

The Blueprint for Success: Optimizing Post-Market Surveillance programs, Technology and Cost of Quality initiatives in the Medical Devices, Pharmaceuticals, and Life Science industries





Jennifer Mascioli-Tudor, MBA

With over two decades of dedicated industry experience, Jennifer has established herself as a seasoned leader in the fields of Quality and Regulatory within the pharmaceutical and medical device industries. Throughout her career, she has successfully led diverse global teams, demonstrating a strong understanding of industry requirements and trends.

Her extensive background encompasses a wide range of responsibilities, including strategic quality, regulatory initiatives, regulatory compliance management, and operational excellence practices. Jennifer has a proven track record of implementing robust quality systems, ensuring adherence to stringent regulatory standards, and driving continuous improvement across organizational processes.

Jennifer has progressed through several roles of increasing leadership responsibility working for companies such as Johnson and Johnson, Kyphon, Medtronic, Nevro, Boston Scientific, Outset Medical and GE Healthcare.

She is the Founder and CEO of JMT Compliance Consulting, LLC (www.jmtcompliance.com), where she partners with small and emerging Medical Technology companies to drive Business, Quality, and Regulatory strategy, as well as Operational Excellence initiatives.

She holds a B.S. in Physiology from Eastern Michigan University and an MBA, Global Management from the University of Phoenix. Jennifer is an Instructor at UC San Diego, teaching courses to support the Regulatory Affairs for Medical Devices certificate program that is offered and is an ASQ Certified Quality Auditor.



Learning Objectives



1. Post-Market Surveillance:

Understand the latest methodologies in post-market surveillance that integrate with continuous improvement processes to enhance product safety and effectiveness.



2. Cultivating a Continuous Improvement Culture:

Learn how to foster a culture of continuous improvement that encourages proactive quality programs and operational excellence.



3. Innovations in Manufacturing Technology:

Explore how new and emerging technologies in manufacturing can significantly improve product quality and operational efficiency.



4. Cost of Quality Management:

Gain insights into establishing a comprehensive Cost of Quality program that tracks, analyzes, and manages quality-related costs, driving better financial performance and quality outcomes.



Learning Objectives

#1 Post-Market Surveillance



Overview of Post-Market Surveillance (PMS)

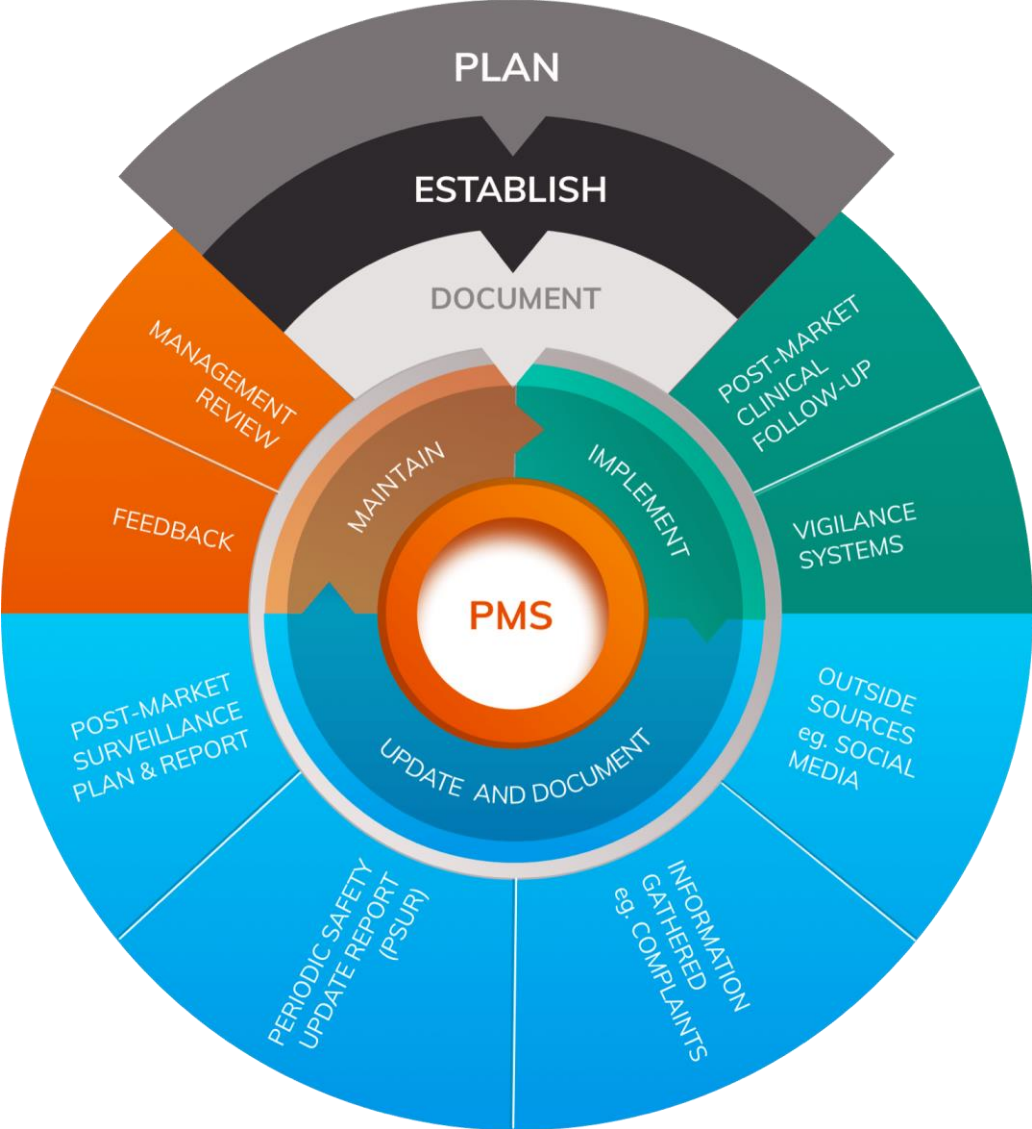
Post-Market Surveillance (PMS) can be defined as a structured process of monitoring the safety and performance of a medical device following its release onto the market.

It involves the proactive collection and review of data relating to clinical experience with the product once released into the market.

Ensures **product safety, efficacy, and compliance** over time.



Overview of Post-Market Surveillance (PMS)



Reference: <https://www.mantrasystems.co.uk/eu-mdr-compliance/post-market-surveillance-pms>

Overview of Post-Market Surveillance (PMS)

A well-designed PMS system will monitor the safety and performance of a medical product through two complementary domains:

Post-Market Clinical Follow-up (PMCF)

Involves the design and conduct of clinical studies to proactively and continually assess safety and performance

