LEAN AND SAFE MANUFACTURING FOR AN ANTIDEPRESSANT TABLETS COATING PROCESS

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ABSTRACT

The Lean and Safe Manufacturing Process (6S event) was selected for implementation in an antidepressant tablets coating manufacturing process. The coating process was identified due to the utilization of toxic ingredients and hazardous materials during the coating solution preparation and during the coating application. In addition, lost time and productivity were identified in the process. The tool selected to perform a Lean and Safe Manufacturing Process in this coating process was 6S (Sort, Set in Order, Shine, Schedule, Score and Safety). Contributions, like the creation of a system that will be used to maintain an organized, clean, safe, and efficient setting that enables the highest level of value-added performance, were achieved during the 6S event implementation. In addition, a decrease in cycle time, in operators needed in the process execution, and minimization of injuries risk, were very important contributions achieved.

INTRODUCTION

Unfortunately, "Lean" doesn't necessarily mean safer even though the two should go hand in hand. After all, a poorly designed task that requires a worker to reach excessively is not only inefficient, requiring more time and motion than needed, but is also likely to cause an injury. Similarly, a worker lifting materials beyond his or her strength capabilities takes more time and energy to perform the task and runs the risk of overexertion. On another level, the lost time and productivity following a workplace injury are indicative of the waste that Lean strategies aim to avoid. When an injury occurs, production halts. Managers spend valuable time on administrative tasks such as locating replacement workers and line workers are distracted and perform less efficiently. Remedying these problems can take a few hours – or a few weeks – and the bottom line impact from direct and indirect costs is significant.

A coating process in a pharmaceutical plant for an antidepressant product was identified for Lean and Safe Manufacturing implementation due to the utilization of toxic ingredients and hazardous materials. The tool selected to perform a Lean and Safe Manufacturing Process in a coating process with solvents is 6S. There are a number of reasons for using 6S, for example:

- Everyone can get their arms around the concept of "a place for everything and everything is in its place" to avoid situations like misplacing parts and spending frustrating and wasteful time looking for them.
- It is a wonderful way to involve people in improving their own work settings enabling greater employee empowerment.
- Finally, the visual impact of a 6S event makes the improvement it produces impossible to miss and this creates a real sense of achievement and pride that can form the beginning of a more significant cultural transition.

Figure 1: *6S Event*

PROBLEM STATEMENT

Due to the utilization of toxic ingredients and hazardous materials, a coating process in a pharmaceutical plant for an antidepressant product was identified as the pilot area to implement the Lean and Safe Manufacturing. The tool selected to perform a Lean and Safe manufacturing process in a coating process with solvents is 6S. The 6S tool is composed of the following items: Sort, Set in Order, Shine, Schedule, Score, and Safety.

As with all Lean tools, 6S is about eliminating waste and maximizing value-added work. To this end, the 6S tool selected to implement a Lean and Safe Manufacturing in an antidepressant tablets coating process, will be used in the process with the objectives of creating and maintaining an organized, clean, safe, and efficient setting that enables the highest level of value-added performance. It achieves its ends by introducing organization and orderliness, eliminating unneeded materials, and establishing self-discipline. In a sense, it transfers some principles of "time management" from the "virtual space of your work schedule" to the physical space of your office or shop area [2].

It is decided to start with only one manufacturing step (coating process) of the complete manufacturing process in order to evaluate its results and have a complete overview of the attitude and compromise of the management and the personnel toward the event. Contributions, like the creation of a system that will be used to maintain an organized, clean, safe, and efficient setting that enables the highest level of value-added performance, are projected to be achieved during the implementation. In addition, a decrease in cycle time, in operators needed in the process execution, and minimization of injuries risk, will be very important contributions to this manufacturing process. The 6S's activities are considered by the management to be implemented as part of the transfer and manufacturing activities for each product.

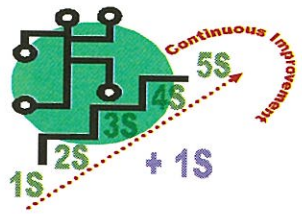

Figure 2: *6S Continuous Improvement*

LITERATURE REVIEW

The research area selected for the design project is the implementation of Lean and Safe manufacturing process in a coating process with solvents for an antidepressant product manufacturing in a pharmaceutical plant. The selection was done due to the utilization of toxic ingredients and hazardous materials in this coating process.

