Design of Human Error Prevention Program for Manufacturing Processes

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Abstract *— During the 2012 Quality Management Review, Stryker Corporation identified that 20% of the company wide Product Field Actions were due to human factor related incidents. The goal of this project was to develop a Human Error Prevention Program that could be deployed in any manufacturing facility across the world. It incorporated the development, design and testing of a series of tools and methodologies to be incorporated within this program. These tools and methodologies would be tested in two pilot sites; Cork Ireland and Mahwah, United States; with the purpose of ensuring the results of the program's deployment was transferrable to any manufacturing site. This project led to an average of 41% of improvement of key performance business process indicators. This project has been developed under the Lean Plan-Do-Check-Act (PDCA) Cycle methodology, in order to identify real systematic root causes and enable the company to reduce human factors incidents.*

Key Terms *— Lean Plan-Do-Check-Act (PDCA) Cycle Methodology, Product Field Actions.*

PROJECT STATEMENT

"Workplaces and organizations are easier to manage than the minds of individual workers. You cannot change the human condition, but you can change the conditions under which people work."

Dr. James Reason

This project focuses on developing an effective, sustainable human error program, that can be deployed among any demographic and any manufacturing process. Throughout this project a series of tools and methodologies were identified, developed and tested in order to meet this goal.

Research Description

This project has been outlined with the purpose of analyzing, developing and testing a series of human error prevention tools. Some of the tools assessed for human factors effectiveness; have been designed by other entities with alternate purposes. These purposes have been from increase production output to reduction of lead times as well. The tools selected for assessment; as part of this research project, will be assessed for its impact on business key performance indicators tied to human factors. Human factors can be linked directly to performance of business metrics; such as product field actions, yield, rework, etc. The assessment of these key performance indicators have the overall goal of being incorporated within an overarching program. The intent of this program is for it to be able to be deployed within any manufacturing site, and reduce the human error occurrences within such processes. The creation of this project would b designed, in addition, with the goal of providing such flexibility that it can be applied to any process in any country. As part of the research strategy, two pilot sites would be used to develop and test such tools; Cork Ireland and Mahwah, United States. The results of these pilot sites would provide objective data towards selecting which tools to incorporate within the overarching program. Tools that result in a lack of positive impact, during the pilot phases, would be eliminated from the program content and therefore will not be incorporated within the final version of the program.

Research Objectives

The objective of this research is to develop a sustainable Human Error Prevention Program which will be relevant to all demographics and

manufacturing sites within the organization. This program should take into consideration the following main factors: Global Cultural Awareness and establishment of a Continuous Improvement Culture among the program's users and clients. The Human Error Program would include a series of documents which will include the details of implementing the program and its tools and methodologies. These documents will have the overall intention of providing the details of the program to its associates leading and executing the implementation of the program within their sites.

Research Contributions

Stryker as an organization is dedicated to improving the healthcare industry value stream, from the main company customers, the orthopedic surgeons to their clients, the patients who receive the Stryker product or service. Deploying a Human Error Prevention Program will provide effective tools to the operational/manufacturing sites. These tools will enable an effective implementation of improvements within the site's processes; that will result in an overall improved product quality. Improving the company's product quality will impact all aspects of the business. Some examples are: increased sales, increase market shares, increase stock value, etc. This program will focus on improving current manufacturing processes and therefore it will render in a consistent delivery of a high quality product to their clients and improved client and customer retention. The program developed as part of this research process will be deployed across all Stryker manufacturing sites across the globe; ranging from sites in the United States, Germany, Ireland, Puerto Rico, Japan, Switzerland and France. It will enable Stryker to continuously improve to make healthcare better, as stated in their Quality Policy.

BACKGROUND

Human Error is defined as "an inappropriate action or response by a person resulting in an undesired outcome". Human error related workplace error rates average from 70% to 96%. Therefore, focusing resources and attention towards this item, is a critical business decision. The typical approach to human error consists of focusing on the person closest to the event, identifying the wrong outcome, identifying steps in procedures that were executed incorrectly and resulting in a re-train or disciplinary action towards the involved associate.

