



**19MCE401 - PROCESS PLANNING AND PRODUCT DEVELOPMENT**  
**STUDY NOTES**

**UNIT 2 - PROCESS PLANNING ACTIVITIES**

**TOPIC 7 – THE CRITICAL PATH METHOD**

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### ***Quality Assurance(QA):***

Quality assurance methods in manufacturing are essential processes and practices used to ensure that products meet established quality standards and customer requirements. Implementing effective quality assurance methods helps manufacturers produce high-quality products, reduce defects, and enhance customer satisfaction. Here are some common quality assurance methods used in manufacturing:

### **Statistical Process Control (SPC):**

Statistical Process Control (SPC) is a fundamental quality assurance method in manufacturing that relies on statistical techniques to monitor, control, and improve processes. It plays a crucial role in ensuring product consistency, reducing defects, and enhancing overall quality. SPC is based on the premise that processes can exhibit natural variation, and by understanding and controlling this variation, manufacturers can produce more consistent and reliable products.

The core of SPC involves the collection and analysis of data from the production process. This data is used to create control charts, which provide a visual representation of process variation over time. Control charts typically include upper and lower control limits, derived from historical data or established quality standards. Any data points that fall outside these limits are considered potential indicators of special cause variation, which may signal a problem in the process that requires investigation and correction.

SPC offers several key benefits. Firstly, it allows for early detection of deviations from the desired quality parameters, enabling quick corrective action to prevent the production of defective products. Secondly, it helps in understanding the process capabilities and determining whether it is capable of consistently producing products within specified tolerances. Thirdly, SPC provides a data-driven approach to decision-making, ensuring that adjustments and improvements are made based on evidence rather than intuition.

To implement SPC effectively, organizations need a structured approach that includes defining critical process parameters, collecting data systematically, and training employees in the use of SPC tools. It promotes a culture of continuous improvement, where employees are actively engaged in monitoring and enhancing processes to achieve higher levels of quality and efficiency.

In summary, Statistical Process Control is a powerful quality assurance method that leverages statistical analysis to maintain and improve product quality. By monitoring processes, detecting



variations, and taking corrective actions, manufacturers can consistently deliver high-quality products, reduce waste, and increase customer satisfaction.

### **Total Quality Management (TQM):**

Total Quality Management (TQM) is a comprehensive and systematic approach to managing an organization's processes and resources with the primary goal of continuously improving the quality of products and services. TQM emphasizes a holistic view of quality, involving all aspects of an organization, from its culture and leadership to its processes and customer interactions.

At the heart of TQM is a commitment to customer satisfaction. It recognizes that the ultimate judge of quality is the customer, and meeting or exceeding customer expectations is essential for business success. To achieve this, TQM principles and practices are integrated into every level of the organization.

### **Key elements of TQM include:**

1. **Customer Focus:** TQM starts by understanding customer needs and expectations. Organizations collect feedback, conduct surveys, and engage in market research to gain insights into customer requirements.
2. **Leadership:** Effective TQM requires strong leadership committed to quality. Leaders set a vision, establish quality policies, and lead by example to create a culture of quality throughout the organization.
3. **Employee Involvement:** TQM values the input and contributions of employees at all levels. Empowered and engaged employees are more likely to identify and address quality issues.
4. **Continuous Improvement:** TQM is based on the philosophy of continuous improvement, often referred to as Kaizen. It involves constantly evaluating processes, making incremental changes, and seeking opportunities for enhancement.
5. **Process Management:** TQM emphasizes the importance of well-defined processes. It encourages organizations to map, analyze, and optimize their processes to reduce waste, increase efficiency, and improve quality.
6. **Data-Driven Decision-Making:** TQM relies on data and facts to drive decision-making. Statistical tools and methods are often used to analyze data and identify areas for improvement.



7. **Supplier Relationships:** TQM extends beyond the organization's boundaries to include suppliers. Close collaboration with suppliers is essential to ensure the quality of incoming materials and components.

8. **Benchmarking:** Organizations practicing TQM often benchmark their processes and performance against industry leaders and best practices to identify areas where improvements are needed.

9. **Training and Education:** TQM invests in training and education to ensure that employees have the necessary skills and knowledge to contribute to quality improvement efforts.

10. **Quality Circles:** These are small groups of employees who meet regularly to identify and solve quality-related problems.

In summary, Total Quality Management is a strategic approach that fosters a culture of quality, continuous improvement, and customer-centricity within an organization. By aligning processes, people, and leadership towards quality goals, TQM helps organizations achieve higher levels of customer satisfaction, increased operational efficiency, and sustained business success.

