



UNIVERSITI PUTRA MALAYSIA

**IMPROVING QUALITY SYSTEMS IN LOCAL
PHARMACEUTICAL MANUFACTURING: USING
ANALYTICAL HIERARCHY PROCESS**

ROBERT PAUL ALEXANDOR

GSM 1997 10



TESIS

**IMPROVING QUALITY SYSTEMS IN LOCAL
PHARMACEUTICAL MANUFACTURING: USING
ANALYTICAL HIERARCHY PROCESS**

ROBERT PAUL ALEXANDOR

MASTER IN BUSINESS ADMINISTRATION

MALAYSIAN GRADUATE SCHOOL OF MANAGEMENT

UNIVERSITI PUTRA MALAYSIA

SERDANG, MALAYSIA

AUGUST 1997



**IMPROVING QUALITY SYSTEMS IN LOCAL
PHARMACEUTICAL MANUFACTURING: USING
ANALYTICAL HIERARCHY PROCESS**

ROBERT PAUL ALEXANDOR

YPM/ UPM 45107

MASTER IN BUSINESS ADMINISTRATION

FACULTY OF ECONOMICS AND MANAGEMENT

UNIVERSITI PUTRA MALAYSIA

SERDANG, MALAYSIA

1995/1997



**IMPROVING QUALITY SYSTEMS IN LOCAL
PHARMACEUTICAL MANUFACTURING: USING
ANALYTICAL HIERARCHY PROCESS**

**ROBERT PAUL ALEXANDOR
MASTER IN BUSINESS ADMINISTRATION**

**FACULTY OF ECONOMICS AND MANAGEMENT
UNIVERSITI PUTRA MALAYSIA
SERDANG, MALAYSIA
1995/1997**



**IMPROVING QUALITY SYSTEMS IN LOCAL
PHARMACEUTICAL MANUFACTURING: A CASE OF ER
PHARMACEUTICALS.**

BY

ROBERT PAUL ALEXANDOR

MATRICULATION NUMBER: 45107

.....

Major Supervisor

.....

Date

.....

Second Reader

.....

Date



Pengesahan Keaslian Laporan

Dengan ini, saya Robert Paul Alexandor a/l S. Joseph, Nombor Matrik 45107, pelajar program MBA mengaku bahawa kertas projek / kajian kes untuk kursus ini adalah hasil usaha asal saya sendiri.



Tanda Tangan

16.08.97

Tarikh.

DEDICATED WITH LOVE

TO

MY WIFE:	NESAMANI
MY CHILDREN:	EDWIN, EDLEENA & EDGAR
MY PARENTS:	MR AND MRS.S.JOSEPH
MY BROTHER AND SISTER:	PRINCE & JOYCE

For their kind support and encouragement during the entire MBA program, without whose support it would have been impossible to see the completion and to my children, for sacrificing their vacation.



ABSTRACT

The primary objective of this research was to identify and address the factors involved in overall quality production of ER Pharmaceutical products. A second objective was to be operationlise. These factors with the system, "cetirus parebus" that enable a company to shift from one with lower level of quality skills to one that would be in line with the call of "Quality 2020". As expected the two factors come to the fore: - a) quality products b) the ability to use quality to meet the needs and satisfaction of customers.

Internal and external customers were assessed by Analytical Hierarchy Process Survey techniques to assess the needs and identify factors in this study. Questionnaires were issued and return monitored. The two objectives was to collect data as integrated factors of Product Quality and Human Resources factors involved in Human Resources related to product quality. There were thirteen product quality factors selected for this research: 1) Visual appearance, 2) Friability 3) Disintegration 4) Taste 5) packaging 6) Embossing 7) Hardness . The human Resource factors included in this paper were 1) willingness to change 2) Knowledge 3) Skill 4) Commitment 5) Attitude 6) Teamwork and 7) leadership. Analytical Hierarchy Process was undertaken to facilitate ranking procedures. The subsequent ranking for product quality was 1) Strip Packing 2) uneven color, 3) Visual appearance 4) Friability 5) Texture 6) Blister Packing 7) Disintegration 8) Taste 9) Crack 10) Packaging 11) shape 12) Embossing and 13) Hardness Th final ranking of the human resources factors was 1) Willingness to Change 2) Knowledge 3) Skill 4) Commitment 5) Attitude 6) Teamwork and 7) Leadership.

It was found that it was vital for process Engineers to consider the identified factors and accord them with fundamental importance in establishing high quality process function. Participation and input from Human resources was also gauged as important factor in determining High Quality. HR participation is the transformation of personnel as vital ingredients in successful output.

Acknowledgments

I would like to take this opportunity to extend my thanks to my lecturer and project supervisor, Dr Salleh Yahya, for his kind support and guidance during the planning, and completion of this work.

