THE SOURCES OF QUALITY IN THE PHARMACEUTICAL INDUSTRY[i]

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ABSTRACT

This paper analyzes the sources of quality of a pharmaceutical product. After identifying eight quality dimensions, a framework of hypothetical sources that contribute the most to shape those dimensions is established.

The framework, based on Garvin's pioneering work, is applied to case studies of laboratories operating in Argentina. Framework relevance is considered using correlation analysis. Laboratories are ranked through expert opinion by the quality of its products using the eight dimensions mentioned above; it is observed that there is no perfect parallelism in ranking along all dimensions, possibly revealing different managerial priorities and uses of resources among laboratories, as well as different sources of quality and different business strategies. Correlation analysis also suggests that the study of a pharmaceutical product is a complex task when a modern concept of quality is considered.

Once the existence of different quality dimensions is accepted, the following two questions are investigated: (1) Are there specific sources of quality that support some dimensions (and not others) and that are based on identifiable organizational aspects or specific technologies? (2) What are the generic sources of quality (affecting all dimensions) and in what way do they contribute to improve performance or highlight quality dimensions? It is assumed as a starting point that among the sources of quality there are generic sources, affecting all dimensions, and specific sources, which affect only some dimensions. In concrete cases, specific quality sources are identified, although the search for specific quality sources for each dimension is not conclusive. The study of generic quality sources, however, suggests that corporate systems, corporate culture, and management policies contribute to incorporate quality in a product. Thus quality results from the interaction between generic and specific sources.

In the final part of the paper, recommendations for academics and industrialists are provided, as well as some conclusions.

JEL: M10, M11, M14.

Key words: Pharmaceutical product, Garvin's quality dimensions, quality sources, pharmaceutical laboratories in Argentina, corporate systems, corporate culture.

[1] The views and opinions expressed in this publication are those of the authors and are not necessarily those of the Universidad del CEMA.

I. INTRODUCTION

Quality is not created spontaneously. It is designed and manufactured: It has its own sources. A somewhat elusive concept, quality is difficult to define and easy to perceive. This combination of traits obscures the study of factors that help to discover, produce, and distribute quality products and services.

Quality presents several aspects and during the last two decades these aspects, called dimensions, have started to be recognized. In his seminal work on quality management, which includes a study on the U.S. room air conditioning industry, Garvin[ii] identified eight dimensions of quality, and he conceived them as a potential source of competitive advantages. The air conditioning study allowed him to rigorously apply quality dimensions, in both subjective and objective evaluations that display qualitative differences among different brands of air conditioners and different manufacturing plants. Garvin explains these differences by looking at the sources of quality and the policies and attitudes towards quality exhibited by managers.

Quality is not just the result of will. It requires systems and processes to make it consistently viable. Quality sources and, in particular, the precise contribution of quality policies in a process industry, deserve study. This paper makes a qualitative exploration, applying the case study methodology[iii] to pharmaceutical laboratories operating in Argentina. The paper is divided into two parts.

In the first part, a classification of quality dimensions for a pharmaceutical product is introduced, and hypothetical sources that contribute the most to shape quality are established. This dimension classification is tentative and its main use in this work was to stimulate managerial judgment at the time of inquiring into the sources of quality. The classification is based on Garvin´s study, and it adapts his approach to the features of pharmaceutical products.

In the second part, theoretical concepts from the first part are applied to the case study of laboratories operating in Argentina. The eight dimensions are utilized in order to classify, by the quality of its products, several laboratories (named 1, 2 ,3, and 4); it is observed that there is no perfect parallelism in rankings along all dimensions. This lack of parallelism reveals the existence of different managerial priorities or types of resources, and suggests different sources of quality as well as different business strategies among laboratories. In addition, it also reveals that the study of pharmaceutical product quality is even more complex when a modern, wide perspective of quality is adopted. Modern perspectives on quality go beyond its basic concept[iv], incorporating organizational arrays, aesthetics concepts and quality of service to the client. Through general surveys, detailed interviews, visits to plants and the examination of relevant documents, the way that management systems and other enterprise assets such as technology contribute to create quality in the different dimensions of a pharmaceutical product are studied. In concrete cases, quality sources are identified.

In spite of the findings of the correlation study, that indicate that multiple quality dimensions exist, the search for specific quality sources for each dimension is not conclusive in this study. On the other hand, important differences among product quality are observed at different laboratories. These facts lead us to study generic quality sources. Thus, through qualitative studies, the research identifies the way in which corporate systems and management policies, as well as other company assets such as corporate

culture, contribute to incorporate quality into the pharmaceutical product. This quality results, in summary, from the interaction among generic sources and specific sources. In the final part of the paper, reflections and recommendations are presented for both academic and industrial practitioners.

II. FIRST PART: QUALITY DIMENSIONS AND QUALITY SOURCES

II.1 PHARMACEUTICAL INDUSTRY PECULIARITIES

The pharmaceutical industry follows general quality requirements common to R&D firms, analytical control laboratories, and chemical plants. It also has characteristics of regulated industries, due to its impact on people´s health. In addition, as a process industry that makes chemical and physical changes on materials, it has its own, specific quality problems, such as the following[v]:

- ◊ Kinetic reactions continue over time, making it necessary to protect samples from dispatch delay, air contamination, packaging contamination, etc.
- ◊ Samples taken during a process can differ noticeably in composition from those of the finished product.
- ◊ The product must be able to be packaged for just one application and nonetheless be attractive to the client.
- ◊ Measurement methods can be diminutive processes of a chemical, physical or biological nature, requiring control.

In addition, packaging must promote inalterability of the product and contribute to its preservation.

Pharmaceutical products are manufactured in different forms: liquids, powder, cream, tablets, capsules, eye drops, lotion, etc. This variety, added to the wide range of existing medicines, each one with specific effects, complicates quality comparisons among products and laboratories. In this exploratory work we overcome this difficulty through the subjective qualification that expert judges (industrial pharmacists with long experience) make on diverse laboratories, establishing a *ranking* among them for different quality characteristics of their products.

II.2 QUALITY DIMENSIONS FOR A PHARMACEUTICAL PRODUCT

Quality is a complex concept, made up of diverse elements. In this section we break down the concept while applying it to pharmaceutical product, creating eight dimensions, classified in three different categories, as shown in Table 1.

These dimensions tend to be thought of as mutually independent, although there are some mutual relationships among them; for example, there is usually a high correlation between performance and reliability; between perceived quality and service; and between conformance and aesthetics. In the following paragraphs we examine the meaning of these dimensions.

A. QUALITY FROM THE PRODUCT VIEWPOINT

1. **Performance**
2. **Secondary features**
3. **Durability**

B. QUALITY FROM THE PATIENT VIEWPOINT

4. **Aesthetics**
5. **Perceived quality**
6. **Service**

C. QUALITY FROM THE PROCESS VIEWPOINT

7. **Conformance**
8. **Reliability**

Table 1. Eight quality dimensions of a pharmaceutical product, grouped in three categories.