TQM is a comprehensive approach to quality assurance that involves all aspects of an organization, including processes, people, and culture. It focuses on continuous improvement, customer satisfaction, employee involvement, and process optimization.

### **Six Sigma:**

Six Sigma is a data-driven methodology and set of tools widely used in business and manufacturing to improve processes, reduce defects, and enhance overall quality. Originally developed by Motorola and popularized by General Electric, Six Sigma aims to minimize variation and ensure that processes consistently deliver results that meet or exceed customer expectations.

The term "Six Sigma" refers to a statistical concept representing a level of process performance where there are fewer than 3.4 defects per million opportunities (DPMO). Achieving this level of quality requires rigorous data analysis, process improvement, and a structured approach, typically following the DMAIC (Define, Measure, Analyze, Improve, Control) framework:



1. **Define:** In this initial phase, the project's objectives are clearly defined, and the critical-to-quality factors (CTQs) are identified. Understanding customer requirements is central to this phase.
2. **Measure:** Accurate measurement is crucial in Six Sigma. Key process metrics are selected, and data is collected to assess the current performance of the process. This step establishes a baseline for improvement efforts.
3. **Analyze:** Data analysis is conducted to identify the root causes of defects or process variations. Tools like Pareto charts, cause-and-effect diagrams, and statistical tests are employed to pinpoint the issues affecting process performance.
4. **Improve:** Based on the analysis, improvements are made to the process to eliminate defects and reduce variability. Creative problem-solving techniques and process redesign are often utilized to achieve better results.
5. **Control:** Once improvements are implemented, control measures are established to sustain the gains. This involves creating standard operating procedures, monitoring the process, and implementing controls to prevent regression.

Six Sigma projects are typically led by trained and certified Six Sigma professionals, including Green Belts (who work on projects part-time) and Black Belts (who are dedicated to Six Sigma full-time). Champions, often senior leaders within the organization, provide support and resources to Six Sigma teams. The benefits of Six Sigma include increased customer satisfaction, reduced costs through waste reduction, improved process efficiency, and higher profitability. It also fosters a culture of continuous improvement within organizations, driving innovation and competitiveness.

In summary, Six Sigma is a systematic, data-driven approach that focuses on process improvement and quality management. By striving for a Six Sigma level of performance, organizations can deliver products and services with minimal defects and better align with customer expectations, ultimately driving success and sustainability.

### **Lean Manufacturing:**

Lean manufacturing is a production philosophy and systematic approach that focuses on eliminating waste, optimizing processes, and continuously improving efficiency to create more value with fewer resources. Originating from the Toyota Production System (TPS) and



popularized by companies like Toyota, lean principles have been widely adopted across various industries. Central to lean manufacturing is the identification and elimination of various forms of waste, often categorized into seven key types:

1. **Overproduction:** Producing more than what is needed at a given time leads to excess inventory, increased storage costs, and potential quality issues.
2. **Inventory:** Excessive inventory ties up capital, takes up valuable space, and can hide production issues or defects.
3. **Transportation:** Unnecessary movement or transportation of materials or products adds no value and increases costs.
4. **Waiting:** Delays or idle time in the production process waste resources and time.
5. **Motion:** Excessive movement or ergonomically poor workstations can lead to inefficiencies and fatigue.
6. **Overprocessing:** Adding features or processes that customers do not value results in wasted effort and resources.
7. **Defects:** Any defects or errors in the production process lead to rework, scrap, and customer dissatisfaction.

Lean principles encourage organizations to focus on customer value, streamline processes, and empower employees to identify and eliminate waste. Key elements of lean manufacturing include:

1. **Just-in-Time (JIT) Production:** Delivering materials and components to the production line only when needed reduces inventory levels and waste.
2. **Continuous Flow:** Creating smooth and efficient production processes with minimal interruptions and batch sizes, allowing for faster delivery times.
3. **Pull Systems:** Production is driven by customer demand, pulling materials and resources into the process as needed.
4. **Standardized Work:** Clearly defined and documented procedures ensure consistency and help identify areas for improvement.
5. **Visual Management:** The use of visual cues, such as kanban cards and boards, makes it easier to monitor and manage processes.



6. **Employee Involvement:** Encouraging employees at all levels to contribute ideas and participate in process improvement efforts.

Lean manufacturing aims to create a culture of continuous improvement, where waste reduction is an ongoing effort. By implementing lean principles, organizations can enhance productivity, reduce costs, improve quality, shorten lead times, and better meet customer demands, ultimately leading to increased competitiveness and profitability.

