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Guidelines to Developing a Corporate Packaging Group for the Medical Device Industry

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GUIDELINES TO DEVELOPING A CORPORATE PACKAGING GROUP FOR THE MEDICAL DEVICE INDUSTRY

By

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_Michael J Piazza_____

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Abstract

The purpose of this study was to reveal and assess improvements that can be made to the candidate selection process when developing a Corporate Packaging Group in the Medical Device Industry. Sixty current and former experienced industry members were polled. Major findings included the following:

1. Corporate Packaging Groups exist within the Medical Device Industry.
2. These existing groups generally reside in:
    a. R&D
    b. Engineering
3. Critical areas of expertise are:
    a. Primary Package Design
    b. Packaging R&D
4. Other areas of expertise that could be considered but not limited to are:
    a. Packaging Graphics Design
    b. Regulatory/Compliance
    c. Environmental Packaging
    d. Distribution
    e. Digital Asset Managing
5. The function of a Corporate Packaging Group appears to still carry out many different tasks depending on the needs of the company. Since there is no distinct commonality found between Corporate Packaging Groups within the

medical device industry, the company will need to assess their primary goals and objectives first before organizing its Corporate Packaging Group.

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Introduction

"If I ran the zoo," said young Gerald McGrew

"I'd make a few changes, that's just what I'd do" (1)

The ability to satisfy corporate demands for a strategic workforce, one with vast knowledge and experience, is a strategic advantage in today's increasingly competitive medical device industry. A poor selection process, shrinking department budgets and limited resources compound the problem. Growing middle to large size medical device companies that are interested in creating a corporate packaging group do not have a template or guideline to work from to develop a centralized department to suit their needs. Without this guideline, the hiring process becomes a bit of a challenge. A resume and interview only reveal the candidate's ability to communicate. Yet how does the company know the candidate will truly meet their needs? With the proper information accessible to them, they may be able to determine what specialties in the packaging industry are needed to ensure this group and the newly hired candidate can handle critical issues that affect the company globally and bring guidance to sub-groups or other departments.

The purpose of this study is to provide guidance to address hiring issues and flush out industry needs. Since guidance is something that gives direction or provides assistance

to a person, place or thing, it was designed to achieve four goals related to fulfilling the needs of creating a corporate Packaging Department. These goals are as follows:

1. Identify whether or not Corporate Packaging Groups exist in the Medical Device Industry.
2. Of those that exist, identify where within the corporate structure they might be found.
3. Help predict what areas of expertise should be considered when forming the group.
4. Determine awareness and understanding of the function(s) of a Corporate Packaging Group.

Literature Review

Based on United Nations Population Division figures, the world population is expected to grow by another billion people over the next 10 years, the majority of whom will be in developing nations in Africa, Asia, and Latin America. Coupled with developing political systems and economics, many bumps, barriers, and buffers on the global playing field are being eliminated. Continuing economic growth will mean growing labor pools, new markets, and further dispersal of competency and capital. (8) At the same time, medical device companies are expanding their business both domestically and abroad to gain valuable market share from their competitors. They are being required to face new challenges which were not realized in the past but are becoming common in order to do business. How does this affect the Packaging function in today's middle to large sized medical device company? For companies with a corporate Packaging group this may not be much of a challenge other than added work load. However, companies who still have yet to develop a corporate Packaging group may see things a bit differently and have a much more difficult time adjusting. Some of these new global challenges may be overlooked due to a lack of specialized expertise, or simply because one group assumes another is resolving the issue when that is not truly the case. In the end, a possible wasting of company resources becomes a result and an underlying question regarding the value of a department(s) as a whole begins to surface.

What is it about a centralized group that gives one company an upper-hand over another? First, there needs to be a basic understanding of how the world business environment affects the company starting with distinguishing between cyclical and

structural change. Cyclical Changes are part of business life's normal ups and downs, and any competent group can deal with them. An example might be seasonal demands on certain products. Structural Changes are fundamental, long-term alterations in the basics of making money. An example would be acquiring another company to expand capabilities and services. These are usually hard to differentiate from Cyclical Changes in their early stages, which is when the group really needs to see them. One reason for this is due to the lack of proper communication being transmitted by corporate decision makers. By the time the Changes are most obvious, the odds of adjusting well to them are sharply lower. (7)

Three structural Changes are driving today's explosion of intensifying worldwide competition: One is the increasing integration of business activity across borders, accelerated by the Internet with its instant communications and vast repository of ideas and dialogues. Its most tangible aspect is the rapid growth of supply chains that stretch from the United States and Europe to all parts of the world – not only for goods, but now for services as well. The second structural Change is worldwide overinvestment, fueled by a vast credit expansion and immense free flow of risk capital. The third is the global buyers' market that has shifted power from the owners and managers of capital to consumers and giant retailers. There's also a wild card. Around the world, government regulators are getting more aggressive, and they are coming at different issues, in different times and places, without coordination or rationalization of their policies…. (7)

The business model brings rationality to these issues of change. It is the guide for when to change and when not to change, what to change and what not to change. If you link the group's assessment of the external environment to your financial targets and the company's internal capabilities, you will have a much clearer picture of the magnitude of change required: whether it's a change in strategy, a change in operations or people, or a change in the business model itself. (7) The improvements chosen must be guided by the priorities in the business model. The critical areas are the operating strengths and weaknesses that affect the business's ability to generate cash earnings over time – things such as cost, productivity, profitable revenue growth, differentiation, speed and quality. (7)

What does the right group consist of for your organization? In this new (business) environment, with its ever intensifying battles for razor-thin advantages, almost any edge you can gain looks attractive. And the list of tools and methodologies an organization can use to improve is endless. These days the most popular initiatives are moving operations to low-cost regions, streamlining the supply chain and Six Sigma quality directives. These initiatives are being widely adopted because they aim squarely at the challenges so many companies face: reducing cost, and improving productivity and quality. (7)

