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The Pursuit of
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in Asset Management



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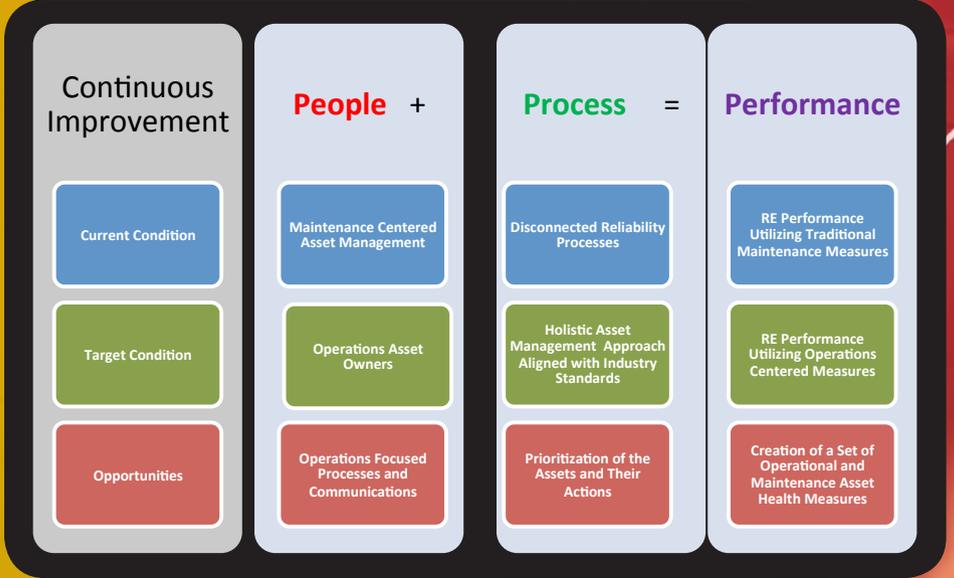


The Pursuit of Continuous Improvement in Asset Management

by Mike Rose and Chris Gould

As an organization, Merck & Co., Inc.'s core values are driven by a desire to improve human life, achieve scientific excellence, operate with the highest standards of integrity, expand access to its products and employ a diverse workforce that values collaboration. To support these values, Merck & Co., Inc. strives to deliver strong operational performance supported by cost-effective asset utilization over the entire asset's lifecycle. Merck & Co., Inc., in West Point, Pennsylvania, is a multi-divisional, 397-acre site that produces a diversified portfolio of vaccines and sterile products. As such, asset management is critical to successful, sustainable performance.

In 2010, Merck & Co., Inc.'s West Point facility re-established a strategic focus on reliability engineering by re-chartering the department and installing a senior leader. A simple framework was established utilizing a continuous improvement methodology integrated with a people, process and performance model. The figure to the right shows how the framework functions at a high level to identify areas for improvement and what levers would be pulled in the people and process space in order to achieve the desired performance.



