a weld as it is being made, dramatically reducing the amount of post-manufacture inspection required.

ROBOTS TAKE ON NEW ROLES



- ✘ Today, these factors are helping to boost robot adoption in the kinds of application they already excel at today: repetitive, high-volume production activities.
- ✘ As the cost and complexity of automating tasks with robots goes down, it is likely that the kinds of companies already using robots will use even more of them.
- ✘ In the next five to ten years, however, we expect a more fundamental change in the kinds of tasks for which robots become both technically and economically viable.

LOW-VOLUME PRODUCTION



- ✘ The inherent flexibility of a device that can be programmed quickly and easily will greatly reduce the number of times a robot needs to repeat a given task to justify the cost of buying and commissioning it.
- ✘ This will lower the threshold of volume and make robots an economical choice for niche tasks, where annual volumes are measured in the tens or hundreds rather than in the thousands or hundreds of thousands.
- ✘ It will also make them viable for companies working with small batch sizes and significant product variety.
- ✘ For example, flex track products now used in aerospace can “crawl” on a fuselage using vision to direct their work. The cost savings offered by this kind of low-volume automation will benefit many different kinds of organizations: small companies will be able to access robot technology for the first time, and larger ones could increase the variety of their product offerings.

HIGHLY VARIABLE TASKS



- ✘ Advances in artificial intelligence and sensor technologies will allow robots to cope with a far greater degree of task-to-task variability.
- ✘ The ability to adapt their actions in response to changes in their environment will create opportunities for automation in areas such as production.
- ✘ These same capabilities will also drive quality improvements in all sectors.
- ✘ Robots will be able to compensate for potential quality issues during manufacturing.
- ✘ Examples here include altering the force used to assemble two parts based on the dimensional differences between them, or selecting and combining different sized components to achieve the right final dimensions.
- ✘ Robot-generated data, and the advanced analysis techniques to make better use of them, will also be useful in understanding the underlying drivers of quality. If higher-than-normal torque requirements during assembly turn out to be associated with premature product failures in the field, for example, manufacturing processes can be adapted to detect and fix such issues during production.

COMPLEX TASKS



- ✘ While today's general-purpose robots can control their movement to within 0.10 millimeters, some current configurations of robots have repeatable accuracy of 0.02 millimeters.
- ✘ Future generations are likely to offer even higher levels of precision.
- ✘ Such capabilities will allow them to participate in increasingly delicate tasks, such as threading needles or assembling highly sophisticated electronic devices.
- ✘ Robots are also becoming better coordinated, with the availability of controllers that can simultaneously drive dozens of axes, allowing multiple robots to work together on the same task.
- ✘ Finally, advanced sensor technologies, and the computer power needed to analyze the data from those sensors, will allow robots to take on tasks like cutting gemstones that previously required highly skilled craftspeople.
- ✘ The same technologies may even permit activities that cannot be done at all today: for example, adjusting the thickness or composition of coatings in real time as they are applied to compensate for deviations in the underlying material, or “painting” electronic circuits on the surface of structures.

WORKING ALONGSIDE PEOPLE



- ✘ Companies will also have far more freedom to decide which tasks to automate with robots and which to conduct manually.
- ✘ Advanced safety systems mean robots can take up new positions next to their human colleagues.
- ✘ If sensors indicate the risk of a collision with an operator, the robot will automatically slow down or alter its path to avoid it.
- ✘ This technology permits the use of robots for individual tasks on otherwise manual assembly lines.
- ✘ And the removal of safety fences and interlocks mean lower costs—a boon for smaller companies.
- ✘ The ability to put robots and people side by side and to reallocate tasks between them also helps productivity, since it allows companies to rebalance production lines as demand fluctuates.
- ✘ Robots that can operate safely in proximity to people will also pave the way for applications away from the tightly controlled environment of the factory floor.
- ✘ Internet retailers and logistics companies are already adopting forms of robotic automation in their warehouses. Imagine the productivity benefits available to a parcel courier, though, if an onboard robot could presort packages in the delivery vehicle between drops.

AGILE PRODUCTION SYSTEMS



- ✘ Automation systems are becoming increasingly flexible and intelligent, adapting their behavior automatically to maximize output or minimize cost per unit.
- ✘ Expert systems used in beverage filling and packing lines can automatically adjust the speed of the whole production line to suit whichever activity is the critical constraint for a given batch.
- ✘ In automotive production, expert systems can automatically make tiny adjustments in line speed to improve the overall balance of individual lines and maximize the effectiveness of the whole manufacturing system.
- ✘ While the vast majority of robots in use today still operate in high-speed, high-volume production applications, the most advanced systems can make adjustments on the fly, switching seamlessly between product types without the need to stop the line to change programs or reconfigure tooling.

