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M.S. degree in PACKAGING

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PACKAGING JOB PROFILE OF PHARMACEUTICAL MANUFACTURING INDUSTRIES

By

José Raúl Sosa

A THESIS

Submitted to
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ABSTRACT

PACKAGING JOB PROFILE OF PHARMACEUTICAL MANUFACTURING INDUSTRIES

By

José Raul Sosa

The purpose of this investigation was to identify and document professional packaging competencies that could be used for the development of a packaging job profile within pharmaceutical manufacturing companies. A second purpose was to determine if the responsibilities for a packaging professional position within pharmaceutical manufacturing companies are affected or vary with respect to educational background, job title and/or number of persons performing packaging functions.

A list of forty-eight competencies was developed through personal interviews and library research. Twenty-two competencies were identified as being significant to the performance of professional packaging activities on the basis of importance and frequency of use.

There were no major differences among educational background in the competencies required for the performance of the professional packaging functions. Therefore, there is no need to develop packaging training programs with variations in content to support these differences.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAPTER I

THE PROBLEM AND DEFINITION OF TERMS

I. INTRODUCTION

Importance of Packaging in the Pharmaceutical Industries

The science of packaging is a necessary part of everyday living. Without it, there could be no preservation of goods, no convenient quantities or mass distribution of products.

The complexities of each product and its unique set of characteristics require that every package be developed to meet the needs of each specific product. Based upon the product characteristics, the package is developed to meet the basic functions of (1) protection, (2) utility and (3) communication. Fulfilling the product needs and the package functions requires considerable time, energy and finances.

In many pharmaceutical companies, packaging is probably the least understood and the most poorly controlled function in the place. The cause of this condition seems to lie in the apparent simplicity of the packaging function. It is only when an organization chart is drawn, or the firm's activities are diagrammed in a way that points out who does what, when and to whom they are responsible, that

the real complexities of the packaging function begin to be revealed.

Packaging may not be well understood by many pharmaceutical companies. Although many large corporations have recognized the needs and understand the benefits of packaging, others are still quite unaware of the significance or ramifications.

Packaging and the Pharmaceutical Industry

Packaging, for the pharmaceutical industry, can be divided into two groups: users and vendors. Users are the pharmaceutical manufacturing companies that produce products which require packaging (over-the-counter and prescription drugs, health care products, medical devices, etc.). In this case, packaging is a function of that company. Vendors or suppliers are those industries that produce packages, materials, packaging machinery and other related supplies to service the user company's packaging needs. Vendors are classified as an industry.

Packaging as a function usually is carried out by an individual(s) or department(s) within a pharmaceutical manufacturing company. These individual(s) or department(s) have the responsibility for the quality and integrity of the product from the point of production on through to the ultimate consumer. Through this span of events the package should contain the product in convenient quantity and weight for efficient handling; it should protect the product

through the handling and distribution system; it should represent the product in the market place in a manner that will make the product desirable for use by the consumer; it should provide convenience or utility while the product is being handled and being used; and it should afford ease of disposability after the product has performed its specific purpose.

Vendor companies are in the business of producing package forms and the related equipment to support the packaging activities of the user companies. They normally specialize in specific kinds of package forms which are usually materials-oriented, such as paper containers, metal cans and glass bottles. The machinery producers are similarly oriented, producing labeling equipment, filling equipment, sealing equipment, etc.

A vendor provides certain additional services to the user. These services, again related to the vendor's specialty, can include assistance with material selections, structural and graphic design, container evaluation and equipment selection. The use of these services is optional.

Each product has a unique set of characteristics that must be considered in order to ensure that it will be able to move from the point of production to the consumer with complete integrity. These characteristics must be analyzed in a systematic manner so that the most efficient, effective, economical and the most appealing package can be developed for each given product.

II. THE PROBLEM

Purpose of the Problem

The primary purpose of this investigation was to identify and document packaging competencies that could be used for the development of a packaging job profile within pharmaceutical manufacturing companies. The second purpose of this investigation was to determine if the responsibilities for a packaging professional position within pharmaceutical manufacturing companies are affected or vary with respect to educational background, job title and/or number of persons performing packaging functions.

Statement of the Problem

The central problem of this study was to identify the packaging competencies required of those individuals performing the packaging activities within the pharmaceutical manufacturing companies at the middle management and technical levels. Specifically, the investigation intended to answer the following questions:

1. Which packaging competencies are the most important to the performance of the packaging professional position, within pharmaceutical manufacturing companies, at the middle management and technical levels?
2. Which packaging competencies are most frequently used by the personnel performing packaging

functions, within pharmaceutical manufacturing companies, at the middle management and technical levels?

3. What relationship do the educational experiences of the packaging personnel have with the competencies utilized in the performance of the packaging professional position, within pharmaceutical manufacturing companies, at the middle management and technical levels?
4. What relationship do the curriculum majors of the packaging personnel have with the competencies utilized in the performance of the packaging professional position, within pharmaceutical manufacturing companies, at the middle management and technical levels?
5. What effect does the job title held by the packaging personnel have with the competencies utilized in the performance of the packaging professional position, within pharmaceutical manufacturing companies, at the middle management and technical levels?
6. What effect does the number of personnel performing the packaging functions have with the competencies utilized in the performance of the packaging professional position, within pharmaceutical manufacturing companies, at the middle management and technical levels?

Limitations of the Problem

This investigation was limited to include only the user pharmaceutical manufacturing companies. Under that umbrella, the investigation was further limited to the packaging activities which fall into the middle management and technical positions. These positions would be responsible in full or in part for the research, design, evaluation and coordination of the packaging activities.

The identification of specific companies and their respective pharmaceutical products was limited to the available literature and to the practical limits of efficient use of time and finances. Those firms that could not be identified in terms of products produced through normal procedures short of individual contact were dropped from the list.

III. DEFINITIONS OF TERMS

A number of terms are presented in this thesis which have various interpretations. So that a proper understanding can be gained from the investigation, the following definitions are presented.

Competencies: The specific knowledge, skills, understanding and attitudes necessary to perform the critical tasks (Crawford and Meyer, 1972).

Functions: A collection of activities, which when taken together leads to the attainment of a particular job. The packaging professional position is generally considered

to be divided into the two functions of technical and management.

Packaging: The use of containers and components with the addition of decoration or labeling to protect, contain, identify, merchandise and facilitate the use of products (Glossary of Packaging Terms, 1988).

Packaging Professional Position: A term used in this investigation in place of the term "packaging engineering."

Responsibilities: A group of major activities necessary to meet the requirements of the job functions.

Task: The smallest unit of performance which can be identified as having a distinct and independent purpose (Krumboltz, 1965).

User Company: Those companies which produce products that in turn require the services or products of the supplier companies to package the products.

Vendor Company: Those companies which produce packages, equipment and special supplies required to facilitate the user's product packaging activities.

CHAPTER II

REVIEW OF THE LITERATURE

I. INTRODUCTION

A review of the literature was undertaken to identify previous research relating to the analysis and development of a packaging job.

II. LITERATURE ON JOB ANALYSIS

The process of identifying the activities necessary to perform the duties of a given job has been discussed by many. One of the early leaders in this area was Fryklund (1965), promoting the technique of activity analysis. Fryklund's system is based upon the analysis of each job or project of the employee in terms of the skills, knowledge and guidance necessary to complete the job. Other approaches have been suggested by Crawford (1972) and Smith (1964). Smith's system begins with the stating of a "mission profile," which forms the basis for what he terms "task inventory." The task inventory is developed by asking the questions: (1) What does the person do? (2) What does he do it to? and (3) What does he do it with?

The above processes, although very effective, deal directly only with those kinds of jobs that are performance-oriented in terms of psychomotor activities. The job in question for this investigation does include psychomotor activities, but it also includes those kinds of performance activities that require decision-making abilities. These kinds of activities are more difficult to identify.

A study completed by Ammerman (1963) and sponsored by the Department of the Army produced a manual of procedures for deriving training objectives for junior grade officers. The intent of the study was to develop procedures for analyzing a job which was composed of skill and management functions. Smith, while describing Ammerman's work, stated:

> "Officers' jobs have generally been more difficult to analyze than those of enlisted men, because the job activities of officers tend to be less standardized, more variable, and more restricted to mental activity than those of enlisted men. Historically, task inventories for officers contain such terms as "responsible for," "insures," or "supervised," phrases that do not permit clear statements of job tasks in terms of performance."