**Failure Mode and Effects Analysis (FMEA):**

Failure Mode and Effects Analysis (FMEA) is a structured and systematic approach used in various industries, particularly manufacturing and engineering, to identify and prioritize potential failure modes within a process, system, or product and assess their potential consequences. The primary objective of FMEA is to proactively mitigate risks and improve product or process reliability.

FMEA is typically conducted by a cross-functional team and follows a step-by-step process:

1. **Scope Definition:** The team defines the boundaries and objectives of the analysis, specifying which process or product aspect will be examined.
2. **Identify Failure Modes:** The team identifies all potential failure modes that could occur within the scope of analysis. A failure mode is a specific way in which a process or component can fail.
3. **Determine Effects:** For each failure mode identified, the team assesses the potential effects or consequences of that failure. This includes evaluating the impact on product quality, safety, performance, and customer satisfaction.
4. **Assign Severity Ratings:** A severity rating is assigned to each failure mode based on the seriousness of its consequences. This rating helps prioritize which failure modes require the most attention.
5. **Identify Causes:** For each failure mode, the team identifies the potential root causes or factors that could lead to the failure.



6. **Assign Occurrence Ratings:** An occurrence rating is assigned to each potential cause, reflecting the likelihood of it occurring. This rating helps prioritize which failure modes are more likely to happen.
7. **Detectability Assessment:** The team evaluates the likelihood of detecting the failure mode or cause before it reaches the customer. This step is crucial in determining the effectiveness of current control measures.
8. **Assign Detection Ratings:** A detection rating is assigned to each potential cause, reflecting the likelihood of detecting the failure mode before it reaches the customer.
9. **Calculate Risk Priority Number (RPN):** The RPN is calculated for each failure mode by multiplying the assigned severity, occurrence, and detection ratings. This provides a numerical value that helps prioritize which failure modes require immediate attention.
10. **Prioritize and Take Action:** Based on the RPN, the team prioritizes failure modes with the highest risk and formulates action plans to reduce or eliminate these risks. These actions can include process improvements, design changes, or enhanced testing procedures.

FMEA is a proactive tool that helps organizations anticipate and address potential issues before they lead to actual failures or defects. It fosters a culture of continuous improvement and risk reduction, ultimately resulting in higher product quality, increased safety, and enhanced customer satisfaction. Regularly revisiting and updating FMEAs as processes evolve or new risks emerge is a best practice to ensure ongoing effectiveness.

### **Design of Experiments (DOE):**

Design of Experiments (DOE) is a systematic and efficient approach used in various fields, including science, engineering, and business, to optimize processes, improve product quality, and enhance decision-making. At its core, DOE involves planning, conducting, and analyzing carefully structured experiments to understand the impact of different factors on a specific outcome of interest.

The key principles of DOE include identifying relevant factors that may affect the process or product, defining appropriate response variables, and systematically varying these factors in a controlled manner. By manipulating these factors simultaneously and measuring their effects on the response variable, DOE allows for the efficient exploration of interactions and the determination of optimal conditions.





DOE offers several advantages over traditional trial-and-error methods. It enables researchers to extract maximum information from a limited number of experiments, reducing time, cost, and resource requirements. Additionally, it provides statistical tools for quantifying uncertainty, making it easier to make data-driven decisions.

One of the most common DOE designs is the factorial design, where factors are varied at multiple levels to assess their main effects and interactions. Other designs, such as response surface methodology and Taguchi methods, are used to optimize processes and products by finding optimal factor settings.

In conclusion, Design of Experiments is a powerful tool for systematic experimentation and optimization. Its structured approach enhances decision-making, accelerates innovation, and ultimately leads to improved quality and efficiency across various domains.

DOE is a method for systematically varying input factors (variables) to observe their effects on the output (product quality). It helps optimize processes and identify the ideal conditions for achieving desired quality levels.

### **Quality Audits:**

Quality audits are systematic, independent assessments conducted to evaluate an organization's adherence to established quality management standards, processes, and procedures. These audits play a crucial role in ensuring product and service quality, regulatory compliance, and continuous improvement.

Quality audits involve a structured review of various aspects of an organization's operations, including its quality management system (QMS), manufacturing processes, documentation, and overall quality performance. Auditors, often trained and certified professionals, conduct these assessments with a focus on identifying non-conformities, areas for improvement, and best practices.

The primary objectives of quality audits are as follows:

1. **Compliance Verification:** Auditors assess whether the organization complies with industry-specific quality standards, regulations, and internal quality policies. This helps ensure that products and services meet legal and customer requirements.



