

# The Evaluation and Application of FMEA in Sepahan Oil Co

Hekmatpanah M. and Fadavinia, A.

**Abstract**—Failure modes and effects analysis (FMEA) is an effective technique for preventing potential problems and actions needed to error cause removal. On the other hand, the oil producing companies play a critical role in the oil industry of Iran as a developing country out of which, Sepahan Oil Co. has a considerable contribution. The aim of this research is to show how FMEA could be applied and improve the quality of products at Sepahan Oil Co. For this purpose, the four liter production line of the company has been selected for investigation. The findings imply that the application of FMEA has reduced the scraps from 50000 ppm to 5000 ppm and has resulted in a 0.92 percent decrease of the oil waste.

**Keywords**—FMEA, Iran, Sepahan Oil Co., Canning, Waste, Scrap

## I. INTRODUCTION

FAILURE modes and effects analysis (FMEA) is a technique used to identify potential problems “before the event”, and to determine what actions can be taken to prevent them (Shahin, 2004). It is an analytical technique through which we set out to determine all possible “potential failure” modes, the effects that will occur if the failure actually happens and all of the causes which can bring about the failure (Slinger, 1992; Healey, 1994; Slack et al., 2001). It is a group-oriented, structured, and stepwise approach to quantify the effects of possible failures, thus allowing a company to set priorities for action (Vandenbrande, 1998). Main benefits of implementing FMEA are improving the product/process quality and reliability and satisfying the customers (Tang and Ho, 1996).

As nowadays business paradigm has move from individual enterprise centric into supply chain centric oriented, the implication to develop FMEA as quality tool assessment within supply chain framework is apparent. There is also necessity to develop service reliability assessment techniques to access product quality in which the products design, development, and manufacturing is distributed among outsourced supplier. Sinha et al. (2004) used FMEA as means to access criticality of risk factors within aeroplane manufacturing supply chain. Kumar et al. (2009) presented FMEA examination to access risk of each steps in reverse logistics activities within pharmaceutical industry. Zhang and Zhu (2006) used FMEA to estimate the risk will incur in outsourcing region. Jennifer et al. (2007) modified FMEA to access the criticality of human error in reading labels on injectable drug containment. Van Leeuwen et al. (2009) used FMEA to identify the rankings of the risk in analytical screening of drugs. Chiozza and Pozzenti (2009) pinpointed key points learnt from applying FMEA in medicinal sectors.

Masoud Hekmatpanah, Islamic Azad University, Ardestan Branch, Ardestan, Isfahan, Iran. Email: m1595h@yahoo.com

Ali Fadavinia, PhD Researcher, Department of Computer Science, University of Warwick Data Networks & Security in Enterprise Scale. Email: a.fadavinia@warwick.ac.uk

Chuang (2010) analysed the impact of disservice using Bayesian probability and concluded his work be extended to quantify the impact of intangible disservice effects such as customer complaints and loss of market share. By FMEA, many world class companies have gained great benefits. In this respect, Iran and its oil industry play a major role in the Middle East and global economy and therefore, it is expected that conducting advanced quality approaches such as FMEA will provide considerable advantages to the country and its stakeholders. As one of the world's leading oil producing country, Iran's importance in the world's oil market is both indisputable and indispensable. Iran presently ranks fifth in the world in terms of proven oil reserves and second rank in natural gas. Based on the latest estimations, released in 2008, it holds 96.4 billion barrels of oil. In Iran according to preliminary estimates, GDP at basic price grew by 5.2 percent at constant prices and amounted to \$ 44.9 billion in 2008. The value-added of manufacturing and mining, services, oil, and agriculture sectors grew by 8.5, 6.5, 3.0, and 4.7 percent, respectively. Moreover, the shares of these sectors in GDP were 17.1, 48.8, 26.5, and 10.4 percent, respectively, at current prices (OPEC, 2008). However, it is expected that preventing oil's waste provides advantages such as cost reduction, quality improvement, higher productivity, and higher satisfied customers. Meanwhile, oil producing companies play a critical role in the oil industry of Iran out of which, Sepahan Oil Co. has a considerable contribution. Therefore, the aim of this research is to show how FMEA could improve the quality of products at Sepahan Oil Co. In the following, FMEA is demonstrated and applied in Sepahan Oil Co.