II.2.1 Performance

Performance deals with the basic characteristics of a product or service[vi]. For a medicine, its selective therapeutic action is a fundamental characteristic of performance; other performance characteristics are the degree of counter-productive effects the product presents and the adverse interactions in which the drug participates. These characteristics or performance components can be objectively measured[vii].

II.2.2 Secondary features

By secondary features we mean aspects that complement basic functions of a product or service. Easiness to provide the required drug amount to the patient, the degree of risk of alterations in the drug, and the possibility that the drug has to substitute other more expensive alternatives can all be considered secondary features or features. Secondary features are a dynamic concept that evolves with time. For instance, in diabetes treatment, ambulatory treatment was for many years a secondary feature, while today it is a performance characteristic[viii].

II.2.3 Durability

The durability dimension relates to the period that can elapse between the moment a product is manufactured and the moment it is consumed. This period is in practice limited by the expiration date printed on the package. Since products such as food, drinks and medicines end their useful life a short time after consumption, the analysis of durability does not present technical or economic complexity, as is the case with products that deteriorate partially or gradually, or those that can be fixed when broken.

II.2.4 Aesthetics

Aesthetics is by etymology a word related to perception by human senses. Thus taste and odor of a medicine and the visual attractiveness of a package are aesthetics components of a pharmaceutical product. To a large extent, these components are subjective, although there is usually a great deal of opinion agreement about them [ix]. Hygienic aspect is another component of the aesthetics dimension.

II.2.5 Perceived quality

Perceived quality is an indirect comparative dimension. Given the complexities of judging the quality of a pharmaceutical product, the public and, to some extent, the medical profession, base their impressions on indirect signals. Drug originality and immediate effect of a medicine are aspects of perceived quality, among others.

II.2.6 Service

A product cannot claim great quality if it is not available at drugstores and other points of sale, or if interested parties cannot obtain clear, easy to read information on the product and its effects. Thus, product availability at pharmacies and ample distribution of information on the part of laboratories constitute a dimension we label "service."

II.2.7 Conformance

Conformance is the degree of adherence of the design and manufacture of a product to accepted industrial standards. In the case of pharmaceutical tablets, for example, conformance measures the presence of cracks and the correspondence between the quantity of tablets declared in the package and its real content. Unlike aesthetics or perceived quality, conformance is a dimension that can be objectively measured.

II.2.8 Reliability

Reliability is the dimension that creates in the client the mental state of security about the properties and effects of a medicine. The absence of adverse effects of components and the correspondence between dose declared in the package and its real contents fall under this dimension.

II.3. THE SOURCES OF QUALITY

Generally speaking, the sources of quality of a pharmaceutical product are found as much in the policies and attitudes towards quality exhibited by management and personnel as in the characteristics of the laboratory´s R&D processes, product design, supplier selection and management, operations management and human resource management. More specifically, the GMP (Good Manufacturing Practices) standards and the GLP (Good Laboratory Practices) standards are quality sources in the pharmaceutical industry. Finally, in an even more specific sense, it is possible to detect "specific sources" corresponding to

different quality dimensions of a pharmaceutical product. Let us look at some of these specific sources.

II.3.1 Sources of perfomance

Effective therapeutical action of a drug is, in a fundamental sense, a function of the R&D laboratory activity. The laboratory invents the product, defines production technology, identifies adverse reactions that could cause quality problems or performance reduction, collects data to design the manufacturing plant, and establishes control parameters based on theoretical considerations on where, when, and how to perform the control process. Likewise, minimal contraindications are searched through the R&D work.

II.3.2 Sources of secondary features

Just like performance, secondary features derive from the R&D laboratory, but in more advanced stages of the R&D work; at these stages, pharmaceutical presentations that are more convenient for the patient are sought. For example, thanks to R&D an injectable medicine could become a nasal aerosol.

II.3.3 Sources of durability

Medicine durability is associated with aspects such as packaging (which protect the product against contamination and excessive heat, light or humidity) and pharmaceutical formulae. Durability of a medicine is born at the development stage of the pharmaceutical form, when drug characteristics as a function of time and its effect on the human organism are studied. In addition, durability depends on the degree of observance of manufacturing conditions, the type of equipment used in each manufacturing country, logistics, and other factors.

II.3.4 Sources of aesthetics quality

To some extent, quality in its aesthetics dimension is obtained by rigorously applying the GMP standards, by providing good training and work habit formation, by achieving hygiene in all processes, by having permanent control of supplies and even by insuring good personal appearance in the laboratory sales force.

II.3.5 Sources of perceived quality

As we mentioned above, indirect signals such as the quality of publicity, which over time creates brand image is a source of perceived quality. The country of origin effect also contributes to the perception of a product quality[x]. Drug originality, especially when it is promoted through the mass media, and immediate effect (without adverse symptoms) of a medicine are further aspects of perceived quality. Likewise, the laboratory history and the quality of information delivered to doctors, pharmacists, and other stages of the health care chain integrate the perceived quality dimension.

For these reasons, institutional marketing is a major source of the perceived quality dimension. Communication components in marketing play a central role in shaping the laboratory image and its brand image. However, in the long run a good marketing approach is not enough if the company products are not valuable. For this reason, drug suppliers are a key source of quality; in particular, the origin certificates of the supplies enhance perceived quality among the pharmaceutical profession.

II.3.6 Sources of service quality

To a great extent, service quality is a consequence of customer-oriented logistics. A good sales forecasting system, for example, can contribute to improve availability at pharmacies of the laboratory products, thus enhancing service quality. In principle, the marketing strategy of the firm, and the larger or shorter time horizon it defines in its relationship with clients will shape service logistics.

II.3.7 Sources of conformance

The manufacturing process, in particular, respect for manufacturing standards, is at the roots of conformance. Manufacturing for conformance requires respect for tolerance of mix proportions and observance of master specifications of components and final products.

II.3.8 Sources of reliability

GMP and GLP standards, if correctly applied, are the basis of reliability; when GMP and GLP are implemented, robust quality assurance systems operate to increase reliability. These systems must be well designed, implemented and controlled, and adequate personnel and equipment are required in order to get quality objectives.

Table 2 summarizes typical components for each one of eight dimensions and specific quality sources.

	Quality seen from the product			Quality seen from the patient			Quality seen from the process	
	Performance	Secondary features	Durability	Aesthetics	Perceived quality	Service	Conformance	Reliability
Examples of dimensions	Therapeutic action Minimal adverse effects Minimal interaction	Convenient form Lack of adulteration Can replace more expensive product Easiness to complete treatment Selectivity	Adequate packaging	Hygienic aspect	Drug originality Quick effect with no adverse effects History of laboratory	Availability at pharmacies Clear and legible information	No cracks Only the indicated number of pills is present. (This dimension differs according to presentation form.	Only declared drugs and quantities. Legible batch.
Sources of quality	R&D Synthesis of new chemical formula Pre-clinic tests	Formulae development Clinical tests Pharmaeconomic studies	Development and standardization of materials	Existence of process control program Existence of batch liberation system	Drug origin certificate Institutional marketing	CRM Customer oriented, long term marketing strategy	Master specification of components and finished products Observance of manufacturing norms.	GMP and GLP application Existence of robust QA system.

