

Risk-Based Error-Proofing...

Helping Teams Anticipate and Prevent Future Problems

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Process Failure Mode and Effects Analysis (P-FMEA) has been a widely accepted quality management tool. Due to QS-9000 requirements, P-FMEA is now applied in the automotive industry with more regularity. Other industries are paying more attention to P-FMEA.

P-FMEA is often misunderstood and is usually developed without knowledge available within the system of work it is allegedly improving. In these situations, the P-FMEA that is created provides the customer with nothing more than a stagnant document that describes various product quality controls.

However, with some basic understanding of the P-FMEA tool, quality and engineering professionals can make a very significant contribution improving their organizations' quality, productivity and profit.

The key is applying P-FMEAs as part of a system working to manage the production process from initiation of process design through the period of regular production. Furthermore, when P-FMEA is linked with

error-proofing techniques, the production process becomes more tolerant of natural variation and becomes more reliable overall.



This article advocates integrating the application of P-FMEA with error-proofing techniques to achieve significant reductions in scrap, rework and customer complaints.

Assess the Process, Not the Preferred Result

Repetitive manufacturing processes are prone to the risk of producing some defective product. Probability theory is confirmed by variation observed in finished product characteristics. Additionally, when a manufacturing line includes any amount of manual activity or decision-making, variation intensifies. Until all variation is minimized, or controlled, process errors will lead to product defects and customer complaints.

“P-FMEA can be defined as a quality management tool that proactively reduces the risk of producing defective parts.”

Overview

- A primer on Process Failure Mode and Effects Analysis (P-FMEA)
- How P-FMEAs improve quality and customer satisfaction
- Finding the riskiest, or weakest, links
- Risk Reduction — Prevention and Detection
- Error-Proofing techniques
- Development of Process Control Plans and Job Instructions
- The role of management

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P-FMEA helps a team critically evaluate the underlying manufacturing system that transfers material inputs into finished product. That system typically includes equipment, tooling, set-up activities, operator actions, gauging, maintenance, material movement and packaging. These factors and others must be controlled to some extent in order to consistently manufacture product that conforms to customer requirements.

P-FMEA can be defined as a quality management tool that proactively reduces the risk of producing defective product. Starting with the manufacturing Process Flow Diagram or identified sequence of process steps, potential errors and causes are identified and assessed with three elements of risk.

Elements of Risk

The three elements of risk evaluated in a P-FMEA are Occurrence, Detection and Severity. The Potential Failure Mode and Effects Analysis Reference Manual developed by the Automotive Big-3 includes suggested evaluation criteria for these rankings. Teams may develop their own criteria to suit their needs as long as they are effective for relative risk assessment and quality improvement.

Occurrence (OCC) is the relative probability that a specific cause may lead to a process error or failure. Detection (DET) is a relative measure of the chance that a failure will not be detected in the process; in other words, DET measures likelihood of the defect escaping. Finally, Severity (SEV) reflects the degree of dissatisfaction which results from the error, assuming that the defect escapes from the process.

$$\text{(Sev)erity} \times \text{(Occ)urrence} \times \text{(Det)ection} \\ = \text{Risk Priority Number (RPN)}$$

Each element of risk (OCC, DET and SEV) is assigned a risk ranking on a scale of 1 to 10, with 10 being an undesirable high ranking. The multiplicative product of these three elements (SEV x OCC x DET) is called the Risk Priority

Number, or RPN. The lowest possible Risk Priority Number is $1 \times 1 \times 1 = 1$. The worst achievable RPN would be $10 \times 10 \times 10 = 1000$, and indicate that process function was out of control.

RPN is a relative measure of the risk of events that could lead to customers receiving defective product. More to the point, if a cause of a defect is likely and the chance of escaping to the customer is high (leading to significant negative consequences to the customer), then that cause is high risk. Such a scenario would be represented with a high RPN in the P-FMEA. (See figure 1 below)

RPN as a Determiner for Potential Risk

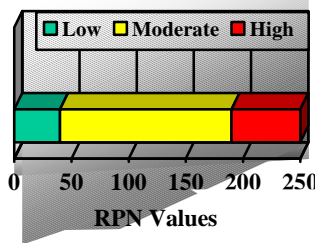


Figure 1

Quality improvements result from preventing and/or better detecting problems, which lowers the RPN. A well-constructed P-FMEA can be used to design and communicate proper process controls which are to be carried out in day-to-day operations in order to control quality.