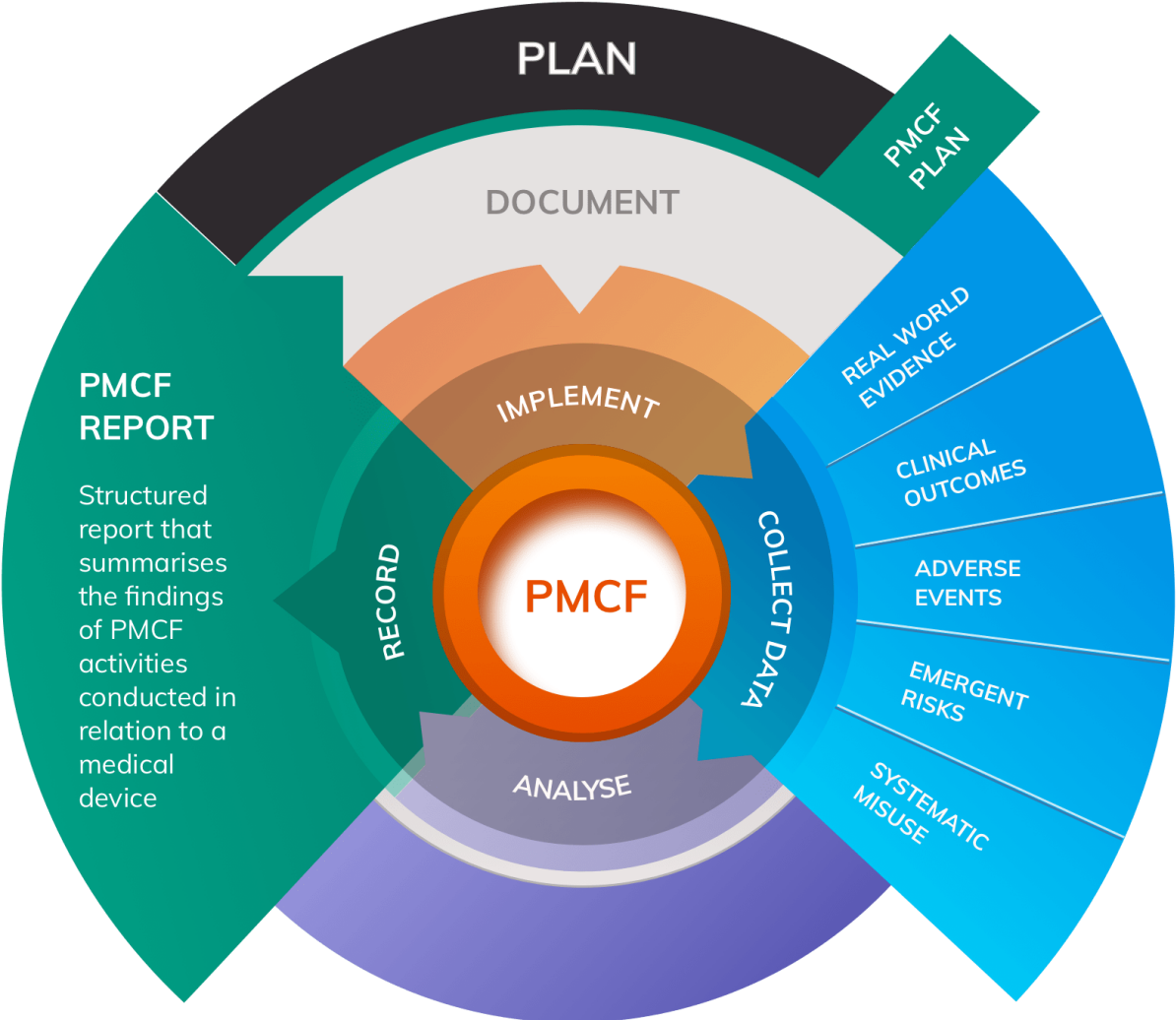


Systems

Monitors and responds to complaints, adverse events, media reports, serious incidents and FSCAs

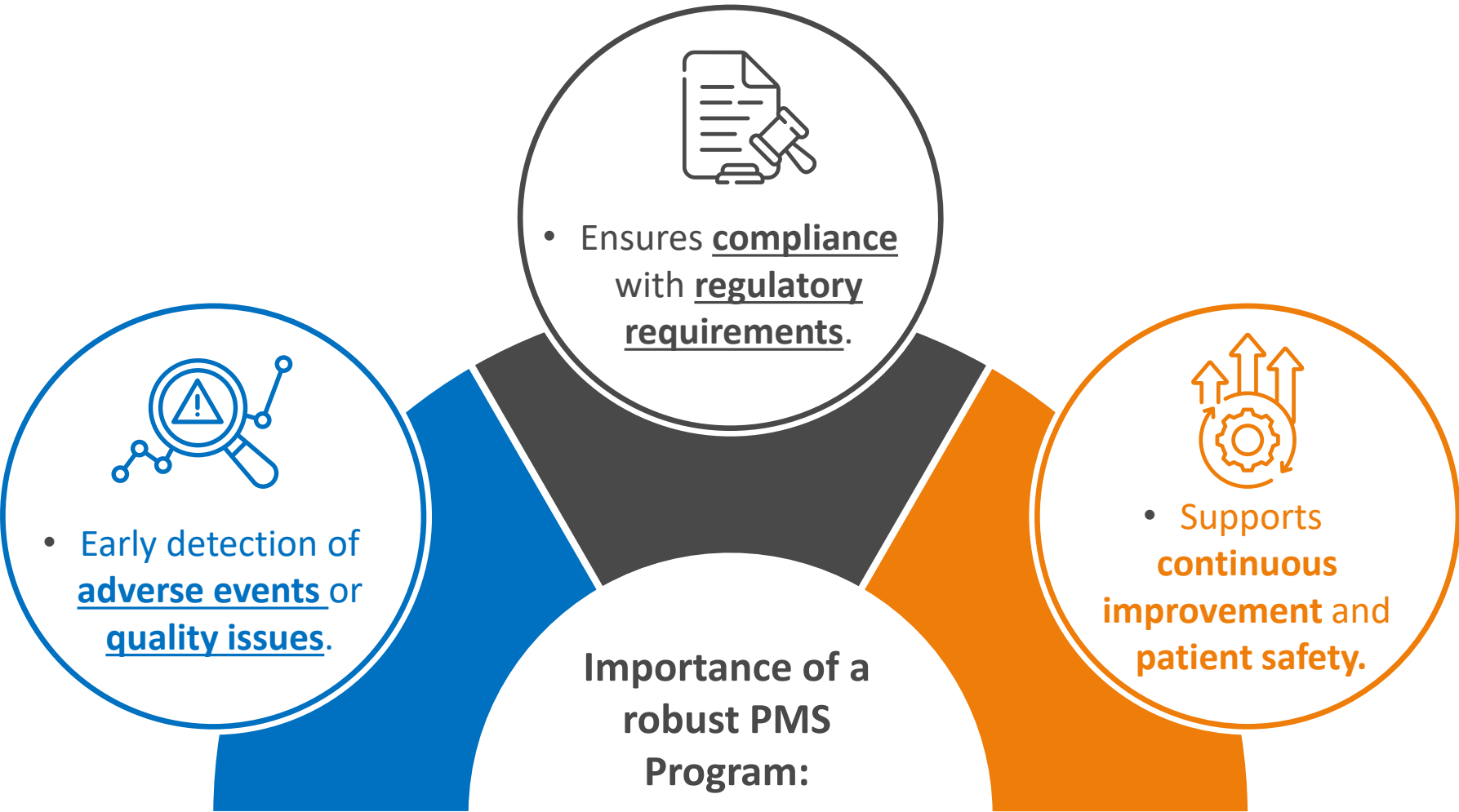


Overview of Post-Market Surveillance (PMS)






Reference: <https://www.mantrasystems.co.uk/eu-mdr-compliance/post-market-surveillance-pms>

Overview of Post-Market Surveillance (PMS)