The nature of the activities performed by the packaging professional position within pharmaceutical manufacturing companies can be considered to be skill- and management-oriented; and thus, they are similar to the kinds of activities of Ammerman's study.

The determination of the job activities, as proposed by Ammerman, is accomplished by first preparing the "initial

job description." The initial job description is prepared by seeking statements which describe the job in terms of:

1. Area of responsibility.
2. Job goals and standards.
3. Determination (making judgments)
4. Information-gathering activities.
5. Controlling activities.
6. Relationship between physical activities and job purposes.

The completion of this list of statements will provide a comprehensive description of the performance requirements for any given job. This list of statements is further analyzed to describe those activities for which training can be accomplished. The suggested procedure is to analyze each statement in terms of:

1. What actions are necessary to obtain information?
2. What judgments must be made?
3. What actions are necessary to correct, maintain, report or operate?

Each job analysis requires its own set of specific criteria to ensure that the job will be analyzed to its fullest extent. Because the packaging professional job under investigation here is not as highly structured in terms of specific job responsibilities as that of the military occupations, certain modifications were implemented to adjust the procedures to the packaging job. Therefore, the

basic steps of procedure followed to determine the packaging competencies were:

1. Determine the major job functions.
2. Determine the areas of responsibilities within each function.
3. Determine the competencies required to perform within each area of responsibility on the basis of:
   a) decision-making activities;
   b) information-gathering activities;
   c) skill activities.

The relationship between Ammerman's manual and the requirements of this investigation was felt to be adequate to support its use as a guide for carrying out the investigation of the packaging competencies within pharmaceutical manufacturing companies.

III. LITERATURE ON PACKAGING DEPARTMENTS

A study on the role of the packaging department was completed in Spring, 1978, and published by the Ohio State University. This research by McGinnis and Hollon (1978) is titled "Packaging: Organization, Objectives, and Interactions." McGinnis and Hollon attempted to answer the following questions:

1. "What effect does the type of product and packaging emphasis (i.e., the relative emphasis on

consumer and industrial packaging) have on the location of the packaging department in the organization?

2. What effect does the type of product and packaging emphasis have on the objectives of the packaging department?
3. What effect does packaging objectives and location of the packaging department in the organization have on the interaction of packaging with others?"

The study was conducted through the survey method, using the mailed questionnaire to collect the data. The study population consisted of packaging engineers who held at least a bachelor's degree in packaging, worked for a packager-user firm and had at least five years work experience.

A confidential mailing list was obtained that included 208 names that met the authors' criteria. While not a random sample, the list included a broad spectrum of large companies in different industries.

McGinnis and Hollon study results can be summarized as follows:

1. Packaging will frequently report to engineering or research and development. Where the package is very important with relation to product's formulation (for example, cosmetics), packaging will report to general management.

2. "Development of packaging for new products, reduction of cost through redesign and improvement of functional performance of packaging are primary objectives of packaging departments. Lower priority objectives are package designs that help control company-wide inventories, package cost reduction through joint efforts with purchasing and high levels of graphic and aesthetic quality. A single exception to this statement is the area of graphics and aesthetic quality (as with cosmetics). Emphasis on graphic and aesthetic quality increases as the company's proportion of consumer packaging increases (McGinnis and Hollon, 1978)."
3. "The pattern of interactions of the packaging organization shows a high level of independence either or organizational placement or packaging emphasis. In all cases, packaging's greatest amount of interaction is with purchasing and production/quality control. Somewhat less frequent contact occurs with engineering/-research and development, marketing and inventory control/physical distribution (McGinnis and Hollon, 1978)."

CHAPTER III

THE DESIGN OF THE INVESTIGATION

I. THE IDENTIFICATION OF THE PACKAGING COMPETENCIES

Product Packaging Functions and Responsibilities

Figure 1 illustrates the organizational structure of the functions and responsibilities developed for this investigation. The packaging professional position within pharmaceutical companies is generally divided into the technical function and management function. These functions are then divided into specific job responsibilities.

Identifying the Packaging Competencies

The development of the list of competencies was based upon the eight responsibilities identified in Figure 1. Each responsibility was analyzed in terms of the decision-making activities, information-gathering activities and skill activities. The first step was to review packaging job descriptions to identify specific activities. Also, a series of interviews and phone calls were conducted with individuals responsible for the packaging activities in both the technical and management functions within pharmaceutical manufacturing companies. This search process resulted in the identification of forty-two competencies.

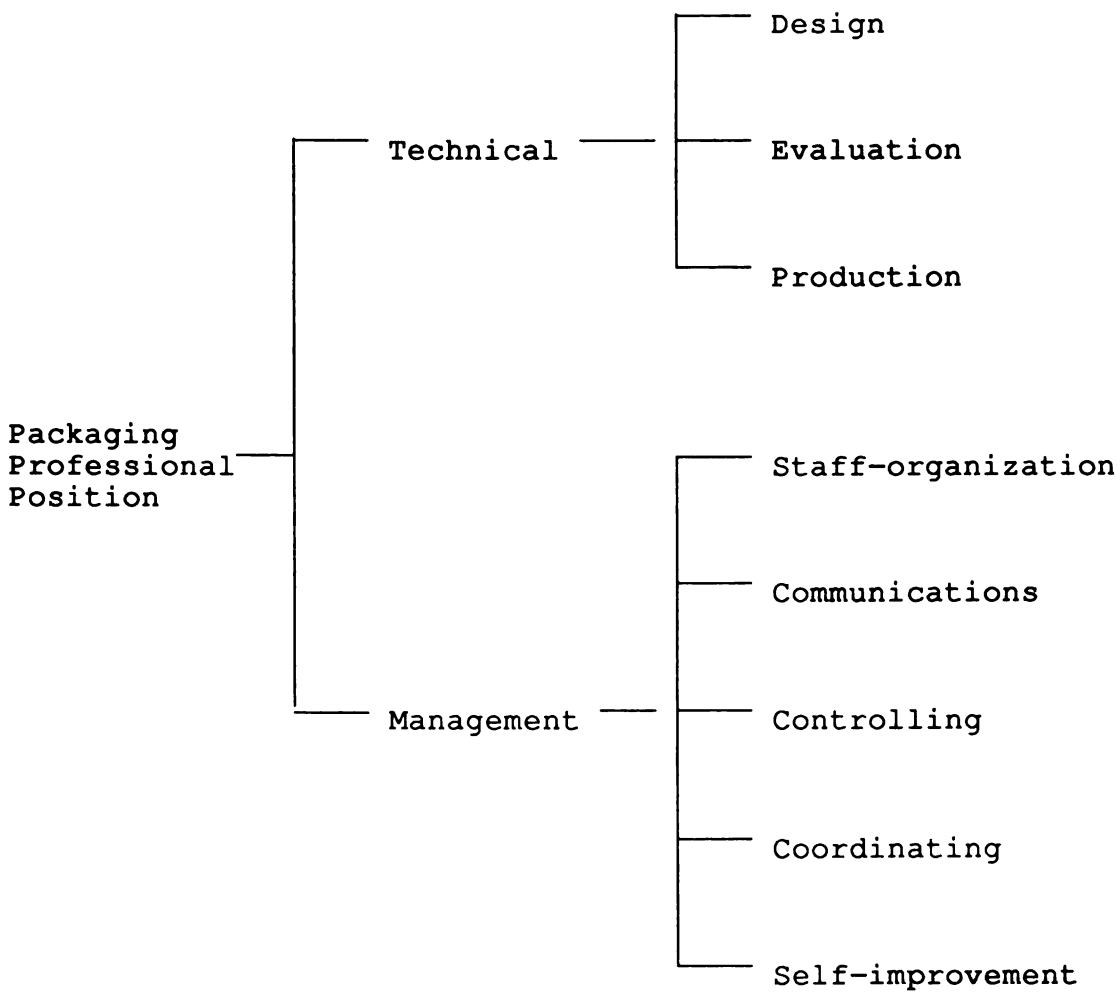

FIGURE 1
FUNCTIONS AND RESPONSIBILITIES FOR A PACKAGING
PROFESSIONAL POSITION WITHIN
PHARMACEUTICAL MANUFACTURING COMPANIES

The list of competencies, as developed through the investigative procedures, was felt to be as complete as possible. The competencies were prepared in a mailed-questionnaire form and given back to the packaging professionals interviewed for their evaluation. With suggested modifications that resulted in six more competencies, a final list of forty-eight packaging competencies was developed.