Table 2. Examples of quality dimension components and specific quality sources for a pharmaceutical product.

III. PART II: CASE STUDIES

III.1 FRAMEWORK AND RESEARCH QUESTIONS

Positive attitudes towards quality and the implementation of appropriate management systems greatly promote improvements in the quality of a product or service. Quality sources of a pharmaceutical product can be classified into generic sources and specific sources. The former include categories applicable to all kinds of products, such as the quality of supplies provided by third parties, or the attitudes toward quality exhibited by managers; among generic sources we point out corporate culture, due to its importance. On the other hand, specific sources are those that hypothetically explain specific quality dimensions. The causal relationship between quality and its sources is graphically presented in the framework of Figure 1.

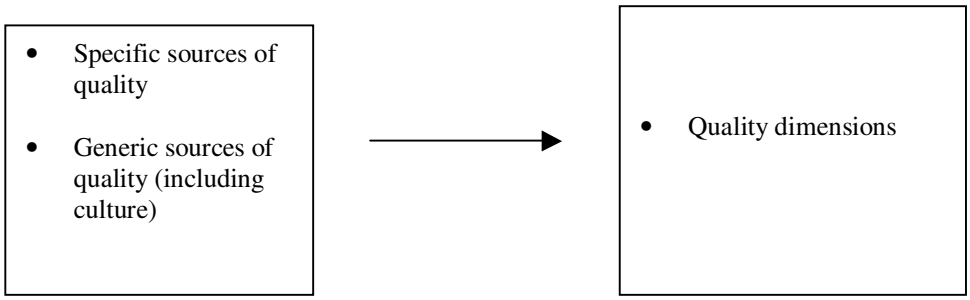

Figure 1. Framework of reference. Quality dimensions obey to both specific and generic sources.

The reference framework invites to ask two questions, which will orient the case studies:

1. Are there specific sources of quality that support some dimensions (and not others) and that are based on identifiable organizational aspects or specific technologies?
2. What are the generic sources of quality and in what way do they contribute to improve quality performance or highlight quality dimensions?

III.2 SPECIFIC SOURCES OF QUALITY

Does it make sense to talk about specific sources of quality for a pharmaceutical product? Lets us examine these sources, that is, those that give origin to the eight dimensions presented in the first part of this paper and ask, in the first place, if these dimensions have enough entity to allow discrimination among independent aspects that are useful from the viewpoint of quality management. We start from the idea that these different quality dimensions exist with their own entity, otherwise it would be meaningless to search for specific, independent sources for each dimension.

In order to check in an exploratory manner the discriminative power of quality dimensions of a pharmaceutical product, we did a small survey among four professionals (three pharmacists and one industrial engineer) with industrial experience[xi]. The object of this survey was to check to what extent quality dimensions differ among themselves.

Interviewed people were asked to establish, for the set of eight dimensions, a ranking of four laboratories identified by their names in the survey and numbered from 1 to 4 in this study for confidentiality. In the first column of Table 3 the eight dimensions are shown. In the second column effective sample size for each dimension is listed. The remaining columns present average expert rankings for all dimensions. Thus, for example, in the Performance dimension, Laboratory 1 was classified in the fourth place by the four experts (average ranking = 4) while in the Service dimension it obtained much better qualifications (average = 1.25). Laboratory 1 is relatively well considered (low ranking) in a few dimensions, while its reputation in other dimensions is not so favorable. This suggests that different dimensions effectively measure different concepts, as we had hypothetically established. Other laboratories present a smaller dispersion among dimensions, which could mean either that the laboratory 'is good at everything" or else that, although in different ways, we are measuring variables which are conceptually close to each other[xii]. The last row in Table 3 indicates the average ranking in all dimensions for all four laboratories.

	Sample size	**Lab 1**	**Lab 2**	**Lab 3**	**Lab 4**
Performance	4	4	1	2,25	2,75
Secondary features	2	3	2	3	2
Durability	4	4	1	2,25	2,75
Aesthetics	4	2,67	1	3,5	2
Perceived quality	4	3,25	1	3,5	2,25
Service	4	1,25	1,75	3,25	3,75
Conformity	4	4	1,75	2	2,25
Reliability	2	4	1,5	3	1,5
AVERAGE		**3,27**	**1,37**	**2,84**	**2,41**

Table 3. Position ra*nkings* for four laboratories in each one of eight quality dimensions of a pharmaceutical product. Values are estimates of industry experts. The meaning of extremes values is: 4 = Worst, 1 = Best; intermediate values are 3 and 2.

A standard way to examine the degree to which different dimensions are linked among themselves is to analyze its correlation matrix. This matrix (Table 4) shows the correlation coefficients among each quality dimension and all the others. For example, given that the correlation coefficient between durability and conformance (0.90) is close to 1, it is estimated that both dimensions move together and it would not be unreasonable to assume that they obey to a common mechanism. Likewise, the aesthetics and perceived quality dimensions are highly correlated. On the contrary, aesthetics with service, as well as aesthetics with conformance, are not highly correlated. It must be borne in mind that this is an exploratory analysis, in which variables and their relationships are studied just to orient the analysis[xiii] (inferences are not to be drawn). In this case, analysis leads us to ask if there are any mechanisms, called sources, that systematically produce quality and that could correctly be associated with specific dimensions.

	Secondary features	Durability	Aesthetics	Perceived quality	Service	Conformance	Reliability
Performance	0,58	1,00	0,54	0,72	-0,14	0,90	0,74
Secondary ffeatures		0,58	0,86	0,89	-0,24	0,57	0,94
Durability			0,54	0,72	-0,14	0,90	0,74
Aesthetics				0,97	0,28	0,31	0,71
Perceived quality					0,15	0,52	0,81
Service						-0,55	-0,46
Conformity							0,80

Table 4. Correlation matrix of rankings for four laboratories. All possible pairs are considered. Data are taken from Table 3.

In Table 5 correlation information among dimensions is presented, grouped into four categories: *Very strong, Strong, Weak,* and *Very Weak or Negative correlation*. These categories were obtained by ordering correlation coefficients in Table 4 and dividing the resulting list in quartiles. The table is self-explanatory.