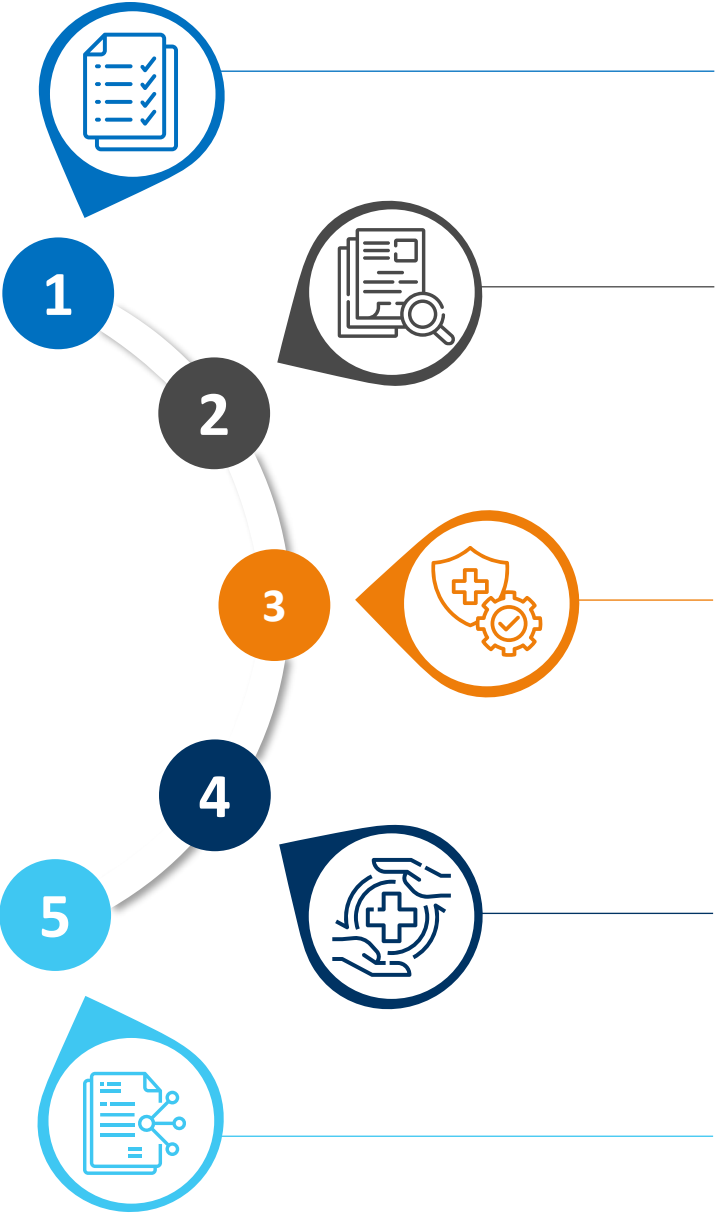


PMS in Medical Devices vs. Pharma vs. Life Sciences

Industry	Focus Area	PMS Approach
 Medical Devices	Device performances, adverse events	PMS Reports, Vigilance Systems, Field Actions
 Pharma	Drug Safety (pharmacovigilance)	Adverse Event Reporting, Periodic Safety Updates
 Life Sciences	Product efficacy and safety	Clinical follow-ups, Monitoring Studies



Key Components of PMS Programs



Complaint Handling and Reporting

- Collection and analysis of feedback from users

Adverse Event Monitoring

- Early detection and reporting to regulatory authorities

Corrective and Preventive Actions (CAPA)

- Identifying root causes and implementing corrective measures

Post-Market Clinical Follow-up (PMCF)

- Ongoing studies to assess product performance in real-world use

Trend Reporting

- Identifying trends in product performance or adverse events over time

Regulatory Requirements

Medical Devices:



- **FDA:** 21 CFR Part 803 – Medical Device Reporting (MDR)
- **EU MDR:** Post-Market Surveillance Reports, PMCF

Pharmaceuticals:



- **FDA:** 21 CFR Part 314 – Pharmacovigilance
- **EU EMA:** Good Pharmacovigilance Practices (GVP)

Life Sciences:



- Ongoing compliance with ISO, FDA, and EMA standards.



PMS Data Sources and Tools



Sources of Data:

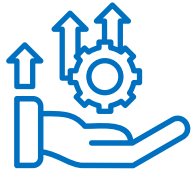
Complaints, adverse event databases, service records, clinical studies, social media

PMS Tools & Technologies:

- PMS databases and dashboards
- AI for trend analysis and signal detection
- Integrated Quality Management Systems (QMS)/Electronic Quality Management System



The Role of PMS in Quality and Compliance



Continuous Improvement:

Use PMS data to refine products and processes.



Compliance:

Demonstrates alignment with regulatory expectations.



Risk Management:

Helps manage product risks proactively through CAPA and PMCF.

Challenges and Best Practices in PMS



Challenges:

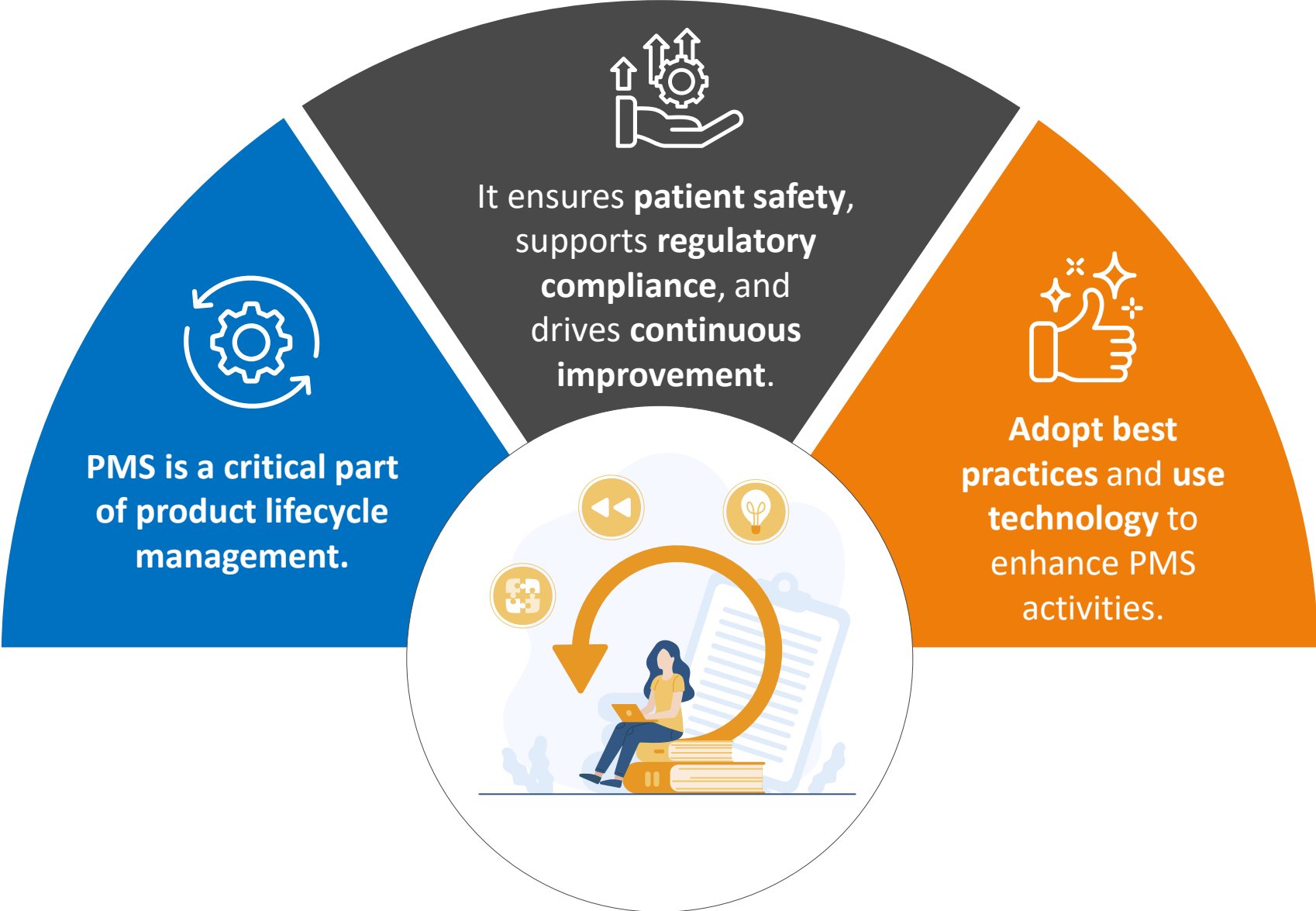
- Data collection and analysis across multiple systems.
- Regulatory compliance in different markets and across different regulatory agencies.
- Quickly evolving regulatory landscape.