III. THE STUDY POPULATION

Professional packaging personnel within pharmaceutical manufacturing companies in the middle management and technical levels were asked to respond to the instrument that was developed. Individuals in charge of packaging functions, both technical and managerial, were asked to respond to the questionnaire.

The population for this investigation was selected from pharmaceutical companies classified as user companies. These companies were identified by referring to the Thomas Register of American Manufacturing Companies (1991). The search was made in each case on the basis of the pharmaceutical products produced by the company, such as over-the-counter and prescribed drugs, health care products and medical devices. Those companies which could not be identified with this reference were excluded. Two-hundred-eighty-one companies were identified, each one receiving one questionnaire for a total of 281 possible respondents.

IV. THE INSTRUMENT

The statement of the problem spells out six questions to be answered. Two of the questions required specific responses which indicated the importance and frequency of use in regard to each of the forty-eight competencies. These responses were provided for in the main body of the instrument. Four questions require information pertaining to educational background, work experience required and number of people performing packaging functions. A fifth question required information about the respondents' job titles. These responses were provided for under the heading of General Information.

The format used for the instrument was as follows. The first page included the purpose of the study and questions of general information. The five questions were: (1) Educational Background, (2) Education Major, (3) Work Experience Required, (4) Number of Persons Performing Packaging Functions and (5) Your Job Title.

The body of the instrument consisted of a listing of the forty-eight competencies. Specific instructions were provided in the procedure for making and completing each response. The two responses requested for each competency are as follows:

1. How important is the competency to the success of the packaging functions?

   _____ No importance

_____ Slight importance

_____ Moderate importance

_____ High importance

_____ Very high importance

2. How often is this competency required in the performance of your duties?

_____ Never

_____ Sometimes

_____ Usually

_____ Frequently

_____ Always

The Mailed Questionnaire Survey

The General Information questions and the forty-eight competencies were written into the final questionnaire form. They were mailed to the 281 individuals representing the different pharmaceutical manufacturing companies. Two and one-half weeks later a follow-up letter was sent as a reminder to those who had not responded (see Appendix B). One and one-half weeks following the reminder, a second reminder was sent which included another copy of the instrument (see Appendix C).

Seven weeks following the initial mailing, 171 questionnaires were returned. The returned instruments included 14 that had no forwarding address and 50 that indicated the respondent was no longer responsible for the

activities described in this investigation. The net result at this point was 107 completed questionnaires.

Each instrument was reviewed to determine if it had been properly completed. Of the 107 instruments, 5 were less than 50 percent complete, and thus were removed from the usable group. The remaining 102 returns resulted in usable forms. The analysis here was based on 48 percent usable responses.

The percentage of replies to the survey was considered adequate to draw conclusions for this investigation. The survey provided a good number and distribution of the responses. The number of personal comments returned with the survey instrument indicated that those individuals who did respond were doing so out of genuine interest in the problem. It was felt, therefore, that those individuals that did respond provided a good picture of the state-of-the-art of the packaging professional position within pharmaceutical manufacturing companies.

CHAPTER IV

SELECTION OF THE COMPETENCIES FOR A PACKAGING JOB PROFILE

I. INTRODUCTION

This chapter will describe the procedures used to summarize the data through the use of the computer. The data taken from the general information section of the survey instrument were used to describe the profile of the respondents. This profile will show the distribution of the respondents in terms of the educational background, number of persons performing packaging functions and job title with work experience required. The chapter will further explain the development of the decision rules and how they were applied to the data to select the competencies.

II. DESCRIBING THE DATA

The data accumulated through the survey instrument will be used to describe what is required to perform the packaging duties. It will be possible to summarize the importance and frequency of use of the several competencies through statistical means, so that the results will indicate the most frequently used and important competencies.

The descriptive survey method was used to design and carry out the data collection process for this investigation. The data will be arranged on an ordinal scale and thus will be described using descriptive statistics. The descriptive statistic is based upon central tendencies, a means of describing the typical or average values and variability, the spread or extent of the values.

Measures of central tendency are the mean, median, and mode. Hays and others indicate that the median is the most serviceable measure for purely descriptive statistics and thus will be used for this investigation (Hays, 1963). The median is defined as that point in which one-half the scores are above and one-half the scores are below.

Variability around the median is best described by the quartile deviation (Downie and Heath, 1965). This deviation is based upon the number of responses divided into four equal parts (intervals of 25 percent responses) and indicates the interval between each of the four parts by Q_1, Q_2 and Q_3. Q_1 describes that point which 75 percent of the responses fall above. Q_2 is the median or that point which 50 percent of the responses fall above and Q_3 is that point which 25 percent of the responses fall above. Therefore, 50 percent of the responses fall between Q_1 and Q_3. The distance between Q_1 and Q_3 is known as inter-quartile range (IQR).

The mathematical formula (Edwards, 1967) for calculating the median (Q_2) is:

$$Q_2 = l + \frac{n/2 - f_b}{f_w} i$$

where:

Q_2 = median or second quartile

l = lower limit of the interval containing Q_2

n = total number of responses

f_b = number of responses below the interval containing Q_2

f_w = number of responses within the interval containing Q_2

i = size or range of the interval = 1

To find Q_1 and Q_3, we would substitute n/4 or 25 percent of n for n/2 and 3n/4 or 75 percent of n for n/2 respectively in the above equation.

The frequency distribution of responses to any one item can be described by the terms: unimodal, bi-modal and one having no mode. The unimodal distribution indicates that the responses fall into one major grouping. This group of responses might form a normal curve or a curve skewed to the right or to the left. The unimodal type of distribution indicates a high level of agreement on the part of the respondents. The bi-modal distribution can be recognized as having two major groupings of scores. This form of distribution would indicate that there are two lesser groups of agreement, and they are not necessarily in accord with one another. The no-mode distribution is used to describe a condition where no groupings occur, but rather there are

nearly equal number of responses to each item. The no-mode distribution would indicate no general agreement on the item.

Analysis of the Data

The analysis of the data for this investigation was compiled on an IBM Personal Computer. The information desired for the data analysis was such that a prepared computer program was available (Lotus 1-2-3). The following calculations were done:

1. Q_1, Q_2 and Q_3 for each item.
2. The inter-quartile range (IQR) for each item.

III. PROFILE OF THE RESPONDENTS

The first page of the instrument asked the respondents to provide information concerning their educational background, work experience required, number of persons performing packaging functions and job title. The data were used to develop a profile of the respondents and their job activities.

Table I provides a summary of the educational experiences of the respondents. Of those individuals responding, 92 percent hold a college degree. This group includes 68 percent with the bachelor's degree, 18 percent with the master's degree and 6 percent with the Master of Business Administration. No one from the group has earned the doctorate. Eight percent of the respondents are performing the

packaging activities with less than a formal college degree. This group includes 5 percent taking additional work through technical schools and 3 percent earning the high school diploma.

TABLE I
EDUCATIONAL EXPERIENCE OF THE TOTAL GROUP OF RESPONDENTS

Level	Percent of Respondents
B.S. Degree	58%
B.A. Degree	10%
M.S. or M.A. Degree	18%
Others (M.B.A.)	6%
Technical School	5%
High School	3%
Doctorate	0%

Of the college major reporting, engineering is the most common with 34 percent of the respondents reporting this major. The sciences major is the second most significant group with 24 percent of the respondents indicating that major. The remaining significant majors reported indicated that 17 percent majored in packaging, 9 percent majored in business as well as liberal arts. Table II itemizes the data for this category.

TABLE II
EDUCATION MAJOR OF THE TOTAL GROUP OF RESPONDENTS

Major	Percent of Respondents
Engineering	34%
Sciences	24%
Packaging	17%
Business	9%
Liberal Arts	9%
Others*	7%

*A further analysis of the "other" group indicated majors such as accounting, pharmacy, industrial management, printing management, industrial arts.

