Inspired Blended Learning™ Case Study

Formulation/Filling/Lyophilisation Reliability Improvement Project

Version 1.0

Where Education Meets Application.

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INSPIRED BLENDED LEARNING™ CASE STUDY

Company X vaccines are manufactured within the premises on a campaign basis. The production of trivalent measles-mumps-rubella (MMR) consists of formulation, filling and lyophilisation (FFL). The focus of my *inspired* Blended Learning program is to develop the reliability engineering skills to guide the FFL value stream through the reliability improvement initiative, specifically on the filling line, while developing the internal skills necessary to sustain the gains.

Below is the Rapid Improvement Process Charter that outlines the direction and the intended benefits gained.

R5 apid Improvement Process Charter

Business Opportunity

Achieve and sustain optimum availability, optimum operating condition, optimum equipment life, and minimum spare parts inventory by implementing solutions aimed at increasing production capacity, OEE and reducing operating costs on the Bosch filling line in FFL.

Strategic Objectives:

- Identify failures and develop action plans to eliminate
- Increase OEE (TBD)
- Reduce operating costs (TBD)

Benefit: $250,000

Target Condition

- PM task lists consistently and effectively identifies defects and potential failures.
- PdM technologies added to PM task list to identify critical failure modes.
- RCM or FMEA performed on entire Fill line are periodically reviewed for effectiveness
- No startup delays due to extended shutdowns and following scheduled/unscheduled maintenance.
- Sustaining an OEE above (TBD%)
- Classification of spare parts

Current Condition

Threats:

- Operator time away from production line
- Maintenance Planning is a role done by either the supervisors or the technicians/EMT's
- PMs aren't based on failure modes

Proposed Action Plan

Asset Health — **Improve Maintenance Effectiveness**

- Analyze Asset Criticality
- Leverage and evaluate Failure Modes identified from CoE FMEA
- Evaluate maintenance plan and ensure at least 50% of plan is based on FMEA

Work Execution — **Reduce Maintenance Costs**

- Develop Effective Work Procedures
- Evaluate Preventive Maintenance Effectiveness
- Develop BOM and link to PM (Material Kitting)

Reliability Engineering — **Increase Bosch Line Performance**

- Resolve Critical Failures to Root Cause
- Establish OEE targets for Bosch Filling line in FFL
- Perform Life Cycle Cost Analysis
- Implement the use of "FRACAS" to track equipment related failures

STRATEGIC ALIGNMENT OF OPERATIONAL RELIABILITY

The business drivers and the strategic objective that led to a focus on reliability were to achieve and sustain optimum availability, optimum equipment life, and minimize spare parts inventory by implementing solutions aimed at increasing Overall Equipment Effectiveness (OEE), reducing operating costs, identify failures and developing action plans to eliminate deviations within the filling process. Our leadership determined that this is one of our critical strategies, the "What We Need to Do First".

The primary area of focus for reliability improvement is the XXXX Filling Line in B46. Some of the cultural risks identified during implementation from shop floor electro-mechanical technicians (EMT's) and operators were "this is the way we always done things" and "why are you taking work away from us". Timing and execution of proposed actions was another challenge due to ongoing production schedules and the perception of a workforce that was already understaffed and overworked.

Improvement Process

The scope for my iBL™ reliability project began immediately, understanding where we are before we can determine which direction to go was the beginning of this reliability journey.