My sincere thanks are also extended to the Managing Director and General Manager of the company for all the assistance and cooperation in the collection of information and data.

TABLE OF CONTENTS

CONTENTS	PAGE
ABSTRACT	
ACKNOWLEDGEMENT	
LIST OF APPENDICES	III
LIST OF TABLES	IV
LIST OF FIGURES	V
LIST OF CHARTS	V

CHAPTER:ONE: INTRODUCTION

1.0 Introduction	1
1.1 Pharmaceutical Market	1
1.2 Quality	4
1.3 Objective of the Study	17
1.4 Importance of the Study	17
1.5 ER Pharmaceuticals	19
1.6 Project Outline	36
1.7 Summary	36



CHAPTER:TWO: LITERATURE REVIEW

2.1	Introduction	37
2.2	Criteria & Factors Affecting Quality in Pharmaceutical Products	39
2.3	Ranking Method	44
2.4	Calculating Weighted Average	51
2.5	Summary	52

CHAPTER:THREE: METHODOLOGY

3.1	Introduction	55
3.2	Quality Factors for Product and Human Resources	55
3.3	Analytic Hierarchy Process	57
3.4	Collection of Data	61
3.5	Data Analysis and Reporting	62
3.6	Summary	62

CHAPTER :FOUR: ANALYSES AND FINDING

4.1	Establishing the Assessment Factors	63
4.2	Quality System Ranking Procedures	68
4.3	Result of Analysis	71



CHAPTER:FIVE: DISCUSION AND CONCLUSION

5.1	Introduction	77
5.2	Discussion	78
5.3	Extensions	80
5.4	Study Recommendations	81

REFERENCES

APPENDICES

LIST OF APPENDICES

SECTION	1:	Preliminary Survey Form
SECTION	2:	Questionnaires(SAMPLE)
SECTION	3:	Survey Average Report Worksheets-Product Factors
SECTION	4:	Survey Average Report Worksheets-HR Factors
SECTION	5:	Layout of Tableting section
SECTION	6:	List of Products
SECTION	7:	Quality Control flow Charts Raw Material to Finished Product
SECTION	8:	Quality Control flow Charts-Coated Tablets
SECTION	9:	Quality Control flow Charts –Tablets
SECTION	10:	Quality Control flow Charts-Granules
SECTION	11:	Quality Control flow Charts-Capsules
SECTION	12:	Job Sheet from start to End
SECTION	13:	Example of job sheet
SECTION	14:	Quality Control Final Report
SECTION	15:	ER Pharmaceutical Data Collected During Personal Visits



LIST OF TABLES

TABLE	1:1	Definition of quality	5
TABLE	2:4:1	Example of Bromhexine Tablets Quality	41
TABLE	2:5:1	Dickson's Criteria For Assessing Vendors	45
TABLE	3:2:1	Factors for Pharmaceutical Products Quality	56
TABLE	3:2:2	Factors for Human Resources Quality	57
TABLE	3:3:1	Scale of AHP	58
TABLE	3:3:1:2	Comparison Matrix	59
TABLE	4:1:1	Summary of Survey On ER Product Range	64
TABLE	4:1:2	Definition of Product Factors	66
TABLE	4:1:3	Definition of Human Resources Factors	67
TABLE	4:2:1	The Relative Important of Criteria Using AHP For Products	69
TABLE	4:2:2	The Relative Important of Criteria Using AHP For Human Resources	71
TABLE	4:3;5	Pairwise Comparison Matrix for Factors –Product	71
TABLE	4:3;6	Pairwise Comparison Matrix for Factors –Product-Visual Appearance	71
TABLE	4:3;7	Pairwise Comparison Matrix for Factors –Product- Packaging	71
TABLE	4:3;9	Ranking of Seven Factors -Product Quality	73
TABLE	4:3:10	Ranking of Packaging	73
TABLE	4:3:9	Ranking of Visual Appearance	74
TABLE	4:3:12	Pairwise Comparison Matrix for Factors –Human Resources	75
TABLE	4:3:13	Ranking of Human Resources	75



LIST OF FIGURES

FIGURE	1	Market tend till Year 2003	3
---------------	----------	-----------------------------------	----------

LIST OF CHARTS

CHART	4:1	Factors for Product Quality	65
CHART	4:2	Factors for Human Resources	67



CHAPTER ONE

INTRODUCTION

CHAPTER ONE

INTRODUCTION

1.0 Introduction

A new millennium, it is very obvious that the general population has become highly aware of the whole concept of "Quality of Life " of special concern is the quality life available in the country. The reference to quality life involves general health, the work environment, food consumed, and others that are essential to developing and establishing styles. Most people are always want quality of the products they take to keep a good life style. A good indicator of this would be the introduction of numerous healthcare products into the Malaysian markets. The consumption of these product has been positively correlated with an increase in the life span from 70 years to 80 years. (Source: Department of Statistics, Malaysia)

1.1 Pharmaceutical Market

From this point of view Quality of Life is also highly linked with the economy of the country. The Malaysian economy is a stable one. It is expected to remain stable with the Barisan Nasional Government providing the necessary economic incentives for the development of self-sufficient local industries. This is in keeping with the Seventh Malaysia Plan. This is in line



with the strategic objective of developing the country into a major export player, as well as in efforts to reduce imports so as to balance out the trade deficits, which the country presently faces.