To begin with, look at corporate structure. Since the heyday of the hierarchical organization – 1950 or so – companies have become increasingly more complicated. They are bigger and more diverse, and these changes make internal navigation more

challenging. (2) Moreover, within these complex structures, things are ever-shifting. Workforces have become more fluid. They feature more temporary workers, contractors, and consultants who must come up to speed quickly to be effective. Further, partnerships, alliances, and outsourcing relationships bring organizations in shoulder-to-shoulder contact with new players at all levels. As companies ad hoc workers and structures for ever more critical processes, navigation becomes increasingly important in determining who does what. Traditional organizational structure is crumbling under the weight of ever-increasing regulations that drive greater accountability and transparency to various areas. Smart companies are on the forefront of building new and improved structures that support and enhance this new compliance environment, and best practices are emerging. (9) People must be able to make the right connections to work effectively – to get the right things done at the right time and in the right way. The capability to connect goes well beyond "nice to have." At times, a team's ability to reach out broadly in the organization is the single factor that distinguishes higher-value from those with a more modest impact. (2)

After a merger or an acquisition, the navigational difficulty that people face is especially difficult. The new organizational charts may be drawn up, but people no longer know how to get things done. A common strategy is to extract and record what people know – and then store it in a database. The problem is that much of this 'know how' is not adaptable to this treatment. It's difficult to capture or convert easily. Much of it is unspoken and unrecorded. So how does this tacit knowledge get managed? Tacit knowledge such as 'intuition,' 'hunches,' and/or 'inherent talent' is difficult to express. It

is not book knowledge so it cannot easily be referenced. It is knowledge gained through experience. As discussed by Boisot, there are three types of tacit knowledge: (3)

1. Things that are not said because *everyone* understands them and takes them for granted;
2. Things that are not said because *nobody* fully understands them; and
3. Things that are not said because, although *some people* understand them, they cannot costlessly articulate them.

To combat this, many companies increasingly rely on alliances and partnerships. They are pooling their assets and capabilities in order to break into new markets, spark innovation, and satisfy their customers. Large pharmaceutical companies, for example, may be managing several hundred partnerships at any given time. With these important relationships all but invisible to most people within an organization, the right hand and left hand can find themselves being introduced to each other by a partner firm. That is undeniably embarrassing; worse, it damages the company's credibility in that partner's eyes – *don't these people know what they're doing?* (2)

From an upper management standpoint, CEOs are aware that individuals want challenge, "space" in which to achieve, and good rewards and recognition; in other words, employees want to make a difference. (4) Every company requires a spine of accountability – layers of management – to deliver on its mission, each layer adding value to those below it. Like a human spine, a healthy organization – whether a public or private company, a Non-Governmental Organization, or a public institution – needs the correct number of vertebrae. (4) The key to organizational health is accountability.

It's impossible to build a healthy organization without a clear idea of the accountabilities required at every level of the company. Accountability occurs when one is answerable to a higher authority for work, resources, or services. It is goal oriented and not just an accumulation of activities or processes. The essence of an accountable hierarchy is one in which a manager is expected to make decisions that subordinates are not allowed to. Similarly, the manager must be able to make decisions that are not replicated or duplicated by the next higher level of management. (4) But how do you identify the right number of accountability levels? According to Dive, at least seven elements determine the number of levels of accountability and therefore the number of management layers that any organization needs:

Nature of work. What is the purpose of the job?

Resource complexity. What people, capital, technology, and knowledge have to be accounted for?

Problem solving. What mental degrees of abstraction are called for when making decisions? Are they concrete or increasingly abstract?

Change. What kind of change is the person accountable for? Is it continuous improvement or breakthrough?

Internal network. What is the extent of the network that has to be influenced *inside* the organization?

External network. What is the extent of the network that must be influenced *outside* the organization?

Time frame. Within what time parameters must a person complete accountable tasks?

Once job levels of accountability have been established, only one layer of value-adding management is required per level of accountability above the first. In other words, the formula for a healthy organizational structure is: The total of accountability levels minus one. (4)

According to Bardi and Kelly, today packaging is more diversified, more sophisticated, and more important than in prior years. It has become an essential marketing ingredient, and an integral part of the complex logistics process which supplies consumers with a seemingly unending flow of goods. (10)

Thus, the packaging function cannot be performed within a vacuum of one department. The aesthetics of packaging is of concern to the marketing or sales department, while the strength, durability and functional requirements of the package fall within the realm of logistics. These package qualities must be compatible with the production line constraints. This suggests that an integrated and formalized packaging department is the logical solution to the efficient management of the packaging function. (10)

One of the major reasons why packaging presents such a management problem is that it is not amenable to the accepted management rules. It is a complex field, filled with activities that defy the traditional approaches to the placing and structuring of

responsibility and authority. Proper management of the packaging area requires a peculiar blending of organizational structure and responsive personalities and a proper balance among the marketing, logistics and production functions. As a result, some experimentation tends to be involved in finding the “best” organizational form for packaging. (10)

A fundamental decision in designing a framework that bolsters compliance is whether to adopt a centralized or decentralized model. A company’s size, industry, geographic dispersion and business complexity determine which model – or a combination of models – is best suited to the organization’s needs. No matter what approach is chosen, all effective plans have a formalized structure that is designed and managed so that compliance activities can be carried out with a significant measure of objectivity and independence. (8)

A centralized model allows for a standardization of compliance and reporting activities across the organization, which results in efficiencies in training, cross-functionality, communication and resources. In a decentralized model, business units can tailor compliance systems to best meet the demands of their markets, locations, and industries. This enables managers to monitor compliance activities more closely and involve employees more in the process. (8)

Companies working to develop responsible, cost-efficient and effective compliance processes also need to establish an accountability structure that ensures that a proper

level of oversight and process ownership exists and that an appropriate ethical attitude pervades the organization. (8)