Best Practices:

- Centralized PMS processes across regions.
- Use of automation and AI for early signal detection.
- Collaboration with cross-functional teams (QA, RA, R&D).

Summary and Key Takeaways





Learning Objectives

#2 Cultivating a Continuous Improvement Culture



Key Elements of a Continuous Improvement Culture



Definition of Continuous Improvement:

- *A mindset focused on ongoing efforts to improve products, services, or processes by making small, incremental changes over time.*



Role in Quality and Operational Excellence:

- *Ensures alignment with organizational goals and compliance requirements.*
- *Drives sustainable growth by promoting consistency and adaptability.*



Key Elements of a Continuous Improvement Culture



Proactive vs. Reactive Problem-Solving:

- *Proactive Approach: Identifying opportunities for improvement before problems arise.*
- *Reactive Approach: Solving issues after they occur, leading to potential inefficiencies.*



Key Benefits of a Continuous Improvement Culture:

- *Enhanced product quality and customer satisfaction.*
- *Employee engagement and reduced turnover.*
- *Increased operational efficiency and cost savings.*



Key Elements of a Continuous Improvement Culture



In her book, "**Mindset**," renowned Stanford psychologist Carol Dweck says that *it's not intelligence, talent or education that sets successful people apart. It's their mindset, or the way that they approach life's challenges.*

Key Elements of a Continuous Improvement Culture



Reference: <https://www.betterup.com/blog/continuous-improvement#what-is-continuous-improvement?>

Measuring the Impact of Continuous Improvement Programs

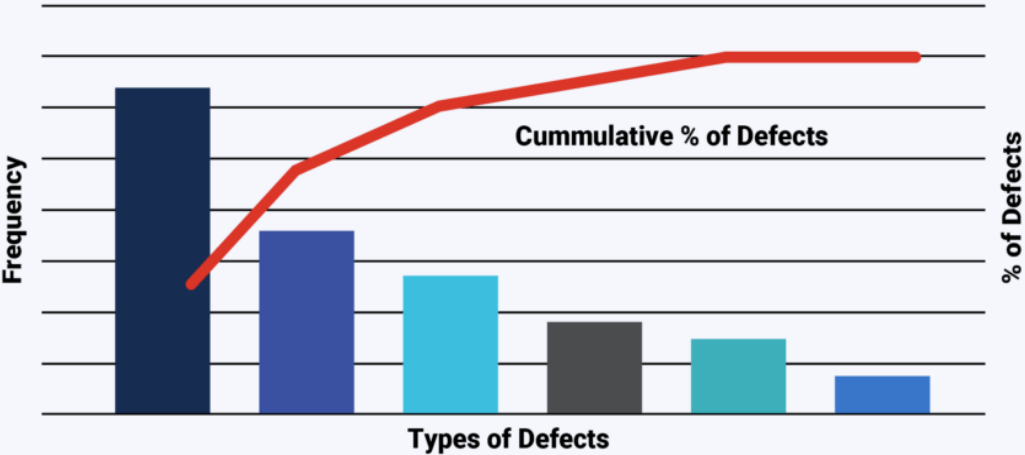


Key Metrics to Measure:

- **Reduction in Non-Conformities:** Track a decline in product defects or process failures.
- **Efficiency Gains:** Measure time savings, productivity improvements, or cost reductions.
- **Employee Engagement:** Monitor employee satisfaction and participation in improvement activities.
- **Customer Satisfaction:** Analyze feedback and satisfaction scores.

Pareto Chart

A Pareto Chart is a bar chart that displays the most significant types of defect occurrences in descending order.



Action Plan for Building a Continuous Improvement Culture



Assess Current State:

Conduct a gap analysis to identify areas for improvement.

Set Clear Goals:

Define measurable objectives aligned with business priorities.

Engage Leadership and Employees:

Communicate the vision and get buy-in from all levels.

Implement Pilot Projects:

Start with small, manageable initiatives to build momentum.

Monitor and Adjust:

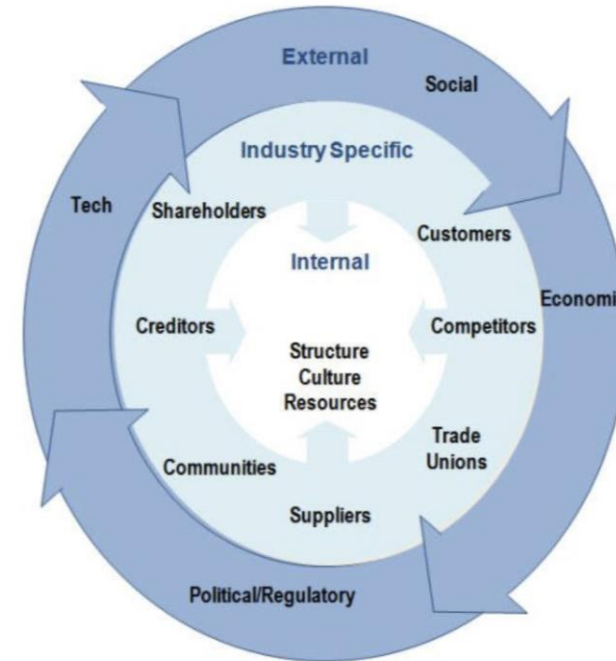
Use metrics to track progress and refine your strategy.

Celebrate Wins and Share Success Stories:

Recognize achievements to sustain motivation and engagement.