Dimension	Very strong correlation with	Strong correlation with	Weak correlation with	Very weak or negative correlation with
Performance	Durability Conformance	Perceived quality Reliability	Secondary features Aesthetics	Service
Secondary features	Aesthetics Perceived quality Reliability		Performance Durability Conformance	Service
Durability	Performance Conformance	Perceived quality Reliability	Secondary features Aesthetics	Service
Aesthetics	Secondary features Perceived quality	Reliability	Performance Durability Conformance	Service
Perceived quality	Secondary features Aesthetics	Performance Durability Reliability	Conformance	Service
Service				Performance Secondary features Durability Aesthetics Perceived quality Conformance Reliability
Conformity	Performance Durability	Perceived quality Reliability	Secondary features Aesthetics	Service
Reliability	Secondary features	Performance Durability Aesthetics Perceived quality Conformance		Service

Table 5. Correlation among dimensions: qualitative view.

As a result of this initial examination of correlation information, it can be sustained that there could be multiple, independents sources of quality, corresponding to an equivalent number of relatively autonomous dimensions. These specific sources will be analyzed in the case studies.

III.3 GENERIC SOURCES OF QUALITY

Generic sources of quality are relatively well understood. Garvin (1988) presents the following generic sources, which are also applicable to the pharmaceutical industry in general: Company policies and attitudes towards quality, characteristics of its R&D activities, product design process, supplier selection and management, manufacturing management and personnel management. To these generic sources, the GMP and GLP standards, as well as technology, should be added. Corporate culture must also be considered, since it is a system that surrounds management decisions and determine, to a greater or lesser extent, how employees act. Let us consider some of these sources as they apply to the pharmaceutical industry.

III.3.1 Technology

Technology used in the pharmaceutical industry deserves special attention. Given that, in some sense, quality is the absence of variability in processes and results, plants that incorporate a higher degree of technology[xiv] will tend, in general, to produce better quality: machines and physical systems are less exposed to variation than human beings, whose work depends upon a great number of difficult to control factors.

Incorporating technology into processes allows greater consistency and less variability in critical attributes of the pharmaceutical product. With higher mechanization, operations that affect quality can be made more efficient: for example, distribution lag times can be shortened, improving service; likewise, the number of rework processes performed for lack of conformance with specifications is diminished.

Technology allows reduction in the manual handling of some operations that affect hygienic conditions and, occasionally, the aesthetics of the final product. In addition, in recent years new materials technology has favorably impacted durability, allowing for wider and more complete distribution operations.

III.3.2 Supplier selection and management

In general, supplier selection and the relationships established with suppliers is better managed when a manufacturer deals with expensive inputs or with supplies that have a great potential impact on the quality of a final product. In recent years, the concept of certified quality has been widely developed and applied in the pharmaceutical industry.

III.3.3 Human resources

Human resources must be at the core of any quality policy for leading manufacturers. Human resource policy is the basis on which application of GMP standards is conducted and it must be lead by top management. Plant personnel attitudes and practices

must be aligned with the values transmitted from the top.

III.3.4 Corporate culture

Corporate culture is 'the way companies do things". Quality culture, for i nstance, is the way organizations develop their efforts to get systems, processes, and products and services of high quality. Culture is a system of symbols, values, myths, and practices that slowly evolve through time. Corporate culture has several elements; some authors[xv] consider the following:

- **Member identity** (degree to which the personnel identifies with the organization as a whole, rather than with the kind or work that each person does)
- **Group emphasis to perform tasks** (degree to which activities organize around groups rather than individuals)
- **People focus** (degree to which preoccupation of management related to the impact that their decisions have on personnel)
- **Unit integration** (degree to which coordinated work among units is promoted)
- **Conflict tolerance** (degree to which personnel is encouraged to openly face conflicts and criticism)
- **Control** (degree to which rules and direct supervision are used to control employees´ behavior)
- **Risk tolerance** (degree to which employees are encouraged to be innovative and risk takers)
- **Reward criteria** (degree to which rewards are given on the basis of performance or other factors)
- **Means and ends orientation** (degree to which importance is given to results over processes used to get them)
- **Open systems approach** (degree to which the organization observes the external environment and responds to it)

An organization is made of people working in teams to produce results, by means of processes that have their own control mechanisms. Among the inputs required by any organization to perform its activities is information; information is captured and used more or less profitably according to the open (or closed) systems approach taken by the organization. Using these four classes: *group functioning, control style, concern for means and ends* and *attitude towards open systems*, it is possible to group the 10 elements of culture presented above in a more manageable set, as shown in Table 6.

Class	Elements
Group functioning	Member identity Group emphasis People focus Unit integration Conflict tolerance
Control style	Control Risk tolerance Reward criteria
Concern for means and ends	Means and ends orientation
Attitude towards open systems	Open systems approach

Table 6. Culture elements are arranged in classes to conform a smaller, more manageable set.

III.4. CASE STUDY

Through a two laboratory case study we try to answer the research questions posed earlier in the paper, that is, whether there is evidence linking strong specific quality sources with better quality results, and eventually determine mechanisms that act so that these specific sources produce quality. For this study we have chosen Laboratories 1 and 4 in the survey presented above[xvi].

III.4.1 General characteristics of the laboratories

Laboratory 1 is an Argentine firm, while Laboratory 4 is the Argentine subsidiary of a multinational company. Both companies have a long history in Argentina[xvii]. In the average ranking of laboratories according to product quality (Table 3) they had occupied positions 4 and 2, respectively.

Table 7 summarizes general characteristics of the laboratories and their markets, leadership styles and internal processes. Both firms operate in competitive markets, although Laboratory 1 deals with an homogeneous market through disperse marketing and production activities, while Laboratory 4 faces an heterogeneous market by realizing relatively fewer, more concentrated activities.

In general, Laboratory 1 is, in leadership terms, a follower, not too much inclined to innovation or change, with relatively unrefined management systems. Although it produces quality products, performance as measured by sales volumes, market share, profitability, and other indicators tends to be unsatisfactory.

On the other hand, Laboratory 4 can be described as a leader firm, oriented to innovation, that actively seeks change and has advanced management systems to project itself into the future. The result of these forces is a relatively satisfactory performance, with products of satisfactory quality.

	Laboratory 1	Laboratory 4
Market	Homogeneous and very competitive	Heterogeneous and very competitive
Production and marketing activities	Very disperse	Concentrated
Leadership	Follower	Leader
Innovation	Weak	Stronger
Planning and management systems	Job descriptions, standard costing systems, short term planning systems.	Job description, standard costing systems, performance evaluation systems, monthly operating report, MBO, manager´s training programs, objective formula for salary determination, fixed assets investment system, sales forecasting system, sales review and analysis system, sales force performance evaluation system, competitor´s analysis, price and publicity planning, cash flow planning system, short and medium range planning system, strategic planning system, capital budgeting system, financial investment system, program and budget system, SBU system, project management systems, product and brand management systems, organization matrix system, MIS.
Job descriptions	General and flexible	Specific
Attitude towards change	Rather neutral	Rather active
***Performance* (sales, market shara, new products, profits, etc.)**	Tends to insatisfactory	Tends to satisfactory
Product quality	Tends to satisfactory	Tends to satisfactory.