The number of persons performing packaging functions can be seen in Table III. Forty-four percent of the respondents work in a department of two to four people. Eighty-four percent of the respondents work in departments of less than eight people. This statistic shows that a high percentage of respondents do perform in relatively small departments. The remaining data indicated that 9 percent work in departments of ten or more people and 8 percent in departments of eight to ten people.

TABLE III
NUMBER OF PERSONS PERFORMING PACKAGING
FUNCTIONS OF THE TOTAL GROUP OF RESPONDENTS

Number	Percent of Respondents
2 to 4	44%
5 to 7	27%
1	13%
10 and over	9%
8 to 10	8%

Table IV lists the job titles held and the work experience required by the respondents. Fifteen percent of the respondents held a packaging manager position with more than 8 years of experience, 12 percent a packaging supervisor position with 5 to 8 years of experience, 11 percent a packaging engineer position with 1 to 3 years of experience, 10 percent a packaging engineer associate as well as a manager of operations positions with 1 to 3 years and more than 8 years of experience respectively. The remainder of the respondents (42 percent) were in a variety of titles, such as engineering manager, manager packaging and equipment engineering, general manager, technology leader, etc.

By combining and synthesizing the profile information, it can be stated that the composite professional packaging position for this investigation had a bachelor's degree in Engineering and worked in a two to four people department.

TABLE IV
JOB TITLES AND WORK EXPERIENCE REQUIRED
OF THE TOTAL GROUP OF RESPONDENTS

Title	Experience	Percent of Respondents
Packaging Manager	More than 8 years	15%
Packaging Supervisor	5 to 8 years	12%
Packaging Engineer	1 to 3 years	11%
Packaging Engineer Associate	1 to 3 years	10%
Manager of Operations	More than 8 years	10%
Engineering Manager	More than 8 years	7%
Manager Packaging and Equipment Engineering	5 to 8 years	6%
General Manager	More than 8 years	5%
Technology Leader (Project Engineer)	3 to 5 years	5%
Packaging Engineer (Senior)	3 to 5 years	4%
V.P. Operations	More than 8 years	4%
V.P.	More than 8 years	3%
Department Supervisor	5 to 8 years	2%
Supervisor Records and Packaging	5 to 8 years	2%
Packaging and Inspection Supervisor	5 to 8 years	1%
Associate Director Technical Services	More than 8 years	1%
Regulatory Affairs Manager	More than 8 years	1%
Director of Scientific and Legal Affairs	More than 8 years	1%

IV. SELECTION OF THE COMPETENCIES

Questions one and two in the statement of the problem relate to the selection of significant competencies which could be considered for a packaging job profile within pharmaceutical manufacturing companies. The selection is based upon the degree of importance of the competency to the performance of the packaging activities as well as the frequency by which the activity must be performed. The summarized data from the survey instrument have provided the distribution of the responses for each competency. These distributions were analyzed further and decision rules were developed to form the basis on which to select the competencies.

The rules were logically developed, based upon the median scores and the level of agreement. The level of agreement can be treated numerically by utilizing the inter-quartile range (IQR). The inter-quartile range is the distance between Q_1 and Q_3, which by definition means that 50 percent of the responses fall within that interval. Should the situation occur in which all of the responses are equally divided among the scale in a given question, the numerical value of the IQR would be 0.5 or the lowest possible value. The other extreme would be a situation when the responses to a given question were equally divided with 50 percent of the responses at the lowest possible scale and 50 percent at the highest scale. In this case, the numerical value of the IQR is equal to the number of item responses to

the question minus one. That is, a question with five item responses would have an IQR of 4.0. Therefore, the lower the numerical value of the IQR, the higher the level of agreement.

The literature did not record any general rules to follow in setting the levels of agreement. However, most studies of this type will seldom have complete agreement on any one item; thus an IQR of 0.5 cannot be expected. It is, therefore, necessary to look at the data and select realistic levels which will best describe the data. The IQR values selected for this investigation are:

High level of agreement . . . . . 0.50 - 1.50

Moderate amount of agreement . . . . . 1.51 - 2.50

Low level of agreement . . . . . 2.51 - 4.00

Although the inter-quartile range is not necessarily bisected by the median, in most instances approximately one-half of the IQR values to the data will lie on either side of the median. The IQR values for a high level of agreement would indicate a unimodal distribution. Applying the moderate and low level IQR values to the data showed that in each case there was a tendency towards a bi-modal or no-mode distribution.

The range of responses to the questions of importance and frequency of use was based upon a five-point scale. These intervals were used to describe the meaning of the data in terms of the median. The numerical values are as follows:

Importance

No importance	0.00 - 0.50
Slight importance	0.51 - 1.50
Moderate importance	1.51 - 2.50
High importance	2.51 - 3.50
Very high importance	3.51 - 4.50

Frequency of Use

Never	0.00 - 0.50
Sometimes	0.51 - 1.50
Usually	1.51 - 2.50
Frequently	2.51 - 3.50
Always	3.51 - 4.50

The first point of consideration in selecting usable competencies from the list was to determine if there were any competencies that were not significant and should, therefore, be dropped from the list. It was assumed that any item which the respondents indicated by a high level of agreement had no importance should be dropped. Decision rule number one was developed.

> Decision Rule #1 - Reject the competency if Q_2 is less than 0.50 and the IQR is less than 1.50 on the question of importance.

The application of rule number one did not identify any such competencies.

A second consideration was that if an item was slightly important and had a low frequency of use, the item would not be valuable and should be dropped. Decision rule number two was developed to meet this criteria.

> Decision Rule #2 - Reject the competency if Q_2 is less than 1.00 and the IQR is less than 1.50 for the question of important, and if Q_2 is less than 1.00 and the IQR is less than 1.50 for the question of frequency of use.

The application of rule number two did not identify any such competencies.

All of the forty-eight professional packaging competencies fall between the range of slight importance to very high importance and between the frequency of sometimes and always. Even though many of the competencies fall in the center to lower edge of the range, there is enough importance and frequency of use to support the inclusion into the usable list of competencies.

The competencies were further analyzed to determine if there were significant items that could be considered as core competencies. These would be competencies which are important to nearly all the respondents, and thus be significant enough to use as a core group for the development of a packaging job profile within pharmaceutical manufacturing industries.

The first consideration for the core competencies was to select those competencies that were rated as having high or very high importance. The third decision rule was developed to meet this consideration.

> Decision Rule #3 - Accept the competency if Q_2 is greater than 2.50 and the IQR is less than 1.50 for the questions of importance.

The application of this rule identified 18 competencies. These competencies are found in Table V and are placed in rank order based upon the median value for the question of importance.

A critique of the competencies indicated a strong trend towards the technical responsibilities of design and

TABLE V
SELECTED PACKAGING CORE COMPETENCIES
BASED UPON DECISION RULE #3

No.	Competency	Importance Q_2	Importance IQR
42	Establish relationships with vendors	3.697	0.803
43	Provide technical assistance within corporation	3.417	1.179
19	Conduct pre-production tests to qualify equipment on the production line	3.333	1.417
38	Anticipate packaging problems	3.159	1.160
22	Assist in making final decision on new packaging production equipment	3.132	1.486
15	Assist in making the final decision on a package design	3.118	1.329
13	Assist in making the final decision on package materials	3.056	1.417
7	Review cost characteristics of packaging materials	2.900	1.458
40	Initiate projects which need improvement or re-design	2.887	0.953
26	Prepare package specifications for new or re-designed packages	2.859	1.308
45	Develop special job skills as required	2.857	1.030
2	Identify critical product characteristics (moisture, temperature, gas)	2.853	1.470
46	Maintain awareness of active and potential social legislation impacts upon packaging	2.851	1.351
14	Prepare the final structure package design for approval by management	2.850	1.275
29	Prepare package data sheets (cost estimate)	2.725	1.275
41	Work with other departments to coordinate packaging functions with total production (Q.C., R&D, production, purchasing, regulation)	2.714	1.190
27	Prepare material specifications for new or re-designed packages	2.706	1.470
1	Identify the physical environment of the product (shock, vibration, storage, display)	2.625	1.402

production and the management responsibilities of communications and coordination.

It was determined that another significant group of competencies existed in the range of moderate importance with a high level of agreement and, thus, could be included in the list of core competencies. The fourth decision rule developed is:

> Decision Rule #4 - Accept the competency if Q_2 is greater than 2.00 and the IQR is less than 1.50 for the question of importance, and if Q_2 is greater than 2.00 and the IQR is less than 2.50 for the question of frequency of use.