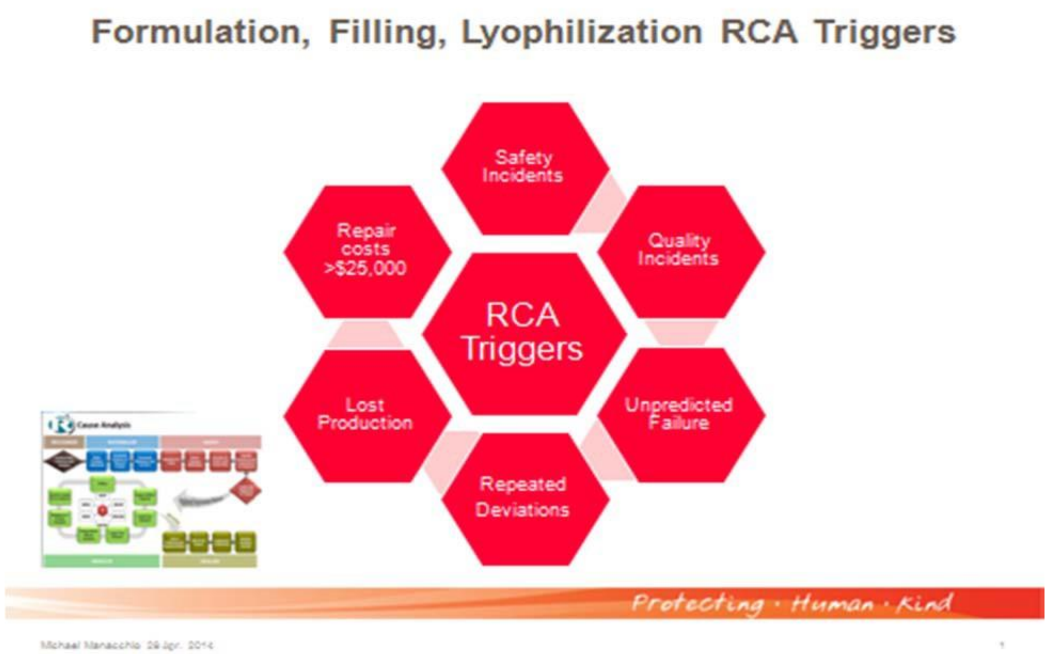
As I started to complete my on-line learning modules and associated skill application activities, I began to identify which tools would best fit the needs of our business and help in the improvement process. I needed to determine the relative ranking of assets in our system so I performed a Criticality Analysis to determine which assets I should focus on first.

				Operations	Safety			Design	Maintenance		MRO	
CMMS No.	System-level Asset Name	Machine-level Asset Name	Asset Description	Operational Severity	Personal Injury	Fire/Explosion	Safety While Maint.	Single Point Failure	Maintainability	Failure Rate	Spares Lead Time	Asset Criticality Score
142795	Formulation/Filling/Lyophilization		Infeed Table	100	24	24	24	60	25	40	20	317
142795	Formulation/Filling/Lyophilization		Infeed conveying scroll	100	24	24	24	80	25	100	20	397
142795	Formulation/Filling/Lyophilization		Vial Washer	100	48	24	24	80	25	40	20	361
142793	Formulation/Filling/Lyophilization		Sterilizer Tunnel	100	36	48	24	100	25	80	20	433
142794	Formulation/Filling/Lyophilization		Filling Machine	100	12	12	0	100	25	100	20	369
193707	Formulation/Filling/Lyophilization		Load/Unload Accumulation Table	100	36	24	24	80	25	100	20	409
193711	Formulation/Filling/Lyophilization		Transfer Cart	100	48	36	24	100	25	40	20	393
144548	Formulation/Filling/Lyophilization		Capping Machine	100	24	36	24	100	25	40	20	369
193709	Formulation/Filling/Lyophilization		Inspection Machine	100	24	24	24	40	25	20	20	277

In collaboration with the value stream process engineer, operations manager, quality manager, value stream leader, reliability engineer and maintenance manager, a decision was made to focus reliability efforts on the following assets;