The P-FMEA Document

Visually, a completed P-FMEA looks like a spreadsheet document. The header includes identification of the product, part number, model year, plant location, responsible engineer and revision date. The body of the document contains rows and columns which comprise a database of all potential risk events for the process under review. The column headings include: Process Function, Potential Failure Mode, Potential Effect(s), SEV, Potential Cause(s), OCC, Current Process Controls, DET and RPN. (See Figure 2 on the following page)

A manufacturing process typically has

many process steps, and each step may have multiple Failure Modes. Usually each Failure Mode will, in turn, have several possible causes.

Since causes branch out from Failure Modes, and Failure Modes branch out of each process step, the number of rows in a P-FMEA

document is directly related to the process complexity. Each P-FMEA row, or branch, defines a “Process Step-Failure Mode-Cause” scenario and has a corresponding RPN, representing that scenario’s relative risk.

While a very thorough P-FMEA can easily exceed 50 pages for a highly featured component such as an engine cylinder block, the value of the P-FMEA lies in its ability to access a subset of relevant information quickly using the P-FMEA as a database of knowledge. Sorting the rows of the spreadsheet in descending order of the RPNs and selecting the top 10% of the RPNs can generate a concise listing of the highest-risk scenarios that require corrective or preventive action. Similarly, printing only the relevant few pages of a P-FMEA can provide information needed to revise job instructions for a specific operation station.

Assigning Risk Rankings

For established manufacturing processes, one should expect a medium to high correlation between actual customer quality concerns and high RPN processing problems. The correlation will not be exact since RPNs consider potential risk. Actual quality performance is the byproduct of probability distributions. The statistical standard deviation (sigma) of the process may predict less likely, but possible, non-conforming results. For example OCC could be low, but by chance the

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defect may occur several times in one week.

For processes that are well controlled, OCC will generally be very low. However, if a cause occurs repeatedly, regardless of detection prior to customer receipt, it should have a higher occurrence (OCC) in the P-FMEA. If it is likely not to be detected as a failure within the process under review, it should also be assigned a higher DET ranking. Here the importance of the Risk Priority Number

becomes more evident, since higher RPNs become the priority for improvement action.

Total Process Risk

When developed correctly, the P-FMEA considers risks at all points in the process – from the receiving dock to the shipping dock. In order to reflect a true picture of risk, historical problem occurrence data must be considered in the P-

FMEA development and current quality data reviewed on a periodic basis. To become a valuable tool, the P-FMEA must have “high fidelity” resolution with the real world. This means that as changes are made to the sequencing or content of the operations, the P-FMEA should be updated. Also, as quality reports are updated over time, the OCC and DET scores, and sometimes the SEV scores, need to be updated to reflect the current reality.

Figure 2: Sample P-FMEA Spreadsheet (abridged)