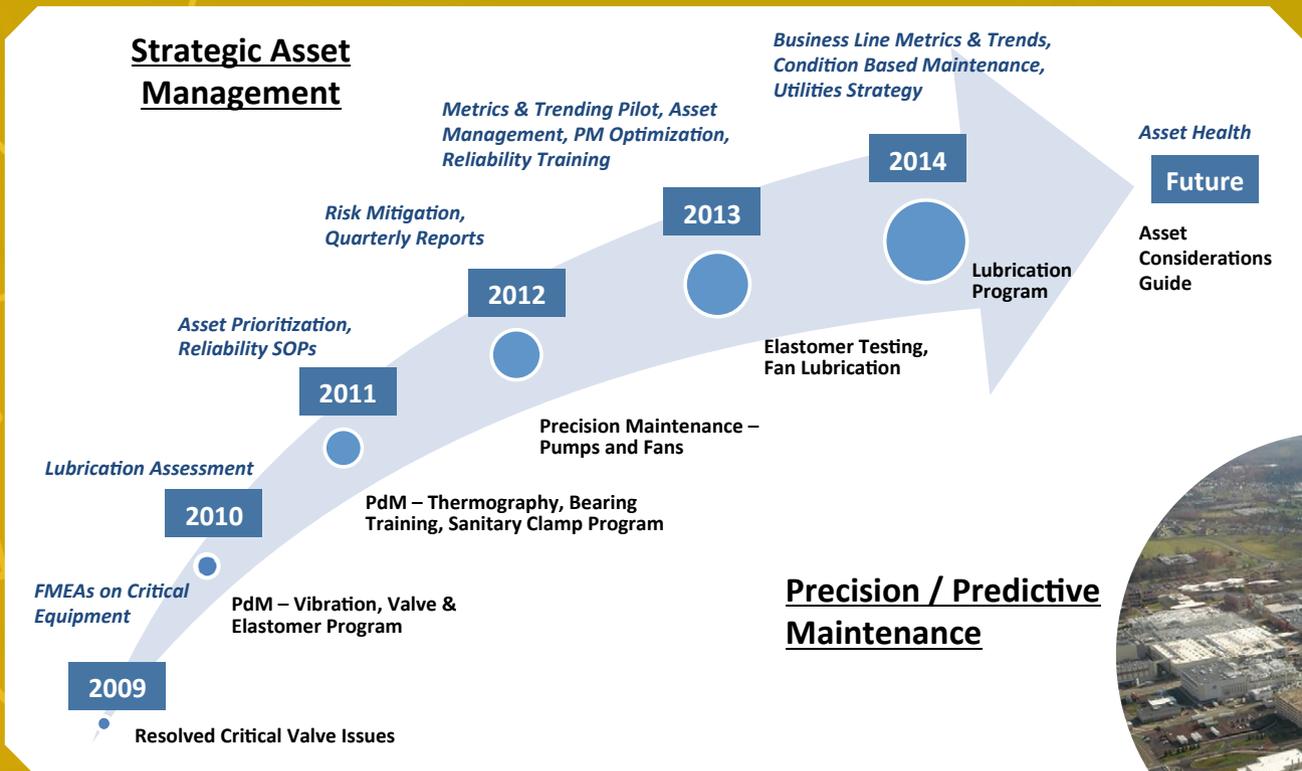
Merck & Co., Inc., West Point's Journey

The Approach

This article presents Merck & Co., Inc.'s, West Point journey in implementing an asset management and reliability strategy, including initiatives in various stages of completion. It is important to note that at the beginning of the journey, the initiatives were performed in reaction to specific events or immediate needs. However, as time progressed, the thought process evolved into supporting a proactive, holistic vision of reliability and, ultimately, asset management.

These initiatives support management of its physical asset portfolio throughout the lifecycle and are in alignment with Merck & Co., Inc.'s goal of assuring supply targets are met with the highest degree of regulatory compliance:

1. **Prioritization** of assets was performed based on their failure probability, coupled with their impact to compliance, supply, strategy and budget.
2. **Risk control strategies** were developed to mitigate or eliminate identified risk, considering continuity, redundancy and contingency.
3. **Predictive maintenance** technology use was expanded to identify risks prior to failure.
4. **Precision maintenance** programs were standardized to help assure lean, "right the first time" execution.
5. **Utility strategies** were developed whereby target conditions were established, gaps assessed and improvements prioritized.
6. **Asset health** was determined by comparing actual key indicators to targets and addressing gaps.
7. **Asset management playbook** was created and adopted, in line with ISO55000, to guide the site's overall asset management plan.
8. **Metrics, trending and reporting** processes were developed to reflect the new initiatives, drive continuous improvement and confirm results.



Prioritization

Prioritization is the foundational methodology that West Point deploys to establish equipment criticality. This process was developed using a continuous improvement methodology that would be implemented during facilitation.

A criterion was established by a team comprised of operations and reliability engineering personnel. The criterion considered the impact to the value stream by determining failure probability and evaluating the risk of a failure to Merck & Co., Inc's four priorities: compliance, supply, strategy and budget. This criterion was then used to create a risk matrix to prioritize assets and actions within the lines of business.