The competencies that met the requirements of decision rule number four are found in Table VI. Four competencies were identified. A review of this group finds a continued strong trend towards the management responsibility of communications.

TABLE VI
SELECTED PACKAGING COMPETENCIES BASED UPON DECISION RULE #4

		Importance		Frequency	
No.	**Competency**	**Q_2**	**IQR**	**Q_2**	**IQR**
11	Recognize the capabilities of the printing processes to be used	2.487	1.365	2.645	1.628
30	Formulate and submit project proposals	2.271	1.457	2.065	2.217
48	Continue education on a formal or informal basis	2.243	1.457	2.328	1.759
31	Prepare project status reports	2.229	1.443	2.022	2.217

A last consideration was the assumption that if a competency is used very frequently, there would be a jus-

tification for including it in a significant list. A competency of this type might be one that is required frequently as a routine job activity but is not extremely important to the total job function. Decision rule number five was developed to support this assumption.

> Decision Rule #5 - Accept the competency if Q_2 is greater than 3.50 and the IQR is less than 1.50 for the question of frequency of use.

The application of this rule yields competency number 42. A check of the core competencies identified by the application of rule number three found that this one competency was already included in that list.

The IQR of the remaining competencies indicated that the values fall in the moderate to low level of agreement. When further analyzing the specific responses, the bi-modal and no-mode distributions were very evident. These items will remain in the list, but with a low level of priority for inclusion in a packaging job profile of pharmaceutical manufacturing companies.

CHAPTER V

A COMPARISON OF THE COMPETENCIES BASED UPON SELECTED CRITERIA

I. INTRODUCTION

The second major phase of this investigation was to determine if the overall performance of the packaging activities within pharmaceutical manufacturing companies is affected or vary on the basis of: educational background, job title and/or number of persons performing packaging functions. The existence of any significant differences may indicate a need to develop packaging training programs with variations in content to support these differences.

II. STATISTICAL TEST

The nature of the data available and comparisons to be made indicated that a statistical test had to be found that could compare two samples of non-parametric data and that could base these comparisons upon the differences of the data distributions. The Kolmogorov-Smirnov Two-sample Test was selected to fulfill the needs of this investigation. The selection was based upon information provided by Siegel (1956) as to the appropriateness of the test.

The Kolmogorov-Smirnov two-sample two-tailed test is based upon the differences in the two cumulative distributions. If two samples are drawn from the same population distribution, the cumulative distributions of both samples may be expected to be very close. If the two sample cumulative distributions are far apart at any point, it would suggest that the samples come from different populations.

The mathematical formula (Siegel, 1956) for calculating the cumulative distribution differences is:

$$D = \text{maximum } Sn_1(x) - Sn_2(x)$$

The test of significance for this investigation has been set at the 0.05 level. The critical value for "D" at the 0.05 level is set down in the mathematical formula:

$$D_{0.05} = 1.36 \sqrt{\frac{n_1 + n_2}{n_1 n_2}}$$

By comparing the critical value of "D" with the computed value of "D," the level of significance can be identified. A computed "D" greater than the critical value indicates a significant difference, which points out that the data were taken from different populations. As it applies to this investigation, a significant difference indicates that certain packaging competencies are significantly more important to one of the two groups compared.

III. ANALYSIS OF THE DATA

The actual data analyzed using the Kolmogorov-Smirnov test were selected according to the number of respondents in a particular group (i.e., bachelor's degree vs. master's degree, engineering major vs. science major, etc.). So that representative data could be obtained, those items with less than ten responses were not compared. The analysis was further limited to the twenty-two competencies which were identified as core competencies in Chapter IV. These competencies were selected because of their high rank, based upon the median and high level of agreement among the respondents. A number of differences did appear for other competencies. However, most of these differences were associated with competencies that were given moderate to low rating on the importance scale (median of 2.00 and less). For the purposes of this investigation, it was felt unnecessary to compare a competency when the differences existed between the "sometimes" or "usually" response ratings.

The comparison was made on the data provided by the questions of importance and frequency of use. Thus, both sets of data will provide input into the final selection of the significant competencies. The specific data for each comparison will be presented in tabular form, indicating the "D" value at the 0.05 level, the computed "D" as calculated from the investigation data, and the group which is favored by the difference.

Question 3: What relationship do the educational experiences of the packaging personnel have with the competencies utilized in the performance of the packaging professional position, within pharmaceutical manufacturing companies, at the middle management and technical levels?

This question was analyzed by comparing the two groups which had the majority of the responses: bachelor's degree and master's degree backgrounds. No competencies with significant differences were found between these two groups.

Question 4: What relationship do the curriculum majors of the packaging personnel have with the competencies utilized in the performance of the packaging professional position, within pharmaceutical manufacturing companies, at the middle management and technical levels?

The three groups in this area which had the majority of the responses were Engineering, Sciences and Packaging. The statistical test applied to these three groups revealed no competencies with significant differences.

A summary of the first two questions relating to the level of education and the major pursued at the college level brings out one important point. The performance of the packaging duties by the individuals in charge of packaging functions within pharmaceutical manufacturing companies finds the same basic competencies required regardless of the level of education, bachelor's or master's degree, or the specialization of engineering, sciences or packaging at the college level.

This may imply that educational background is not important in the packaging field within pharmaceutical manufacturing companies. However, before such an inference can be made, it is necessary to recognize that many pharmaceutical companies have not recognized the importance of packaging, including educational background. This has meant that persons with other backgrounds have had to be hired and trained on-the-job to perform the packaging functions.

Question 5: What effect does the job title held by the packaging personnel have with the competencies utilized in the performance of the packaging professional position, within pharmaceutical manufacturing companies, at the middle management and technical levels?

This question was analyzed by comparing the combination of packaging engineer, packaging engineer associate and senior packaging engineer titles (technical level) with the packaging manager title (management level).

A significant difference existed for competency number 23 to the question of importance (see Table VII). This difference would indicate that the individuals with a management position tended to give more importance to interview job applicants for packaging positions than those individuals with a technical position.

TABLE VII
PACKAGING ENGINEER, PACKAGING ENGINEER ASSOCIATE AND SENIOR PACKAGING ENGINEER VERSUS PACKAGING MANAGER BASED UPON IMPORTANCE

$N_1 = 25$ $N_2 = 15$

No.	Competency	"D" at .05 Level	Computed "D"	Group Favored
23	Interview job applicants for packaging positions	0.444	0.480	Packaging Manager

Four items were found to have a significant difference in responses to the question of frequency of use (see Table VIII). Three of the items are oriented toward decision-making activities. This would indicate that the management position does become more frequently involved in the decision-making activities than the technical position. The fact that a difference does not occur on these three items for the question of importance would imply that both groups feel them equally important, but that the management position performs the activity significantly more often.

TABLE VIII
PACKAGING ENGINEER, PACKAGING ENGINEER ASSOCIATE AND SENIOR PACKAGING ENGINEER VERSUS PACKAGING MANAGER BASED UPON FREQUENCY OF USE

$N_1 = 25$ $N_2 = 15$

No.	Competency	"D" at .05 Level	Computed "D"	Group Favored
23	Interview job applicants for packaging positions	0.444	0.626	Packaging Manager
22	Assist in making final decision on new packaging production equipment	0.444	0.600	Packaging Manager
15	Assist in making the final decision on a package design	0.444	0.573	Packaging Manager
13	Assist in making the final decision on package materials	0.444	0.493	Packaging Manager

Item 23 appears again for the question of frequency of use, which signifies that this item is not only more important, but also significantly more frequently used by those in management positions.

Question 6: What effect does the number of personnel performing the packaging functions have with the competencies utilized in the performance of the packaging professional position, within pharmaceutical manufacturing companies, at the middle management and technical levels?

The analysis of the data for question six was based upon the department sizes of a one-person department, two- to four-person department and the five-to seven-person department. It would seem obvious that the one-person department has to perform all of the normal professional packaging activities. It is not necessarily true, however, that the multi-person department has each individual per-

forming a smaller number of specialized activities. This trait depends upon company organization. A department may be organized so that certain people specialize in certain areas of the total packaging program. However, many pharmaceutical companies are organized such that individuals are assigned product groups and are responsible for the total packaging of that product group. Thus, these individuals act as a basic one-person department. The scope of this study did not include a cross-analysis of the data to determine and analyze the many variables that could exist.