P-FMEA Guidance Document and Sample Spreadsheet											
	Process Function/ Req.	Potential Failure Mode(s)	Potential Effect(s) of Failure	SEV	Class	Potential Cause(s) / Mechanism(s) of Failure	OCC	Current Process Controls	DET	RPN	Recommended Action
Requirement	Describe the manufacturing process.	Possible errors or incorrect actions. How the process may fail to meet the requirement(s) Consider all potential failures.	Downstream consequences which may result from the failure mode.	Severity rating of the worst-case Effect.	Indicate any Special Characteristics.	Root Cause of the failure mode. There are usually multiple causes for each failure mode.	Likelihood that the cause identified in the column to the left could occur.	List all measures in place to both: 1) Prevent, and/or 2) Detect this error. Each method should be ranked individually.	Probability of escape. Rank only Detection items; <u>not</u> Preventive items.	Severity x Occurrence x Detection = RPN	The team's short-term and/or long-term solution to address high risk concerns.
Suggestion	Begin with a verb.	Most process steps will have multiple potential Failure Modes.	List the sequence of effects to show logical linkage from the Failure Mode to the "worst-case" effect.	Each Effect may be ranked individually. Chose the highest ranked Effect in this column.	Often specified by the customer. If not a Special Characteristic, leave this field blank.	Each cause should be on a unique row of the FMEA.	Not the Occurrence of the Failure Mode, but the Occurrence of each specific root cause.	Indicate Preventive measures with a "(p)".	Choose the lowest ranked Detection method in each row. That is the best "gate" to rely on to detect the problem.	Always calculate with the formula, as opposed to just entering the resultant number.	The full FMEA spreadsheet also includes columns for the responsible individual and target completion date.
Sample P-FMEA	Select and place motor bracket	Part omitted	Can't attach motor at next station - rework (3)	3		Operator did not select part	2	Training (p) Can't build at next station (2)	2	12	None - low risk
		Wrong Part	Weaker bracket will not support larger motor. Early field failure (7)	7		Wrong part supplied	1	Training (p) Visual inspection (7)	7	49	Redesign to eliminate additional brackets.
				7		Operator selected wrong part	4	Training (p) Visual inspection (7)	7	196	Redesign to eliminate additional brackets.
		Part reversed	Can't start both bolts at this station (1)	1		Operator mis-oriented part	1	Training (p) Part design -- bolts fit only if properly oriented (1)	1	1	None - bracket design mistake-proofs improper alignment.
	Hand-start and torque 2 bolts to motor bracket with hand tool	Improper start	Cross threaded -- Loose bolt in field (8)	8	Safety	Dirt or debris on bolt or in bore	2	Clean parts (p)	10	160	Implement electronic tooling to sense torque and check angle.
				8	Safety	Operator improperly started bolt	3	Training (p)	10	240	Implement electronic tooling to sense torque and check angle.
		Excessive Torque	Bolt breaks or stripped threads -- Loose bolt in field (8)	8	Safety	Operator applied tool for an excessive time	1	Training (p) 100% check at motor mount station (6) Periodic torque audit (9)	6	48	Implement electronic tooling to sense torque and check angle.
		Inadequate Torque	Loose bolt in field (8)	8	Safety	Operator removed tool too soon	2	Training (p) 100% check at motor mount station (6) Periodic torque audit (9)	6	96	Implement electronic tooling to sense torque and check angle.

One way to think about the total risk in a manufacturing process is to calculate the sum of all RPNs in the P-FMEA. For example, on a 200 line P-FMEA whose average RPN is 50.0, the cumulative RPN would be 10,000. While that cumulative RPN is meaningless by itself, it may be used to compare total process risk for the same manufacturing line over time (e.g., month-to-month or year-to-year). As the process improves through corrective or preventive actions the cumulative RPN will generally decrease.

Management may set targets for the rate of risk reduction activity as measured by the downward slope of the cumulative RPN line when graphed over time. (See figure 3 below)

Risk Reduction – Prevention and Detection

The highest RPNs items within a P-FMEA document represent the riskiest events, or weak links, in the process. Risk reduction initiatives should therefore be targeted at those items.

As the name implies, risk reduction is those activities that make a process or design more robust and reduce variation (e.g., Cp and CpK).

Process changes that prevent or reduce the likelihood of a cause will reduce RPN by lowering the occurrence (OCC) ranking. Similarly, process changes that improve detection of a problem will reduce the likelihood of the defect escaping, which will lower the DET ranking and thereby reduce the RPN.

Once recommended actions are developed for the high RPN rows in the P-FMEA, a responsible individual and target completion date should be identified. These columns are also found on a P-FMEA spreadsheet.

“Applying P-FMEA in a systematic fashion to reduce risk will produce tremendous benefits in quality, productivity and profit.”