Prioritization is a team-based initiative, whereby members from operations, technology, maintenance and reliability evaluate assets using a structured process. The team evaluates each asset as follows:

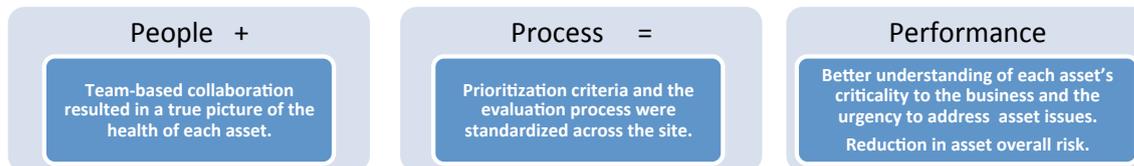
1. Identify issues or improvements based on downtime, deviations and corrective maintenance.
2. Determine actions to address issues or improvements, including risk control strategies.
3. Prioritize assets according to the specified criteria.

Continuity, redundancy and contingency are considered part of this activity. A single point accountable person and due dates are assigned to each action. Complex actions are given tracking numbers to be vetted through the portfolio and capital planning processes to track and update through implementation. Operations risk profiles are then developed and communicated.

The prioritization process is updated annually, but the status of actions is monitored quarterly to understand and communicate progress.



Impact Assessment					
Failure Probability	Probability of equipment having a failure based upon historical events. [NOTE: Failure = Inability to perform designed function]				
Compliance	If asset fails, impact on GMP compliance, product quality, environmental compliance, personnel safety.				
Supply	If asset fails, impact on the ability to meet supply requirements, considering product impact, discards and/or critical path production time lost.				
Strategy	Determination of Asset Obsolescence				
Budget	If asset fails, impact to Profit Plan considering cost impact of a failure (e.g. discards or lost transfers) and savings benefits due to improvements.				
Impact Scores					
Multiplication Factor	Failure Probability [% per lot / run]	Compliance [Impact of a single failure]	Supply [Impact of a single failure]	Strategy	Budget [Impact of a single failure]
1	N/A	4	3	2	1
2	Insignificant ≤ LOW	None ≤ LOW	None ≤ LOW	Not Obsolete	None ≤ LOW
3	LOW < Failure Rate ≤ MEDIUM	LOW < Impact ≤ MEDIUM	LOW < Impact ≤ MEDIUM	Obsolete in 5 years	LOW < Impact ≤ MEDIUM
4	MEDIUM < Failure Rate ≤ HIGH	MEDIUM < Impact ≤ HIGH	MEDIUM < Impact ≤ HIGH		MEDIUM < Impact ≤ HIGH
5	> HIGH	> HIGH	> HIGH	Obsolete	> HIGH
Risk Level					
Failure Probability x [Compliance x 4 + Supply x 3 + Strategy x 2 + Profit Plan x 1]					
	Total Score		Risk Level		
	Min	Max	Symbol	Description	
	10	99	L	Low	
	100	129	M	Medium	
	130	250	H	High	
<i>For illustrative purposes only. Criteria actually more granular.</i>					



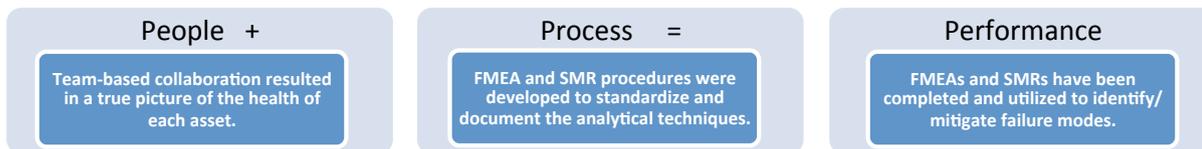
Risk Control Strategies

A risk control strategy is a means to understand asset risks and then develop actions to mitigate those risks. Risk control strategies were developed from information derived from failure mode and effects analysis (FMEA) and simplified maintenance reviews (SMR). FMEA is a team-based, structured way of assessing risk through identification of failure modes and reducing the chance of failures through development of actions to control the risk, such as preventive maintenance (PM) activities. The FMEA process is based on the International Electrotechnical Commission's IEC 60812: Analysis techniques for system reliability – Procedure for failure mode and effects analysis. The SMR was developed internally and is a team-based, structured way of creating a risk control strategy based on a review of vendor recommendations and asset history.