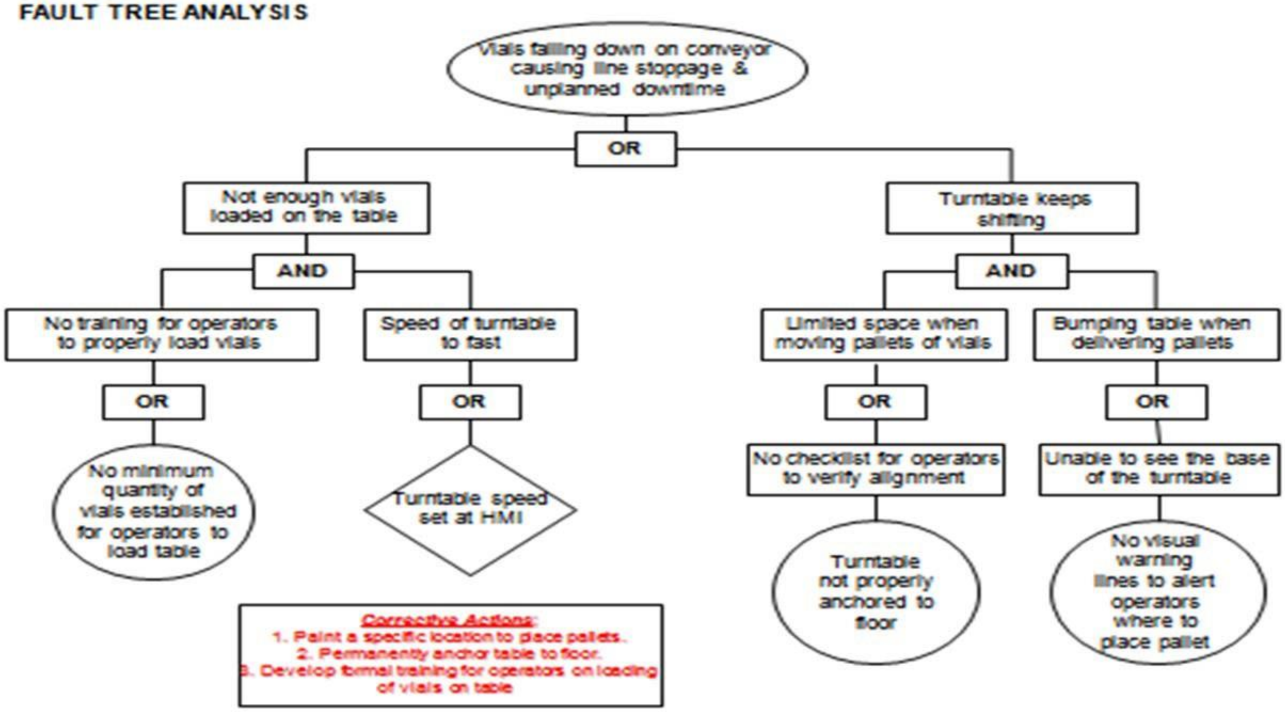
- In-feed Table
- In-feed Conveyor Scroll
- Vial Washer
- Sterilizer Tunnel
- Filling Machine

The team also developed "Triggers" that would define when to perform formal Root Cause Analysis (RCA) so that the proper resources could be allocated.



I began reviewing the AAR's from each commercial batch that was completed to look for equipment failures or issues that would impact our OEE target of 42.2% as of Jan. 2014. I quickly found opportunities to deploy iBL™ learning's, for example, vials kept falling down on in-feed table causing line stoppage and unplanned downtime of 135 minutes. A fault tree analysis was performed to determine root causes and identified corrective actions needed to eliminate failures from occurring again. A simple tool used in collaboration with the operators and EMT's easily identified how to prevent this failure from reoccurring, and was the start of developing a culture of reliability on the shop floor because of their involvement with this problem solving method.

FAULT TREE ANALYSIS



Another issue causing 121.4 minutes of lost production and unpredicted failures was guide rail adjustments needed following startup. A "5 Why's" problem solving template was given to the operators and EMT's to identify root causes and determine the appropriate corrective actions. The operators and EMT's identified the third shift crew would loosen the guide rails to perform a routine cleaning of the line between each commercial batch and re-tighten the guide rails to where they thought they should be. The conclusion from the 5 Why exercise was that there are no work procedures on the proper set up, adjustment or inspection of guide rails following cleaning of the lines or maintenance. An iBL™ work procedure tool was deployed to develop standard ways of working, and eliminated this failure from reoccurring.

Another area I began to focus on was the preventative maintenance program. Using the iBL™ single minute exchange of die (SMED) task analysis, I evaluated existing maintenance procedures and removed non-value added activities to improve standard work, and reduce 65 minutes of labor utilization, for 50 HVAC assets throughout the site. This is an example of how the iBL™ program is expanding beyond my focus line so the benefits are shared across all value streams.