On the basis of department size, the one-person department was compared with the two- to four-person department. The question of frequency of use identified item 43 as having a significant difference. The item found the difference in favor of the two- to four-person department. Item 43 states that the two- to four-person department frequently provide technical assistance within corporation. This would seem to indicate that there are cooperative efforts in the multi-person departments, which would not exist in a one-person situation. Table IX presents the data for the comparison to the question of frequency of use.

TABLE IX
ONE-PERSON DEPARTMENT VERSUS TWO- TO FOUR-PERSON DEPARTMENT BASED UPON FREQUENCY OF USE

$N_1 = 13$ $N_2 = 44$

No.	Competency	"D" at .05 Level	Computed "D"	Group Favored
43	Provide technical assistance within corporation	0.429	0.528	Two - Four

The question of importance based upon the above comparison did not identify any items as being significantly different.

Comparing the one-person department with the five- to seven-person department produced an item of significant difference to the question of importance (see Table X).

TABLE X
ONE-PERSON DEPARTMENT VERSUS FIVE- TO SEVEN-PERSON DEPARTMENT BASED UPON IMPORTANCE

$N_1 = 13$ $N_2 = 27$

No.	Competency	"D" at .05 Level	Computed "D"	Group Favored
43	Provide technical assistance within corporation	0.459	0.516	Five - Seven

The same indication shows up here as in the previous test, that there is an indication that the multi-person departments do depend upon the cooperation with each other.

Comparing the two- to four-person department with the five- to seven-person department produced a significant

item for the question of frequency of use. Table XI presents the data for the question of frequency of use.

TABLE XI
TWO- TO FOUR-PERSON DEPARTMENT VERSUS FIVE- TO SEVEN-PERSON DEPARTMENT BASED UPON FREQUENCY OF USE

$N_1 = 44$ $N_2 = 27$

No.	Competency	"D" at .05 Level	Computed "D"	Group Favored
30	Formulate and submit project proposals	0.3325	0.334	Five - Seven

The test of this data indicates that there is a significant difference in the frequency of preparing project proposals. The larger departments apparently require the need for more formal methods of operation. The size necessitates the need for project proposals to be approved prior to their implementation.

Question six did identify significant items for both the question of frequency of use and importance. The items identified relate to the general responsibilities of communications and coordination on the part of the department members. As would be assumed, multi-person departments require good communications, coordination and cooperation to keep the department and the corporation moving smoothly. Good communications are generally important at all levels of all areas and this would logically be included as a necessary part of the responsibility for a packaging professional position within pharmaceutical manufacturing companies.

CHAPTER VI

SUMMARY AND CONCLUSIONS

I. SUMMARY

Packaging is a relatively new function within pharmaceutical manufacturing companies. While many companies have recognized the need and advantages of good product packaging, others have done little with the possibilities other than to contain their products.

An important factor in assisting these industries with their packaging problems is to establish the functions of the persons in charge of packaging activities. By determining what the functions and responsibilities of a packaging professional position are, a better understanding of the packaging profession will result and consequently a higher level of efficiency can be reached within a given company.

The purpose of this investigation was to determine the competencies that are significant to the functions of packaging within pharmaceutical manufacturing companies, thereby providing meaningful information to be used in the development of a packaging job profile.

The following is a re-statement of the problem. The central problem of this investigation was to identify the packaging competencies required of those individuals

performing the packaging activities within pharmaceutical manufacturing industries at the middle management and technical levels. Specifically, the investigation intended to answer the following questions:

1. Which packaging competencies are the most important to the performance of the packaging professional position, within the pharmaceutical manufacturing companies, at the middle management and technical levels?
2. Which packaging competencies are most frequently used by the personnel performing packaging functions, within pharmaceutical manufacturing companies, at the middle management and technical levels?
3. What relationship do the educational experiences of the packaging personnel have with the competencies utilized in the performance of the packaging professional position, within pharmaceutical manufacturing companies, at the middle management and technical levels?
4. What relationship do the curriculum majors of the packaging personnel have with the competencies utilized in the performance of the packaging professional position, within pharmaceutical manufacturing companies, at the middle management and technical levels?

5. What effect does the job title held by the packaging personnel have with the competencies utilized in the performance of the packaging professional position, within pharmaceutical manufacturing companies, at the middle management and technical levels?
6. What effect does the number of personnel performing the packaging functions have with the competencies utilized in the performance of the packaging professional position, within pharmaceutical manufacturing companies, at the middle management and technical levels?

A list of packaging competencies was identified using the literature, personal interviews, and phone calls. The list was presented to the packaging professionals interviewed for their evaluation and critique. With suggested modifications, a final list of forty-eight packaging competencies was produced.

The population for this investigation was selected from pharmaceutical companies classified as user companies. These companies produce products that in turn require the services or products of the supplier companies to package the products. Two-hundred eight-one companies were identified, each one receiving one questionnaire for a total of 281 possible respondents.

The forty-eight competencies were prepared in a mailed questionnaire form, seeking information on the importance and

the frequency of use of each competency. A section on general information was included to determine a profile of the respondent and the positions they held within their companies. The questionnaire was sent to the investigation sample and the net result of the mailing was a return of 48 percent.

The data from the questionnaire were transferred into a computer. Using a prepared data processing program (Lotus 1-2-3), the distribution of the responses was given in terms of the first, second and third quartile rank and the inter-quartile range. The quartile rank provided the central tendencies of the data, while the inter-quartile range described the variability or level of agreement of the responses. Based upon the second quartile rank and the numerical values of the inter-quartile range, five decision rules were developed to statistically select the significant packaging competencies.

The data were further analyzed to determine if there were any significant differences in the competencies required to perform the packaging activities within pharmaceutical manufacturing companies on the basis of educational background, job title, and number of persons performing packaging functions. The two-sample Kolmogorov-Smirnov statistical test based upon the differences of two cumulative distributions was selected for this analysis. A significant difference would indicate different competency requirements for certain groups; thus, the need for different training programs.

II. CONCLUSIONS

The following conclusions have been made, based upon the six questions presented in the Statement of the Problem. The job analysis procedures identified forty-eight packaging competencies. Statistical procedures isolated the following twenty-two competencies as being significant on the basis of frequency of use and importance. These twenty-two competencies have been identified as core competencies.

1. Identify the physical environment of the product (shock, vibration, storage, display).
2. Identify critical product characteristics (moisture, temperature, gas).
7. Review cost characteristics of packaging materials.
11. Recognize the manufacturing processes and characteristics of all packaging materials.
13. Assist in making the final decision on package materials.
14. Prepare the final structural package design for approval by management.
15. Assist in making the final decision on a package design.
19. Conduct pre-production tests to qualify equipment on the production line.
22. Assist in making final decision on new packaging production equipment.

26. Prepare package specifications for new or redesigned packages.
27. Prepare material specifications for new or redesigned packages.
29. Prepare package data sheets (cost estimate).
30. Formulate and submit project proposals.
31. Prepare project status reports.
38. Anticipate packaging problems.
40. Initiate projects which need improvement or redesign.
41. Work with other departments to coordinate packaging functions with total production (quality control, research and development, production, purchasing, regulation).
42. Establish relationship with vendors.
43. Provide technical assistance within corporation.
45. Develop special job skills as required.
46. Maintain awareness of active and potential social legislation impacts upon packaging.
48. Continue education on a formal or informal basis.

It is concluded, based upon the significance of the items, that the core competencies should be used as a basis for developing a packaging job profile within pharmaceutical manufacturing companies.

Further statistical treatment of the data sought additional information from the selected core competencies.

Based upon the two-sample Kolmogorov-Smirnov statistical test of differences, the analyzed data produced only a few isolated competencies as being significantly different. Because of the small number of identified competencies and the variation in the relationship of the competencies, no general trends could be identified. From this analysis the following conclusions can be offered:

1. There is no effect upon the competencies utilized in the performance of the packaging functions within pharmaceutical manufacturing companies based upon educational experience.
2. There is no effect upon the competencies utilized in the performance of the packaging functions within pharmaceutical manufacturing companies based upon the major studied at the college level.
3. There is no effect upon the competencies utilized in the performance of the packaging functions within pharmaceutical manufacturing companies based upon the job title held.
4. There is no effect upon the competencies utilized in the performance of the packaging functions within pharmaceutical manufacturing companies based upon the number of persons performing packaging functions.