Both contain the following:

1. Gap analysis;
2. Maintenance strategy;
3. Preventive maintenance and job plans;
4. Replacement spare part identification;
5. Spare parts availability.

FMEAs have been completed, with actions implemented for many key assets, including autoclaves, controlled temperature units (CTUs) and inspection machines. SMRs have been completed on numerous processing skids. FMEAs or SMRs are now developed when identified through the prioritization process.

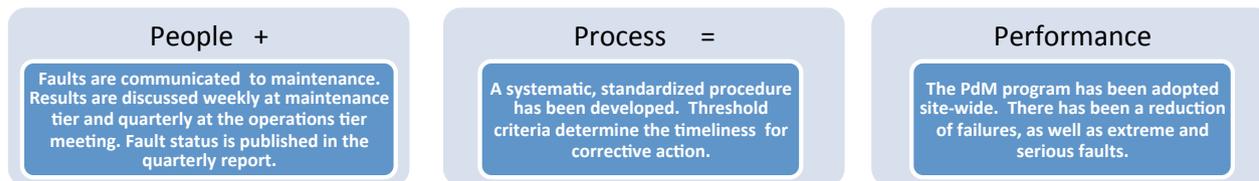


Predictive Maintenance

The predictive maintenance (PdM) program was initiated and currently consists of vibration analysis and thermography. Over 1,000 assets are currently contained in a vibration route and over 3,000 assets are covered by thermography. The predictive maintenance faults are categorized as extreme, serious, moderate, or slight. These categories are tied to the National Electrical Testing Association's (NETA's) maintenance testing specifications for thermography and to the Naval Sea Systems Command's (NAVSEA's) technical specification S9073-AX-SPN-010/MVA for vibration. These categories then define the urgency of the actions needed to correct the faults. All corrective actions resulting from the PdM program are entered and tracked within the work order system or computerized maintenance management system (CMMS). The action status is tracked closely with overdue repairs discussed weekly at the maintenance tier and communicated at the operations tier meeting.

Areas of Business	Total	Extreme	Serious	Moderate	Slight	Extreme & Serious Repairs Overdue
A	321	0	4	25	64	0
B	201	0	3	16	39	0
C	66	0	0	9	21	0
D	41	0	3	2	12	0
E	141	0	6	5	42	0
F	268	0	0	17	38	0
TOTALS	1038	0	16	74	216	0

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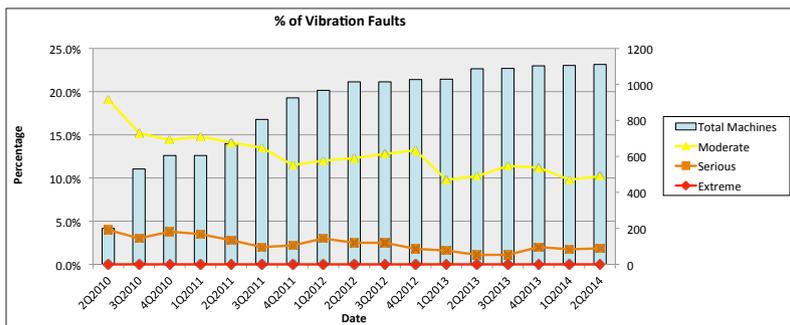


Precision Maintenance

Predictive technology results, in conjunction with input from mechanics, indicated that although maintenance was adequately performed, there was an opportunity to optimize certain programs. As a result, based on potential impacts to compliance and supply, the following core maintenance programs were standardized, proceduralized and systematically rolled out with training and/or communications:

- **Lubrication:** Includes types, quantities, frequencies and technology by equipment.
- **Fan maintenance:** Includes belt and sheave alignments and shaft runout. This has been shown to significantly reduce fan performance issues.
- **Elastomers:** Includes specific preventative maintenance and single use requirements.
- **Valves:** Includes rebuild requirements, preventive maintenance, post maintenance testing and parts listings.

- **Sanitary clamps:** Includes material requirements, installation and assembly criteria.
- **Pump alignments:** Includes job plans for performing the task.