However, one must not identify "human error" as the direct and real root cause in the event of an error. The human error is simply the last domino in a long line of affecting variables. When investigating a human error, the root causes may be upward in the event chain. When the focus is on the person; this leads to not preventing the reoccurrence in the long term. When re-training is executed; the investigator assumes the issue or the event were a result of a knowledge gap during the execution. When disciplinary actions are executed without focusing on process improvement; it is assumed that the person could have prevented the error it they wanted to do so. Therefore, creating a **Human Error Cycle**:

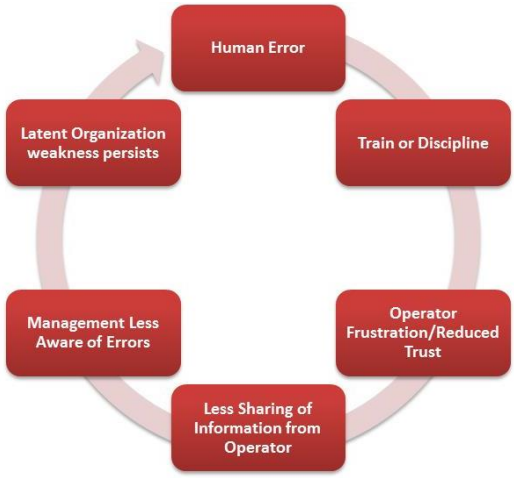

Figure 1
Human Error Cycle

There are two (2) main principles, when developing a sustainable and effective human error prevention program.

1. Human Error is not a root cause an organization should focus solely. It must learn to understand, identify and minimize the

factors that are contributing to such errors within the workplace

2. Learn to identify what controllable factors are present within an area or process that lead up to the execution of an error.

As an organization; it cannot intent to control the personal issues that its associates can have as part of their day to day lives. As humans; there is much that occupies and concerns our thoughts. Family, kids, careers, bills, etc; they all occupy and concern the workforce significantly. Parting from the premise that employees do not come to work to perform an error, they come with the greatest intent of executing an excellent task and providing an amazing product for the customers. Therefore; when a company chooses to focus on factors, as personal issues, that the organization cannot control, will result in an ineffective approach towards process improvement and positive impact on business key performance indicators. However, when a company focuses on controllable factors, an organization will be much more successful in its journey towards process improvement; when it comes to human related errors. Controllable factors refer to procedures, tools and fixtures, product assembly design, work area layout, etc.

METHODOLOGY

The project methodology to be used in this research is the PDCA Cycle derived from the Lean methodology.

Figure 2
PDCA Cycle

PDCA is an acronym for the four (4) stages of this cycle: Plan, Do, Check and Act. Which in turn encompass the following elements:

- **PLAN** – This phase focuses on establishing the objectives and processes necessary to deliver results in accordance with the expected output (the target or goals). During this phase the problem statement is defined, the process is understood and the root cause assessment is performed and verified for feasibility.
- **DO** – This phase focuses defining an action plan based on the root causes identified and monitoring its progress and completion. The action plan defined in this stage is monitored against completion by reviewing its commencement date, proposed closure date and its actual closure date. This data can later be assessed by a project management office in order to identify how robust is the project planning process. After implementation of actions; process data (output) is collected as part of this phase, which will later on be assessed for actions impact in the next phase.
- **CHECK** – Actual results measured and gathered during the DO phase, are assessed and compared against actual Goal established. Study the actual results and identify if any deviations from the goal have been performed.
- **ACT** – This phase focuses on identifying significant differences between actual and planned results. Based on this assessment, identify any corrective, systematic action that may be needed to meet established goal. This phase serves as closure for the PDCA cycle process.

RESULTS AND DISCUSSION

This section presents the problem analysis and improvement results using the Lean Problem Solving Methodology: PDCA Cycle.

Plan Phase

- Problem Definition: 20% of product field actions performed for all manufacturing

facilities were due to human factors within the manufacturing process.