During the literature review process, for this project, it was observed a recent industry tendency to implement a safety environment for their personnel during the manufacturing process. Also, the selection of Lean Manufacturing to implement a safety environment was performed and executed successfully in various situations, demonstrating the effectiveness of this important process.

The goal of the Lean Manufacturing implementation is to eliminate the waste in a manufacturing process. Kincaid [2] defines waste as anything not essential to the process like overproduction, unnecessary motion, inventory, waiting, transportation, defects, underutilized people and extra unnecessary processing. When this process is implemented right, better ways to do the most productive work with the least expenditure of time and materials are found, and accident prevention benefits will be obtained as a side effect. Some elements, that have prevention aspects, are the following: Sort, Set in Order, Shine, Standardize and Score. These elements present a disciplined program for cleaning, sorting, removing unused items and organizing remaining items. The program implementation resulted in housekeeping improvements. This article makes emphasis in Lean

implementation good results as an industry collective work and a safety professional active participation. All the programs working together can make a safer, more productive and efficient workplace.

An important aspect to consider in the Lean implementation is making Lean and Safety work together. In this point is necessary the active participation of a safety professional. Newman and Braun [3] said that some managers perceive Lean events as only production-oriented. The safety professional can make an analysis of where the accidents are happening or will be happening, describe the problem using visuals in a way that will get their attention, analyze the production process from a safety perspective and find the root cause of the injuries or possible injuries, and apply new design principles to reduce or eliminate the sources of possible injuries. It is necessary to explain the value of safety intervention in productivity terms to obtain the management attention. Better safety means less waste.

One of the tools to perform a Lean and Safe manufacturing process is 6S. 6S is a methodology for organizing, cleaning, developing, and sustaining a productive work environment. It is about eliminating waste and make a value added work. The 6S components [4] are the following:

- Sort - Distinguish between what is needed and not needed and to remove the latter.
- Set in Order - Enforce a place for everything and everything in its place.
- Shine - Clean up the workplace and look for ways to keep it clean.
- Schedule - Maintain and monitor adherence to the first three Ss.
- Score - Follow the rules to keep the workplace 6S-right - "maintain the gain."
- Safety - Eliminate hazards. (We added this sixth "S" so we could maintain the focus on Safety within our Lean events and embed safe conditions into all our improvements.)

There is a three phases approach to implement the 6S methodology: Get ready for the event, doing the event, and get the facts.

The selection of Lean Manufacturing process to obtain a safety environment was performed and successfully executed in various industries events. Some examples were found in different articles that demonstrate the effectiveness of the Lean manufacturing process implementation.

The first example, taken from an article written by Savasta [5], is in the Ceramic Industry. The article situation is the selection process of a health and safety professional. Companies that hire a qualified health and safety professionals will achieve much better results, producing waste reduction through sound health and safety practices, which play an integral part in the overall effectiveness of the lean manufacturing process. There are several ways to get the results wanted:

- Make a gap analysis to assess the status of OSHA compliance issues (complying with government regulations).
- Make a job safety analysis (evaluate potential hazards and ways to control the identified hazards).
- Move toward implementation (integrated recommended controls).

In the second example Humantech [1] assisted TRW's company to reduce costs and increase profitability with lean manufacturing implementation following the steps below:

- Perform a survey to quantify the ergonomic risk at workstations.
- Give essential skills with ergonomics training course.
- Utilize a job improvement process emphasizing operator involvement.

The information obtained in the literature research about the Lean and Safe manufacturing process explained different general aspects about beginning, implementation and end of the process. Following these suggestions could conduce to a successful Lean and Safe manufacturing process event implementation.

The articles used as examples of the lean manufacturing process implementation concentrate their efforts in the ergonomics area. The area selected to implement the lean event is specifically the manufacturing coating process with solvents for an antidepressant product manufacturing in a pharmaceutical plant. Based on the literature research, this is a challenging event for the lean implementation. The implementation of Lean and Safe Manufacturing Processes effectively can produce successful Pharmaceutical Processes.

METHODOLOGY

A cross-functional team is selected for the implementation of the event: Technical Operations, Manufacturing, Engineering and Safety Departments. Training is given to the team, which include their supervisors, to discuss the purpose, mission, objectives and goals for the 6S event. Also, a tabletop is performed to get the customer's expectations (From supervisors, managers, etc), to build a scope document, and to define mission, goals, and "do's and don'ts" for the event. These ideas will be used as part of the information to analyze in detecting waste due to workplace disorganization and the lack of visual information.