An accountability structure establishes who maintains ownership of the design and operation of controls within the organization and provides mechanisms for regulating individuals to ensure they act ethically and in the company's best interests. In this way, a robust accountability structure ultimately becomes a strong defense against corporate malfeasance because it provides guidance for making sound decisions and ensures that needed information is available in a timely manner. It also promotes an appropriate "tone at the top." (8)

Once defined, companies need to regularly update organizational roles and responsibilities to keep pace with changes in their business and in the regulatory environment. Many are also including compliance responsibilities in their codes of conduct. Some are even creating compliance mission statements, which every employee is expected to champion. (8)

Another approach is to integrate reporting roles and responsibilities into policies and procedures, including employee job descriptions. Having clearly defined roles and responsibilities has the effect of reducing companies' exposure to risk and lessening the likelihood of employees becoming involved in malfeasance. (8)

A study by the Packaging Management Council which was recognized in *Packaging Digest Magazine* stated, “staying abreast of regulatory or environmental issues is a necessity for any packaging department, and these multibillion-dollar firms are right on top of the game. Nearly three-fourths of the respondents say they have an in-house expert on the subject, and 15 percent say they use the service of an outside expert, or each packaging professional is required to maintain expertise in his/her specific project area.” (9)

The creation of a packaging department as an independent entity with authority over all facets of responsibility is an evolutionary process. The operating personnel who design and develop packages and packaging policy must constantly promote packaging not as a peripheral activity, but as an essential element of a product/market mix. (10)

Some firms have adopted three approaches to solving the packaging dilemma. These are the appointment of a packaging specialist, the use of a packaging committee, and the establishment of a formal packaging department. (10)

The packaging specialist approach is an attempt to coordinate the fragmented packaging decisions performed by various departments with vested interests in some aspect of packaging. The packaging specialist coordinates or blends these fragmented interests to ensure that the function is completed. The establishment of a packaging specialist places responsibility for this function in one person rather than among numerous individuals. (10)

The packaging committee is an attempt to provide an integrated decision making or systems approach to packaging. Membership on such a committee consists, in part, of those departments having some degree of packaging responsibility. It serves the purpose of unifying viewpoints, exchanging ideas and achieving positive support for agreed upon courses of action. (10)

The most advanced form of packaging organization is the creation of a separate packaging department which centralizes the activities formerly carried on by other operating and staff units. The establishment of such a department denotes recognition of the importance of the packaging function in the firm and the realization of an integrated decision making or systems approach to packaging. (10)

The principal obstacle associated with organizing the packaging function is the tendency of firms to view packaging narrowly and departmentally. Marketing management continues to look at packaging strictly from the silent salesman point of view. Packaging engineers, frequently reporting to a purchasing or manufacturing department, look at packaging as a protective device. What is required is a systems approach. (10)

Formal packaging departments are most often established after management recognizes that packaging has become highly specialized and require a coordination of company packaging activities. Respondents gave considerable weight to the following

factors as influential in establishing a formal department: new packaging materials, company size, extension of the product line, and top management wishes for greater packaging emphasis. Thus, the size of the firm, the complexity of the packaging arena and the attention of top management are the primary motivators in the establishment of a formal department. (10)

Today, packaging is too important to be assigned anything less than a specific responsibility and strategy in the attainment of goals for most medium and large companies. Packaging is too closely related to the profit and loss statement and too definitely connected to a company's growth potential to be left to chance. Packaging is an important and strategic tool of management. (10)

The concept of packaging is relatively new and in an established organization there is resistance to restructuring the organization to include the packaging function specifically. This reluctance to reorganizing is attributable to the packaging functions affecting many varied departments and crossing many traditional organizational lines. However, as packaging costs increase and become a more significant portion of total costs, the packaging department becomes a necessity in the corporate structure. (10)

The large companies have begun to recognize the benefits of a coordinated/centralized packaging department. Yet, since so many activities are affected by packaging, it is understandable that the responsibility for packaging is found in different departments. In part, this stems from the various functions that packaging serves and the importance

of these functions to a given firm; for example, where promotional considerations are important, packaging responsibility may be located in the marketing or sales departments. (10)

Where should the Packaging function fall in the organization?

Most companies have a packaging function, recognize it, but on an informal rather than formal basis. It would be wrong to conclude that a formal packaging department is the answer in all companies. But, packaging deserves more attention than being just a necessary evil and managed accordingly. (10)

The packaging function covers several divisions or the entire corporation; packaging decisions and projects reside at the divisional or brand level. Explains Nieder, “The packaging department structure will vary depending upon how the company itself is structured. If it’s a marketing company, the manager must be quick at ideas and fast to the market. If the company is manufacturing, the packaging department leans toward the operations side of the business.” (11)

Proving his point, there seems to be no commonality as to how the packaging department is structured. Forty percent of companies are organized along one or multiple product lines, another third are organized in the same way, but with separate international business units, and one-fourth by region within the US or internationally. Ratcliff believes, “You need to customize the packaging department to your product.

Some products – say, gum – would be the same everywhere they are sold; but food companies gear their packages to the interest of the consuming public, and that might be different in Japan than in Europe, the US or South America." (11)

The largest percentages of companies are set up to have the packaging group report to research and development or technical services. Beyond that arrangement, there seems to be little uniformity. Some say packaging reports to corporate top management, even less to engineering, and a handful to plant management or division unit management. (11)

Aside from reporting directly to a higher department, the packaging group very often interfaces with the purchasing department, outside vendors, and marketing/brand management. Often they must work with engineering, plant management and R&D departments. Less frequently, the packaging group cooperates with quality assurance personnel. Elaborates Jay Gouliard, director of package development and design, Coca Cola Co., "Packaging is the intersection point for a wide variety of departments: marketing, engineering, operations, graphics, legal, quality, procurement. The 'home' for the packaging function can just as easily be in marketing as it can be in engineering or procurement. Packaging departments often have very specific areas of focus, cost savings, innovation or operational qualities that allow the packaging department to organize and structure in different ways, and to report into different areas." (11)