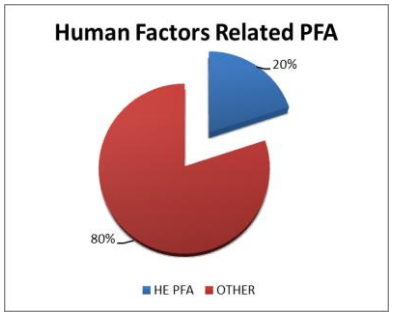

Figure 3
Human Factors Related PFAs for 2012

- Understanding the Process: A project strategy was defined as designing the program based on two pilot sites performance. The data of these two pilot sites would be used to design, develop and test the program's purpose and effect.

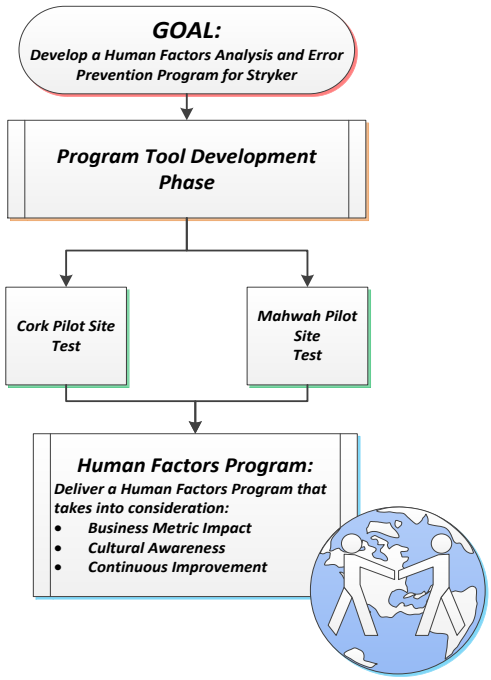

Figure 4
Program Development Strategy

- *Goal Definition:* Develop a Human Factors Analysis and Error Prevention Program for Stryker.
- *Probable Root Cause Analysis:* As a result of the Root Cause assessment performed; 44 probable root causes where identified. These root causes were categorized in the following elements:
  - General Process
  - Manufacturing Process Development
  - Manufacturing Process
  - Manufacturing Procedures
  - Records and Documentations
  - Training
  - Metrics/KPIs/Analytics
  - People/Culture
- *Data Collection:* As part of the Data collection phase; each of the 44 probable root causes were assessed for feasibility. After this assessment; only 40 probable root causes were left as real root causes. These root causes were determined as triggers for improvement systematic actions and input for the program's development.

Do Phase

Within this phase, based on the assessment performed; a specific action schedule was developed and monitored for progress and completion.

- Initial Root Cause Analysis
- Human Factors Science Training
- Development of Tools Rev 1
- Root Cause Analysis Review
- Development of Tools Rev 2
- Pilot Improvement Activities Completion
  - Cork, Ireland
  - Mahwah, United States
- Pilot Verification of Effectiveness Phase
  - 6 months; Cork, Ireland
  - 5 months; Mahwah, United States

The tools developed during this phase are: Human Factors Risk Index, Human Error Investigation Process, Quality Awareness Test, Process Mapping, GMP Assessment, Effective Procedure Design, Effective Form Design, 5S + 1, Visual Workplace, Device Defect Awareness, Little Wins Program, Workstation Design, Workstation Training and Qualification Process, Poke-Yoke, 4Step Cell, and Leader Standard Work.