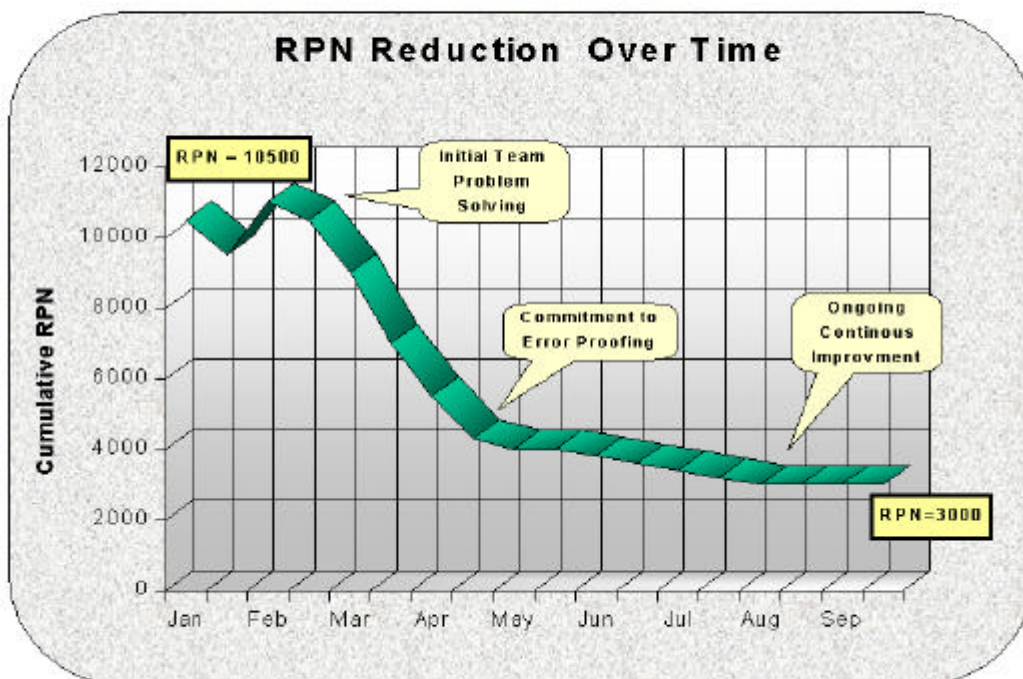
Prevention by Error-Proofing

Effective P-FMEAs isolate causes, identify solutions and lead to verifiable corrective actions that improve quality. Recommended actions may include additional data collection, problem solving, and investigation, but at some point, must lead to one or more actions which reduce risk.

If nothing changes on the production floor (e.g., product design, tooling and equipment, sensing devices, methods or other aspects which impact manufacturing) the quality levels observed by the customer will not change. Developing P-FMEAs is an excellent way to pinpoint problems, but the value of P-FMEA as part of a process management system is solving problems.

The best action that can be taken for high-risk problems (especially those high RPNs with above average Severity rankings) are error-proofing, mistake-proofing or Poka-Yoke systems. These powerful methods prevent problems from occurring, or detect and react to variation

Figure 3



in the process before they materialize as product defects.

When defects can be prevented, process controls can be minimized or eliminated entirely. With fewer items for the operators to control on a daily basis, the chance or risk of producing defective product is lowered and the operators can truly focus on the critical few things that may still require attention.

Technical vs. Behavioral Solutions

Causes of Failure Modes can be categorized as being either technical or behavioral. Technical causes include equipment malfunctions, tooling failures and design problems. Behavioral causes result from the conscious and unconscious actions of employees and managers. Since humans work in partnership with the tooling and equipment on the plant floor, technical and behavioral causes can have a great impact on each other.

To effectively reduce process variation the P-FMEA team must learn how to ac-

curately identify the type and source of the problematic variation. Once the causes are identified, many simple and low-cost devices are available to detect and react to process abnormalities. Significant profit and quality improvements result from applying reliable, low-cost technical error-proofing solutions to remedy the causes associated with high-risk process errors.

If the problem is a mislocated or wrong part, jigs and guides can be used to prevent improper part placement. If the problem is a missing part, detection devices may include limit switches, proximity switches or light beam sensors. To detect wear in equipment guides or spindles, vibration or load sensing devices can be used. More examples of process monitoring and sensing devices can be found in references listed in the bibliography at the end of this article.