## II. FAILURE MODES AND EFFECTS ANALYSIS

FMEA is a systematic procedure enabling designers to i) identify potential failures; ii) evaluate them; iii) investigate them; and iv) take action to prevent them. Through the use of a simple rating method specifically constructed to serve the company's requirements, a risk priority number (RPN) is established for each cause of failure. Those potential causes with high RPN values are selected for corrective action to reduce the risk of failure occurring. Attention is also given to those parts of a system where failure would produce adverse customer reaction and loss of company image. An FMEA form is given in figure 1.

*Column A: Part number and function* : In this section, every component needs to be identified, including assemblies and sub-assemblies with their own part numbers. We must also state concisely the function of the part or assembly. Where an assembly has several functions and may fail in several ways, it may be necessary to list the functions separately.

*Column B: Potential failure mode* : In this section we must consider and describe all ways in which it could conceivably fail to perform its intended function. A good starting point is to look at past FMEAs, tests and quality, warranty, durability and reliability reports. The team must anticipate how the part or process might fail to meet engineering

requirements.

**Column C: Potential effect(s) of failure:** In this section we need to describe the effects of the failure in terms of what the customer might notice or experience, by listing both the "local" and the "overall" effect of failure. Of course, one failure mode could have more than one effect and the same effect could apply to a number of different failure modes.

POTENTIAL FAILURE MODE AND EFFECTS ANALYSIS (DESIGN FMEA)																
SYSTEM .....						PREPARED BY .....										
OTHER AREAS INVOLVED .....						FMEA DATE .....										
						RESPONSIBILITY .....										
Part number and function	Potential failure mode	Potential effect(s) of failure	Severity	▽	Potential cause(s) of failure	Occurrence	Design verification	Detection	RPN	Recommended action(s)	Area/individual responsible & completion date	Action results				
												Actions taken	Severity	Occurrence	Detection	RPN
A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q

Fig. 1 Sample FMEA form

**Column D: Severity (of failure):** Severity is an assessment of the seriousness of the effect of the potential failure mode on the customer after it has occurred. In this section we must predict the severity of the failure and record it on a 1 to 10 scale. This is called a severity rating. Since the severity rating is based solely on the effect, not the cause, of failure, it always remains the same, regardless of its possible causes.

**Column E: ▽** If the item under consideration has been classified by your customer as safety critical, then this column would be ticked to identify that special attention is required.

**Column F: Potential cause(s) of failure:** There may well be more than one cause for each failure mode, so all possible causes of failure must be listed in this section. Once the list is complete, we must rank the causes of failure in order to calculate a risk priority number. Rankings are entered in columns N to Q.

**Column G: Occurrence (of failure):** When considering "occurrence of failure", we must evaluate the risk i.e. the probability that the failure mode will occur as a result of a specific cause (Important: this is different for a process FMEA). A design change is the only way a reduction in the occurrence can be affected. After considering the failure mode and its possible causes, we record their estimate of the probability of the failure actually occurring, using all available knowledge and ranking the probability of occurrence on a 1 to 10 scale.

**Column H: Design verification:** In this section it is important to recognise that we are considering how you currently verify the design, and not how you intend to verify it in the future.

**Column I: Detection (of failure):** In this section we estimate the probability that a potential failure will be detected before it reaches the customer. Again, we use a 1 to 10 scale here.

**Column J: Risk priority number (RPN):** The RPN is the product of the occurrence, severity and detection ratings ( $RPN = O \times S \times D$ ). The RPN must be calculated for each cause of failure. RPN shows the relative likelihood of a

failure mode. The higher the number, the more serious the failure mode. From the RPN a critical summary can be drawn up to highlight the areas where action is needed most. Regardless of the resultant RPN, special attention must be given to any cause of failure with a severity rating of "9" or "10".