The coating process for this antidepressant product is identified as the pilot area to implement the 6S event.

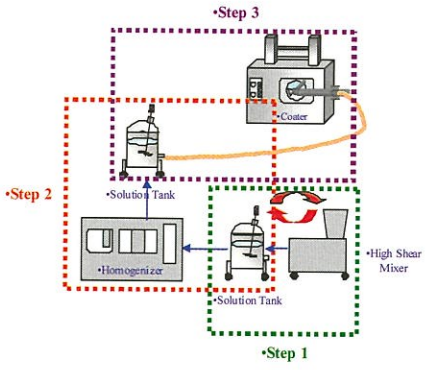

Figure 3: *Antidepressant Tablet Coating Process*

A brief summary of the activities to be performed as part of the implementation is detailed below:

SORT

Red/Blue Tag System – This method is used for identifying things in the work area that are not needed for performing day-to-day work. Each red-tagged item is dated and moved to a central holding area. If the item is not used after a certain period of time, it is then disposed. This system is the way to free up valuable floor space and eliminate such things as broken tools, obsolete jigs and fixtures, scrap and excess raw material and unneeded documents, file cabinets, old correspondence, and office supplies or equipment in office and service settings.

SET IN ORDER

The work areas are organized and properly labeled. All the needed materials as well as the cleaning materials are located in cabinets inside the room or adjacent areas for easy access.

SHINE

Clean, inspect and prevent. Procedures are revised for optimizing the cleaning process of the equipment/parts needed to run the process. Also, checklists are created to monitor the cleanings and evaluate their effectiveness. After the evaluation and optimization of the procedures most effective cleanings are performed in less time. In addition, a cleaning schedule is performed in which an area is assigned to each operator to maintain clean, organized and in order the work areas.

SCHEDULE

A monthly manufacturing schedule is designed in which all the activities to be performed as part of the coating process and the 6S event implementation are detailed. This schedule as part of the implementation is printed (poster size) and located in the manufacturing area where it is discussed every morning. The schedule is a good tool to verify that each activity is completed at the end of the process.

SCORE

Every team member is given a copy of the scale and asked to evaluate the workplace after the completion of each process. From these evaluations some observations are made and windows of opportunity are identified to optimize the process. Radar chart is used to visualize the whole picture of the status before and after the implementation.

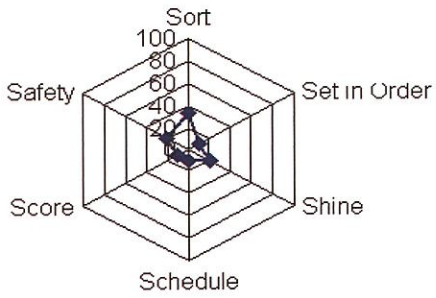

Figure 4: *Example of Radar Chart*

SAFETY

A Safety evaluation is performed to identify links between unsafe practices and waste. The assessment is based on the actual facilities and equipment design. A series of meetings, and visits to the area for equipment tests and inspections with the plant Engineering and Technical Services group are conducted to evaluate the manufacturing steps, equipment, facilities and related utilities.

PROJECT EXECUTION AND RESULTS

Registration lots of the antidepressant product experimental campaign were selected to execute the 6S event project in order to have more tangible results to present to the high management area for the commercial phase implementation. A project proposal was generated and presented to obtain the project execution approval. In addition, after the 6S event execution, a brief summary report was generated and presented for results discussion and next project steps decision making.

Implementation results were satisfactory and a registration lots manufacturing coating process time reduction of three (3) hours per lot was obtained with a cost reduction of $724.50.

Table 1: *Total Time Reduction*

Description	Time before 6S Application	Time after 6S Application
Set up time in step 1	1.5 hr	0.5 hr
Process time in step 1	2.0 hr	2.0 hr
Total process time in step 1	*3.5hr*	*2.5 hr*
Set up time in step 2	1.5hr	0.5 hr
Process time in step 2	3 hr	3 hr
Total process time in step 2	*4.5 hr*	*3.5 hr*
Set up time in step 3	2 hr	1 hr
Process time in step 3	8 hr	8 hr
Total process time in step 3	*10hr*	*9 hr*
Total process time	**18 hr**	**15 hr**

Total time reduction per coating process is 18hrs – 15hrs= *3hrs*.