P-FMEA as an Information Hub

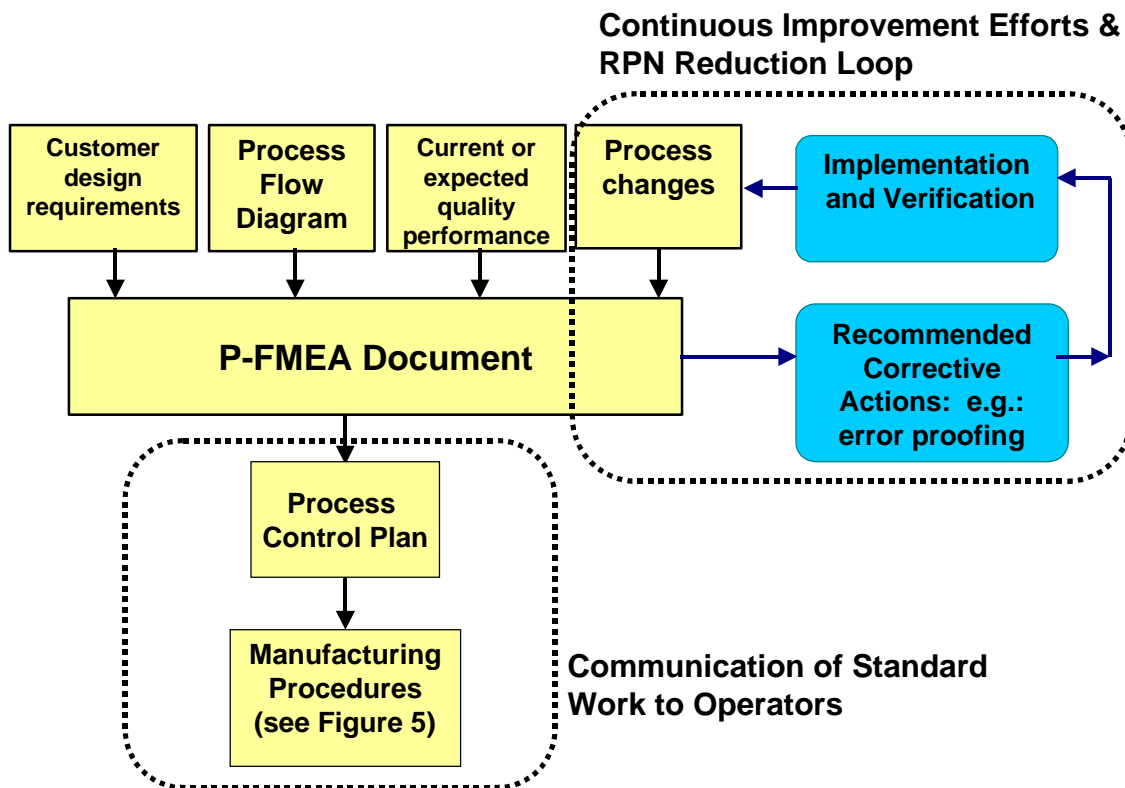
QS-9000 element 4.9 establishes that operator instructions, process monitoring and control of process capability should

be derived through Advanced Product Quality Planning (APQP). This requirement provides an elegant flow of relevant information needed to control the manufacturing process. Figure 5 lists some of the typical manufacturing procedural documentation that should be derived through the P-FMEA and Process Control Plan database.

When applied properly within an Advanced Product Quality Planning (APQP) methodology, the P-FMEA becomes the hub of relevant information needed to proactively control the production process. Once error-proofing is applied to reduce risk, the changes that were made need to be documented in a revised P-FMEA. The P-FMEA in turn will provide updated information to drive an updated Process Control Plan. This Process Control Plan defines operating process specifications and daily checks to verify that the error-proofing is in place. Finally, Job Instructions may be developed to communicate proper operating methods to personnel on the factory floor. (See figure 4 below)

Through this sequence of events, the error-proofing can be institutionalized with

Figure 4: P-FMEA as an Information Hub



relevant manufacturing documentation updated and a revised list of remaining high RPN concerns can be generated.

A Process Management System

As the hub of a process management system, P-FMEAs become the information source for two major quality assurance activities: 1) development and communication of standard work to the process operators, and 2) guidance for continuous improvement efforts.

P-FMEAs are most valuable in reducing lifetime costs when they are developed early during product and process development. In the initial stages of process planning, P-FMEAs guide establishment of the best process controls and define appropriate lean guidance for operators and skilled trades. P-FMEAs completed prior to production launch also begin a hit list of unaddressed high-risk problems and trigger work plans to continuously reduce those risks.

P-FMEAs can be beneficial even if not completed during the planning phases. P-FMEAs developed after production launch help drive continuous improvement by guiding development of appropriate technical changes for high risk problems. Also, after production launch, regular reviews of the P-FMEA will assure that the P-FMEA database is a current ‘snapshot’ of process risk. As a living document it should reflect all process changes and the current risk rankings that represent the actual quality performance observed.

