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Evaluating the feasibility of a vendor certification program for a mid-sized pharmaceutical company

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ABSTRACT

Title of Thesis: Evaluating The Feasibility Of A Vendor Certification Program For A Mid-Sized Pharmaceutical Company

Clarice P. Johnson, Master of Science, 1990

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To compete effectively in the global market-place of the 1990's, manufacturers and suppliers must give up the orthodox practices of the past and create more innovative, quality oriented partnerships. One way to do this is through vendor certification.

The implementation process is examined with particular emphasis upon total management involvement and commitment. A case study approach utilizes a literature search, questionnaires from a limited number of pharmaceutical companies in New Jersey, and questionnaires from primary and secondary component suppliers.

It is confirmed that the implementation of a vendor certification program is a slowly evolving process whose success is not dependent upon the size of the company, but is a reflection of management commitment, team involvement, and supplier agreement. This paper gives a frame to any mid-sized pharmaceutical company considering such a program.

EVALUATING THE FEASIBILITY OF A VENDOR CERTIFICATION PROGRAM FOR A MID-SIZED PHARMACEUTICAL COMPANY

by

CLARICE P. JOHNSON

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This thesis is dedicated to all the family, friends and colleagues whose understanding, patience and assistance made it what it is!

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CHAPTER I

INTRODUCTION

I. INTRODUCTION

This is a study on vendor certification and its application to the pharmaceutical industry. The focus of the study is a mid-sized pharmaceutical company (Company X) with a need to change to a more comprehensive program to improve and control vendor quality.

In the U.S., quality has so many different meanings that there is no agreement across the nation, in an industry, or even in an individual plant, about what quality means. Quality definitions are confused by such slogans as "do it right the first time," "zero defects," "corporate commitment," "excellence plus," "quality mandate" and so on. When you ask plant managers what they mean by these slogans, they usually answer in a general way: "In our company, everybody works together to achieve the highest possible quality standards and our top management is totally committed to meeting quality objectives". If you probe deeper into various company quality goals, you find that they usually translate into an objective to manufacture and ship parts that fall within engineering specification limits or local quality acceptance standards. Therefore, the operational definition of "zero defects" is that all parts (as sampled) are within specification limits.[1]

Historically, we have not been too concerned about process variability as long as parts are within limits using go/no-go checks; parts could vary from the high side one day to the low side another day and very little action would be

taken. In fact, many suppliers pride themselves on being able to control a process at either the high side or the low side to accommodate a particular customer's assembly problem. They even cite this ability as evidence or proof of their dedication and customer service.[2]

It is this process variability and all the problems associated with it that started a move towards vendor certification. There is considerable interest in industry today in the subject of vendor certification, and a number of companies have explored the potential of introducing it to their operations. Some are in various stages of implementation with differing degrees of success. The reasons for implementation vary from improved delivery, improved vendor-customer relations, improved quality, reliability, cost reduction, and a pre-requisite to just-in-time.

Vendor certification is particularily important in the pharmaceutical industry because it is regulated by the Food and Drug Administration (FDA) and quality control procedures are more stringent than in unregulated industries such as automobiles. The FDA is empowered to issue implementing regulations that inform the industry and the public exactly how provisions of the Food, Drug and Cosmetic Act (FD&C) will be applied.

Pharmaceutical industry quality control procedures are covered in the Code of Federal Regulations Parts 211 thru 229 which contain the minimum Current Good Manufacturing Practice (CGMP) for methods to be used in, and the facilities or

controls to be used for, manufacturing, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess.[3]

Section 211.22 of the regulations states:

> "that there shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company. Further these responsibilities and procedures shall be in writing and shall be followed".[4]

Company X is a mid-sized pharmaceutical company located in Northern New Jersey. The company manufactures ethical drugs and is regulated by the FDA. Company X currently uses two methods of determining the quality of incoming material. One is acceptance sampling plans patterned after MIL-STD-105. This is a procedure for inspection by attributes which is generally used in industry. For example, the plastic flip-off buttons for the West Company are sampled by the manufacturer before shipment to ensure they meet Military Standard-105D Acceptable Quality Levels (MIL-STD-105D AQLS), Level II, normal plan, single sample. Upon receipt they are sampled again with the same plan. This time-consuming, costly redundancy cannot be tolerated in today's competitive market.

There is some level of acceptable non-conformance inherent in acceptance sampling methods. This means that occasionally parts on the high or low end of the specifications would be used in the manufacturing process, resulting in poor yields and high manufacturing costs.