The Malaysian Economy is still expected to register an 8.5% growth for the year 1997 and is forecasted to continue at 8% over the marketing plan period. This is owed to the numerous mega construction and development projects which have been initiated over 1995 and 1996.

With an growing economy we have a nationally growing market of this constitutes the pharmaceutical market at present stands at is one billion Malaysian Ringgit, 40 % of it supplied by local manufactured pharmaceuticals.

Figure 1 , showed a forecast of Malaysian local pharmaceutical market trend. It is believed that current 40 % market share would be increased up to 47 %. Various effort have been done to ensure this forecast become a reality. One of its or suggested by this project is using quality System.

Malaysia Local Pharmaceuticals Market Trends Year 1994 -2003

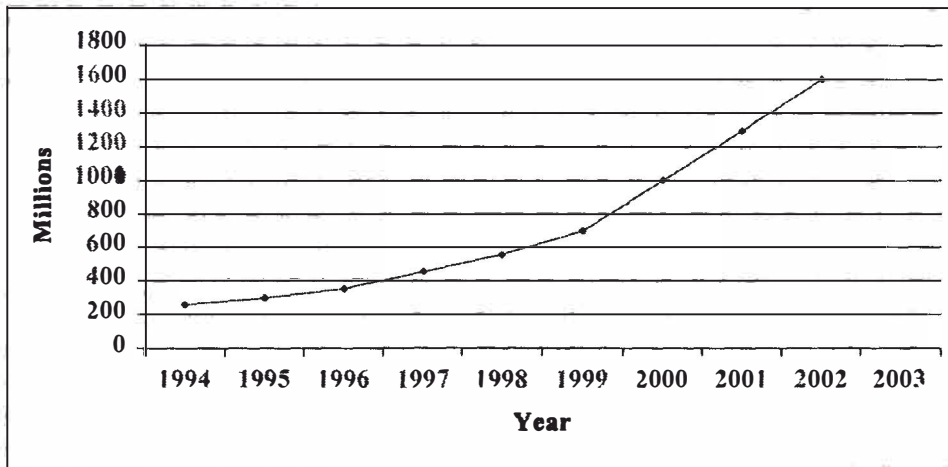


Figure 1: Market Trend till Year 2003

The above figure from IMS Report 1996 which say that 60 % is imported pharmaceuticals, which means that 40 % contributes to local manufactured pharmaceuticals. This was confirmed from observations in the market, sales report and forecast of the market that is available.

The balance of 60 % of the National Pharmaceutical requirement is dominated by Multinational corporations. They have achieve this through professional and aggressive marketing strategies with the support of by their parent company.

Most of these pharmaceuticals are imported with only a handful of them being manufactured locally. Although there are some 56 registered

local manufacturers of pharmaceuticals in the country, less than five have had any significant impact on the industry, by way of reputation of quality and market shares. May be if the majority of them are small producers, producing small range of lower level products. This manufacturers have little or ineffective marketing. Realizing their weakness, many small manufacturers are now try to consolidate among them. Especially with the facilitation by Malaysia corporate giants who are keen of diversifying their business and venture to health sector.

1.2 Quality

Several individuals have strongly influenced companies in both manufacturing and services sectors to emphasize quality. Initially, their ideas found greater acceptance in Japan than in the United States.

There are three gurus or experts in quality.

- ❖ W. Edwards Deming, considered to be the father of quality control in Japan, summarized the far reaching, long lasting effects of improving quality with his five steps chain reaction:
- ❖ First, cost declines because of less rework, fewer mistakes, fewer delays and better use of time and materials, which

- ❖ Result in improved productivity, which
- ❖ Increases market share because of better quality and prices, which
- ❖ Increase profitability, allowing the company to stay in business, which
- ❖ Results in more jobs.