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Utility Strategies

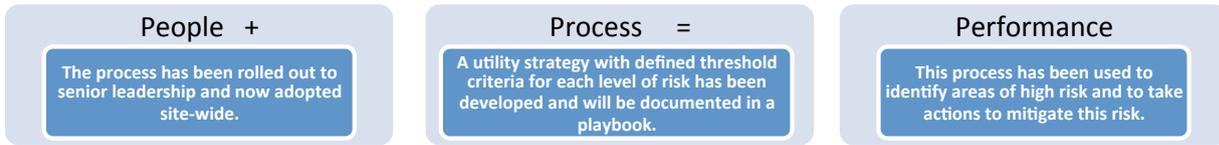
A utility strategy was developed to understand utility risk and opportunity to the process and, ultimately, to product compliance, supply and budget. Continuity, redundancy, contingency and impact minimization criteria were developed and each utility in each building was assessed against this criteria. Gaps were determined and actions to close gaps were identified, planned and are in various stages of implementation.

Using electrical reliability as an illustration, examples of scoring criteria include:

- **Continuity:** UPS systems for critical controls/monitoring;
- **Redundancy:** Double ended substations with automatic transfer;
- **Impact minimization:** Medium voltage cascaded substations;
- **Contingency:** Electrical contingency procedures.

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	ELECTRICAL	CHILLED WATER	PLANT STEAM	GLYCOL	POTABLE WATER	COMPRESSED AIR	WATER FOR INJECTION	HVAC BAS	Score	Risk
CONTINUITY	3.71	3.71	4.00	4.00	3.89	4.00	4.00	3.72	<2	High
REDUNDANCY	4.00	4.00	4.00	3.25	3.88	4.00	3.67	4.00	2 to 3.99	Medium
MINIMIZE IMPACT	3.36	4.00	4.00	2.81	4.00	4.00	4.00	3.83	4	Low
CONTINGENCY	3.32	2.29	4.00	4.00	4.00	4.00	3.69	3.74		



Asset Health

Asset health determination is the site's method of pulling all pertinent information together to understand the health of an asset in relationship to specific targets. These targets were developed in alignment with the division's four priorities. The optimal asset performs within the targets.

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Priority	Attribute	Ranking Legend		
		Undesirable	Marginal	Acceptable
Supply	Uptime *	<80%	80-89%	90-100%
Compliance	Equipment Deviations	3 or more	1 to 2	0
Strategy	Risk Prioritization Failure Probability	5	4	1 to 3
Compliance	Corrective Maintenance Count	Top 20 Count on site	21-100 Count on site	Not in Top 100 Count on site
Budget	Work Order Man-Hours	Top 20 Count on site	21-100 Count on site	Not in Top 100 Count on site

***Note:** Uptime = Asset available when needed for operation.



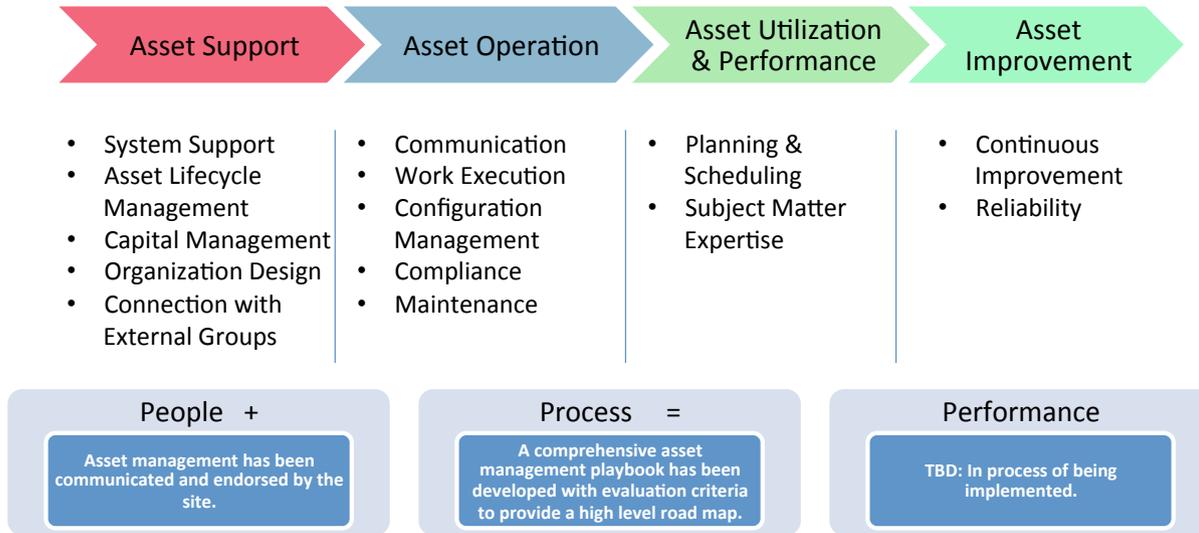
The focus on **people, process and performance** was essential to successful implementation of each initiative and the reliability program