Development of a P-FMEA always begins with a Process Flow Diagram. After an initial screening of “risk inherent” vs. “minimal risk” process steps, focus is placed on identifying potential failure modes and their associated causes for the riskier process steps. Once causes of error are identified, preventive and detection controls for the causes are established. These controls are the key input to the development of job instructions, gauging plans, tool change programs, preventive maintenance plans, and other guidance to the people who will perform the work on a daily basis.

The establishment of standard work will reduce variation in critical human actions that are part of the manufacturing system.

When good planning and design prevent problems, the resultant process will aid workers in performing unsafe, difficult and/or repetitive aspects of their jobs. In that environment operators can focus on those remaining critical few aspects of their work that need to be done correctly.

If operators are given too many job elements to monitor, it is less likely they will be able to protect their customers, resulting in defects and reduced productivity. (See figure 5 below)

By providing the best design, best process, best equipment and tooling, and generously implementing error-proofing, the operators can use innate human nature and senses to be guardians for quality.

Leadership Commitment

Management has a key role in evolving the use of P-FMEA from merely a product control document to a source of information for process design and process management. There are three important steps leadership should take to change existing poor habits of P-FMEA development.

First, management must understand that P-FMEA is a proactive tool to prevent risk. They need to assure that responsible individuals receive proper training and then hold those individuals accountable for development of the P-FMEA early in the process design phase. They should insist that the P-FMEA guide development of process control methods and job instructions, and set priorities for high-impact risk reduction initiatives.

Second, management should establish, along with the team, the desired quality metrics for the new or current manufacturing process. Often developing the P-FMEA and implementing recommended actions occurs over several months; therefore management must be patient, but still maintain a sense of urgency. Through periodic management reviews of progress toward target metrics, management will keep the team’s attention

“If nothing changes on the production floor, the quality observed by the customer will not change.”

Figure 5: Sample manufacturing floor procedural documentation

Job Set-up Instructions	Tool Change Program
Operator Job Instructions	Daily Process Check Sheets
Gauging Plans	Maintenance Plans
Process Control Logic	Troubleshooting Guides
Process Andon Signals	Prioritized list of issues for Error-Proofing

focused on the desired results. Where risk remains at unacceptable levels, management should determine if the RPN assessments are valid, and if so, request and review an appropriate business case to redistribute or request additional program resources.

Finally, involving the people that know the process best is the third crucial element in making P-FMEA an effective quality tool. When operators are involved in the development of P-FMEAs they contribute intimate information that can be known only by those who perform the job on a daily basis. In turn their involvement in the P-FMEA promotes their understanding of the entire process, their customers' needs and the relative risk of their own operations.

Conclusion

Applying P-FMEA in a systematic fashion to reduce risk will produce tremendous benefits in quality, productivity and profit. P-FMEAs can help teams anticipate what might go wrong, and then design appropriate error-proofing and detection controls into the manufacturing process. When established with credible rankings, the P-FMEA can effectively guide both appropriate operator actions and prioritize deployment of resources for continuous improvement.

Bibliography

- Kolbe, Andreas, "Does FMEA Terminology Cause Preventable Errors in FMEA Development?" *The Quality Management FORUM* of ASQC. Vol. 22, No. 4, Winter 1996, p. 1.
- Lindland, John L. *Mistake-Proofing* seminar. The Luminous Group, 1999.
- Potential Failure Mode and Effects Analysis Reference Manual*, Second Edition, February 1995. Available from the Automotive Industry Action Group (AIAG). Telephone 248.358.3003.
- Shingo, Shigeo. *Zero Quality Control: Source Inspection and the Poka-Yoke System*, Productivity Press, 1986.

About the Author

Murray Sittsamer is the president and a lead consultant at The Luminous Group. He has extensive experience helping cross-functional teams plan and implement quality improvements. During the past five years, Murray has focused his work supporting automotive OEMs and suppliers with their QS-9000 implementation efforts, especially in the areas of Advanced Product Quality Planning (APQP) and Failure Mode and Effects Analysis (FMEA).

Murray holds a Master of Science in Industrial Administration from Carnegie Mellon University. He earned his undergraduate degree in industrial engineering from the University of Pittsburgh.

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About this Article

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