Table 2: *Total Cost Reduction*

Description	Cost	Total Lots Qty.	Total Cost
Total process cost before 6S implementation	$621.00	7	$4,347.00
Total process cost after 6S implementation	$517.50	7	$3,622.50

Total cost reduction per coating process per seven lots is $4,347.00-$3,622.50=*$724.50*

Next project steps consider the implementation of the 6S event during the commercial phase campaign. This implementation will result in a favorable quantity of cost reduction during the commercial process.

The sections below present the results during the different steps of the 6S implementation.

CROSS FUNCTIONAL TEAM

Conversations with different areas personnel were performed to recruit volunteers that could work in this pilot project. The conversations were

performed to explain the project and its usefulness for the expected antidepressant product commercial campaign in terms of time, money, safety and others benefits established. After that, a cross-functional team was selected for the implementation of the event.

The selected team consisted of the following members: two technical operations personnel, three manufacturing operators, one engineering mechanic and one safety department member. A meeting with the team was performed, which included their supervisors, to discuss the following items:

- 6S event project purpose- Improve the coating process of an antidepressant product with the 6S method implementation.
- 6S event project mission- Implement 6S in the antidepressant product commercial campaign and to be the guidance or example for other 6S implementations.
- 6S event project objectives:
  - Eliminate waste and maximize value-added work.
  - Create and maintain an organized, clean, safe, and efficient setting that enables the highest level of value-added performance.
  - Introduce organization and orderliness, eliminating unneeded materials, and establishing self-discipline.

Process and Strategy Identification

The coating process for an antidepressant product is identified as the pilot area to implement the 6S event. Refer to Figure 3 that shows the manufacturing process for the antidepressant tablets product selected to implement the concept.

Include Managers and Other Related Personnel

People involved in this early stage of the 6S pilot project were team member's supervisors and managers. High management (directors) was involve to obtain the execution approval but will be involved completely after the pilot project completion in order to present more tangible results with a 6S event implementation summary report and the final project charter document that recommended the 6S concept to the expected antidepressant product commercial campaign.

Ready?

Verification of the efficient completion of the first three steps was performed in order to start the 6S event pilot project implementation. Checklists were generated to verify the following information:

- ***Trainings***- explanatory meetings with team members were performed to clarify project steps and requirements.
- ***Materials***- materials required for the 6S event implementation were identified. Due to this is a pilot execution in order to verify results and perform the full implementation in the commercial campaign project purpose, only a portion of the requested material were provided. Pending materials will be provided before commercial campaign implementation.
- ***Labels***- Two color labels were prepared (in Spanish) to distinguish between what is needed and not needed in the manufacturing coating area.

Figure 5: *Red/Blue Labels*

- ***Resources***- some resources were identified to help in the implementation process, but only internal resources were approved for this pilot project execution.
- ***Approve documentation (if necessary)*** – a preliminary project proposal was submitted to have approvals for the pilot 6S project execution.
- ***Schedules or timelines***- schedule system and Microsoft-project timelines were implemented to follow project status daily.
- ***START pilot 6S event implementation.***

SORT

Materials, equipment and tools used in the antidepressant coating manufacturing process were identified and labeled with the cooperation of all team members. Not needed parts were removed and needed parts stayed in the working area.

Figure 6: *Example of Sort Process (Labeled needed and not needed parts)*

SET IN ORDER

The work areas were organized and properly labeled. All the needed materials as well as the cleaning materials were located in cabinets inside the room or adjacent areas for easy access. An example of one of the coating areas used in the process before and after is presented in the figure below.

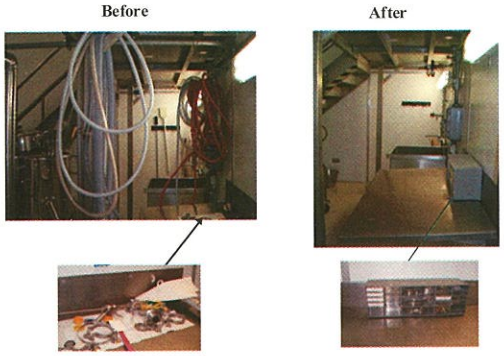

Figure 7: *Examples of Set in Order Process*

Hoses and auxiliary parts needed during the process were classified and storage in designated area.

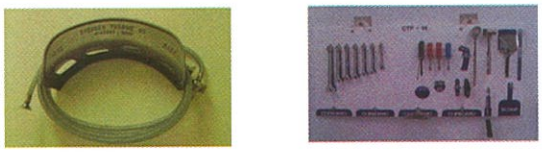

Figure 8: *Hoses and Auxiliary Parts Ordered*

SHINE

Materials, equipments and tools were cleaned, inspected and verified to prevent any safety event. Procedures related to manufacturing, assembly, cleaning and other related process were identified and commented (red lines) by team members to optimize the manufacturing process and cleaning of the equipment/parts needed to run the process. Complete revision of these procedures will be performed before the antidepressant product commercial campaign execution.