Within these companies, change appears to be inevitable. About 75 percent of the companies have reorganized or restructured the packaging department in the past five years. Yet, tight management of the function is apparent. More than 90 percent of the respondents say they use overall objectives, and 85 percent report that the packaging development process is clearly defined. (11)

The packaging department gets pulled into new projects from initiation of the idea up to product launch. A number of the respondents report that they always or usually initiate new packaging ideas on their own, but most say the packaging department is brought into a new project at the first team meeting. (11)

Multiple functions are performed by the packaging team. Everyone seems to report that they are responsible for new package development, for both new and existing products, and for major modifications to existing packaging. Almost all say they are also involved in packaging research, packaging line extensions, specification changes, and plant support or troubleshooting. Nieder explains: “There are four functions of the packaging department. The number one priority is packaging development. Second, develop clear specifications; once that is done, it’s done. Third is technical service or support – in other words, making the package run on the machinery. Then, finally, as the product matures, take costs out of the system.” (11)

Asserts Gouliard, “In today’s economy, cost savings is still an important priority in most packaging departments. Whether you are cutting the bottom line through packaging

material reductions, or growing the top line through packaging innovation, packaging is a key component in business success. In some organizations, the responsibility for innovation often resides within marketing or research and development, making cost reduction a higher priority for the packaging group. The breakdown between cost savings and innovation focus is unique for each company." (11)

In any business enterprise several distinct and different packaging functions are needed and used. Two issues arise most frequently: (1) whether the work is effectively accomplished at a minimum cost, and (2) whether opportunities are being lost by shortcomings either in skills and facilities or in organization and direction. (12)

For each product, someone must establish what kind of protection it needs, how much, and for how long. The nature of the product usually identifies the kind of protection needed, while the distribution pattern and cycle will identify required levels of protection and duration. (12)

The scope of "package development" starts with given product qualities and criteria for shelf life, plus some marketing targets for net content by size, count, volume, or weight. A development normally ends with issuance of a tested specification for packaging that protects the product, can be purchased at an affordable price, and can be handled in production. (12)

The term “packaging department” does not mean two or more coordinators of equal level and with parallel responsibilities, differing only in the product lines or marketing areas they serve. (12)

An accommodation of that kind brings about more problems than it solves. For example, while two coordinators may work with different marketing groups, they have to work with the same purchasing, manufacturing, engineering, and distribution people, and a third party would have to sort out their respective priorities in respect to their demands on the line and staff departments. (12)

Thus, a packaging department is definable as “a staff functional department composed of two or more individuals with specialized skills in package development, one of whom is the responsible department head.” (12)

The definition arouses in the management mind an immediate, almost automatic response, in the form of several questions: (12)

To whom does the department report?
What are its functions?
Where should it fit in the organization?
How big should it be?

It is obvious that the department represents a higher commitment to personnel costs. Total costs may be the same either way, if the coordinator must contract for the purchase of consulting and lab testing services to accomplish his objectives. (12)

Two major functions in package development have been given star billing: structural development and graphics development. A third actor in the drama of putting new or changed packaging into the distribution stream and the marketplace is the engineering function, which must set up or modify packaging-line production facilities to the specific package dimensions and features in question. (12)

The net result is that the workload of a package development department will almost invariably consist of a mix of projects with marketing, cost reduction, quality, and new-package-exploration objectives. The same would be true in the package engineering department, which deals with line equipment, except that the exploratory work would be on new machinery concepts rather than on new packages. The design department would be likely to follow new design trends, improvements in inks and printing processes, and developments in such decorative features as embossing and metalizing, for example, in addition to pursuing assigned marketing objectives. (12)

Packaging Director – This position requires thorough knowledge of the functional departments, the people in them, the objectives of the business, and the art of communicating with diplomacy. (12)

It would be a mistake to conclude that there is one best principle of packaging management for every business, inasmuch as no business is static. Each changes, hopefully grows larger and stronger, and as it does so its organizational needs change. Most businesses would do well to reexamine their package development resources not less frequently than every five years. Patterns of management must be flexible enough to cope with changing needs, and the packaging side of the business is no exception. (12)

After all, technical work isn't glamorous; often it's tedious. But there's satisfaction in focusing on a problem, educating oneself, mustering the discipline to embark on an uncertain journey toward some unknown revelation. (5)

Why being strategic is so important now? The principal reason can be summed up in one word: Value. Everyone in an organization will welcome any enhancement in value. The key is to understand what value your group can add – and then to take action. (6) In the case of the Packaging function, the place to start: Get to know the business of your company. (6)

What keeps the CEO or key business people up at night?

What is the most important component of the business?

Who are your customers?

How is wealth created for your company?

Who are your market analysts (for publicly owned companies)?

How is the company funded?

How is business performance measured?

Limitations

The collection of data will be restricted to existing packaging professional organizations and the data compiled may not be conducive to implementation for certain firm sizes. Large collections of data will need to be left up to research firms that are used by the medical device industry to supply market information at regular intervals throughout the year. The survey should also be conducted and/or the firms should re-evaluate their structure periodically (i.e. – every five years) to validate the template's usefulness.

Assumptions

Medical device companies have a difficult time recognizing and pinpointing critical functions and division of responsibilities in the creation of their corporate Packaging department. Those that do create a department find they are lacking proper guidance in certain areas. A template, boiler-plate, or reference guide will reduce and/or eliminate this problem. If done properly, it would also grow and/or change with the needs of the industry.

Methodology

In an effort to show that this guidance could help medical device companies, this study examines what functions of packaging are involved with typical corporate demands in the medical device industry. The data will be collected from popular professional packaging organizations that allow the use of their clients to participate free of charge.