The other is a modified skip-lot procedure. Depending on the component, complete testing is performed on every second to tenth lot or twice annually whichever is sooner. This process as stated previously does not adhere to the concept of total quality control - make it right the first time. If rejections or failures occur at any step in the procurement - manufacturing - distribution cycle, they create ten-fold cost when they are detected and corrected later. Vendor certification might help companies such as Company X handle quality control more efficiently.

A. Definition of Vendor Certification

Vendor Certification as defined within the Pharmaceutical Manufacturers Association (PMA) guidelines is a total quality management system that assures that a supplier's product is produced, packaged, and shipped under a controlled process that results in consistent conformance to customer requirements. It is a program based on the principle of defect prevention as opposed to defect detection and selection. It supports the concept of quality at the source by doing it right the first time thereby substantially reducing or eliminating the need for final quality inspections

by the customer. Finally, if successfully implemented, vendor certification should achieve the desired objectives of improving quality, improving delivery performance, increasing productivity, and reducing costs in terms that are quantifiable.

The primary objective of the certification process is to assure consistent high quality as demonstrated by predictable conformance to customer requirements. The basic premise is that when the customer and supplier work together to establish the proper product design characteristics, specifications and test criteria, and process controls, the result will be that it is consistently fit for use and free of defects. While the customer is responsible for assuring the suitability of an item for its particular use or application, it is the supplier's sole responsibility to meet customer requirements.

Certification is based on the ability of the supplier to control a given process at a given site to within desired tolerances. To achieve this, the program recommends extensive use of statistical quality control techniques. The manner in which a supplier manages its overall quality systems should not be overlooked in the pursuit of statistical controls. Understanding and application of GMP requirements is also an integral part of this process. In addition management attitude, integrity, and honesty are necessary components which assure successful certification efforts.[5]

In the pharmaceutical industry vendor certification may apply to suppliers of bulk pharmaceutical chemicals and their

raw material, drug product components, and drug product containers, closures and other packaging materials. Because of the diversity of the materials and the processes involved, becoming certified requires different kinds and levels of effort from different suppliers. It is recognized, therefore, that circumstances may vary depending on the type of operation, the nature of the process involved, and product standards requirements.[6]

For example, certification of bulk material suppliers requires the correlation and validation of laboratory results so that the customer can utilize the supplier's results as it would its own.[7] The certification requirement for a closure or a vial on the other hand, is a suppliers demonstration of statistical process control.

In addition, the FDA guidelines specify different testing requirements for components, and containers and closures. Specifically, each component (raw material) shall be tested for conformity with all appropriate written specifications for purity, strength and quality, whereas for containers and closures the testing is visual inspection. In both cases testing may be conducted by the supplier. For components, in lieu of such testing by the manufacturer, a report of analysis may be accepted from the supplier. For containers and closures in lieu of such testing by the manufacturer a certificate of testing may be accepted. In both instances the manufacturer must establish the reliability of the supplier's analyses and or test results through appropriate validation of

the supplier's results at appropriate intervals.[8]

Vendor certification programs have often been discussed within the context of the "just-in-time" (JIT) approach to manufacturing and inventory management. It is the most appropriate technique to bringing a supplier into a just-in-time inventory system, where supplier-furnished material is brought into the customer's facility just in time to go into the process or on the assembly line. It also reduces costs through the reduction of incoming inspection and test.[9] However, while JIT may provide a strong impetus toward vendor certification, it need not necessarily be the primary reason behind the effort and is not a prerequisite. It is also important to understand that vendor certification should not be confused with the routine supplier selection, qualification, and approval process, or the so called "reduced testing programs" based strictly upon supplier quality history and statistical quality control assessments. Stated differently, vendor certification does not replace existing supplier/customer procedures and relationships but it is an additional tool for achieving the maximum benefits resulting from those relationships.

B. Problem

Producing a high quality product that meets the customer's needs in a timely fashion requires a well-orchestrated program of prevention. There is no place for firefighting if one is to remain competitive. Design

integrity, manufacturing repeatability, strong supplier-customer partnerships, and a clear understanding of the needs of the marketplace are key to the success of total quality control. Senior management must create a corporate climate that emphasizes excellence in manufacturing. Developing this corporate quality climate is not easy; it is an arduous task that involves the creation of a quality philosophy that says that everyone from design to delivery shares responsibility for quality.[11]

The problem with the two methods used by Company X is that by the time in-process quality control discovers the discrepancy, hundreds of parts in the pipeline are affected, resulting in long lead times to correct the problem, loss of productivity in line change-overs, increased labor to administer and perform the extra work, more time to dispose of and to handle the discrepant material, and more effort to analyze and correct the problems after they arise. Companies are being challenged to introduce programs that will meet the challenge of total quality control. Company X is not alone. Other companies also use these methods and have these problems. What will help Company X, will also help them.