Figure 5
Tree Diagram based on Root Cause Assessment Performed

PHASE	Initial Root Cause Analysis	Human Factors Science Training	Development of Tools Rev 1	Root Cause Analysis Review	Development of Tools Rev 2	Pilot Improvement Activities	Pilot: Verification of Effectiveness	Final Program Completion
Program Development	Apr-13	Jun-13	May-13	Jun-13	Sep-13	N/A	N/A	Dec-14
Cork, Ireland Pilot	Apr-13	Jun-13	May-13	Jun-13	N/A	Jan-14	Apr-14	N/A
Mahwah, US Pilot	Jun-13	Jul-13	N/A	Aug-13	Sep-13	Aug-14	Dec-14	N/A

Figure 6
Project Major Milestones

Cork Pilot KPIs	Goal	Actual
Human Factors Non Conformance	25% ↓	27% ↓
Human Factors Device History Record Issues	25% ↓	46% ↓
Product Field Actions	0	0
Human Factors Risk Index	20% ↑	50% ↓

Figure 7
Cork Pilot Goal and Results

Check Phase

A Verification of Effectiveness Phase was performed as part of the Check Phase of this project. This Verification of Effectiveness Phase was performed as the revision of key performance indicators to assess the program's impact on current business processes. The key metrics selected were: Human Factors Non Conformance Reports, Human Factors Device History Record Issues, Product Field Actions, and Human Factors Risk Index.

At the end of the verification of effectiveness phase the following results were achieved:

At the documentation of this report, the Mahwah, US Pilot area is currently undergoing Verification of Effectiveness Phase. All key

performance indicators are displaying same impact as the Cork, Ireland Pilot Area.