In addition, checklists were created to monitor the cleaning processes and evaluate their effectiveness. Experimental cleaning study document were generated and executed during this pilot campaign. After the evaluation of the cleaning procedures the most effective cleanings will be performed in less time. Before the 6S event implementation a cleaning process was performed in one shift of 8 hours and after de implementation in 6.5 hrs. Changes to the existent cleaning procedures will be performed before the antidepressant product commercial campaign execution. A cleaning schedule was performed for each operator assigned area (two manufacturing areas: solution preparation and coating process execution) to maintain the work areas clean, organized and in order.

Figure 9: *Clean Rooms*

SCHEDULE

A monthly manufacturing schedule was designed in which all the activities to be performed as part of the process and the 6S event performance were detailed and revised on a daily basis.

This schedule as part of the implementation was printed (poster size) and located in the manufacturing area where it was discussed every morning with the involved personnel. Processes

were differenced by colors assigned to each manufacturing step. The schedule is a good tool to verify that each activity is completed at the end of the process.

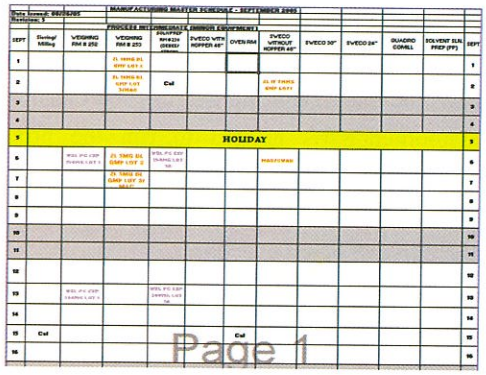

Figure 10: *Manufacturing and Cleaning Schedule*

In the process initiation a paper schedule was used located in a visible manufacturing area. During the process a board was used to facilitate the schedule changes documentation.

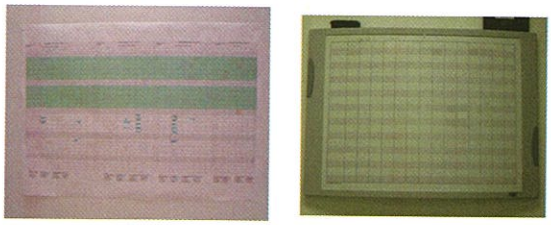

Figure 11: *Example of Schedule Used*

SCORE

The operator activities were measured regularly and the score system was implemented to assign points for every activity related to the first 4S's implementation.

1S - SORT *(Distinguish between what is needed and not needed.)*	Score Guideline	Score
1. Are workstations clear of unnecessary items and clutter?		
Workstations are cluttered with unneeded items, tools, and materials	0	
Workstations are free of unneeded items, but are cluttered with tools and materials	2	
Workstations are free of unneeded items, and tools are organized	5	
Comments:		
2. The floor is free from safety hazards (i.e.: loose wires, pallets, cables, oil/chemicals)?		
Safety risks with items not being stored or restrained properly; Oils/chemicals on the floor	0	
Potential safety issues that require attention (i.e loose wires, chemicals dripping into a container)	2	
Tools & materials are stored off the floor; Wires are tied together out the way; No leaking equipment	5	
Comments:		
3. Are storage areas free of clutter and unnecessary items?		
Storage areas are cluttered with unneeded items, un-used or out-dated tools, and old materials	0	
Storage areas are free of unneeded items, but are cluttered with extra tools and excessive materials	2	
Storage areas are free of unneeded items, and store proper tools and materials	5	
Comments:		
4. Are the aisleways, emergency exits, and fire extinguishers clear?		
Aisleways, emergency exits, or fire extinguishers are blocked by materials	0	
Items are stored nearby, but are not a complete barrier	2	
Aisleways, emergency exits, and fire extinguishers are cleared and easy to get to	5	
Comments:		
Subtotal score for (1S) Sort	20	

Figure 12: *Example of Score System*

Every team member had a copy of the scale and was asked to evaluate the workplace after the completion of each process. From these evaluations some observations were made and windows of opportunity were identified to optimize the process during the commercial campaign execution.