Key Elements of a Continuous Improvement Culture

- Enhanced Self-Awareness
- Identification of Opportunities
- Threat Mitigation
- Strategic Planning and Decision-Making
- Resource Optimization
- Improved Communication and Collaboration
- Competitive Advantage
- Performance Measurement and Tracking
- Employee Engagement
- Risk Management
- Innovation and Growth
- Informed Decision-Making for Mergers and Acquisitions



References: <https://www.linkedin.com/pulse/benefits-conducting-swot-analysis-your-business-gavin-bottrell/>



Learning Objectives

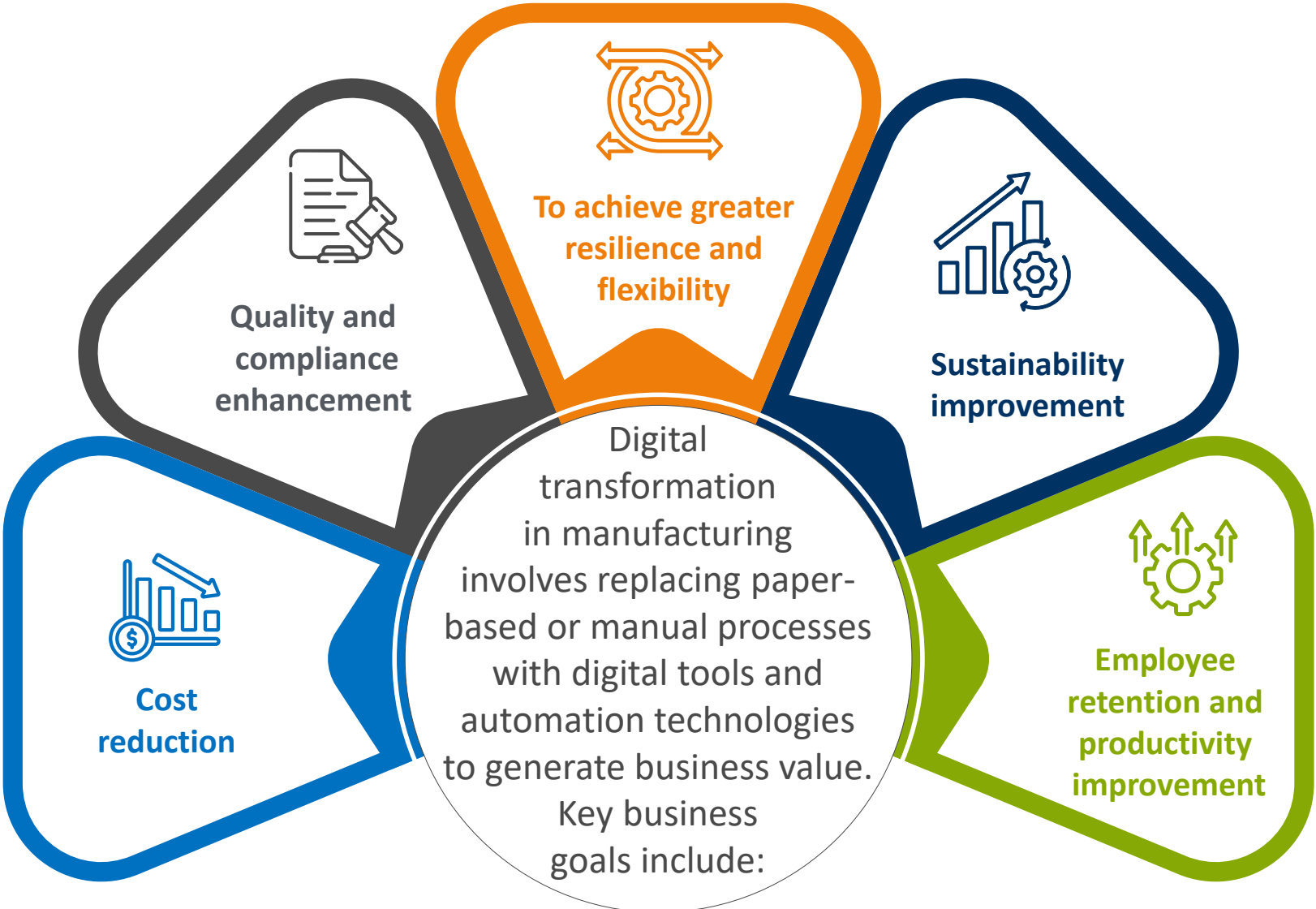
#3 Innovations in Manufacturing Technology



Overview of Emerging Manufacturing Technologies

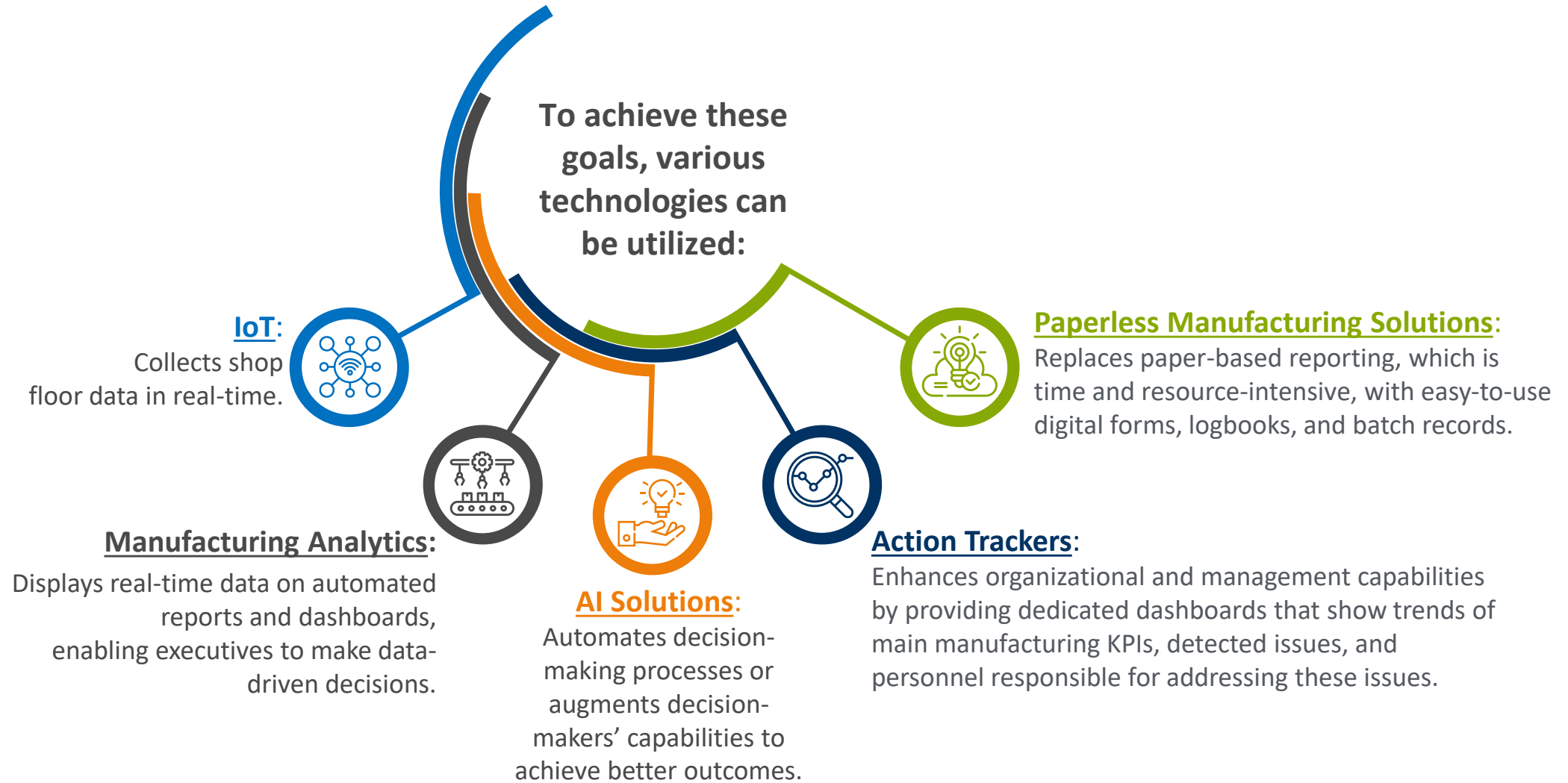
- According to [McKinsey](#), digital transformation in manufacturing can boost throughput by 10% to 30%, improve cost of quality by 10% to 20%, and cut machine downtime by up to 50%.
- Despite these benefits, a [PwC](#) study found that only one-third of manufacturers have progressed beyond the planning or initial stages of digital transformation, missing significant opportunities.
- This slow adoption is often due to a lack of knowledge about digital transformation in manufacturing.