Table 7. Comparison of Laboratories 1 and 4 regarding markets, processes, quality, and leadership styles.

The results of both laboratories in terms of quality and other operating indicators are not easy to compare. However, we have relatively strong evidence of the superiority of Laboratory 4. In fact, besides the judgement of four experts, managers at both laboratories gave us their opinions on the quality of their products and a variety of other indicators (please see the Appendix).

III.4.2 Specific sources of quality: comparative study

Specific sources of quality highlighted by experts at each laboratory are shown in Table 8. The comparison is not clear-cut. Although in Table 3 we saw that Laboratory 4´s product quality is better regarded than that of Laboratory 1 in seven out of eight dimensions

(service quality being the exception), from the information we have, there is no clear evidence of the superiority of Laboratory 4´ s mechanisms over those of Laboratory 1 to produce quality. There do exist, however, differences between the nature of the mechanisms that laboratories use to produce quality. Let´ s analyze similarities and differences, which should be the subject of a deeper analysis.

Sources of dimension	Laboratory 1	Laboratory 4
Performance	Drug and market evolution at the advanced countries is followed through the activities of an ad-hoc committee.	Pre-clinic tests are performed. For example, bio'equivalence tests, double blind tests. GMP: Personnel training at the classroom and the plant. Critical points studies. There exists a quality assurance system.
Secondary features	There is a Development Department that develops the pharmaceutical form of the product.	There is no Development Laboratory. The formula is selected among a range of alternative formulas according to drug availability in the local market or at the supplier that the laboratory usually deals with. A small lot is prepared for analysis and stability and once approved it is made on an industrial scale.
Durability	The Development Department conducts studies of natural and accelerated stability. What is required by the Health Authorities is done.	Stability studies are performed under local conditions (for the local market) and with special conditions (for the regional market).
Aesthetics	Aesthetics is very important, specially when dealing with medical samples. Sometimes external agencies are contracted for package design. Specifications and standards of packaging machinery are respected. Process control with check sheets is carried out. There are 650 procedures for plant quality.	International standards are used to develop packaging.
Perceived quality	There is a customer care service. Each claim is followed and acted upon (reactive control).	Supplies are bought from the head company or from suppliers with international reputation and acceptance. As a byproduct this fact creates a quality image.
Service	The laboratory has its own distribution network, including an urgency service. There are company distribution centers in the interior cities.	Distribution is contracted. There is an information system that performs sales follow-up. There are standards for printed materials.
Conform-ance	There exists a productivity record sheet for one of the product lines. GMP standards are applied.	Processes are adjusted to master registers so that consistency is guaranteed.
Reliability	Reliability standards for multinational companies are followed. The laboratory is about to completely apply the OMS ´ 92 GMP standard.	The reliability of factory operations is constantly kept in line with GMP demands. There are auto-inspections and international audits to check the normal work of all plant processes.

Table 8. Specific sources of quality corresponding to different dimensions for both laboratories.

Both laboratories seem to have their own pattern of responses to the challenge of obtaining quality in its different dimensions. Laboratory 1 exhibits the use of units such as departments or committees, or systems, as well as adherence to standards; regarding service, they have their own distribution system. Laboratory 4, on the other hand, highlights tests and research studies, as well as training and relationships with international firms, standards and audits. The role of the GMP standards is important for both laboratories and the experts mention them as a source of quality for several dimensions, such as reliability and conformance.

There is a general perception of a proactive attitude and great deal of strictness at Laboratory 4. For each dimension, sources are identified that imply concern for operations, the observation of international standards or an active interaction with suppliers. For example, in order to enhance the performance dimension, pre-clinical tests are performed, personnel is trained in GMP standards, plant critical points are studied and a quality assurance (QA) program is applied. In the aesthetics dimension, international standards are applied to packaging. To get reliability, production operations are constantly kept in line with GMP guidelines, auto-inspections are performed and international audits examine factory processes.

Laboratory 1 presents a set of specific sources somewhat more "passive." This phenomenon is particularly noticeably in the performance dimension: There is an ad-hoc committee that follows the evolution of the most important drugs and markets; although the functions of this committee are adequate for the laboratory needs, it is not less true that, for not paying attention to other sources, opportunities to develop good management practices are lost. It is important to discriminate quality sources for each dimension as they allow to clarify specific aspects of management. For example, by noticing the good reputation that the service of Laboratory 1 enjoys in the market, it is possible to inquire into the sources of this reputation and determine that customer service and its own distribution system, including an urgency system, are the primary sources of quality in this dimension. Eventually this information could be used for new corporate developments, especially in light of a new competitive environment that will be stimulated by the new patent law in Argentina.

III.4.3. Generic Quality Sources: Application to Laboratories 1 and 4

III.4.3.1 Technology

Since product lines differ, comparison of Laboratories 1 and 4 along the technology variable is not direct. In general terms, however, some contrast is detected between technologies used by each laboratory. Laboratory 1 utilizes intermediate technology and, in general, it presents relatively low mechanization indexes: An index of 0.14 corresponds to an average manufacturing line. On the contrary, Laboratory 4 employs in its operations relatively advanced technology, with high mechanization indexes going from 0.85 in the packaging areas to 1 in manufacturing.

In the search for quality products, at both laboratories there is a tendency towards plant specialization by technology or by products; specialization brings scale advantages and process improvements for greater profitability and quality. Although technology applied to processes is common to both firms, there are differences in favor of Laboratory 4

in the quality of the attention paid to each manufacturing stage. These differences are reflected, for example, in the quality, relevance, and quantity of documentation produced and kept up to date, including operations records.

III.4.3.2 Human Resources Management

At both laboratories top management personally oversees human resources issues. There are, however, differences in the approach to hiring decisions; while Laboratory 1 has shorter planning horizons, Laboratory 4 is capable of designing a long-term personnel strategy.

Laboratory 4 is "quite modern" an enterprise, which allows even its lower rank employees to be informed about corporate policies. Nonetheless, just as in the case of Laboratory 1, it gives a rather scant importance to middle management suggestions. Laboratory 4 provides a more intense TQM training than Laboratory 1, and this has an impact on human resource management.

III.4.3.3 Compared Cultures

Corporate culture strongly conditions, although not always in a conscious way, personnel actions. When studying generic sources of quality, culture comparison is important as it orients the selection of means and ends for quality creation. In Table 9, our observations on culture at both laboratories are shown, classified according to the framework of 4 classes and 10 aspects.

Laboratory 1 is a family enterprise with which its personnel develops strong ties, but the firm cannot integrate units and people in teamwork due to a strong tendency to individual work. There is a lack of systems, for example, to solve conflicts and a lack of "process culture" to get objectives; results are valued higher than the means used to get them. Top management attitude towards risk not only conditions employee behavior but also the ability to innovate and learn from interacting with the environment or just watching it.