2. **Process Evaluation:** Audits examine key processes to identify inefficiencies, bottlenecks, and deviations from established procedures. This process-focused approach helps organizations streamline operations and reduce errors.
3. **Risk Mitigation:** Audits help identify potential risks and vulnerabilities in the organization's processes, allowing for proactive measures to prevent quality issues and ensure the safety of products and services.
4. **Continuous Improvement:** Quality audits provide valuable feedback for ongoing improvement efforts. Auditors often recommend corrective actions and improvements that can lead to enhanced quality, cost savings, and increased customer satisfaction.
5. **Performance Measurement:** Audits assess the effectiveness of the organization's quality management system by evaluating key performance indicators and metrics. This data-driven approach helps monitor progress over time.

Quality audits can be conducted internally by an organization's own audit team or externally by third-party auditors. They are a critical component of quality assurance and provide stakeholders with confidence in the organization's commitment to delivering high-quality products and services. Moreover, they help organizations identify areas for improvement and drive a culture of continuous quality enhancement.

### **Quality Control (QC) Inspections:**

Quality Control (QC) inspections are systematic processes employed by organizations to assess and ensure the quality and conformity of products or services to established standards, specifications, and customer expectations. These inspections are integral to quality management systems and are typically conducted at various stages of production or service delivery to detect and rectify defects, deviations, or non-conformities. QC inspections play a pivotal role in maintaining consistent quality, reducing defects, and meeting regulatory requirements.

Key aspects of QC inspections include:

1. **Inspection Planning:** Before conducting inspections, organizations outline inspection criteria, methodologies, and acceptance criteria. This planning phase ensures that inspections are consistent, standardized, and aligned with quality standards.



2. Sampling and Testing: QC inspections often involve taking samples of products or services from a larger batch or population. These samples are then subjected to rigorous testing, measurements, or visual examination to determine if they meet predefined quality standards.
3. Defect Identification: During inspections, trained inspectors identify defects, inconsistencies, or deviations from established specifications. Common defects may include product flaws, missing components, incorrect labeling, or service errors.
4. Documentation: Detailed records of inspections, including findings, test results, and corrective actions, are typically maintained. This documentation is essential for traceability, accountability, and process improvement.
5. Root Cause Analysis: When defects are discovered, QC inspectors often investigate the root causes to prevent recurrence. Identifying the underlying issues allows organizations to implement corrective and preventive actions.
6. Continuous Improvement: The data gathered from QC inspections can be used to analyze trends, identify recurring issues, and drive continuous improvement efforts in production or service processes.

QC inspections can be conducted by in-house quality control teams, third-party inspection agencies, or a combination of both. They are essential for ensuring that products and services meet quality standards, reducing the risk of product recalls, minimizing customer complaints, and enhancing overall customer satisfaction. Moreover, QC inspections are fundamental in industries such as manufacturing, healthcare, construction, and food production, where product safety and quality are paramount.

### **Supplier Quality Assurance:**

Supplier Quality Assurance (SQA) is a vital component of modern supply chain management that focuses on ensuring that the products and services provided by suppliers consistently meet or exceed predefined quality standards and customer expectations. SQA aims to mitigate risks, enhance product quality, and optimize the performance of the supply chain by establishing rigorous processes and procedures for supplier evaluation, monitoring, and improvement.

Key elements of Supplier Quality Assurance include:



1. **Supplier Selection and Evaluation:** SQA begins with the careful selection of suppliers based on their capabilities, track record, and commitment to quality. Ongoing evaluation assesses supplier performance against predefined criteria, including quality, delivery timeliness, and cost-effectiveness.
2. **Quality Audits:** Regular quality audits are conducted to assess a supplier's adherence to quality management systems, standards, and specifications. These audits ensure that suppliers comply with industry regulations and customer requirements.
3. **Quality Agreements:** Establishing clear and documented quality agreements with suppliers is essential. These agreements outline quality expectations, inspection protocols, and procedures for addressing non-conformities or deviations.
4. **Continuous Monitoring:** SQA involves continuous monitoring of supplier performance through key performance indicators (KPIs) and real-time data analysis. This allows for early detection of issues and proactive problem-solving.
5. **Root Cause Analysis:** When quality issues arise, SQA teams engage in root cause analysis to identify the underlying reasons for defects or deviations. This analysis informs corrective and preventive actions to address the issues at their source.
6. **Collaborative Improvement:** SQA fosters collaboration between organizations and their suppliers to drive continuous improvement initiatives. This may involve joint efforts to optimize processes, reduce costs, and enhance product quality.
7. **Risk Management:** Identifying and managing supplier-related risks, such as supply chain disruptions or quality fluctuations, is a critical aspect of SQA. Contingency plans and risk mitigation strategies are developed to ensure a reliable supply of high-quality products.