**Column K: Recommended (corrective) action:** After completing sections N to Q of the FMEA form, we must establish what action is needed. The aim of an FMEA is to highlight potential failure modes to enable us to take appropriate corrective action, or to ensure such action is taken. The aim of the design FMEA is to ensure that the main hazards are removed from the specification by re-engineering. The three remedies in order of desirability include i) to eliminate the problem altogether through a design change; ii) to reduce the probability of failure occurring; and iii) to improve the chances of detection through improved quality control.

**Column L: Responsibility for action:** Column L should clearly identify the person or department responsible either for taking corrective action or for ensuring it is taken, and agreeing a completion date.

**Columns M, N, O, P & Q: Actions results:** In this section we record the action which has actually been taken in column M and, following this action, a re-evaluation of severity (N), Occurrence (O) and detection (P) can be carried out, and a new RPN (Q) calculated. Note: after corrective action has been taken, a new FMEA should be performed, taking all the changes into consideration.

### III. CASE STUDY: SEPAHAN OIL CO.

Sepahan Oil Co. was funded and established by the National Iranian Oil Company Employees' Pension in April 2002. The company trades in petroleum and petrochemical products in the world. Today, this company operates in most of the world's countries and is best known by our familiar brand names like Exxon, Esso, and Mobil. Sepahan Oil Co. makes products that drive modern transportation, power cities, lubricate industry and provide petrochemical building blocks that are vital to thousands of consumers. Ever since its establishment and with regard to the type of design and anticipated capacity, Sepahan Oil Co. was considered the major supplier of motor oil in the country. The Company is capable of securing over 30% of approximately 600 million liters of engine oil used domestically. "Alvand" and "Arzhan" engine oils allocated the highest share of the market to themselves for years, and at present, special trade names of Sepahan Oil Co. such as "Speedy" and "Jey" are ranked as first among domestic and foreign suppliers. It produces almost all types of engine oils required domestically including those for gasoline, diesel, gas, dual fuel, two-stage and four-stage engines, tractors, locomotives, generators, gear boxes as well as manual and automatic differentials. Oil canning can be defined as a perceived waviness in the flat areas of metal roofing and metal siding panels. Generally, the period and amplitude of the wave depend of the continuous width of the flat. Oil canning is an inherent part of light gauge cold formed metal products, particularly those with broad flat areas. Profiles having wide flat surfaces are often referred to as "architectural" roofing and siding panels. Such panels are distinguished from corrugated shapes as the latter are more fluted in design, have much narrower flats, and are less likely to exhibit oil canning. AS

it is clear from Table 1, the most crucial line is four liter can among the four production lines of the company. The waste values are mostly related to a period of time starting from May 2007 to August 2007. It is important to note that the production of four liter can is highest amongst the mentioned production lines. Therefore, it reasonable to target this line as having the highest waste in terms of canning with six percent waste and filling with one percent waste, leading to huge loss of totally seven percent of the total production of this line. Respectively, FMEA is adopted to improve the quality of this production line.

TABLE I  
PERCENTAGE OF WASTE IN CANNING AND FILLING PROCESSES OF THE  
SEPAHAN OIL Co.

Wastage Line Production line	Canning (Percentage)	Filling (Percentage)	Total (Percentage)
1 Lit	1%	0.1%	1.1%
4 Lit	6%	1%	7%
20 Lit	-	0.001%	0.001%
210 Lit	-	0.002%	0.002%

#### A. Data collection method

The data in the improvement project are collected from internal complaint records and files from historical documents, which give information about the capability of the production line. Data, in forms of downtime are gathered from the documents of maintenance department. Also some information is gathered from the Sepahan Oil Co. websites such as annual reports and company internal documents describing work approach and economical statistics. Information was also gathered within the company from conversations with employees.