Laboratory 4, on the other hand, operates in a network of international subsidiaries. Its culture, although in a state of flux due to a recent merger, gives priority to long term values, such as professional development of its personnel and the creation of quality products in a teamwork environment. Risk taking is encouraged to some extent (when no great economic risk exists). In general, corporate culture promotes order and the utilization of standard processes.

Class	Aspect	Laboratory 1	Laboratory 4
Group	**Member identity**	Personnel feels identified with the company (this is a majority opinion, but not unanimous).	The laboratory is the result of a recent merger: there is a culture change going on. Values are being operationalized. There is no fix identity yet. However, quality is a priority, while before the merger costs were the key. The long term is considered, although stock prices are also important. Innovation and quality are paid attention. "Deming is present at the company."
	Group emphasis	Teamwork is promoted at the plant level, but there is a tendency towards individual work.	There is a tendency to teamwork. Communication is somewhat informal, inside the limits allowed by standards and regulations. Information is widely shared.
	People focus	Family enterprise, with a family-like environment.	The organization highly values individual development in a professional community.
	Unit integration	There are "small societies" that form around specific needs. However, there is not a strong relationship between administration and other functions. At the plant level integration is felt, but, although there is a consensus about the advantages of teamwork, this is not always achieved due to a tendency towards individual work.	There are some actions that reflect the initial stages of a more integrated kind of work. These actions are centered around a control panel.
	Conflict tolerance	There are no established techniques for conflict resolution. Some people have their own strategy to deal with conflict and are successful. Others do not.	Communication workshops are organized. Inter-departamental relations are enhanced taken as focus the concept of internal client.
Control	**Control**	Work is quite liberal.	Work is organized around annual objectives with annual feedback and rewards.
	Risk tolerance	Risk taking is encouraged as long as no economic risk is at stake.	There is not much room for taking economic risks, but (only) as a principle risk taking is encouraged.
	Reward criteria	There is no system.	There is a bonus system for key personnel, based on performance.
Means and ends orientation	**Means and ends orientation**	Results have priority.	Processes are evaluated through performance indicators that divide processes in stages to facilitate partial evaluation.
Open systems approach	**Open systems approach**	Sometimes there is an open attitude towards the external world, but what is seen outside is not applied at the laboratory. "I like it, but I don´ t like to invest and spend money." Extreme conservatism and austerity are obstacles to openness and change.	A new and truly systemic culture is being sought. This culture will integrate all employees, who are increasingly conscious of the company values and vision. A systemic attitude provides more realism to the change process.

Table 9. Comparison of laboratories along 10 aspects of organizational culture.

III.4.3.4 Attitudes toward quality and quality systems

It is reasonable to think that the attitudes towards quality of personnel and management, as well as the quality systems implemented at a company will condition quality results and explain (at least in part) differences among laboratories. In this section we explore the relationship between attitudes and quality, and between systems and quality through survey results.

Table 10 summarizes results of a questionnaire survey answered by quality experts at both laboratories[xviii]. The answers were grouped to form families of similar ideas (affinity). Each frame encloses one family of ideas. The leftmost column shows each family name. The second column provides the content of the question, using affirmative sentences. Columns third and fourth present the points given to each answer by the interviewed professionals at Laboratories 1 and 4, respectively, using a scale from 1 to 5 where 1 means "total agreement" and "5" "total disagreement".

At the bottom line of each frame the response average for each laboratory has been calculated: Given that statements are in line with good quality management practices, a lower average implies greater proximity to quality. In this sense, Laboratory 4 is stronger than Laboratory 1 regarding its general view of quality, plans and objectives, procedures and systems, application of modern concepts, information handling and human resources management. However, in terms of quality costing, Laboratory 1 is in a better position than Laboratory 4. In the last family of ideas, process and results, numerical values are not necessarily related to either good or bad practices, but the current mainstream of quality thought suggests the convenience of focusing on processes[xix] (rather than results, since these will emerge from good processes). In this sense Laboratory 1 would be better positioned than Laboratory 4. In general, conclusions than emerge by looking at different families are internally consistent, as are the answers inside each family of ideas. Column "Diff." in Table 10 shows, for each family, the difference between average qualification for each laboratory. The greatest difference occurs at "general view of quality", which is the foremost component in a change process.

Family	Concept	Lab.1	Lab. 4	Diff.
General view of quality	In all areas there are procedures to obtain quality.	4,00	2,00	
	There are guidelines on quality for all activities.	4,00	4,00	
	Quality policy is applied in the whole organization.	4,00	2,00	
	Quality affects every area of the organization, not just Production.	2,00	1,00	
	Management pays attention to quality as much as to other issues and activities.	4,00	2,00	
	There are guidelines to promote the participation of everyone in quality related activities.	4,00	4,00	
	The organization is conscious about the importance of quality.	4,00	3,00	
	AVERAGE	**3,71**	**2,57**	**1,14**

Table 10. Comparison between laboratories on mechanisms for and attitudes towards quality. (Continued.)

Plans and objectives	The level of quality in products and services is evaluated.	2,00	4,00	
	Improvement proposals with action plans are produced.	3,00	2,00	
	Problem analysis produce quality improvements.	2,00	2,00	
	Quality plans are developed to achieve objectives.	4,00	2,00	
	There are objectives for each quality indicator.	4,00	4,00	
	Quality objectives are evaluated.	4,00	2,00	
	AVERAGE	**3,17**	**2,67**	**0,50**

Procedures and systems	The quality system is described in writing.	4,00	2,00	
	The quality system includes auditing procedures applicable in each area.	3,00	2,00	
	There are procedures for quality analysis of internal operations.	2,00	4,00	
	Analysis methods allow setting priorities for improvement.	3,00	2,00	
	Quality consciousness and motivation campaigns are performed.	4,00	4,00	
	There are procedures to present results and get recognition.	4,00	4,00	
	AVERAGE	**3,33**	**3,00**	**0,33**

Application of modern concepts	The criteria "Do it well the first time" is widely shared.	2,00	2,00	
	Quality is an investment, not a source of expenses.	3,00	2,00	
	The concept of internal client is applied.	4,00	2,00	
	Satisfying both internal and external clients is a company policy.	4,00	4,00	
	Prevention and early defect elimination are used.	4,00	4,00	
	AVERAGE	**3,40**	**2,80**	**0,60**

Information handling	Market analysis on product quality	4,00	4,00	
	Company results are widely and adequately informed.	4,00	3,00	
	Quality is actively explained to customers.	2,00	2,00	
	There exists a quality information system.	4,00	4,00	
	The quality information system has information on activities, indicators, cost, etc.	4,00	4,00	
	The quality information system has information on clients, competitors and suppliers.	4,00	4,00	
	Information from the quality information system is used as a management tool.	4,00	2,00	
	AVERAGE	**3,71**	**3,29**	**0,43**

Quality costing	There are procedures for estimating quality costs.	4,00	5,00	
	The cost of no quality is accounted for.	4,00	5,00	
	Quality costs discriminate by prevention costs, etc.	5,00	5,00	
	Quality costs are calculated in all areas.	4,00	5,00	
	There is a system to manage quality costs and their evolution.	4,00	5,00	
	The company regularly establishes objectives for quality costs.	4,00	5,00	
	AVERAGE	**4,17**	**5,00**	**-0,83**

Process or results	Quality efforts focus on activities and processes.	2,00	4,00	
	Quality efforts focus on products and services.	3,00	2,00	

Table 10. Comparison between laboratories on mechanisms for and attitudes towards quality.