Supplier Quality Assurance is indispensable in industries like automotive, aerospace, pharmaceuticals, and electronics, where the quality and reliability of components and materials are paramount. Effective SQA practices not only ensure product quality but also contribute to long-term supplier partnerships and overall supply chain resilience.

### **Root Cause Analysis (RCA):**

Root Cause Analysis (RCA) is a structured and systematic process used to identify the underlying causes of problems or incidents in various fields, including engineering, healthcare, manufacturing, and business. The primary goal of RCA is to go beyond addressing immediate



symptoms and instead discover the fundamental reasons behind issues, allowing for effective corrective and preventive actions.

Key elements of RCA include:

1. **Problem Identification:** RCA begins with the clear definition and documentation of the problem or incident. This involves gathering data, descriptions of the issue, and its impact on processes or outcomes.

2. **Data Collection:** Comprehensive data collection is crucial for RCA. It involves gathering information, facts, and evidence related to the problem. This data may include process data, interviews, observations, and historical records.

3. **Cause Analysis:** RCA employs various techniques and tools, such as the "5 Whys" method, Fishbone diagrams (Ishikawa diagrams), or fault tree analysis, to systematically explore and trace back to the root causes of the problem. These tools help identify contributing factors, dependencies, and interactions.

4. **Root Cause Identification:** The analysis typically reveals multiple contributing factors. RCA aims to identify the root causes – the factors that, if addressed, would prevent the problem from recurring.

5. **Action Planning:** Once the root causes are identified, action plans are developed to address them. These plans may involve process improvements, changes in procedures, additional training, or other corrective and preventive actions.

6. **Implementation and Monitoring:** The identified actions are implemented, and their effectiveness is monitored over time. This ensures that the changes made are successful in preventing the problem from happening again.

7. **Documentation and Communication:** Throughout the RCA process, documentation is essential to record findings, actions taken, and outcomes. Effective communication of results and lessons learned is also crucial to prevent similar issues across the organization.

RCA is a valuable problem-solving tool that helps organizations improve their processes, enhance product quality, reduce costs, and prevent recurring issues. It encourages a proactive approach to addressing problems and fosters a culture of continuous improvement by tackling the root causes, rather than merely treating symptoms.



### **Continuous Improvement (Kaizen):**

Continuous Improvement, often referred to as Kaizen, is a philosophy and approach to enhancing processes, products, and services by making incremental and ongoing improvements. Kaizen originated in Japan and has since become a globally recognized methodology for achieving excellence in various industries.

Key principles and practices of Kaizen include:

1. **Incremental Progress:** Kaizen emphasizes small, continuous steps towards improvement rather than large, disruptive changes. It encourages employees at all levels of an organization to identify and address even minor inefficiencies or opportunities for enhancement.
2. **Employee Involvement:** Kaizen promotes a culture where all employees, from frontline workers to senior management, actively participate in the improvement process. Employees are encouraged to provide suggestions and take ownership of the changes they propose.
3. **Data-Driven Decision-Making:** Kaizen relies on data and performance metrics to identify areas for improvement. Analyzing data helps organizations make informed decisions and prioritize improvement efforts based on their impact.
4. **Standardization:** Standardizing processes and procedures is a fundamental aspect of Kaizen. By establishing best practices and standard work procedures, organizations can reduce variations, errors, and inefficiencies.
5. **Continuous Learning:** Kaizen encourages a mindset of continuous learning and adaptation. Teams regularly review their processes, gather feedback, and adjust their approaches based on what they learn.
6. **Elimination of Waste:** A core concept of Kaizen is the identification and elimination of various forms of waste, including overproduction, waiting, unnecessary transportation, excessive inventory, defects, and underutilized employee skills.
7. **PDCA Cycle:** Kaizen often follows the Plan-Do-Check-Act (PDCA) cycle. This iterative process involves planning improvements, implementing changes, evaluating their effectiveness, and adjusting as needed to drive further enhancements.

Kaizen can be applied to various aspects of an organization, from manufacturing processes to customer service. It fosters a culture of continuous improvement, innovation, and problem-solving. By consistently seeking ways to do things better, organizations practicing Kaizen can



achieve increased efficiency, reduced costs, improved quality, and enhanced customer satisfaction, ultimately leading to long-term success and competitiveness in their respective industries.

Effective quality assurance methods in manufacturing require a combination of these approaches tailored to the specific needs of the organization and its products. Continuous monitoring, data analysis, and a commitment to improvement are key elements in maintaining and enhancing product quality.