With regard to the fact that the four liter canning and filling production line includes most of the scraps in the selected company, hence the improvement team seeks the following targets by the implementation of the proposed methodology:

- 1- Cost reduction and the increase of production speed through scrap reduction
- 2- Improvement of teamwork culture towards the improvement of management functioning
- 3- Income increase through production increase and cost reduction
- 4- Determination of a set of solutions resulting in the scrap reduction of 4-liter can production line

To monitor the production line and evaluate the improvements, the scrap rate index which is the product of the division of the number of scrap cans by the total number of the cans produced and the percentage index of wasted oil which is the product of the division of the wasted oil by the total oil produced times 100, are determined. After the preparation of the index and with regard to the registered data for the identification of the exiting situation, the trend of this index is examined four months prior to the project and is compared with the present condition. The can scrap rate is considered as 6% (60/1000) and oil waste as 1% before the implementation of the improvements.

Also, six failure modes with highest share in the scraps are selected and emphasized by the company's chief manager. These modes include cut, weld, bottom seamer, towards the filling, filling, and top seamer.

#### B. Identifying CTQs

After determination of the six major failure modes for

concentration, the Critical to Quality (CTQ) factors for each of them are indentified. These CTQ are factors which cause scraps in the canning and filling sections and some have negative impact on the customer. The most important factors which cause the scrap cans in the cutting section are imprecision of the dimensions of the plate, low and high hardness, plate thickness, and unadjusted device with regard to the type of the plate. Furthermore, due to the unadjusted feeder, the worn out parts in the welding section during production, inappropriate thickness, hardness of the bare electrode, and unadjusted crown of the device are most important factors causing scrap cans in this line. In the bottom seamer production section, important factors such as unadjusted side pressure and the perpendicularity of the reels exit result in the production of scrap cans. From the seamer production section to the filling section, which includes many conveyor devices and due to the lack of precise study of this section and on factors such as can cripple before filling and can dirtiness, a number of cans are scrapped and low-quality oil is produced. In the filling section, important and varied factors such as overflowing of the oil from the cans, entrance of air into the filled oil can and cripple of the can in the filling section result in scrap can and oil waste. For the last mode, i.e. the top seamer, due to inappropriate sewing of the filled can and its cripple in its path, both the oil and the can are wasted. The CTQs of the four liter line are addressed in Table 2.

TABLE II  
THE IDENTIFIED CTQs AT THE 4-LITTER LINE

Section	CTQ	Operational definitional of CTQ
Plate cutting	Imprecise plate dimensions	The number of scrap cans
	Low and high hardness of the plate	The number of scrap cans
	Low and high thickness of the plate	The number of scrap cans
	Unadjusted device with regard to the type of the plate	The number of scrap cans
Welding section	Unadjusted feeder	The number of scrap cans
	Worn out parts during production	The number of scrap cans
	Inappropriate thickness and bare electrode hardness	The number of scrap cans
	Unadjusted device crown	The number of scrap cans

The measured values of the CTQs are illustrated in Table 3. With regard to the obtained CTQs, the most and the least scraps at the plate cutting section are 0.6 and 0.09 for the high and low thickness and hardness of the plate, respectively. The factors which produce the most scraps at the welding section are unadjusted feeder, worn out parts during production, inappropriate thickness and hardness of the bare electrode, and unadjusted device crown which comprise 0.1, 0.4, 0.5, and 0.6 percentage of the scrap, respectively. Unadjusted side pressure and perpendicularity of the reels each with 0.75% of the scrap are also observed in the seamer section. The scarp is calculated as 0.15% from seamer to filling with can cripple and dirtiness of the cans before filling. In the fifth mode, the CTQ is divided into two groups of filling and canning. The most important factors include oil overflow, entrance of air into the can, and cripple of the can in the filling section with 0.2%, 0.3%, and 0.05% for filling section and the percentage of canning scrap for the third item is calculated as 0.3%. In the top seamer section, two groups of scraps of filling and canning exist.

The most important CTQs are can cripple and inappropriate sewing of the filled can lid with 0.05% and 0.4% of scrap in the filling section, respectively and it is calculated as 0.75% and 0.75% for the canning section.