Interviews (Qualitatively)

The data provided by various packaging professional organizations will be conducted through the use of a survey program available on the Internet, “SurveyMonkey.com”. That way, any future studies could easily replicate and identify shifts in corporate departmental needs. Questioning would consist of yes/no responses, a few open ended questions, and general demographic data collection which would further assist in substantiating findings. Examples of the questions follow.

Data Analysis

The Visual Statistics System (VISTA) was used for the data analysis. This software is a free program developed by Professor Forrest W. Young and is available to the public for download and use at www.visualstats.org.

Corporate Packaging Department Survey Questionnaire

The following questions are to establish demographic data about the participants in this survey.

Gender? ○ Male ○ Female

What is your age? ○ ≤ 30 ○ 31 – 35 ○ 36 – 40
○ 41 – 45 ○ 46 – 55 ○ > 55

What is your highest level of education? ○ < B.S. ○ B.S.
○ M.S. ○ Doctorate

Geographical location of your company? ○ Inside the U.S.
○ Outside the U.S.

If within the U.S. please specify general area? ○ Northeast
○ Mid-Atlantic
○ Southeast
○ Midwest
○ Central
○ Southwest
○ West
○ Northwest

Which segment of the medical device industry do you fit in?

○ User ○ Supplier ○ Other

How many people does your company employ?

○ < 1000 ○ 5000 – 10,000 ○ 10,000 – 50,000 ○ > 50,000

Does your company have a Corporate Packaging department? ○ Yes ○ No

If yes, where does it reside?

○ Marketing
○ Planning
○ Operations
○ R&D
○ Purchasing
○ Other

If no, where do you feel one should reside? _____

For the following question, state your level of agreement that each function is necessary in a Corporate Packaging department. *1 =strongly agree, 2 = agree, 3 = undecided, 4 = disagree, 5 = strongly disagree.*

Packaging Graphic Design	1	2	3	4	5
Secondary Packaging Structural Design	1	2	3	4	5
Primary Package Design	1	2	3	4	5
Packaging R&D	1	2	3	4	5
Packaging Equipment Design	1	2	3	4	5
Mold/Tooling Development	1	2	3	4	5
Regulatory/Compliance	1	2	3	4	5
Specification Development/Clerical	1	2	3	4	5

Are there any other area(s) that you feel have not been addressed, what are they and why?

_____

_____

_____

Thank you for your time and your valuable input to this survey!

DATA ANALYSIS AND HOW IT WAS INTERPRETED

The purpose of this study was to create a template of sorts for Medical Device Companies to use in forming a Corporate Packaging Group. The study was designed to satisfy the following four issues:

1. Identify whether or not Corporate Packaging Groups exist in the Medical Device Industry.
2. Of those that exist, identify where within the corporate structure they might be found.
3. Help predict what areas of expertise should be considered when forming the group.
4. Determine awareness and understanding of the function(s) of a Corporate Packaging Group.

In order to satisfy these issues, thirteen questions were developed and analyzed. Results from these questions, categorically separated, follow.

Demographic Data

Tables 1 through 9 are the demographic information describing the questionnaire participants. Data used to record the demographics were: employment by a medical device company, company size, gender, age, level of education, and geographical location.

Gender and Age

Table 1 shows that 38.33% of the total respondents were male and 10.00% were female. Ultimately, just over half (51.67%) of the respondents did not record their age.

Table 1. Distribution of Respondents by Gender

Gender	*Number*	*Percent (%) of Population*
Male	23	38.33
Female	6	10.00
Unrecorded	31	51.67
Total	60	100.00

Table 2 shows that the largest percentages of respondents 18.33% were 46 – 55 years of age. The next largest age groups at 10.00% were 55 or older and 41 – 45 years of age. Again, just over half (51.67%) of the respondents did not record their age.

Table 2. Distribution of Respondents by Age

Age Group	*Number*	*Percent (%) of Population*
30 or Under	0	0.00
31 – 35	1	1.67
36 – 40	5	8.33
41 – 45	6	10.00
46 – 55	11	18.33
>55	6	10.00
Unrecorded	31	51.67
Total	60	100.00

Employment by a Medical Device Company

Table 3 shows that both respondents employed 53.33% and respondents not employed 46.67% by a medical device company is nearly equivalent.

Table 3. Distribution of Respondents by Employment

Answer	*Number*	*Percent (%) of Population*
Yes	32	53.33
No	28	46.67
Unrecorded	0	0
Total	60	100.00

Education

Table 4 shows the greatest recorded education level to be a Bachelor's Degree 26.66%, with a Masters Degree closely following 16.66%. This question again had a large number of Unrecorded responses (51.67%).

Table 4. Distribution of Respondents by Level of Education

Level of	*Number*	*Percent (%) of Population*
High School	0	0.00
Associates	1	1.67
Bachelor's	16	26.66
Masters Degree	10	16.66
Doctorate Degree	1	1.67
Other	1	1.67
Unrecorded	31	51.67
Total	60	100.00

Geographic Location

Table 5 reflects a majority of the respondents 46.67% residing within the United States while more than half (51.67%) did not answer the question.

Table 5. Distribution of Respondents by Geographic Location

Location	*Number*	*Percent (%) of Population*
Inside the United States	28	46.67
Outside of the United	1	1.67
Unrecorded	31	51.67
Total	60	100.01[a]

[a]Reflection of numerical rounding

Geographic Location – Area

Table 6 goes one step further in narrowing the respondents' location within the United States. The two areas out of all respondents which had the largest participation were the Midwest 20.00% and Northeast 15.00%. Unrecorded respondents accounted for (51.67%).

Table 6. Distribution of Respondents by Geographic Location within the United States

Location	*Number*	*Percent (%) of Population*
Northeast	9	15.00
Mid-Atlantic	2	3.33
Southeast	3	5.00
Midwest	12	20.00
Northwest	0	0.00
Southwest	0	0.00
West Coast	3	5.00
Unrecorded	31	51.67
Total	60	100.00

Company Size

Table 7 reflects the approximate size of some of the companies which employ the respondents. The largest grouping of respondents did not answer the question (51.67%), however out of those which did, 20.00% of respondents were employed by a company that has at least 5000 or more employees.