There were no major differences among educational background in the competencies required for the performance of

the professional packaging functions. Therefore, there is no need to develop packaging training programs with variations in content to support these differences.

APPENDICES

APPENDIX A

PROFESSIONAL PACKAGING COMPETENCIES QUESTIONNAIRE

MICHIGAN STATE UNIVERSITY

SCHOOL OF PACKAGING

EAST LANSING, MICHIGAN

December 20, 1991

Sirs:

As a candidate for a Master's degree in Packaging at Michigan State University, I am conducting research to determine the requirements and duties of positions within pharmaceutical industries with packaging responsibilities. You are one of a selected group of companies being asked to assist with this study. The data you provide will have significant value in terms of helping to clarify what the functions and responsibilities of Packaging professionals are in today's pharmaceutical environment.

This study has been designed to survey individuals performing packaging and packaging related functions, both managerial and technical. Many pharmaceutical industries identify such individual(s) with a Packaging Engineer title. Other pharmaceutical companies do not have a Packaging Engineer within their organizational structure, but they do have one or more individuals or a department responsible for the packaging functions.

Since job titles are not as descriptive as one would like, the packaging functions are defined as the performance of a group of duties including either totally or in part the design, evaluation, pre-production, handling, organizing, controlling, communicating, and coordinating packaging. This study is limited to pharmaceutical companies that manufacture products which require packaging.

I am aware of the demands on your time and am appreciative of your professional assistance. I have included a questionnaire that takes about 10-15 minutes to complete. Once completed please return in the enclosed envelope. Your early response by January 6 will be appreciated.

A copy of the results of this study can be sent to you by filling your name and address out at the end of the questionnaire. Name of individuals or companies will not be identified in the study.

Respectfully yours,

José Sosa

José Sosa

PACKAGING COMPETENCIES

QUESTIONNAIRE

PURPOSE OF THE QUESTIONNAIRE

The purpose of this questionnaire is to seek your assistance in providing information which will be useful in the development of a packaging job profile within the pharmaceutical industry.

GENERAL INFORMATION

Do your job responsibilities include performing packaging activities within a manufacturing pharmaceutical company? Yes _____ No _____

If your answer is "Yes", complete the questionnaire and return in the envelope provided. If your answer in "No", stop here and return the materials.

Instructions: Place an (X) in the blank provided that <u>best</u> describes you in your present position.

1. Educational Experience:
   - 1.1 ____ High School
   - 1.2 ____ Technical School
   - 1.3 ____ B.S.,B.A.
   - 1.4 ____ M.S.,M.A.
   - 1.5 ____ Doctorate
   - 1.6 ____ Other (specify)
     _____

2. Major In:
   - 2.1 ____ Business
   - 2.2 ____ Sciences
   - 2.3 ____ Engineering
   - 2.4 ____ Packaging
   - 2.5 ____ Liberal Arts
   - 2.6 ____ Other (Specify)
     _____

3. Work Experience Required:
   - 3.1 ____ Up to 6 months
   - 3.2 ____ 6 months to 1 yr.
   - 3.3 ____ 1 to 3 yrs.
   - 3.4 ____ 3 to 5 yrs.
   - 3.5 ____ 5 to 8 yrs.
   - 3.6 ____ More than 8 yrs.

4. Number of persons performing packaging functions:
   - 4.1 ____ One
   - 4.2 ____ 2-4
   - 4.3 ____ 5-7
   - 4.4 ____ 8-10
   - 4.5 ____ 10 and over

Your job title _____

INSTRUCTIONS FOR THE COMPLETION OF THE QUESTIONNAIRE

1. Your are being asked to indicate your responses in terms of YOUR DUTIES to fulfill the requirements of YOUR JOB.

2. Answer all items - There are no right or wrong answers. If a response does not describe your duties accurately, pick the response that comes closest to it.

3. Your are being asked two questions about each of the following competencies. The two questions are:

   a) How important is this competency to the success of packaging functions?

   IMPORTANCE: 0=NO 1=SLIGHT 2=MODERATE 3=HIGH 4=VERY HIGH

   b) How often is this competency required in the performance of your duties?

   FREQUENCY: 0=NEVER 1=SOMETIMES (1-39% OF PROJECTS) 2=USUALLY (40-60% OF PROJECTS) 3=FREQUENTLY (61-99% OF PROJECTS) 4=ALWAYS

   The term "project" refers to each product/package assignment

4. A group of possible responses for the questions follow the competency. Indicate your response by circling the number that best describes your job activities for the two questions.

PACKAGING COMPETENCIES QUESTIONNAIRE

DESIGN:	IMPORTANCE	FREQUENCY
1. Identify the physical environment of the product (shock, vibration, storage, display)	0 1 2 3 4	0 1 2 3 4
2. Identify critical product characteristics (moisture, temperature, gas)	0 1 2 3 4	0 1 2 3 4
3. Use critical product characteristics obtained from others	0 1 2 3 4	0 1 2 3 4

		IMPORTANCE	FREQUENCY
4.	Identify the existing capabilities and limitations of packaging production equipment	0 1 2 3 4	0 1 2 3 4
5.	Review the legal requirements for each new or re-designed package	0 1 2 3 4	0 1 2 3 4
6.	Review performance characteristics of packaging materials	0 1 2 3 4	0 1 2 3 4
7.	Review cost characteristics packaging materials	0 1 2 3 4	0 1 2 3 4
8.	Develop new ideas for graphic design	0 1 2 3 4	0 1 2 3 4
9.	Prepare accurate drawings of designed packages	0 1 2 3 4	0 1 2 3 4
10.	Recognize the capabilities of the printing processes to be used	0 1 2 3 4	0 1 2 3 4
11.	Recognize the manufacturing processes and characteristics of all packaging materials	0 1 2 3 4	0 1 2 3 4
12.	Request and review design suggestions from vendors for possible adaption	0 1 2 3 4	0 1 2 3 4
13.	Assist in making the final decision on package materials	0 1 2 3 4	0 1 2 3 4
14.	Prepare the final structural package design for approval by management	0 1 2 3 4	0 1 2 3 4
15.	Assist in making the final decision on a package design	0 1 2 3 4	0 1 2 3 4
	EVALUATION:		
16.	Analyze damaged products and containers for probable causes of failure	0 1 2 3 4	0 1 2 3 4
17.	Make the final decision on the test method to be used to evaluate packages	0 1 2 3 4	0 1 2 3 4
18.	Make the final decision on the package test standards to be met	0 1 2 3 4	0 1 2 3 4
	PRODUCTION:		
19.	Conduct pre-production tests to qualify equipment on the production line	0 1 2 3 4	0 1 2 3 4

	IMPORTANCE	FREQUENCY
20. Conduct pre-production tests to qualify the personnel on the manual packaging production line	0 1 2 3 4	0 1 2 3 4
21. Assist or advise in pre-production set-up of new packaging production equipment	0 1 2 3 4	0 1 2 3 4
22. Assist in making final decision on new packaging production equipment	0 1 2 3 4	0 1 2 3 4
STAFF ORGANIZATION:		
23. Interview job applicants for packaging positions	0 1 2 3 4	0 1 2 3 4
24. Train subordinates for their duties	0 1 2 3 4	0 1 2 3 4
25. Initiate requests for new or additional equipment for the packaging production line	0 1 2 3 4	0 1 2 3 4
COMMUNICATION:		
26. Prepare package specifications for new or re-designed packages	0 1 2 3 4	0 1 2 3 4
27. Prepare material specifications for new or re-designed packages	0 1 2 3 4	0 1 2 3 4
28. Prepare performance specifications for new or re-designed packages	0 1 2 3 4	0 1 2 3 4
29. Prepare package data sheets (cost estimate)	0 1 2 3 4	0 1 2 3 4
30. Formulate and submit project proposals	0 1 2 3 4	0 1 2 3 4
31. Prepare project status report	0 1 2 3 4	0 1 2 3 4
32. Develop procedures and instructions instructions for on-line personnel	0 1 2 3 4	0 1 2 3 4
CONTROLLING:		
33. Supervise the packaging production line	0 1 2 3 4	0 1 2 3 4
34. Originate material orders	0 1 2 3 4	0 1 2 3 4
35. Originate package work orders	0 1 2 3 4	0 1 2 3 4