Asset Management Playbook

As the risk-based asset management strategy matured, an overall asset management playbook was created to support the site's five- and 10-year strategic plan and business objectives. This asset management playbook, based on the British Standards Institution's Publicly Available Specification 55 and the draft copy of ISO55001 – Asset management standards, is expected to provide

positive business impact. The asset management playbook is organized with each element fully defined with acceptance criteria.

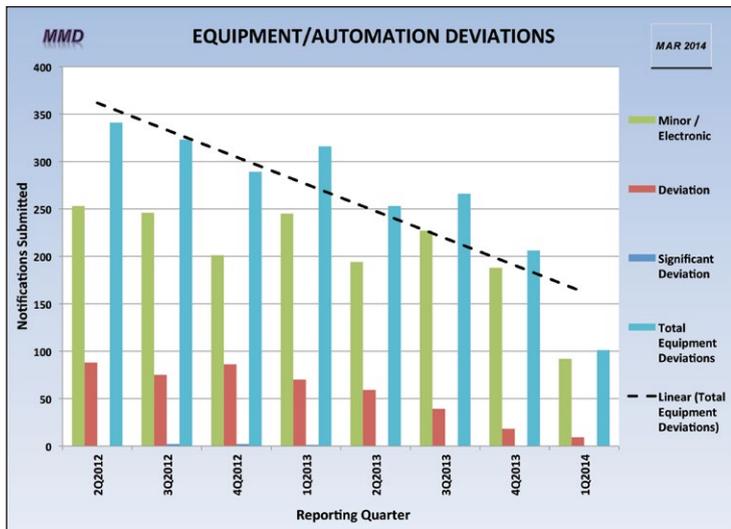
The elements are being addressed as part of the journey, but in various stages of completion. Reliability is far along the journey, but as with all elements, will be continuously improving.



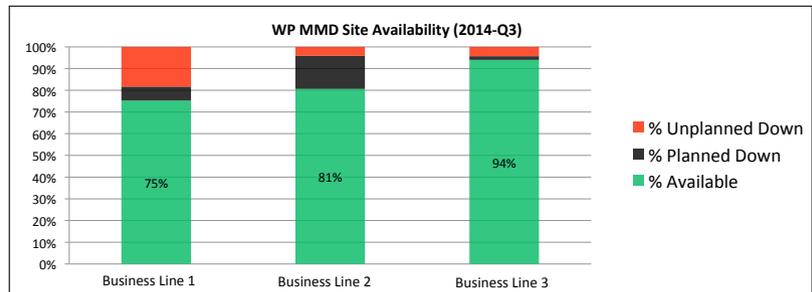
Metrics, Trending and Reporting

Metrics, trending and reporting are actually the tools to tie **people, process and performance** together. The entire purpose of the metrics, trending and reporting process is to be able to communicate progress in a clear, concise and structured manner. The reliability report is presented via e-mail and face-to-face on a quarterly basis. This report has become a key component of the reliability program by providing a tailored report for each line of business (four at the site) and a roll up of the entire site. It includes:

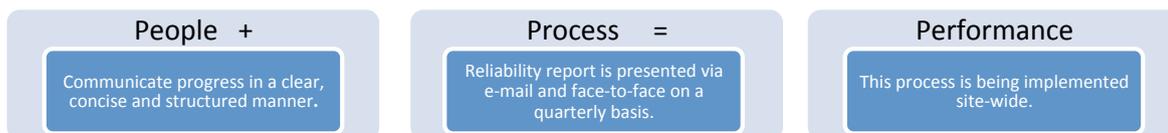
- Prioritization results, including action status;
- Predictive maintenance results (thermography and vibration);
- Availability of key assets;
- Metrics on assets, including man-hours spent, deviations, corrective maintenance, etc.;
- Utility strategies;
- Trends of asset risk, deviations, manpower spent;
- Reliability metrics.