Overview of Emerging Manufacturing Technologies



Reference: <https://scw.ai/blog/digital-transformation-in-manufacturing/#:~:text=Digital%20transformation%20in%20manufacturing%20involves,Quality%20and%20compliance%20enhancement>

Overview of Emerging Manufacturing Technologies



Reference: <https://scw.ai/blog/digital-transformation-in-manufacturing/#:~:text=Digital%20transformation%20in%20manufacturing%20involves,Quality%20and%20compliance%20enhancement>

Planning for Technological Integration: Advanced Manufacturing Technology

- 1 • Advanced manufacturing technology encompasses a broad spectrum of technologies and processes that enhance the manufacturing process.
- 2 • At its core, AMT is about leveraging data, automation, and digital transformation to create more efficient and responsive production environments.
- 3 • Key components of AMT include the Internet of Things (IoT), artificial intelligence (AI), robotics, and cloud computing.
- 4 • These technologies, when integrated effectively, can unlock significant potential for manufacturers.
- 5 • The benefits of adopting AMT are manifold. By automating repetitive tasks, manufacturers can improve productivity and reduce labor costs. Data-driven insights derived from AMT enable informed decision-making, leading to optimized resource allocation and waste reduction. Moreover, AMT empowers businesses to produce higher quality products with greater consistency.

Reference: <https://www.lillyworks.com/blog/what-is-advanced-manufacturing-technology-a-guide-to-smarter-production-scheduling/>


Overview of Emerging Manufacturing Technologies




**Automation
and Robotics**



**Additive
Manufacturing
(3D Printing)**



**AI in
Production**



**Internet of
Things (IoT)**



Overview of Emerging Manufacturing Technologies-Benefits



Improved Product Quality



Operational Efficiency



Flexibility



Impact of Automation and Robotics on Manufacturing Quality

Minimizing Human Error

- Robots perform repetitive tasks with precision, reducing variability.
- Automated systems follow strict protocols, ensuring consistent output.

Enhancing Consistency

- Real-time monitoring to detect and correct errors immediately.
- Automated inspection systems ensure product compliance throughout production.



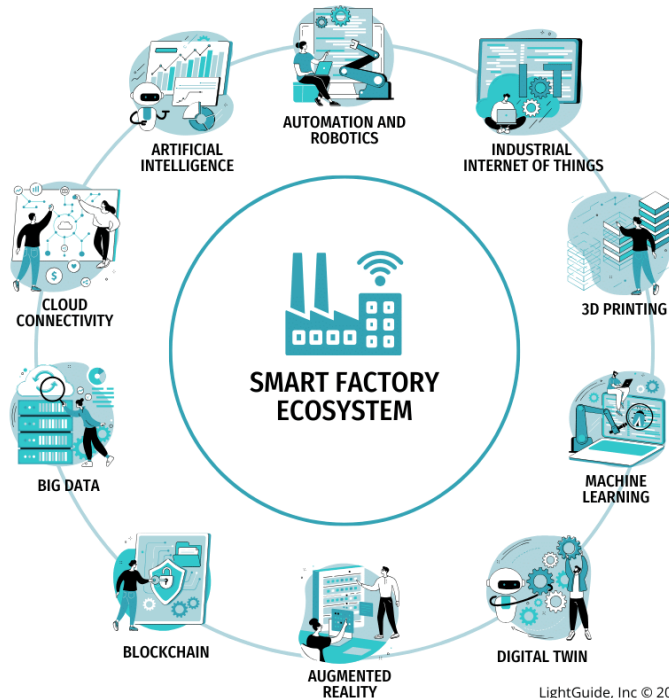
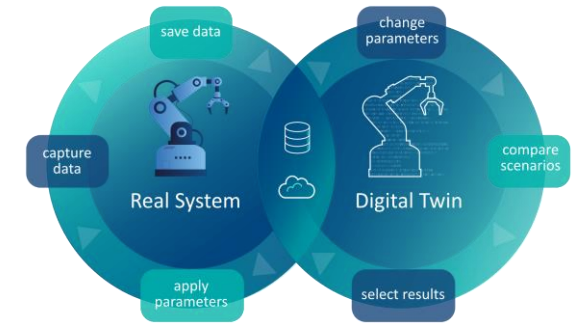
Digital Transformation and Smart Factories

Digital Twins:

- *Virtual replicas of physical assets to simulate production scenarios.*
- *Optimizes processes before real-world implementation.*

IoT Integration:

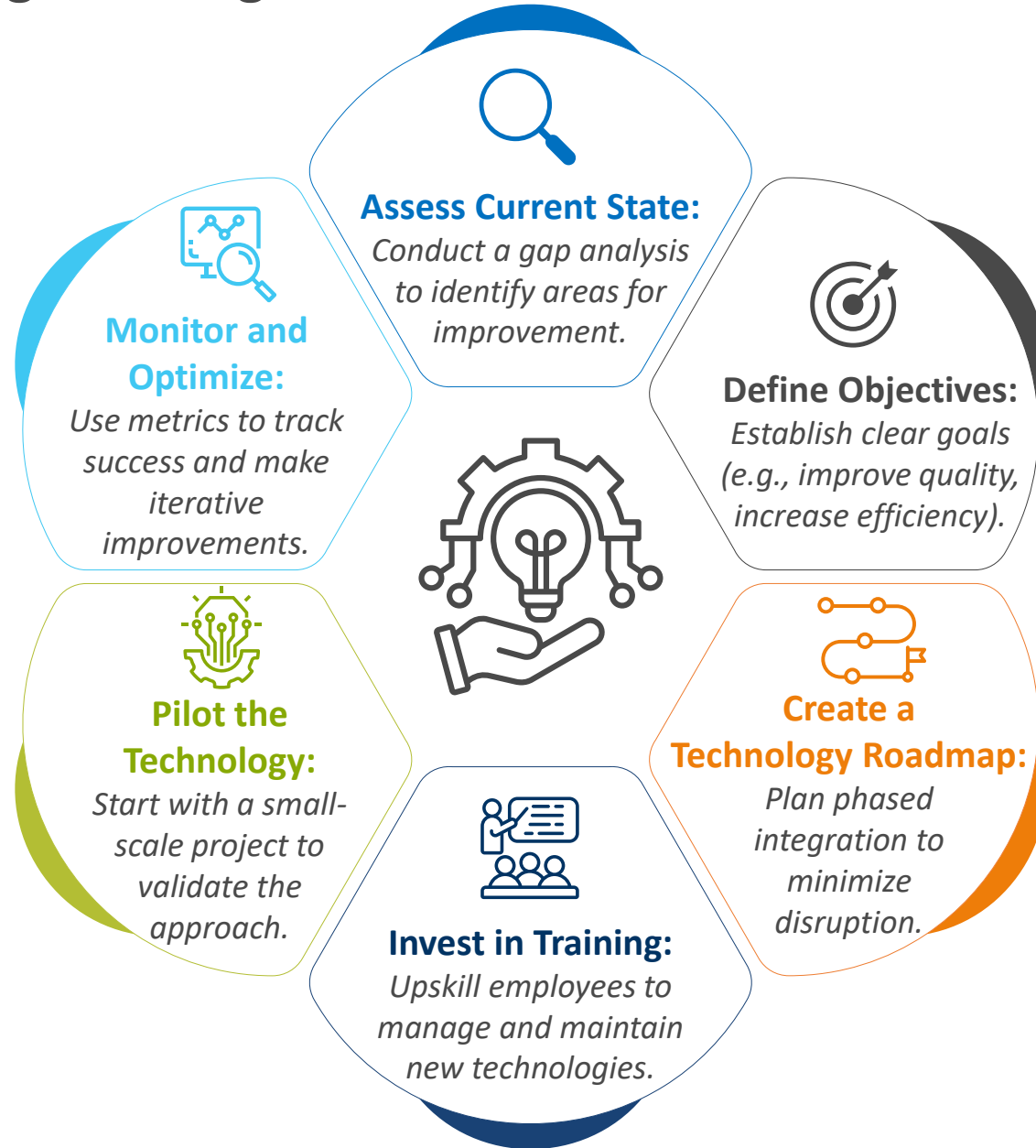
- *Sensors collect real-time data to monitor equipment performance.*
- *Predictive maintenance prevents unexpected downtime.*