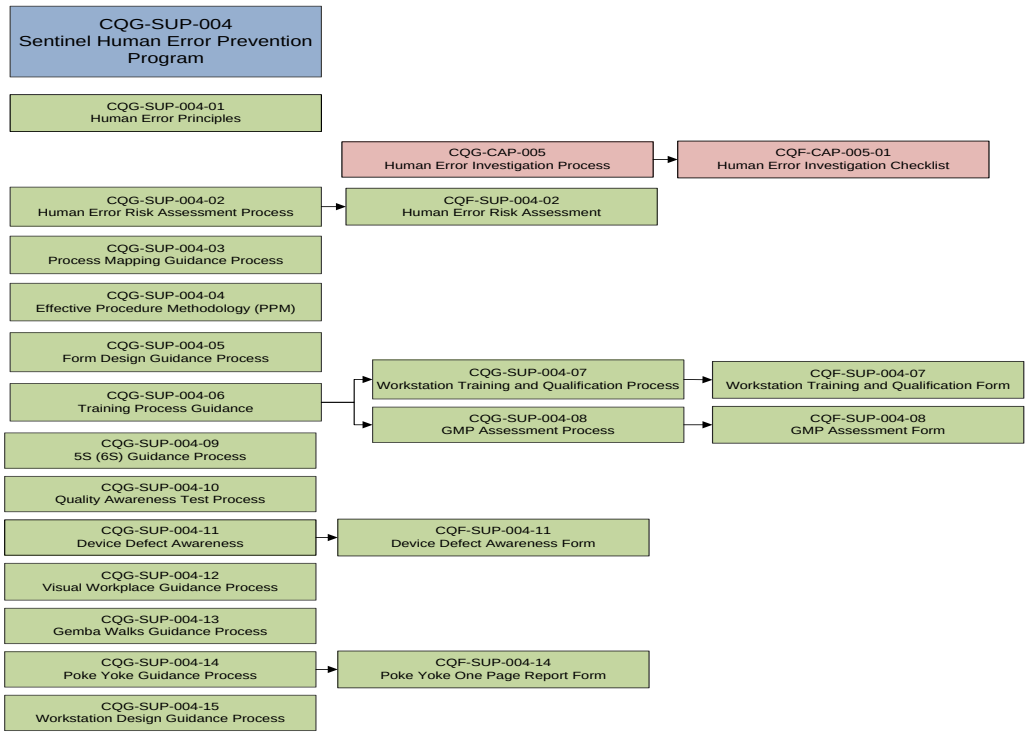

Figure 8

Program Corporate Document Structure

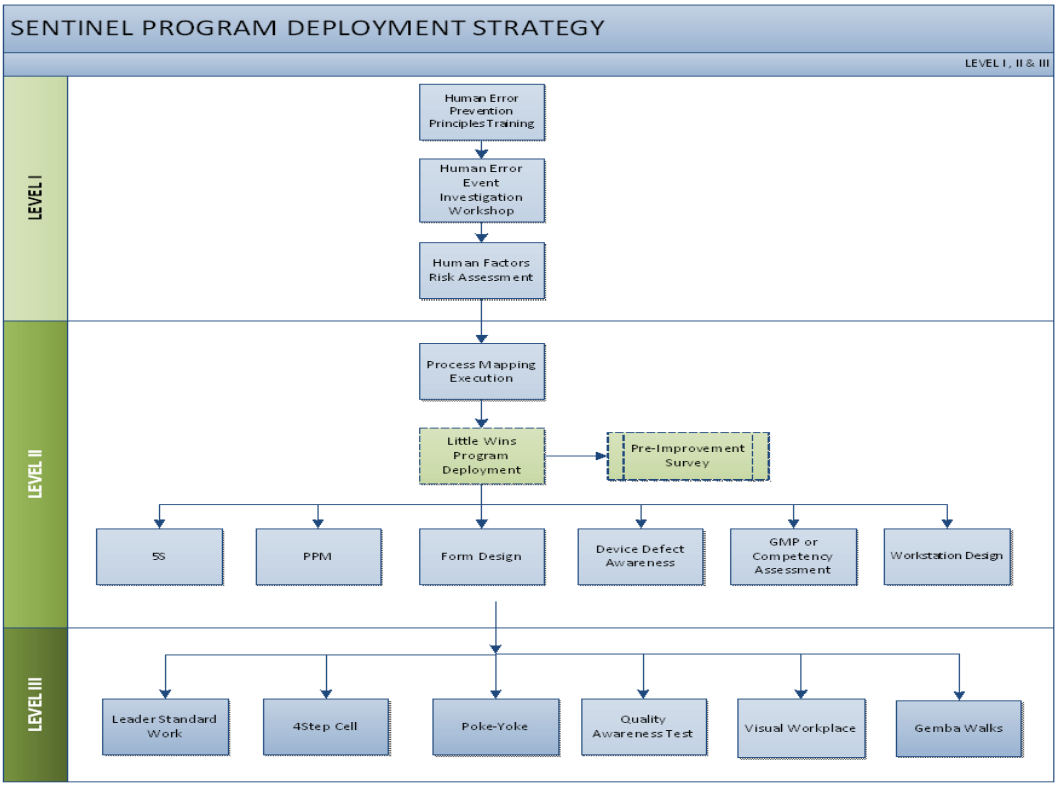

Figure 9

Program Deployment Strategy

Act Phase

As part of the Final Program Completion milestone; a program branding has been created with the purpose to formalize and instill the programs focus, purpose and impact into our sites. In addition, the following elements have been created to ensure program standardization and sustainment:

- Corporate Guidance Procedures
- Program Deployment Strategy
- Program Policy
- Governance Structure

CONCLUSIONS

The PDCA Cycle provides a standard, visual and effective approach for business improvement. Its methodology is easy to understand and apply. By providing a standard visual mechanism to report status and results; it is more likely to gain buy-in and approval from the organization. The PDCA Cycle methodology may be applied to individual technical problems or it may be applied, like in this case; to global overarching projects. This technique facilitated an effective structured methodology towards developing a Human Error Prevention Program.

This program's development process has been proven to become a key organizational strength. It has been developed with the culture of constantly pursuing improvements within the manufacturing processes in order to provide customers with product of the highest quality in a consistent manner; as stipulated by the Stryker Quality Policy.

This research project resulted in a Human Error Program, which provided key business performance indicator's impact on an average of 41% improvement in the overall goals established. In addition to the quantifiable results; an increased employee ownership towards process improvement and increased employee engagement was also observed among the sites that deployed the program throughout the project.

In conclusion, due to these results; this program will be incorporated within the Corporate Quality Document System, as the Human Error Prevention Program; to be used by all sites; with the overall goal of reducing the probability of human error within their process.

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