Single Minute Exchange of Die (SMED)
TASK ANALYSIS

Types of Improvement

1	N/A - Remove Activity
2	Convert to External Activity As-Is
3	Refine Activity and Convert to External
4	Refine Activity
5	Mark for Future Continuous Improvement

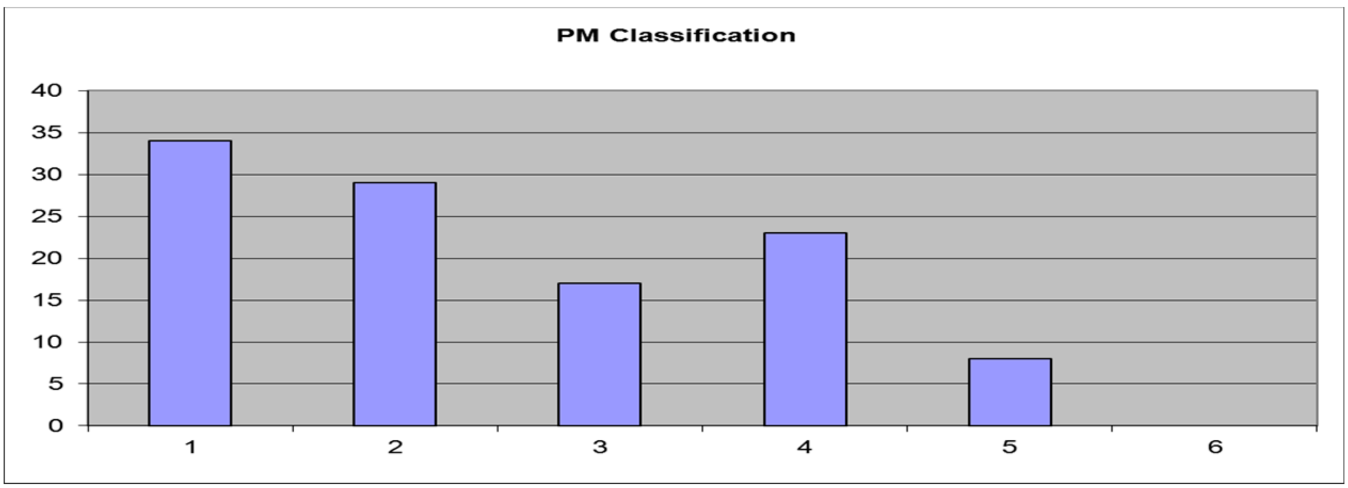
No.	Activity Start Time (minutes)	Activity End Time (minutes)	Description of Activity	Activity Breakdown (minutes)			Notes:	Type of Improvement					Proposed Solution	Estimated Time Reduction (minutes)
				Walking	Waiting	Working		1	2	3	4	5		
1	0	12	Lock out Tag out	2	0	10								2
2	12	31	Replace defective or burnt out lights	16	5	10	Light bulbs in stock room		x				Kit light bulbs	16
3	43	67	Replace belts, check sheaves for wear(>1/32" replace sheaves) perform laser alignment, tension belts using frequency meter(deflection force in Lbs.=17.3/ HZ.=19.2)	10	5	52	Belts were not staged, picked up belts, laser alignment & frequency meter on the way to job		x				Stage belts near AHU prior to change out	15
4	110	34	Replace filters	8	0	26	Filters were delivered to mechanical room			x			Stage filters near AHU prior to change out	8
5	144	5	Perform IR scan of elctrical components	0	0	5	Picked up TI camera on the way to job							
6	149	8	Check fan assembly and motor, tighten mounting hardware	0	0	8	No torque values					x	Add torque ratings for fastners	
7	157	18	Lubricate motor and fan bearings	0	0	18	Over/under greasing					x	Greasing fan & motor bearings can be improved by using the ultra sonic grease caddy	
8	175	15	Check fan wheel, shaft and scroll for rust	4	0	15	Fan wheel and shaft have a polymer coating to prevent rust	x					Remove task	4
9	190	16	Inspect/clean air handler coils	20	5	16	Needed to pick up pressure washer from maintenance shop		x				Stage pressure washer and hose near AHU prior to inspection	20
10	206	12	Inspect/clean dampers, actuators, linkage for proper operation	0	0	12			x					