TABLE III

THE MEASUREMENT OF THE IDENTIFIED CTQS AT THE 4-LITTER LINE (CANNING)

Section	CTQ	Scrap percentage
Plate cutting	Imprecise plate dimensions	0.11
	Low and high hardness of the plate	0.09
	Low and high thickness of the plate	0.60
Welding section	Unadjusted device regarding the type of the plate	0.15
	Unadjusted feeder	0.60
	Worn out parts during production	0.50
	Inappropriate thickness and bare electrode hardness	0.40
	Unadjusted device crown	0.10

### C. Plate cutting

Table IV shows the FMEA of the plate cutting. As it is observed, four modes of potential failures are considered to result in can scraps. Three of these four modes of potential failures are relevant to sending of unsuitable plates by the providers that result in can scrap and some problems in the production line. At the present situation, the Company does not impose any control over sending of the plate; but the fourth mode of potential failure is pertained to the absence of system adjustment with due attention to the type of the applied plate. This mode is has the maximum RPN and highest degree of importance. The cause behind this problem is the imprecision of the operator and lack of any effective control. The severity of this mode of potential failure is high, and it is of almost high frequency, therefore teams of 8 and 6 members are respectively assigned to them.

TABLE IV  
FMEA FOR PLATE CUTTING SECTION

Potential failure mode	Potential failure effects	S	Potential causes of failure	O	Current process control	D	RPN
Imprecision of the plate dimensions	Can Scraps	5	Providers	5	No control	2	50
High and low hardness of the plate	Can Scraps	3	Providers	2	No control	2	12
High and low thickness of the plate	Can Scraps	4	Providers	4	No control	2	32
Unadjusted device regarding plate type	Can Scraps	8	Operator	6	No precise control	6	288

### D. Welding Section

Table V displays the FMEA of the welding section. The problems of this section result in scraps in can bodies. Maximum RPN is relevant to feeder nonalignment that is originated from the lack of operator skill and the imprecise tools. Daily, weekly and monthly control on the feeder is not fully fruitful. The second RPN is pertinent to the erosion of

the system segments while manufactured. Additionally, unfit diameter and the severity of bare electrode as well as unfit system crown are respectively, the next cases with RPNs of 60 and 27.

TABLE V  
FMEA FOR WELDING SECTION

Potential failure mode	Potential failure effects	S	Potential causes of failure	O	Current process control	D	RPN
Unadjusted feeder	Number of scrap bodies	8	Operator of precision tools	6	Daily, weekly, and monthly control	5	240
Part wear and tear during production	Number of scrap bodies	5	Operator of precision tools	5	Weekly control	5	125
Unfit hardness and thickness of the bare electrode	Number of scrap bodies	4	Operator of precision tools	5	Daily control	3	60
Unadjusted device crown	Number of scrap bodies	3	Operator of precision tools	3	Daily control	3	27

### E. Improvement

Improvement starts after the analysis of the root causes of the problems. For this purpose, the improvement team identifies ways to remove the root problems through brainstorming and taking advantage of the creativity and innovation of the members in the meeting. Then, the approaches suggested for the solution are evaluated with regard to the cost-benefit analysis for each of the approaches and finally the optimal approaches are addressed for the improvement of the process. Next, the solutions are completely reevaluated for their risk factors in execution, and finally with regard to its effectiveness in the improvement of the process and in the reduction of scraps, the improvement plan is implemented. In Table 6, the solutions recommended for the six failure modes by the improvement team are presented with a sequence of importance.

TABLE 6A  
SOLUTIONS SUGGESTED BY THE IMPROVEMENT TEAM AT PLATE CUTTING

Improvement	CTQ	Before FMEA	After FMEA
Operator training and use of expertise	Imprecise dimensions of the plate	0.11	0
Sensor preventing double-sheet lifting	High and low hardness of the plate	0.09	0.01
Calibration of the device every several days	High and low thickness of the plate	0.60	0
Checking the plate before unloading and making the provider committed	Unadjusted device with regard to the type of the plate	0.15	0