Table 7. Distribution of Respondents by Company Size

Size	*Number*	*Percent (%) of Population*
Less than 250	4	6.67
250 - 1000	5	8.33
1000 - 2500	3	5.00
2500 - 5000	5	8.33
Greater than 5000	12	20.00
Unrecorded	31	51.67
Total	60	100.00

Existing Corporate Packaging Department

Table 8 accounts for how many of the respondents are employed by a company which has a Corporate Packaging Department. Of the responses, 36.67% have a Corporate Packaging Department while (11.67%) do not. The remaining (51.67%) did not respond.

Table 8. Distribution of Respondents by Corporate Packaging Department

Answer	*Number*	*Percent (%) of Population*
Yes	22	36.67
No	7	11.67
Unrecorded	31	51.67
Total	60	100.01[a]

[a]Reflection of numerical rounding

Function Where Corporate Packaging Department Resides

Table 9 looks at what corporate function is responsible for the Corporate Packaging Department. Here we see that two functions, Operations and R&D, account for 23.34% of the responsibility. Other was very close behind with 11.67% and (63.33%) simply went unrecorded.

Table 9. Distribution of Respondents by Function Location of Corporate Packaging Department

Location	*Number*	*Percent (%) of Population*
Marketing	0	0.00
Planning	1	1.67
Operations	6	10.00
R&D	7	11.67
Purchasing	1	1.67
Other	7	11.67
Unrecorded	38	63.33
Total	60	100.01[a]

[a]Reflection of numerical rounding

Importance of Functions within the Corporate Packaging Group

Respondents were given a list of 10 functions typically found in a Medical Device Company, ranging from Packaging R&D to Legal, and were asked to rate the necessity of each function as it relates to a Corporate Packaging Group. Respondents rated each function on a type of 1 to 5 Likert scale, where 5 = “Strongly Agree” and 1 = “Strongly Disagree”.

Analysis of responses revealed that each function should be considered when forming a Corporate Packaging Group. The level of importance varied from function to function but no one was considered unnecessary.

In order to test the reliability of the multi-item scale, Cronbach’s reliability coefficients, a coefficient alpha and standardized alpha were determined. The coefficient alpha of

.984 and 95% confidence intervals of .974 and .992 indicated respondents were consistent and the results have a high degree of reliability. Cronbach's alpha measures how well a set of items (or variables) measures a single one-dimensional latent construct. Cronbach's alpha is not a statistical test - it is a coefficient of reliability (or consistency). Preferably, a reliability coefficient of .70 or higher is considered "acceptable". The results are shown in Table 10 in order based on the mean importance scores.

As shown in Table 10, the respondents indicated that all functions were necessary to a Corporate Packaging Group (mean for all functions = 3.58). For individual functions, respondents indicated that the R&D and Primary Package Design functions were the most important (mean = 4.48) while the Legal function was deemed least important (mean = 2.72).

Table 10. Professionals' Perception of Necessary Functions

Variable	*Mean*	*Std Dev*
Packaging R&D	4.48	0.91
Primary Package Design	4.48	0.99
Secondary Packaging	4.10	1.14
Structural Design Specification Development/Clerical	3.97	1.18
Packaging Graphic Design	3.69	1.11
Regulatory/Compliance	3.45	1.33
Packaging Equipment	3.21	1.26
Mold/Tooling Development	2.93	1.22
Purchasing	2.79	1.01
Legal	2.72	1.16
Overall	**3.58**	**0.13**

Reliability Coefficients = 10 items
Alpha = .984 95% Confidence Interval for Alpha = .974, .992
Standard error of measurement based on Alpha = 1.328
Standard error of estimation based on Alpha = 1.318

SUMMARY OF THE RESULTS

1. Corporate Packaging Groups exist in Medical Device Companies.
2. Most Corporate Packaging Groups are found under the following umbrella in the corporate structure:
    a. R&D
    b. Operations (Manufacturing)
    c. Other
        i. Engineering
        ii. Corporate/Headquarters
        iii. Product Supply
3. Critical areas of expertise considered important when forming a Corporate Packaging Group are:
    a. Primary Package Design
    b. Packaging R&D
    c. Secondary Packaging Structural Design
    d. Specification Development
4. Other areas of expertise that could be considered but not limited to are:
    a. Mold/Tooling Development
    b. Packaging Equipment Design
    c. Packaging Graphics Design
    d. Regulatory/Compliance
    e. Environmental Packaging
    f. Distribution Packaging

5. The roll of a Corporate Packaging Group appears to still carry out many different tasks depending on the needs of the company. There is no distinct commonality found between Corporate Packaging Groups within the medical device industry.

The purpose of this study was to create guidance or a template for Medical Device Companies considering establishing a Corporate Packaging Group. Given the results, it is apparent each company will have to decide for themselves how to develop their Corporate Packaging Group. The number of respondents that answered all the questions and provided useful information was clearly outweighed by the number of respondents that neglected to respond at all. This could have been associated with an unclear direction given in the questioning format or simply a large number of participants who do not work in the medical device industry and were able to move beyond the initial two questions by answering correctly. Although much of the survey results had Unrecorded responses, it is still possible to be used as a starting block for those companies that may be struggling for ideas on who to hire, what areas of expertise are needed and where the group should be positioned within the company. The study was not an entire loss but should be used with prudence.

Recommendations for further studies would be to evaluate the existing questions and perhaps look for improvements to ensure full participation in the entire survey. A critical recommendation would be to involve a professional data collection service to provide assistance in deployment or soliciting participants in the survey. With this type of

service, participants could be better screened and a larger number of participants may be obtained.