III.4.3.5 Corporate culture, attitudes, and systems

As can be seen in Table 11, corporate culture has an impact on different aspects of quality management, including attitude formation and smaller or greater easiness to implement quality systems.

Attitudes and systems / Culture concepts	General view	Plans and objectives	Procedures and systems	Application of modern concepts	Information handling	Concern for human resources	Process and results (including quality costing)
Group	Identification with the firm and its groups, unit integration, open conflict resolution, etc. facilitate a global view of quality.		A good working relationship at the group level facilitates the shaping of organizations where the concepts of process and internal client are diffused and accepted.		If the group works properly, company results are better informed and the environment signals are better received.	A good team working environment facilitates human resource management.	Processes are better handled when groups work properly.
Control (rules, risk, rewards)		If risk taking is not rewarded, a "controlling" organization will establish down-to-Earth (but not ambitious) plans and objectives.	A "controlling" organization will have more affinity with the application of rules and some reluctance to risk taking.	Greater, rigid control means that modern management concepts are more difficult to apply, especially when the reward system does not promote innovation.	Bureaucratic, rigid information systems are not tuned with quality management.		The reward system will reflect the relative importance given to processes and results.
Means and ends		More planning for quality (*hoshin* type) leads to pay more attention to means and their planning.				The kind of training differs: more technical and specific vs. more general.	One or the other will take a more relevant place according to the culture of each organization.
Open systems	Facilitate a modern view of quality, incorporating trends and creating an environment prone to change.		Facilitate incorporation of new approaches.	Facilitate incorporation of new approaches.	Facilitate proactive action.		

Table 11. Ways in which corporate culture contributes quality systems and attitudes.

The table shows a theoretical framework that relates central concepts of corporate culture with the core attitudes and systems of quality management explained in Table 10.

III.4.3.6 Case study results

The case study leaves several teachings[xx]. Here we summarize the most important ones.

- **Quality dimensions of a pharmaceutical product.** Are there mutually independent quality dimensions for a pharmaceutical product? The case evidence suggests that there are. Although correlation among some pairs of dimensions is high[xxi], other correlation measures are low, indicating independence among the concepts measured by each dimension. It is not possible to say that the number of dimensions is exactly eight, but it is possible to conclude that there is a plurality of them. At any rate, independently of the statistical analysis, in the course of the case we assumed that the eight dimensions have a conceptual substratum and on this basis we used them. Confirmatory statistical analysis demands an important amount of data, far greater than the amount we have at this time.

- **Specific sources of quality.** The assumption that quality dimensions have their own entity invites to study the existence of specific sources of quality for each dimension. This is one of the research questions posed above. Table 12 shows identifiable organizational aspects and specific technologies that act as a source of quality for each dimension.

Dimension	Quality sources for each dimension
Performance	♦ Statistical Analysis ♦ Training ♦ Quality Assurance Systems ♦ Access to up-to-date information
Secondary features	♦ Development at the laboratory ♦ Deals with trustworthy suppliers ♦ Small scale tests
Durability	♦ Stability studies ♦ Official rule observance
Aesthetics	♦ Specialized suppliers ♦ Standards observance ♦ International standards
Perceived quality	♦ Customer support system ♦ Deals with world class suppliers ♦ Marketing efforts oriented to create brand image
Service	♦ Ownership of distribution service
Conformance	♦ Standards observance, including GMP
Reliability	♦ GMP and other international standards ♦ International audits

Table 12. Mechanisms that produce quality in its diverse dimensions.

This table, based mainly on Table 8, is a stock of methods that both laboratories use (albeit somewhat unconsciously) to work on each quality dimension; however, it does not allow to establish the superiority of some mechanisms over others to achieve quality. A more in-depth causality study would be required, as it could help to focus strategic choices, means and ends.

- **Generic sources of quality.** Our second research question inquired into generic sources of quality, which contribute either to improve quality *performance* as a whole or some quality dimensions. These sources appeared as indeed important, especially as builders of institutional support on which specific sources operate. For example, it would be worthless to conduct pre-clinic studies (specific dimension of performance) if there is no set of GLP standards (generic source) that assures quality. Generic sources include culture, technology and human resources administration, among other elements.

IV. RECOMMENDATIONS

IV.1 RECOMMENDATIONS FOR MANAGERS

- **Understand the dimensions of quality.** Managers should consider a more detailed analysis of quality dimensions in order to have better strategic alternatives. Good knowledge of quality sources would allow for greater leverage. For example, the use of available resources for customer care could expand the range of business opportunities for the laboratory.

- **Need to discriminate among concepts.** It is important to understand the competitive potential of laboratories, especially that of the smaller ones. It could be said that, because it is international, Laboratory 4 "has everything": financial resources, advanced technology, brand and country of origin image, culture of quality, R&D, etc. These advantages are indeed real, but, as we saw regarding customer service, it is possible to find quality dimensions in which laboratories (like Laboratory 1) with fewer resources have strategic advantages. Discrimination among dimensions helps to improve understanding, increases industry know-how, and allows its application to other fields with potential interest. Our fieldwork suggests that in this industry there is no clear understanding of what the quality sources for each dimension are. There might not even be a clear a understanding of generic sources beyond GMP and GLP. However, if quality dimensions and quality sources are not understood, innovative competitive strategies that take advantage of them cannot be designed.

- **Attention to generic sources of quality.** Specific sources do not explain by themselves all quality differences: in fact, generic sources also contribute to quality. For example, Laboratory 4´ s technology has a high mechanization index and this is a quality source benefiting several dimensions. Likewise, human resource management (including training) is broader and deeper than that of other laboratories and contributes to increase the quality gap.

IV.2 RECOMMENDATIONS FOR ACADEMICS

- **Need for a more complete statistical study.** For operative reasons this study database is small. In further studies it would be advisable to enlarge the database and compare analysis results.

- **Study of the causal mechanisms that produce quality for each dimension.** It would be important to study more in-depth those mechanisms that shape quality in each of its dimensions. This understanding would help to apply the right tools and methods with more consistency and simplicity.