This process is being implemented site-wide.



For illustrative purposes only.



Conclusion and Takeaways

The focus on **people, process and performance** was essential to successful implementation of each initiative and the reliability program in general.

- **People:** Don't underestimate the people component of any initiative. The best of processes will not succeed without proper buy-in.

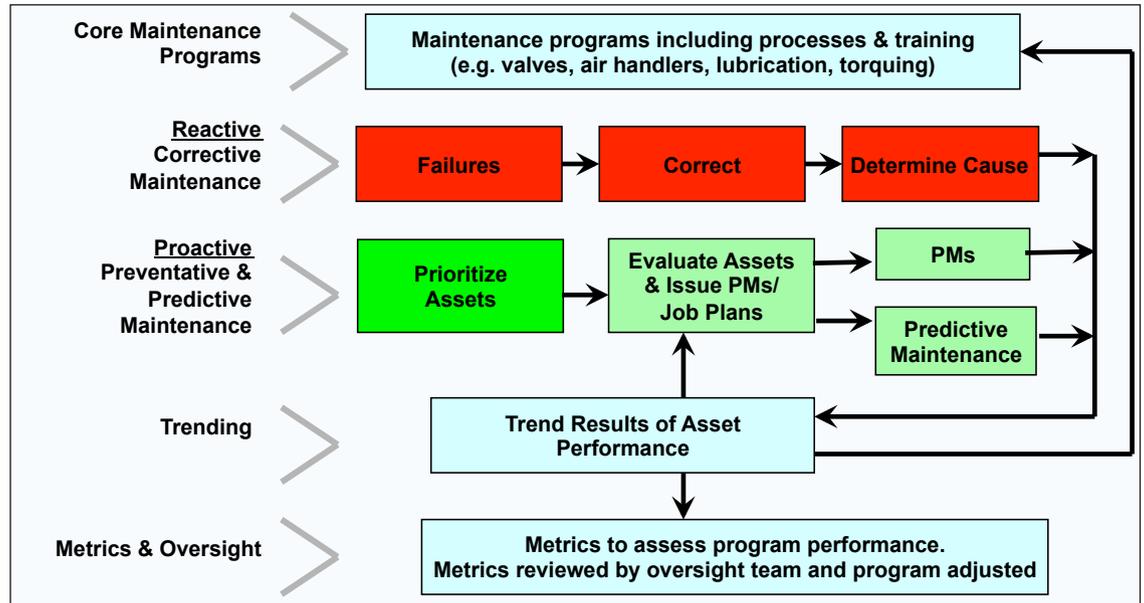
Change Management: This is of the highest priority, therefore, a simple plan, a simple model and continual communication in the language of the audience is critical.

For instance, an initial step to assist change management was to create a simple model to visualize and communicate the actions needed to evolve from a reactive to a proactive culture. This model helped communicate that there was a "bigger picture" and the initiative was part of the plan. Ultimately, this model was incorporated into an even bigger picture – asset management.

Operations Involvement: All proactive enhancements in the area of reliability and asset management would not be possible without a strong partnership with operations (the asset owners). These employees recognize the importance of strong asset management programs and understand it is their role to endorse/sponsor the path forward.

Mechanic Engagement: Input from mechanics/technicians is valued. They truly understand the condition of the asset. Their active involvement is crucial to the health of the equipment and sustaining asset performance.