		IMPORTANCE	FREQUENCY
36.	Perform quality control procedures on incoming materials.....	0 1 2 3 4	0 1 2 3 4
37.	Perform finished product/package inspection.....	0 1 2 3 4	0 1 2 3 4
38.	Anticipate packaging problems.....	0 1 2 3 4	0 1 2 3 4
39.	Write Q.C. procedures.....	0 1 2 3 4	0 1 2 3 4
	COORDINATION:		
40.	Initiate projects which need improvement or re-design.....	0 1 2 3 4	0 1 2 3 4
41.	Work with other departments to coordinate packaging functions with total production (Q.C., R&D, production, purchasing, regulation).....	0 1 2 3 4	0 1 2 3 4
42.	Establish relationships with vendors.....	0 1 2 3 4	0 1 2 3 4
43.	Provide technical assistance within corporation.....	0 1 2 3 4	0 1 2 3 4
44.	Conduct or participate in vendor qualification.....	0 1 2 3 4	0 1 2 3 4
	SELF-IMPROVEMENT		
45.	Develop special job skills as required.....	0 1 2 3 4	0 1 2 3 4
46.	Maintain awareness of active and potential social legislation impacts upon packaging.....	0 1 2 3 4	0 1 2 3 4
47.	Join and participate in professional packaging organizations and standards groups.....	0 1 2 3 4	0 1 2 3 4
48.	Continue education on a formal or informal basis.....	0 1 2 3 4	0 1 2 3 4

---List any additional competencies you feel appropriate---

Would you like a copy of the results of this study?

Yes _____ No _____

Name: _____

Address: _____

_____

_____

APPENDIX B

FIRST REMINDER LETTER FOR THE PROFESSIONAL PACKAGING COMPETENCIES QUESTIONNAIRE

MICHIGAN STATE UNIVERSITY

SCHOOL OF PACKAGING

EAST LANSING, MICHIGAN

48824

January 7, 1992

Dear Professional Packager:

Recently I mailed you a questionnaire asking for your participation in a very important study.

If you have already returned the questionnaire, please consider this letter a "Thank you" for your valuable help.

If you have not had a chance to do so as yet, may I ask you, please, to return the completed form. The data which you provide will mean a great deal to determine what the functions and responsibilities of Packaging professionals are within pharmaceutical industries.

Sincerely,

José Sosa

José Sosa

APPENDIX C

FINAL REMINDER LETTER FOR THE PROFESSIONAL PACKAGING COMPETENCIES QUESTIONNAIRE

MICHIGAN STATE UNIVERSITY

SCHOOL OF PACKAGING

EAST LANSING, MICHIGAN

48824

January 17, 1992

Dear Professional Packager:

As a professional packager, I am sure you are aware that packaging still suffers from a lack of understanding by many pharmaceutical manufacturing companies. Many of the large corporations have recognized the needs and understand the benefits of product packaging, others are still quite unaware of the significance or ramifications. The questionnaire that you received was designed to identify those competencies which are important to the performance of the packaging functions within pharmaceutical companies.

If you have already completed and returned the questionnaire, please consider this letter as an expression of my appreciation. If you have not had a chance to respond, would you do so now ? A second copy of the material is enclosed for your convenience. Your early response by February 3 will be appreciated.

Would you help the packaging profession by taking your time to provide this very important information. Thank you again for your cooperation.

Respectfully yours,

José Sosa

José Sosa

APPENDIX D

PROFESSIONAL PACKAGING COMPETENCIES WITH QUARTILE DATA

PROFESSIONAL PACKAGING COMPETENCIES WITH QUARTILE DATA

		Importance		Frequency	
		Q_2	IQR	Q_2	IQR
1	Identify the physical environment of the product (shock, vibration, storage, display)	2.625	1.402	2.368	2.658
2	Identify critical product characteristics (moisture, temperature, gas)	2.853	1.470	2.521	2.104
3	Use critical product characteristics obtained from others	2.304	1.803	2.022	2.217
4	Identify the existing capabilities and limitations of packaging production equipment	3.182	1.530	3.109	1.547
5	Review the legal requirements for each new or redesigned package	2.326	2.218	2.105	2.605
6	Review performance characteristics of packaging materials	2.815	1.871	2.944	1.889
7	Review cost characteristics of packaging materials	2.900	1.458	2.500	3.188
8	Develop new ideas for graphic design	1.114	1.443	0.905	1.191
9	Prepare accurate drawings of designed packages	1.318	2.273	1.106	1.515
10	Recognize the capabilities of the printing processes to be used	2.118	1.500	2.172	1.741
11	Recognize the manufacturing processes and characteristics of all packaging materials	2.487	1.365	2.645	1.688
12	Request and review design suggestions from vendors for possible adaption	1.909	1.136	2.053	2.605
13	Assist in making the final decisions in package materials	3.056	1.417	3.207	1.742

		Importance		Frequency	
		Q_2	IQR	Q_2	IQR
14	Prepare the final structural package design for approval by management	2.850	1.275	2.839	1.803
15	Assist in making the final decision on a package design	3.118	1.329	3.136	1.515
16	Analyze damaged products and containers for probable causes of failure	2.025	1.275	1.792	2.125
17	Make the final decision on the test method to be used to evaluate packages	1.794	1.500	1.921	2.684
18	Make the final decision on the package test standards to be met	1.989	1.134	1.976	2.429
19	Conduct pre-production tests to qualify equipment on the production line	3.333	1.417	3.207	1.742
20	Conduct pre-production tests to qualify the personnel on the manual packaging production line	1.789	1.134	1.648	1.889
21	Assist or advice in pre-production set-up of new packaging production equipment	2.344	1.594	2.539	1.961
22	Assist in making final decision on new packaging production equipment	3.132	1.486	3.075	2.525
23	Interview job applicants for packaging positions	2.396	2.104	2.150	2.550
24	Train subordinates for their duties	2.617	1.683	2.871	1.429
25	Initiate requests for new or additional equipment for the packaging production line	2.707	1.758	2.611	2.834
26	Prepare package specifications for new or re-designed packages	2.859	1.308	3.109	2.217
27	Prepare material specifications for new or re-designed packages	2.706	1.470	3.200	2.550
28	Prepare performance specifications for new or re-designed packages	1.756	1.123	1.444	2.833
29	Prepare package data sheets (cost estimate)	2.725	1.275	1.833	3.40
30	Formulate and submit project proposals	2.271	1.457	2.065	2.217

		Importance		Frequency	
		Q_2	IQR	Q_2	IQR
31	Prepare project status reports	2.229	1.443	2.022	2.217
32	Develop procedures and instructions for on-line personnel	2.059	1.500	1.848	2.218
33	Supervise the packaging production line	1.018	1.803	0.833	2.833
34	Originate material orders	1.250	2.125	0.944	2.77
35	Originate package work orders	1.563	1.063	1.313	3.18
36	Perform quality control procedures on incoming materials	0.773	2.318	0.667	2.08
37	Perform finished product/package inspection	1.056	1.889	0.984	1.646
38	Anticipate packaging problems	3.159	1.160	2.796	1.889
39	Write Q. C. procedures	1.525	1.275	1.500	3.188
40	Initiate projects which need improvement or re-design	2.887	0.953	2.694	1.645
41	Work with other departments to coordinate packaging functions with total production (Q.C., R&D, production, purchasing, regulation)	2.714	1.190	3.000	1.62
42	Establish relationships with vendors	3.697	0.803	3.638	0.862
43	Provide technical assistance within corporation	3.417	1.179	3.259	1.37
44	Conduct or participate in vendor qualification	3.177	1.500	2.925	1.275
45	Develop special job skills as required	2.857	1.030	2.764	1.40
46	Maintain awareness of active and potential social legislation impacts upon packaging	2.851	1.351	2.603	1.48
47	Join and participate in professional packaging organizations and standards groups	1.855	1.328	1.875	1.40
48	Continue education on a formal or informal basis	2.243	1.457	2.328	1.75

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