TABLE 6B  
SOLUTIONS SUGGESTED BY THE IMPROVEMENT TEAM AT WELDING SECTION

Improvement	CTQ	Before FMEA	After FMEA
Preventive maintenance schedule	Unadjusted feeder	0.60	0.09
Part defect finding	Wearing of the parts during production	0.50	0.10
Hardness control and its surface alloy for the electrical conductivity during production for every 2 hours, since the two ends of the wire are different	Inappropriate thickness and hardness of the bare electrode	0.40	0.08
Rechecking hardness and thickness of the plate before entering the feeder	Unadjusted device crown	0.10	0.02

## DISCUSSION AND CONCLUSIONS

In this paper, Failure Modes and Effects Analysis (FMEA) was applied for improving the quality of four liter production line of Sepahan Oil Co. as a key player in Iran's oil industry. This production line consisted of two important sections of can making and can filling. Therefore, two important wastes investigated were the percentage of the wasted cans and the percentage of the wasted oil. The caning process was more emphasized in this research.

The results imply that the application of FMEA led to loss reduction which in turn leads to profitability. Almost all the criteria measured before and after the implementation of FMEA denote considerable improvements. CTQs were measured in different specified parts. The percentages of scrap in the canning section consisting of plate cutting and weld points were 9.86 and 1.6, respectively. The processes were analysed to identify existing problems. In this analysis, the convergence of the views of the problem-solving team members for discovering the causes of the problems and testing to validate the views of the problem-solving team was beneficial. At this stage, FMEA, were used to find the root causes of the problems. In "Cutting mode" based on the analysis of RPN values obtained from FMEA, most scraps in the cutting section (RPN=288) resulted from the unadjusted machinery. The results obtained from the cause and effect and Pareto diagrams by the improvement team indicated that operator's negligence to adjust the device has resulted in the production of scrap. This has also been confirmed by field research and statistical analysis. In the "Welding mode", the values obtained from RPN in FMEA showed that unadjusted feeder and worn out parts during production had the most effect on the production of scraps (RPN=125 and RPN=240). The results obtained from the cause and effect and Pareto diagrams by the improvement team shows that the device problems result in scrap which calls due attention to the welding section devices. This was confirmed by field research and statistical analysis. The improvement team embarked on the identification of possible solutions by enjoying many brainstorming meetings and after studying all the solutions, they announced the most important improvement methods for the intended sections. In the plate cutting section, training of the operator and employing expertise were conducted; in the welding section, special attention was made to the maintenance plans. However, after implementation of the improvement actions, the can scrap percentage was reduced from 50000 ppm to 5000 ppm and the percentage of the oil waste was reduced from one percent to 0.08 percent.

What is clear in this study is the significant improvement in each of the criteria made after the implementation of FMEA, highlighting the fact that the new methodology has significant effect on the oil production line. However, one of the most important criteria of the FMEA project which justifies the application of the proposed methodology is the monetary savings. The calculation of the project team shows that the net profit of implementing FMEA is reached to 558726\$.

In addition to the above summary of results, it is concluded that the number of CTQ criteria depends on the number of products and the extent of the manufacturing

processes and whether the quality improvement approaches have been implemented previously or not. Some of the major limitations of the proposed model include time consuming in complicated cases for instance, since the required data will be gathered from company's records, any limitation in gathering reliable data will affect the results considerably; limitation in gathering the average rate of defects or the average level of quality of competitors; and it would be more difficult to implement the technique in organizations that have not experienced any quality design or improvement program previously. Readiness and willingness of managers to use advanced quality engineering techniques might not be similar in every country. It is important to note that Implementation of FMEA for the first time in Iran's oil industry and lack of sufficient experience of the managers and engineers for the execution of the FMEA project could reduce the efficiency of the project at the beginning stages. Certainly, by constant implementation of the technique, better result will be obtained. In this research, FMEA was customized for the oil canning companies and was applied in the Sepahan Co. as a sample. It is important to note that there might be challenges in applying the methodology in other companies of the oil industry and with more confidence in other industries.