- **Process:** All initiatives need to be well documented, clear and concise, with standardized practices. Each initiative should have a method of measuring success of the implementation and its effect on the end game, which is improved compliance and supply.
- **Performance:** In order to determine if Merck & Co., Inc., is on the right track of its journey, the areas of deviations, transfers to inventory,



proactive maintenance and total maintenance man-hours are evaluated for their performance over time. The three high impact areas all had similar results: (1) Reduced equipment/automation related deviations, (2) Increased transfers, and (3) Improved ratio of preventive versus corrective maintenance. As expected, maintenance manpower was lagging. In two of three cases, maintenance manpower decreased, but in one case, manpower had increased slightly. This assessment provided three data points, but also substantiated the need for robust metrics.

In conclusion, continuing to mature the asset management program at West Point and leveraging action oriented, risk-based asset management methodology will enable a culture to realize the benefits of improved asset health, including:

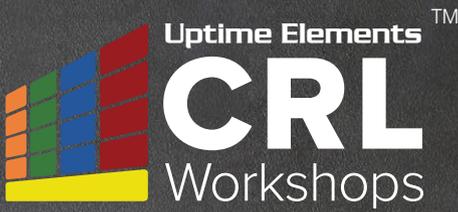
- Reliable supply;
- Greater utilization of installed capacity;
- Greater personal and environmental safety performance;
- Lower energy costs;
- Reduced deviations, providing improved current good manufacturing practices (cGMP) compliance.



Mike Rose is an Associate Director - Engineering at Merck's Manufacturing Division (MMD), West Point Facility. He is responsible for the development and execution of the site's Reliability Centered Maintenance (RCM) program and supervises a team responsible for the site's asset management and risk mitigation program. www.merck.com



Chris Gould is an Executive Director at Merck's Manufacturing Division (MMD), West Point Facility. Chris and his team are responsible for the site's reliability and capital programs as well as engineering and project support for critical GMP utility systems. They are also facilitating the site's transformation to a proactive asset management program tied to the asset's life cycle. www.merck.com

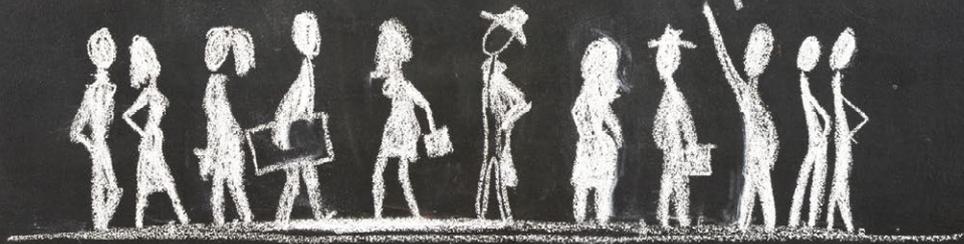


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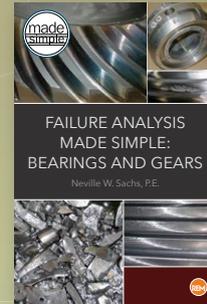
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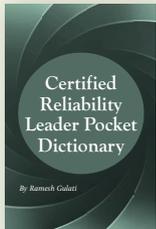
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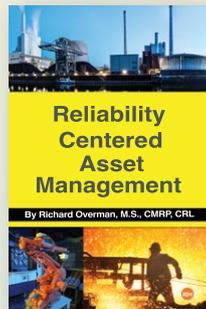
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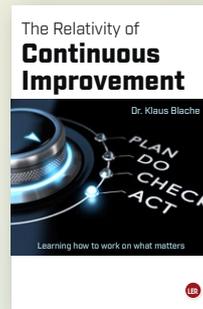
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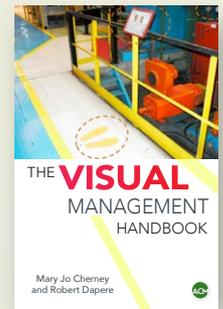
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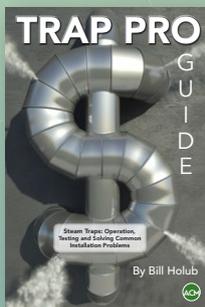


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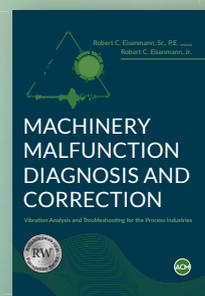


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