Smart Factory Ecosystem:

- *Fully automated production lines controlled by centralized systems.*
- *Adaptive production capabilities for on-demand manufacturing.*

Planning for Technological Integration



slido

Please download and install the Slido app on all computers you use



Which emerging technology do you think will have the greatest impact on improving manufacturing quality and efficiency?

① Start presenting to display the poll results on this slide.



Learning Objectives

#4 Cost of Quality Management



Introduction to Cost of Quality (CoQ)

Cost of quality (COQ) is defined as a methodology that allows an organization to determine the extent to which its resources are used for activities that prevent poor quality, that appraise the quality of the organization's products or services, and that result from internal and external failures. Having such information allows an organization to determine the potential savings to be gained by implementing process improvements.



Reference: <https://images.app.goo.gl/2889m3UDsFs2P4DN6>

Introduction to Cost of Quality (CoQ)

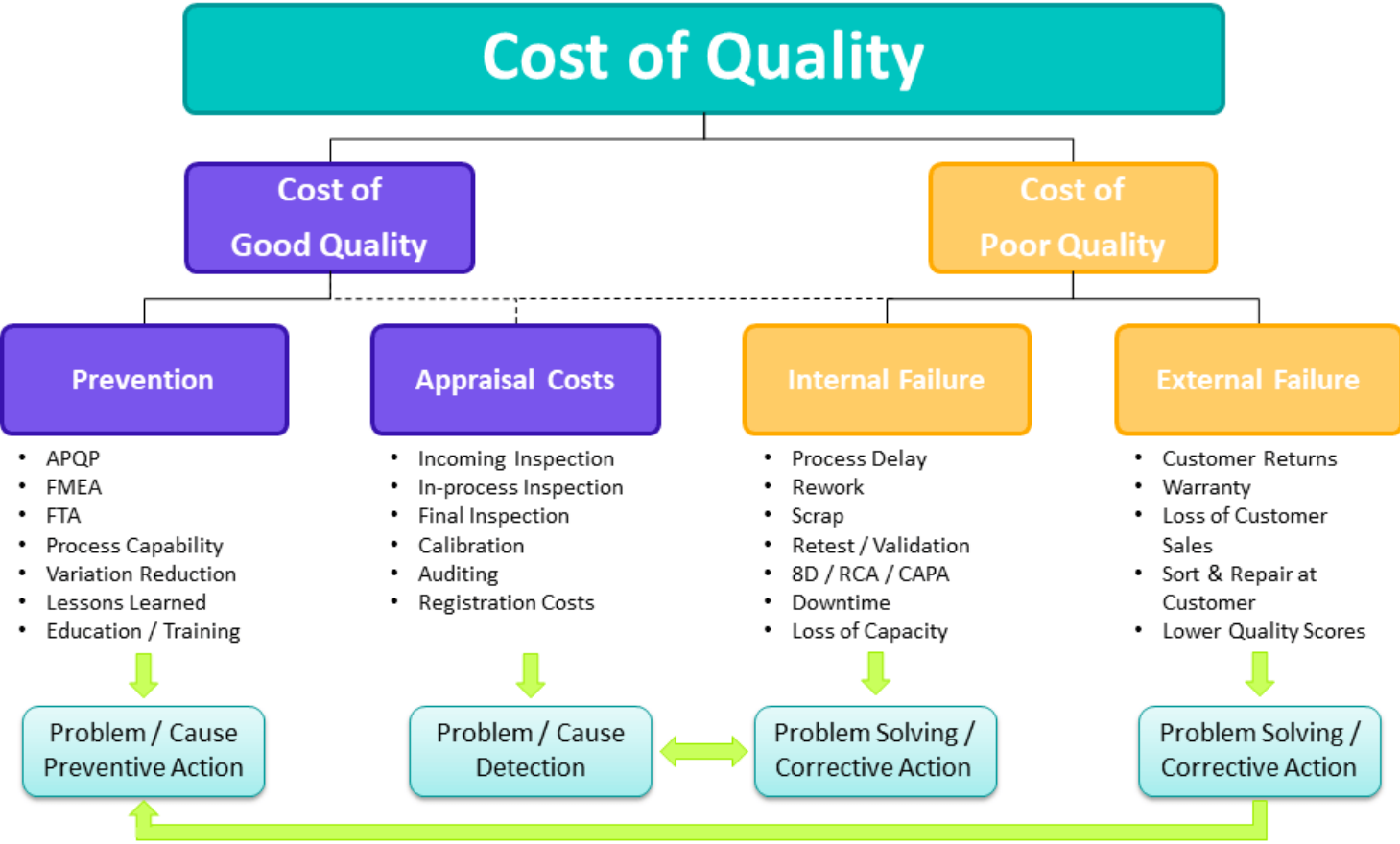


Reference: <https://images.app.goo.gl/2889m3UDsFs2P4DN6>

Introduction to Cost of Quality (CoQ)



Cost of Quality Example



© 2015 Quality-One International

www.quality-one.com

Reference: <https://images.app.goo.gl/2889m3UDsFs2P4DN6>

Breakdown of Cost of Good Quality (COGQ) Components

Prevention Costs:

These are costs incurred to prevent quality problems from occurring. They involve activities related to designing, implementing, and maintaining Quality Management System (QMS). Examples include training programs, process planning, quality improvement projects, and preventive maintenance.



Appraisal Costs:

These costs are associated with measuring and monitoring activities related to quality. They involve evaluating suppliers, inspecting materials, testing products, and conducting audits to ensure conformance to specifications.