However, there seems to be a high demand for quality development in Iran's oil industry, as energy is becoming increasingly important and this importance will continue to grow over this century. The application of techniques such as FMEA can be further developed and applied to the whole oil industry of Iran. Regarding the achieved results, advantages such as increased return rate, increased process capacity, increased efficiency, reduction of process time cycles, and reduction of scraps are expected to be gained by other companies involved in Iran's oil industry. The results at each stage of implementing the technique should be compared with the intuitive views of the team members. Where a divergence is noted, analysis can be directed at identifying the factors responsible. The appropriate changes can then be made to the results of different stages of the technique.

While in this investigation, the new methodology was implemented in specific section of the production line of Sepahan Oil Co., the approach could be further examined and investigated in other remaining sections of the production line. It is important to note that the size of companies may affect the application of FMEA; therefore, an investigation about the relationship between the size of organizations and the efficiency and effectiveness of the technique is recommended. Applying FMEA in the oil industry of other countries and comparing the results between two countries could provide great research opportunities and outcomes. It seems more research work remains to be undertaken in order to make FMEA more robust. For example, mathematical tools such as optimization theory and other associated quality techniques could be applied during the implementation process to further enhance its applicability. The integration of FMEA and other quality and improvement methodologies such as theory of constraints (ToC) and lean manufacturing (e.g. lean sigma), could also be further analyzed.

## REFERENCES

- [1] Chuang, P.T. (2010). Incorporating Disservice Analysis to enhance Perceived Service Quality. *Industrial Management & Data Systems*, 110(3), 1-22.
- [2] Chiozza, M.L., and Pozzali, C. (2009). FMEA: A Model for Reducing Medical Errors. *Clinica Chimica Acta*, 404(1), 75-78.
- [3] Healey, J. (1994). "Failure mode and effects analysis". *Engineering Designer*, 20(2), 4-7.
- [4] Jennifer, J., Hyland, S., Burns, C.M. and Momtana, K. (2007). Challenges with Applying FMEA to The Process for Reading labels on Injectable Drug Containers. *Proceedings on Annual Meetings of Human Factors and Ergonomics Society*, 735-739.
- [5] Kumar, S., Dieveney, E. and Dieveney, A. (2009). Reverse logistic Process Control measures for the Pharmaceutical Industry Supply Chain, *International Journal of Productivity & Performance Management*, 58(2), 188-204.
- [6] OPEC, (2008), OPEC in the world economy, 5.
- [7] Shahin, A. (2004), "Integration of FMEA and the Kano model: An exploratory examination", *International Journal of Quality & Reliability Management*, 21(7), 731-746.
- [8] Sinha, P.R., Whitmann, L.E. and Malzan, D. (2004). Methodology to Mitigate Supplier Risk in An Aerospace Supply Chain. *Supply Chain Management: An International Journal*, 9(2), 154-168.
- [9] Slack, N., Chambers, S. and Johnston, R. (2001). *Operations Management*, 2nd ed., Harlow: Financial Times, Prentice-Hall, Inc.
- [10] Slinger, M. (1992). "To practise QFD with success requires a new approach to product design", *Kontinuert Forbedring*, February, 20-1.
- [11] Tang, S.H. and Ho, S.Y. (1996), "Failure mode and effects analysis: an integrated approach for product design and process control", *International Journal of Quality & Reliability Management*, 13(5), 8-26.
- [12] Vandenbrande, W.W. (1998). "How to use FMEA to reduce the size of your quality toolbox", *Quality Progress*, 31(11), 97-100.
- [13] Van Leeuwen, J.F., Nauta, M.J., de Kaste, D., Odekerken- Rombouts, Y.M.C.F., Oldenhof, M.T., Vredenbert, M.J. and Barends, D.M. (2009). "Risk Anaysis by FMEA as an Element of Analytical Validation", *Journal of Pharmaceutical & Biomedical Analysis*, 50(5), 1085-1087.
- [14] Zhang, J. and Zhu, Q. (2009). "FMEA Based Potential Risk Analysis of Lower Cost Region Sourcing", *Proceedings of IEEE International Conference on Service Operation, Logistics & Informatics*, Shanghai.