Appendices

Appendix A

Survey

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Pre-Screen

Do you currently or have you been employed by a medical device company?

- ◯ Yes
- ◯ No

Have you previously taken this questionaire?

- ◯ Yes
- ◯ No

Introduction

The following questions are to help establish demographic data about the participants in this questionnaire

Gender

- ◯ Male
- ◯ Female

What is your age

- ◯ 30 or under
- ◯ 31 - 35
- ◯ 36 - 40
- ◯ 41 - 45
- ◯ 46 - 55
- ◯ >55

What is your highest level of education?

- ◯ High School
- ◯ Associates Degree
- ◯ Bachelorate
- ◯ Masters
- ◯ Doctorate
- ◯ Other (please specify)

Geographical location of your company?

- ◯ Inside the United States
- ◯ Outside of the United States

If within the U.S., please specify the general location.

- ◯ Northeast
- ◯ Mid-Atlantic
- ◯ Southeast
- ◯ Midwest
- ◯ Northwest
- ◯ Southwest
- ◯ West Coast

Data

The following questions are designed to obtain feedback about your thoughts of what functions should be considered when developing a Corporate Packaging Department in the Medical Device Industry.

How many people does your company employ?

- ◯ Less than 250
- ◯ 250 - 1000
- ◯ 1000 - 2500
- ◯ 2500 - 5000
- ◯ Greater than 5000

Does your company have a Corporate Packaging Department?

- ◯ Yes
- ◯ No

If yes, what function does it reside in or report to?

- ◯ Marketing
- ◯ Planning
- ◯ Operations (Manufacturing)
- ◯ R&D
- ◯ Purchasing
- ◯ Other (please specify)

If no, where do you think the ideal placement of the Packaging Department is?

State your level of agreement that each function is necessary in a Corporate Packaging Department.

	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree	N/A
Packaging Graphic Design	◯	◯	◯	◯	◯	◯
Secondary Packaging Structural design	◯	◯	◯	◯	◯	◯
Primary Package Design	◯	◯	◯	◯	◯	◯
Packaging R&D	◯	◯	◯	◯	◯	◯
Packaging Equipment Design	◯	◯	◯	◯	◯	◯
Mold/Tooling Development	◯	◯	◯	◯	◯	◯
Regulatory/Compliance	◯	◯	◯	◯	◯	◯
Specification Development/Clerical	◯	◯	◯	◯	◯	◯
Purchasing	◯	◯	◯	◯	◯	◯
Legal	◯	◯	◯	◯	◯	◯

Are there any other function(s) that you feel have not been addressed, what are they and why?

Untitled Page

Thank you for your time and your valuable input to this survey!

Appendix B

Survey Response Summary

Corporate Packaging Department Questionnaire

1. Do you currently or have you been employed by a medical device company?

	Response Percent	Response Count
Yes	53.3%	32
No	46.7%	28
answered question		60
skipped question		0

2. Have you previously taken this questionaire?

	Response Percent	Response Count
Yes	3.3%	2
No	96.7%	58
answered question		60
skipped question		0

3. Gender

	Response Percent	Response Count
Male	79.3%	23
Female	20.7%	6
answered question		29
skipped question		31

4. What is your age

	Response Percent	Response Count
30 or under	0.0%	0
31 - 35	3.4%	1
36 - 40	17.2%	5
41 - 45	20.7%	6
46 - 55	37.9%	11
>55	20.7%	6
answered question		29
skipped question		31

5. What is your highest level of education?

	Response Percent	Response Count
High School	0.0%	0
Associates Degree	3.4%	1
Bachelorate	55.2%	16
Masters	34.5%	10
Doctorate	3.4%	1
Other (please specify)	3.4%	1
answered question		29
skipped question		31

6. Geographical location of your company?

	Response Percent	Response Count
Inside the United States	96.6%	28
Outside of the United States	3.4%	1
answered question		29
skipped question		31

7. If within the U.S., please specify the general location.

	Response Percent	Response Count
Northeast	31.0%	9
Mid-Atlantic	6.9%	2
Southeast	10.3%	3
Midwest	41.4%	12
Northwest	0.0%	0
Southwest	0.0%	0
West Coast	10.3%	3
answered question		29
skipped question		31

8. How many people does your company employ?

	Response Percent	Response Count
Less than 250	13.8%	4
250 - 1000	17.2%	5
1000 - 2500	10.3%	3
2500 - 5000	17.2%	5
Greater than 5000	41.4%	12
answered question		29
skipped question		31

9. Does your company have a Corporate Packaging Department?

	Response Percent	Response Count
Yes	75.9%	22
No	24.1%	7
answered question		29
skipped question		31

10. If yes, what function does it reside in or report to?		
	Response Percent	Response Count
Marketing	0.0%	0
Planning	4.5%	1
Operations (Manufacturing)	27.3%	6
R&D	31.8%	7
Purchasing	4.5%	1
Other (please specify)	31.8%	7
answered question		22
skipped question		38

11. If no, where do you think the ideal placement of the Packaging Department is?	
	Response Count
	11
answered question	11
skipped question	49