C. Purpose

The purpose of this study is to gather and analyze information relevant to the implementation of a vendor certification program for companies with the same characteristics as Company X - companies who: 1) are using

incoming inspection as the only means of quality; 2) spend an inordinate amount of time expediting; 3) have constant changes in schedule priorities; and 4) are plagued by long leadtimes and late deliveries.

Past procurement practices have focused on obtaining the lowest unit prices. The trade-offs of poor quality, erratic delivery performance, and a myriad of other problems have been buffered by inventory cushions, quality control personnel, and multiple vendors with short-term interests.

In this case study of Company X, the current procedures for planning, purchasing, and in-coming inspection of components are reviewed. Parameters and requirements for adopting a certification program to these procedures are defined. Problem areas are defined and then addressed in terms of solutions. Information obtained will serve as a guide to other companies similar to Company X.

By studying the processes of companies in other industries who have successfully implemented programs, the best practices consistent with the pharmaceutical industry's needs can be identified.

Studying the characteristics of other pharmaceutical companies' programs and processes, allows analysis to determine similarities to Company X, and thus the potential benefits of the programs to companies of this type.

D. Methodology

This study has four parts. Part one is a literature

search which describes the vendor certification implementation process and how companies such as West, Polaroid, Merrel Dow, Burroughs Wellcome, and Dorsey Labs have used this process to successfully implement vendor certification programs.

The second part describes the results of a field study on vendor certification in pharmaceutical companies in the New Jersey area. This survey on New Jersey expands the literature's geographic focus. This study evaluates the feasibility and identifies the potential success of a vendor certification program for companies with characteristics similar to those of Company X.

A questionnaire was sent to eighteen pharmaceutical companies in New Jersey. The three page questionnaire gathered information on the firm's: (1) primary reason for implementing the program; (2) implementation process; (3) items included in the program; (4) success with the program; and (5) implementation team. The questionnaire was directed to either the purchasing manager, the quality control manager or the quality assurance manager.

The questionnaire was mailed, accompanied by a letter of explanation and a self-addressed stamped envelope. It was expected that the response rate would be at least 50%. Although a great deal of consideration was taken to make the questionnaire as short and simple as possible, the low response rate was expected because questionnaires are often seen as an imposition to the respondent. Incomplete and unreturned questionnaires may result in an unrepresentative

study. However, mailed questionnaires have the advantage of eliminating interviewer bias and enabling the respondent adequate time to answer which may not be the case in an interview.

The samples for the study were obtained from the 1989 Membership Directory of the American Society for Quality Control. The directory includes pharmaceutical industries both nationally and internationally. However, the samples were limited to companies in the state of New Jersey. By using companies within New Jersey, problems in comparing data gathered from different areas of the country were eliminated, but relationships obtained may be limited to companies within the state. Judgmental sampling was used to select eighteen different companies.

The third part - a case study describes the current management involvement and procedures for planning, purchasing, and incoming inspection at Company X and defines parameters and requirements for adopting this culture and these procedures to a certification program. It also includes a field study of vendor willingness and experience in a vendor certification program. A three page questionnaire was sent to eighteen packaging component suppliers for the pharmaceutical industry.

The survey to the current suppliers gathered information on: (1) their willingness to participate in a vendor certification program and, (2) their experience in a vendor certification program. This gives an indication as to the

amount of training that will be required for the suppliers should they decide to become involved in such a program.

Finally, the study includes a summary of findings, the potential benefits and recommendations, and conclusions based on the research and analysis. This will provide Company X and other companies similar to it with performance metrics for evaluating a vendor certification program.

CHAPTER II

THE CERTIFICATION PROCESS

II. THE CERTIFICATION PROCESS

A. Introduction

This section of the study focuses on established practices. Through a search of the literature (periodicals published over the past seven years), industries that have initiated certification programs are examined to establish targets based on industry practices.