AGILE PRODUCTION SYSTEMS (CONTD.)



- ✘ Many current and emerging production technologies, from computerized-numerical-control (CNC) cutting to 3-D printing, allow component geometry to be adjusted without any need for tool changes, making it possible to produce in batch sizes of one.
- ✘ One manufacturer of industrial components, for example, uses real-time communication from radio-frequency identification (RFID) tags to adjust components' shapes to suit the requirements of different models.
- ✘ The replacement of fixed conveyor systems with automated guided vehicles (AGVs) even lets plants reconfigure the flow of products and components seamlessly between different workstations, allowing manufacturing sequences with entirely different process steps to be completed in a fully automated fashion.
- ✘ This kind of flexibility delivers a host of benefits: facilitating shorter lead times and a tighter link between supply and demand, accelerating new product introduction, and simplifying the manufacture of highly customized products.

MAKING THE RIGHT AUTOMATION DECISIONS



- ✘ With so much technological potential at their fingertips, how do companies decide on the best automation strategy?
- ✘ It can be all too easy to get carried away with automation for its own sake, but the result of this approach is almost always projects that cost too much, take too long to implement, and fail to deliver against their business objectives.
- ✘ A successful automation strategy requires good decisions on multiple levels. Companies must choose which activities to automate, what level of automation to use (from simple programmable-logic controllers to highly sophisticated robots guided by sensors and smart adaptive algorithms), and which technologies to adopt.

At each of these levels, companies should ensure that their plans meet the following criteria:



- ✘ *Automation strategy must align with business and operations strategy.* As we have noted above, automation can achieve four key objectives: improving worker safety, reducing costs, improving quality, and increasing flexibility. Done well, automation may deliver improvements in all these areas, but the balance of benefits may vary with different technologies and approaches. The right balance for any organization will depend on its overall operations strategy and its business goals.
- ✘ *Automation programs must start with a clear articulation of the problem.* It's also important that this includes the reasons automation is the right solution. Every project should be able to identify where and how automation can offer improvements and show how these improvements link to the company's overall strategy.
- ✘ *Automation must show a clear return on investment.* Companies, especially large ones, should take care not to over-specify, over-complicate, or over-spend on their automation investments. Choosing the right level of complexity to meet current and foreseeable future needs requires a deep understanding of the organization's processes and manufacturing systems.

PLATFORMING AND INTEGRATION



- ✘ Companies face increasing pressure to maximize the return on their capital investments and to reduce the time required to take new products from design to full-scale production.
- ✘ Building automation systems that are suitable only for a single line of products runs counter to both those aims, requiring repeated, lengthy, and expensive cycles of equipment design, procurement, and commissioning.
- ✘ A better approach is the use of production systems, cells, lines, and factories that can be easily modified and adapted.
- ✘ Just as platforming and modularization strategies have simplified and reduced the cost of managing complex product portfolios, so a platform approach will become increasingly important for manufacturers seeking to maximize flexibility and economies of scale in their automation strategies.
- ✘ Process platforms, such as a robot arm equipped with a weld gun, power supply, and control electronics, can be standardized, applied, and reused in multiple applications, simplifying programming, maintenance, and product support.
- ✘ Automation systems will also need to be highly integrated into the organization's other systems. That integration starts with communication between machines on the factory floor, something that is made more straightforward by modern industrial-networking technologies.

PLATFORMING AND INTEGRATION

(CONTD.)



- ✘ But it should also extend into the wider organization. Direct integration with computer-aided design, computer-integrated engineering, and enterprise-resource-planning systems will accelerate the design and deployment of new manufacturing configurations and allow flexible systems to respond in near real time to changes in demand or material availability.
- ✘ Data on process variables and manufacturing performance flowing the other way will be recorded for quality-assurance purposes and used to inform design improvements and future product generations.
- ✘ Integration will also extend beyond the walls of the plant. Companies won't just require close collaboration and seamless exchange of information with customers and suppliers; they will also need to build such relationships with the manufacturers of processing equipment, who will increasingly hold much of the know-how and intellectual property required to make automation systems perform optimally.
- ✘ The technology required to permit this integration is becoming increasingly accessible, thanks to the availability of open architectures and networking protocols, but changes in culture, management processes, and mind-sets will be needed in order to balance the costs, benefits, and risks.

CONCLUSION



Cheaper, smarter, and more adaptable automation systems are already transforming manufacturing in a host of different ways. While the technology will become more straightforward to implement, the business decisions will not. To capture the full value of the opportunities presented by these new systems, companies will need to take a holistic and systematic approach, aligning their automation strategy closely with the current and future needs of the production.



THANK YOU