12. State your level of agreement that each function is necessary in a Corporate Packaging Department.

	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree	N/A	Rating Average	Response Count
Packaging Graphic Design	24.1% (7)	**41.4% (12)**	17.2% (5)	13.8% (4)	3.4% (1)	0.0% (0)	2.31	29
Secondary Packaging Structural design	**51.7% (15)**	20.7% (6)	17.2% (5)	6.9% (2)	3.4% (1)	0.0% (0)	1.90	29
Primary Package Design	**69.0% (20)**	20.7% (6)	3.4% (1)	3.4% (1)	3.4% (1)	0.0% (0)	1.52	29
Packaging R&D	**65.5% (19)**	24.1% (7)	6.9% (2)	0.0% (0)	3.4% (1)	0.0% (0)	1.52	29
Packaging Equipment Design	13.8% (4)	**37.9% (11)**	13.8% (4)	24.1% (7)	10.3% (3)	0.0% (0)	2.79	29
Mold/Tooling Development	6.9% (2)	**34.5% (10)**	17.2% (5)	27.6% (8)	13.8% (4)	0.0% (0)	3.07	29
Regulatory/Compliance	24.1% (7)	**34.5% (10)**	13.8% (4)	17.2% (5)	10.3% (3)	0.0% (0)	2.55	29
Specification Development/Clerical	**41.4% (12)**	31.0% (9)	17.2% (5)	3.4% (1)	6.9% (2)	0.0% (0)	2.03	29
Purchasing	3.4% (1)	20.7% (6)	**37.9% (11)**	27.6% (8)	10.3% (3)	0.0% (0)	3.21	29
Legal	6.9% (2)	20.7% (6)	24.1% (7)	**34.5% (10)**	13.8% (4)	0.0% (0)	3.28	29
						answered question		29
						skipped question		31

13. Are there any other function(s) that you feel have not been addressed, what are they and why?

	Response Count
	9
answered question	9
skipped question	51

Appendix C

Survey - Open Response Summary

What is your highest level of education?

	Comment Text	Response Date
Find	1. BA with Grad Work	Fri, 8/24/07 7:04 AM

What Function does your Corporate Packaging Group reside in?

	Comment Text	Response Date
Find	1. engineering	Fri, 5/2/08 8:22 AM
Find	2. each division has their own structure; I report inot Operations; others report into R&D.	Fri, 5/2/08 7:26 AM
Find	3. Engineering	Fri, 8/24/07 12:38 PM
Find	4. corporate	Fri, 8/24/07 8:43 AM
Find	5. Engineering	Fri, 8/24/07 6:42 AM
Find	6. Headquarters	Fri, 8/24/07 6:12 AM
Find	7. Product Supply	Fri, 8/24/07 5:39 AM

Where do you think the ideal placement of the Corporate Packaging Group is?

	Comment Text	Response Date
Find	1. Stand alone reporting to Division or Corporate President	Fri, 5/2/08 8:35 AM
Find	2. regulatory or marketing	Fri, 5/2/08 8:22 AM
Find	3. Operations	Fri, 5/2/08 7:52 AM
Find	4. There are many good rationales. We tend to agree as packaging engineers that it is most helpful to be part of R&D so you are part of the new product development team.	Fri, 5/2/08 7:26 AM
Find	5. Stand alone service and profit center	Fri, 5/2/08 7:21 AM
Find	6. Operations and R&D	Thu, 9/13/07 8:21 AM
Find	7. Operations	Fri, 8/24/07 6:14 PM
Find	8. Within business units	Fri, 8/24/07 10:31 AM
Find	9. R&D	Mon, 7/9/07 11:48 AM
Find	10. Design and development	Mon, 6/25/07 4:13 PM
Find	11. Product Development / R&D	Sat, 6/23/07 12:53 PM

What other functions should be considered when developing a Corporate Packaging Group?

	Comment Text	Response Date
Find	1. Systems Engineering. Many times the package must drive the processing system and other upstream and downstream equipment and methods (e.g. RFID) and this is best left in the hands of Packaging. Packaging is the only function with a holistic view of the product, process, and package from beginning to end.	Fri, 5/2/08 8:35 AM
Find	2. sales has a large impact on packaging design and development and should also be considered	Fri, 5/2/08 8:22 AM
Find	3. the other functions I interact with closely are quality engineering, regulatory affairs...	Fri, 5/2/08 7:26 AM
Find	4. Digital asset management	Fri, 5/2/08 7:21 AM
Find	5. Environmental packaging	Fri, 8/24/07 10:31 AM
Find	6. Distribution packaging from distribution center to cutomer.	Fri, 8/24/07 8:43 AM
Find	7. In case this is last screen or cannot change, I am in a Development group at Eli Lilly and Co. We are not a "device" company, per se, but have/make certain types of devices.	Fri, 8/24/07 7:08 AM
Find	8. Labeling, standards, testing lab, clinical packaging (seperate from product launch packaging, supplier development	Mon, 7/9/07 11:48 AM
Find	9. Packaging Operations - obvious, no throwing designs over the fence; Sterilization Sciences - very synergistic relationship, if not the same department, very close by.	Sat, 6/23/07 12:53 PM

Bibliography

(1) Geisel, T.S. (1950) *If I Ran The Zoo.* (By Dr. Seuss [pseudo.]) Random House, New York.

(2) *How Do Things Really Work Around Here?* Jane Linder. Across The Board (2005) pp. 25 – 26; 29.

(3) Boisot, M. H. (1999) *Knowledge Assets: Securing Competitive Advantage in the Information Economy.*

(4) *When Is an Organization.* Brian Dive. Across The Board (2003) pp. 21 - 23

(5) *What drives the innovator.* Chappell Brown. Electronic Engineering Times (2006) p. 4

(6) *Tips for Expanding Your Corporate Role.* Susan F. Sandler. HRFocus (2003) p.1, 13

(7) *Confronting Reality.* Larry Bossidy and Ram Charan. CIO Magazine (2004) pp.1 – 3; 6 – 7

(8) *Best Practices: Organizational Structure That Supports Compliance.* Joe Atkinson and Susan Leandri. Financial Executive (2005) pp. 37 – 40

(9) *Factoring people into the packaging equation.* Mary Ann Falkman. Packaging Digest (2001) p. 78

(10) *Organizing for Effective Packaging Management.* Edward J. Bardi and Larry G. Kelly. Transportation Journal (1974) pp. 53 – 57

(11) *Packaging function, structure defined.* Mary Ann Falkman. Packaging Digest (2001) pp. 75 – 76

(12) Leonard, Edmund A. (1977) *Managing The Packaging Side of The Business. Amacom, New York*