Radar chart will be used to visualize the whole picture of the status before the 6S event in the commercial campaign implementation.

SAFETY

A safety assessment document was generated to evaluate and identify links between unsafe practices and waste. The assessment was based on the actual facilities and equipment design. This assessment is an internal pharmaceutical document and no publication was permitted in the final project document.

A series of meetings and visits to the area for equipment tests and inspections with the safety, manufacturing personnel and technical services group were conducted to evaluate the manufacturing steps, equipment, facilities and related utilities.

Examples of some of the safety equipment necessary in the process due to hazard solvents solutions exposure are the following:

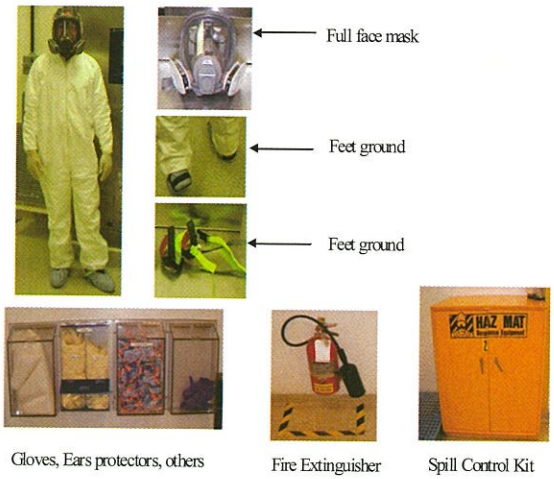

Figure 13: *Safety Equipment*

CONCLUSIONS AND RECOMMENDATIONS

The following figure presents the findings after the pilot project execution of 6S implementation during the experimental antidepressant product coating process.

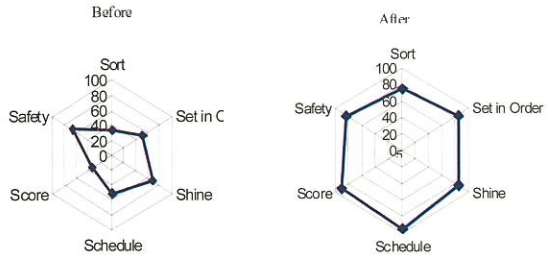

Figure 14: *Radar Chart Results Before and After 6S Implementation*

Considerable improve was observed during the 6S event implementation as shown in Figure 14. In addition, evaluation of process results was performed and a reduction of three (3) hours in manufacturing process time was observed.

The cleaning process was improved with successful results: Parallel with the 6S event pilot execution an experimental cleaning study was executed in order to verify if the cleaning procedures were effective during the equipment/tools parts cleaning process. Cleaning results were satisfactory in the most of the executed procedures. When an out of specification result was obtained a revision of the procedure was performed and additional execution was required. Final procedures revision will be performed before commercial campaign execution.

A safety assessment document was generated before process execution and recommendations were performed. Additional items were found during the project execution and will be implemented before commercial campaign process starts.

The original intention of the project was to implement all findings obtained from the pilot 6S project execution in the product commercial campaign after FDA manufacturing product approval. In addition this type of experience will be used to implement them as part of the transfer and manufacturing activities for other products.

Due to a business decision, the site that executed the 6S pilot project will be closed, therefore the commercial campaign will not be executed and the project completion with all process improvements will not be executed either. However, the experiences during the pilot project execution impacted positively all team members and additional personnel involved and created a precedent in this type of manufacturing activities.

REFERENCES

[1] Humantech. "TRW Improves Health and Safety While Increasing Productivity with Humantech" (2002), *Human Performance Ergonomics*, Vol. 1. Retrieved December 5, 2005, from http://www.humantech.com.

[2] Kincaid, W. H. (Jun 2004). "Lean Manufacturing: Unexpected Benefits for Accident Prevention", *Occupational Hazards*, Vol. 66. Retrieved November 27, 2005, from http://www.pupr.edu at EBSCOhost.

[3] Newman, K., Braun, T. (August 2005). *Keep it Lean and Safe.* Retrieved December 7, 2005, from http//www.occupationalhazards.com.htm.

[4] Roll, D. (2005). *An Introduction to 6S.* Retrieved December 5, 2005, from http://vitalentusa.com.

[5] Savasta, J. W. (Oct 2003). "Health & Safety in a Lean Environment", *Ceramic Industry*, Vol. 153. Retrieved November 27, 2005, from http://www.pupr.edu at EBSCOhost.

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