Total Job Duration: 218

Total Time Reduction: 65

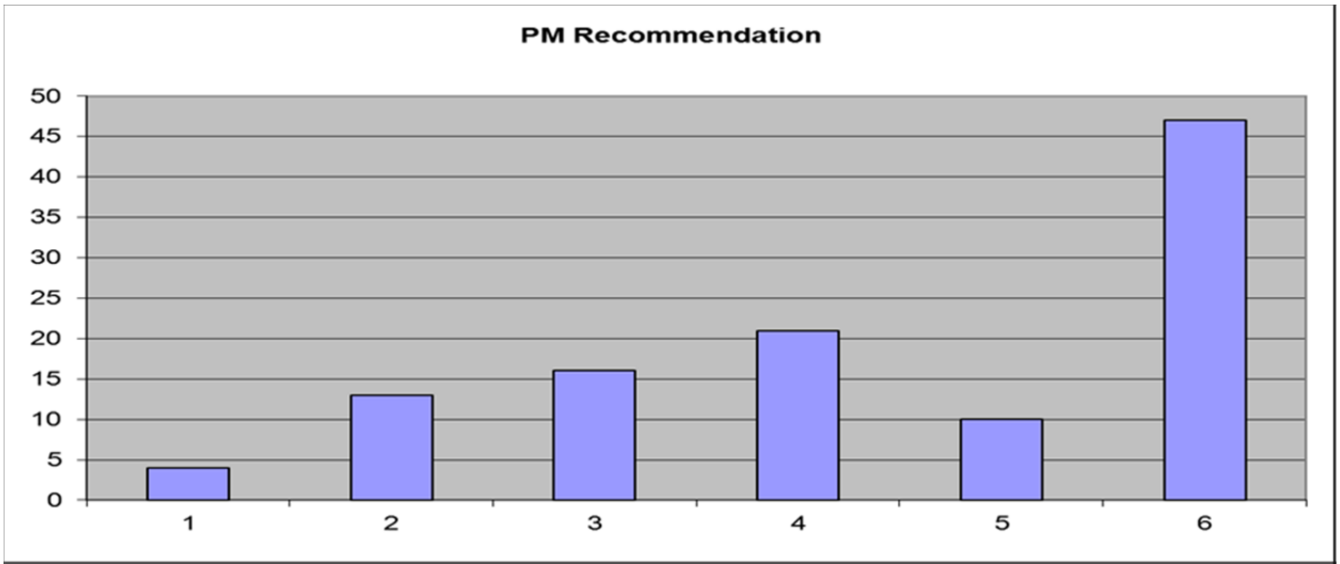
Evaluating the effectiveness of our existing preventative maintenance (PM) program on our focus line also allowed me to determine if the PM's were designed properly, if there are opportunities to add predictive/condition based tasks, or eliminate non-value adding tasks.

BEFORE



34	29	17	23	8	0
Asset Care	Inspection	Quantitative PM	Time Based Replacement/ Reconditioning	Regulatory	Administrative & Safety
1	**2**	**3**	**4**	**5**	**6**

AFTER



4	13	16	21	10	47
Non-Value Added Reassign	Non-Value Added Reassign: Lubrication Route	Non-Value Added Reassign: Operator Care	Replace with PdM / NDT	Reengineer	No Modifications Necessary
1	2	3	4	5	6
	30%		19%	9%	42%

RESULTS

The impact the iBL™ program has had on Company X has been very successful. Our OEE target increased from 42.2% to 45.9%, which is roughly a revenue increase for each commercial batch of $188,235. The results from implementing the preventive maintenance evaluation (PME) classification, SMED and RCA techniques gained an additional $74,880, bringing the year to date total benefit of this iBL™ project to $263,115. Our organization has seen the benefits of the reliability initiative, and is now embracing the program and has become more involved and empowered to engage in these types of activities throughout the plant. These benefits will continue to exceed the business case throughout the year as we produce commercial batches.

SUSTAINABILITY

In order to sustain the gains already realized by iBL™, and to provide better long-term focus on operational and reliability performance within our organization, we have re-organized the value stream by embedding an FFL Engineering team which consists of process engineers, a reliability engineer, and an automation engineer who will be responsible for all internal FFL equipment maintenance and improvement. The priority will be to deliver on specific reliability targets defined for 6 month, 12 month and 18 month performance improvement intervals.

LEARNING FROM THIS JOURNEY

My advice for organizations that are beginning their iBL™ reliability journey is to have the right people in place that can drive this program. It takes passionate people that are dedicated to look at the big picture, analyze the data and begin the process of building a solid foundation in which to continuously make improvements. You must work strongly on embedding a reliability culture that is supported by your leadership team.

A final quote from Walt Disney- "You can design and create, and build the most wonderful place in the world, but it takes people to make the dream a reality."