Breakdown of Cost of Poor Quality (COPQ) Components

Internal Failure Costs:

These are costs incurred to remedy defects discovered before the product or service is delivered to the customer. Examples include scrap, rework, re-inspection, and the cost of corrective actions.



External Failure Costs:

These costs arise from defects found after the product or service has been delivered to the customer. They include warranty claims, returns, repairs, replacements, and the cost of handling customer complaints.



Business Impacts of Cost of Poor Quality (COPQ)

Impact	Description
Reduced Profitability	Increased costs associated with defects, rework, and warranty claims can erode profit margins.
Damaged Reputation	Subpar products and services can harm a company’s reputation and reduce customer trust.
Decreased Productivity	Time and resources spent addressing quality issues can negatively impact productivity.
Increased Compliance Risk	Failing to meet quality standards can result in regulatory penalties and legal liabilities.
Reduced Employee Morale	Persistent quality problems can demotivate employees and affect their performance.
Loss of Competitiveness	A company’s inability to consistently deliver high-quality products can hinder its ability to compete in the market.
Reduced Profitability	Increased costs associated with defects, rework, and warranty claims can erode profit margins.
Damaged Reputation	Subpar products and services can harm a company’s reputation and reduce customer trust.

Reference: <https://www.compliancequest.com/bloglet/balance-expense-and-excellence-with-coq/>

Strategies to Minimize the Cost of Poor Quality (COPQ)

Action	Summary
Implement an Effective QMS	Establish a robust QMS for consistent quality and continuous improvement.
Provide Training and Development	Invest in training to enhance employee skills and knowledge.
Digitize Documentation Practices	Use digital tools to streamline and improve documentation accuracy.
Minimize Downtime	Reduce downtime, Meant Time to Failure (MTTF), and Mean Time to Repair (MTTR) for optimal efficiency.
Perform Preventive Maintenance	Maintain equipment regularly to prevent breakdowns.
Manage Customer Feedback	Establish a robust complaint handling program and manage feedback effectively.
Identify Non-Conforming Products	Implement methodologies to detect and address poor-quality products at the specified manufacturing stage.
Make Data-Driven Decisions	Use data analytics to identify trends, measure performance, and drive continuous improvement.

Reference: <https://www.compliancequest.com/bloglet/balance-expense-and-excellence-with-coq/>



Learning Objectives



Learning Objectives



1. Post-Market Surveillance:

Understand the latest methodologies in post-market surveillance that integrate with continuous improvement processes to enhance product safety and effectiveness.



2. Cultivating a Continuous Improvement Culture:

Learn how to foster a culture of continuous improvement that encourages proactive quality programs and operational excellence.



3. Innovations in Manufacturing Technology:

Explore how new and emerging technologies in manufacturing can significantly improve product quality and operational efficiency.



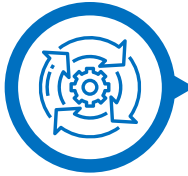
4. Cost of Quality Management:

Gain insights into establishing a comprehensive Cost of Quality program that tracks, analyzes, and manages quality-related costs, driving better financial performance and quality outcomes.

LESSONS
LEARNED



Summary



- Leverage PMS methodologies to enhance product safety and effectiveness.



- Foster a culture of improvement through leadership, employee engagement, and proactive quality programs.



- Embrace new technologies like automation, AI, and IoT to optimize quality and efficiency.



- Position your organization to be more adaptive to changing industry demands.



- Implement a CoQ program to track and manage quality costs efficiently.



- Link quality management efforts to financial outcomes for better performance and ROI.



Summary

By combining continuous improvement, post-market surveillance, innovative technology, and a focus on the cost of quality, organizations can achieve sustainable excellence, mitigate risks, and drive compliance and business excellence!



About ComplianceQuest



About ComplianceQuest

Transform to a fully connected business with a next-generation AI-Powered Product Lifecycle, Quality and Safety management platform, built on Salesforce.

300,000+
Users

1000+
Customer Sites

100M+
Active Records being
Managed

1000+
Man years
Domain Expertise

Award
Winning
Solution

Inc. 5000
169
2019

Frost & Sullivan

Worldwide
Direct and Partner
locations



Financially Strong



Quality & Compliance
begins at home and
with Salesforce



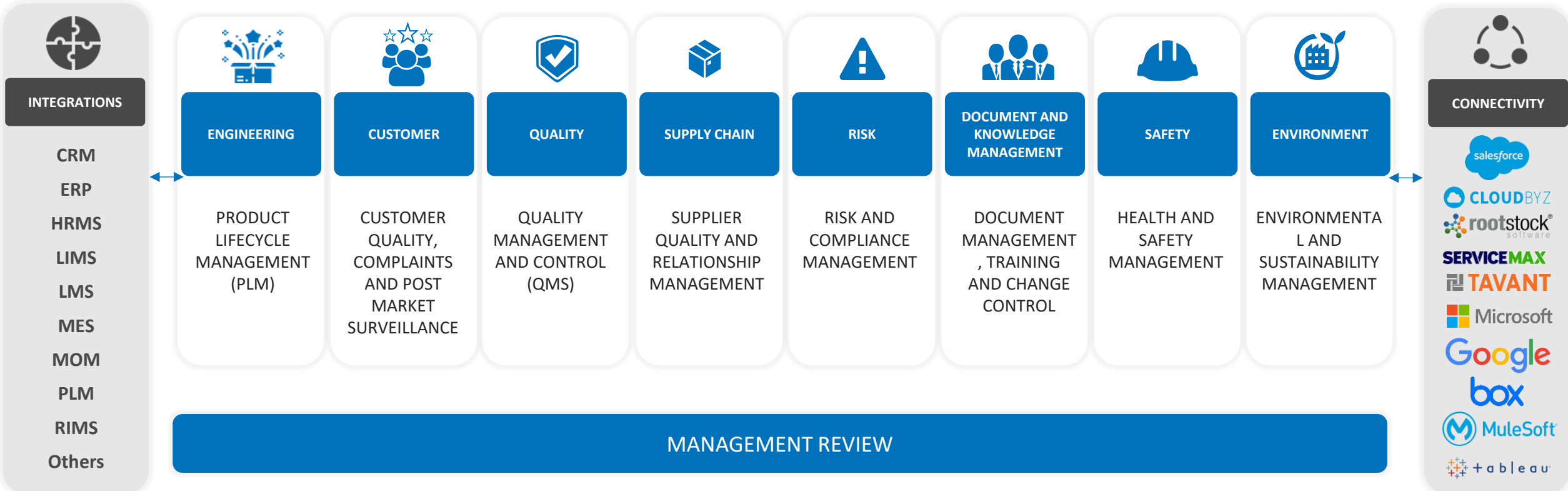
Recognized



Time Tested and Proven

Achieve your Quest for Digital Operations

CQ intelligently automates operations from product innovation to customer success



Embedded & Advanced Analytics | Collaboration (Chatter, MS Teams) | 2-Way Portal | Alerts and Notification | Forms Designer/Runner | Mobile | Pre-Validated | Ratings | CQ.AI | MyCQ for casual users

PLATFORM POWERED BY




THANK YOU



 marketing@compliancequest.com

 www.compliancequest.com

Jennifer Mascioli-Tudor

 650-336-3222

 Jennifer@jmtcompliance.com

 www.jmtcompliance.com