IV.3 ADVICE FOR BOTH MANAGERS AND ACADEMICS

- **Define alternative strategies on the basis of quality dimensions.** Greater understanding of quality dimensions in a pharmaceutical product should serve a laboratory as a basis to design alternative strategies allowing to better compete with other laboratories on the basis of its own advantages, placing itself on specific quality dimensions. This task requires both industrial experience and academic approaches.

V. CONCLUSIONS

The paper integrates a number of concepts related to quality and quality management, with emphasis on the pharmaceutical industry. In particular, the treatment, through a case study, of corporate culture and corporate systems at two laboratories in Argentina, as well as and their impact on quality management, is reasonably developed. The work provides useful advice on quality-related subjects to practitioners in different fields.

Further research could confirm the validity of our study by means of a wider survey. In addition, a more detailed analysis of cause-effect mechanisms operating to produce quality would be beneficial.

APPENDIX

RELATIVE PERFORMANCE OF LABORATORIES

Performance evaluation is not an easy task. Although simple forms of evaluations (such as revenue annual growth rate or internal rate of return) can be adopted, performance of a complex organism such as a business firm deserves consideration of multiple factors. Due to information limitations, we have based our comparison between Laboratories 1 and 4 on our informants' criteria. In a 1 to 5 scale, where 1 is "great displeasure" and 5, "very satisfactory", managers at the laboratories evaluated indicators as shown in Table A1.

Area	**Indicator**	**Lab. 1**	**Lab. 4**
Marketing	Sales growth	1	4
Marketing	Growth in *market share*	2	4
Marketing	New product introduction (percentage)	2	3
Marketing	Strengthening of Marketing capability	2	4
	Marketing indicators' average	**1,75**	**3,75**
Finance	Earnings growth rate	1	3
Finance	Return on investment	1	3
Finance	Stockholders' capital gains	1	2
Finance	Asset liquidity	3	3
	Finance indicators' average	**1,5**	**2,75**
Quality	Improvement in product quality	3	4
Operations	Production efficiency and physical distribution	3	4
R&D	Strengthening of R&D capacity	3	4
R&D	Improvement in product portfolio	3	3
	Operations indicators' average	**3**	**3,75**
HH.RR.	Improvement in employees' morale	2	3
HH.RR.	Improvement in employee welfare (e.g. salary increase, internal promotion, improvement in work environment).	3	3
HH.RR.	HH.RR. development.	3	4
HH.RR.	Reduction in personnel turnover.	3	3
	HH.RR. indicators' average.	**2,75**	**3,25**

Table A1. Comparison of Laboratory 1 and Laboratory 4 performances.

Laboratory 4 is consistently better evaluated than Laboratory 1. Indicators are classified in Marketing Indicators, Financial Indicators, Operations Indicators (that include quality and R&D) and HH.RR. indicators. Laboratory 1 presents its best results in Operations, while Laboratory 4, evaluates itself well in Marketing and Operations, although their evaluation in other functions is not bad. Distance between laboratories is greatest among Marketing and Financial indicators, while the minimum distance belongs to Operations and HH.RR.

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NOTES

[i] The authors acknowledge the kind encouragement of Dr. Rodolfo Benedix and the valuable assistance of Prof. Alejandra Falco, who suggested improvements to an earlier draft of this paper. All remaining errors, however, are our sole responsibility. A preliminary version of this work appeared in Pharmaceutical Management, Año 2, No. 4, pp. 36-43 (Part 1, September 2000) and Año 3, No. 5, pp. 34-55 (Part 2, January 2001); the authors thank the editor of Pharmaceutical Management for authorizing the publication of this article.

[ii] See Garvin (1988).

[iii] We deal with case studies as a research tool rather than as a teaching devise. Research-oriented case studies allow generalization "toward theory." In this regard, they differ from large scale quantitative studies that allow inference "towards a population." See for example Yin, R.K. (1981 y 1984).

[iv] A basic definition of quality for a pharmaceutical product is the following (Sharp, 1992): "Quality is the capacity for the proposed use. A pharmaceutical product is capable for use when:

- It is the correct product
- It has the adequate power
- It is free of contamination
- It has not deteriorated, expired or decomposed
- It is conditioned in the correct package
- It has the correct label
- It is perfectly sealed in its package, to protect it from damage and contamination."

[v] See Bingham, R. S. Jr. and Clyde H. Walden (1988).

[vi] For example, in a household product, such as a transistor radio, major performance components are: power, number of frequency bands, size and weight.

[vii] An approach to the definition of quality dimensions (presented as customer requirements) of a pharmaceutical product and an objective way to measure them is presented in: Martín, Fernando and Enrique Yacuzzi (1997).

[viii] In a different context, devises such as a washing machine's electronic control, which until a few years ago could have been considered a secondary feature, is today, thanks to the popularization of these controllers, a component of performance.

[ix] See Garvin (1988), page. 59.

[x] The country of origin effect is a wide-spread phenomenon, observed in many situations. For example, if no other information is available, a French wine will generally be considered to have greater quality than another one produced in Eastern Europe, regardless the objective quality of the wines. A similar phenomenon occurs in the pharmaceutical market.

[xi] Although sample size is very small, we have tried to incorporate the opinion of experts with in-depth knowledge of the market and industry. At the time of having to choose between a large number of responses or quality of the respondent knowledge, we preferred the latter alternative. At any rate, we are aware of the small sample size and its limitations.

[xii] The small sample size does not allow in-depth analysis to determine whether the eight dimensions are in fact measuring different concepts. A much greater sample size would be required to determine, through factor

analysis or similar techniques, the relevance of the eight dimension scheme. As far as this study is concerned, the eight dimension structure will be considered valid.

[xiii] It must also be remembered that correlation among variables does not necessarily shows causality; correlation must be thoroughly explained and superficial conclusions on causality must be avoided. The interested reader can see for example Miles y Huberman (1984) on causality and related issues, such as intervening variables.

[xiv] A method –certainly imperfect but relatively simple— to measure technological content is through a mechanization index, defined as:

Mechanization index = total machine hours/total man hours.

This index is defined and measured for every production line. In general, as we advance along a productive process (i.e., as we get closer to the final customer), the mechanization index decreases: for example, mechanization indexes are smaller at the packaging areas than at the manufacturing areas.

[xv] See, for example, Robbins et al. (1996), Cap. 3.

[xvi] Availability of information and willingness of laboratory personnel to participate in the study were the main reasons for our choice.

[xvii] Information for these studies was obtained during the year 2000 in several personal interviews with middle managers, followed by telephone conversations and e-mail correspondence.

[xviii] The questionnaire form can be requested to the first author. It is partially based on Kagono et al. (1985).

[xix] See Shiba (1993).

[xx] Qualitative case studies always elicit questions about their validity. In this case we have tried to strengthen our conviction on data validity by interviewing several people at the same firm and by making redundant questions in the questionnaire and during the interviews.

[xxi] A causal explanation for these high correlation coefficients can be requested to the first author.