The central concern of 'Quality' is its very definition in Table 1:1 shows some of the functional definition proposed. Joseph M. Juran (1989), stressed that quality is "fitness for use". This implies that the products on consumption, must be successfully beneficial to the user meets their needs and satisfaction. Juran explained that quality has a dual meaning; product features that meet those customers needs and a product free from deficiencies

Table 1:1 Definition of quality

PRODUCT FEATURES THAT MEETS CUSTOMERS NEEDS	FREEDOM FROM DEFICIENCIES
Higher quality enables companies to :	Higher quality enables companies to:
❖ Increase product saleable	❖ Reduce error work
❖ Meet Competition	❖ Reduce rework, waste
❖ Increase market share	❖ Reduce customers dissatisfaction
❖ Provide sales income	❖ Reduce inspection, test
❖ Secure premium price	❖ Increase yield, capital

Source: Joseph M. Juran, *Juran on Leadership for Quality*, 1989

According to Kivenko (1984), there is five common definition of quality: a) relative excellence, b) value for money, c) conformance to drawings, d) conformance to the purchase order and e) fitness for intended function. Relative excellence means the product can give what the customers actually want (the satisfaction) so that they are interested to continue buying the product from the same companies or manufacturer. Conformance to drawings and specification are certainly one of the best way of measuring the quality of the product. If the drawings and specifications of the product are clear, it is adequate to provide all things that the users expect. The concept practice in conformance to purchase order. Fitness for intended function means that the product being what it is supposed to be and doing what it is supposed to do.

1.2.1 The Need for Quality

The need for quality in the manufacturing sector is obvious. This is more prominently seen, in the pharmaceutical-manufacturing sector, the strongest competitor will get all the business because they deliver quality product that performs to customer satisfaction. Not only this deal with human life, nevertheless failure in quality exposes the manufacturers to legal issue. Quality is also a moral issue. If the customer finds that a product doesn't conform to a certain specifications, its will ruin the business

enterprise. Companies will then not be able to survive in a growth market without a working quality system in place.

Since quality of pharmaceutical products are always affecting the human health, therefore quality should always be the deciding factor in the purchase of the product, not the price. Continuous and consistent product consumption by consumer can only be maintained if the product contains quality or as requirement by standards of that drug.. There is apparently a need for quality in the design of products. Poorly designed product never will reach sufficient level of quality to meet customer needs. No matter how hard the manufacturing organisation tries, that marketing effort or other means consumption and demand for a product will ultimately rest on its quality and design.

In pharmaceutical product quality must start from research and development design, production and with people marketing pharmaceutical, it will be able to sustain in the market place. Therefore it is not a one quality assurance department responsibility. It involves many complex areas in the life of a product. Furthermore it is important that manufacturer must take a specific steps to improve the quality of product in every stage of the production line.

Commitment to quality in a company requires a systems approach. It requires the participation from all managers, workers and every person who are involved in the production process. This is the only approach, that secures the manufacturer of quality goals, of high quality products and assurance of meeting the customer needs and satisfaction.

As most of the manufacturing sector had some form of quality control system to assure that the market received goods of some defined standards set by the government of Malaysia. In the case of pharmaceutical, the criteria for quality were more stringent; the controlling body was **Drug Control Authority of Malaysia of the Ministry of Health**. Which follows the British Pharmacopoeia or the Russia Pharmacopoeia standards.

The Malaysian Ministry of Health was one of the important primary sources of control to all pharmaceuticals in Malaysia. This needs much documentation to be full filled before the drug is released into the market. It provides documentation in the form of several certificates, which are mandatory by the health authorities locally, and oversea market.

The export of pharmaceuticals from Malaysian manufacturers to destination abroad in 1996 amounted to less than 0.5% of the country's gross exports of manufactured goods. Nevertheless, with the government's call

for Malaysian manufacturers to aggressively consider the export potential to boost the country's earnings, the local pharmaceutical industry should be encouraged to rise to this call and not be contented to limit their operations to the domestic sector alone.

The purpose of this paper is to provide some insights into how one may proceed with obtaining the relevant information prior to exporting their products overseas. This needs quality to be maintained.

Some of the primary documentation required as a precondition of consideration by parties overseas might be obtained from the Malaysian authorities, some of which are briefly mentioned in the following paragraphs:

1.2.2 Malaysian Drug Control Authority of the Ministry of Health

The Malaysian Ministry of Health is one of the important primary sources of documentation. It provides documentation in the form of several certificates, which are mandatory, required by the corresponding health authorities in the importing countries as a quality control guideline for the products.

i. Product Registration Certificate/Product License

This certificate is one, which is issued by the Drug Control Authority upon the registration of a manufactured product. Products, which fulfil the requirements of product registration under the Control of Food and Drugs Act, 1954 are granted a product, license. Implied in such granting of license is the fact that the authorities are satisfied that the products have met the quality, efficacy and safety considerations warranting approval.

Product Registration Certificates or Product licenses are a basic requirement of the authorities abroad as they serve to confirm that a particular pharmaceutical preparation has met the basic requirements as previously mentioned, for it to be on the local market. However, not all countries insist on having this certificate as compared to the Free Sales Certificate.

ii. Certificate of Free Sales in Malaysia

This certificate confirms that the product registered is freely sold in the country of manufacture. Hence, most authorities accept the Free Sales Certificate in lieu of the product license.