The concept of certification, which has received a good deal of attention abroad, particularly in Japan, gained a foothold in the U.S. in the late 1970's with its use by the Defense Department in dealing with key suppliers. Vendor certification has been actively employed as a quality tool by the U.S. automobile and other industries during the 1980's. Drug industry interest surfaced in the mid-1980's and is continuing to gain momentum.[12]

Industry analysts draw a parallel between the development of the concept of certification today and that of validation a decade ago.[13] Like validation before it, interest in certification reflects the overall change in emphasis from end-process sampling to better control of the process itself. The difference is that validation is a company developed documented procedure that shows that an item or a process can perform its intended function for a specified interval under stated conditions. Certification, on the other hand, is a joint program between the company and the supplier. At this stage companies are still trying to work out the steps needed to develop a workable program, one that adheres to CGMP regulations. Although the CGMP regulations only apply to pharmaceutical manufacturers, there may be certain regulatory

standards that suppliers to the pharmaceutical industry must meet to satisfy customer needs. Examples include: lot traceability and product status controls; controls to prevent product mix-ups or foreign contamination; and raw material traceability, such as for plastic resins used in bottle manufacture. In addition, legal liability for defective products under the FD&C Act may extend back to the supplier. For example, a single label supplier could potentially be guilty of violating the Act if it negligently supplies defective labels in such a manner that the drug firm, even if it followed CGMPs could not have detected the problem.[14]

A program to select, evaluate, and use certified suppliers is hard, time consuming, and expensive. Yes the rewards are comprehensive and long lasting, but do not think of supplier certification as a cheap fix. It is any thing but that.[15] There are certain steps that are required if a program is to be successful. It requires a commitment from both the customer and the supplier. Both have specified responsibilities that are defined prior to implementation. The steps according to the Parental Drug Association (PDA) include: initiation, candidate selection, assessment, verification, certification and maintenance.[16]

B. Initiation

One of the key components to successful implementation of a vendor certification program is the establishment of an effective internal organization. Key members of this group may include

representatives from Purchasing, Quality Assurance, Engineering, and Manufacturing. Once the internal team is formed, the group effort must be directed towards seeking concurrence on objectives, definitions, and the approach that would be communicated to the suppliers.[17]

It is wise to have a detailed procedure for all team members to follow. Forms for control of the program should be created that will answer as many questions as possible. One of the first issues to be discussed should be a serious appraisal of quality costs since the certification program will be a general upgrading of the current supplier quality program. The program should have a significant payback, first in the customer's facility, later at the supplier's plant.[18] Although in some instances the savings are hard to quantify, one pharmaceutical company - Schering Corp. - reported savings over $1 million in four years.[19]

Continuous communication about policies, potential problems, and individual roles is vital to the success of the program. Many people will have to live with the program's decisions therefore they must be involved in the final vote. The first stage of consent may be strictly within the quality group. Ratification might then involve manufacturing, purchasing, material planning and control and R & D. Requesting wide participation in the certification has an additional benefit. This program is not foolproof-even the best supplier could occasionally stumble and fall. Having all people concur that the risks for any one supplier are appropriate at the time of certification could save a lot of "I told you so" later.[20]

C. Selection Of A Candidate (Feasibility Analysis)

The criteria for candidate selection may vary from firm to firm. These criteria support the objectives established by the certification team. The team decides, based on the results of data presented, which suppliers to pursue.[21] The selection should be based on the firm's historical performance in terms of quality and business.

1. Historical Performance - Quality

Supplier/Product certification provides a climate which emphasizes feed-foreword control. Its upstream quality orientation is aimed at preventing present or future deviations from goals rather than reporting deviations after the fact. Deming stresses that we are in a new economic age and that we can no longer accept defective materials and processes. He recommends assuring supplier product quality through the use of control charts. He encourages purchasing quality control along with the product, and he suggests finding cooperative vendors who are willing to provide evidence of required quality time and time again.[22]

Merrell Dow, for example, has been actively involved with a supplier certification program in the label printing area. The program has recently resulted in the certification of label printer Patton as sole-source supplier for the roll labels used on Merrell Dow's prescription and over-the-counter drug products. The firm's certification effort was motivated by the desire to: increase the supplier's responsibility for product quality through

self-inspection; improve the product through better knowledge and control of the supplier's process; and reduce duplicate testing through acceptance of receipts using the supplier's data.

According to Lou Pfeffer, Merrell Dow packaging engineer, Patton was an attractive candidate for certification because of the firm's familiarity with GMPs. An audit by Merrell Dow quality assurance personnel confirmed that Patton had established GMP procedures in such areas as documentation, traceability and separation of areas. In addition they had Standard Operating Procedures (SOPs) that were being followed. An important step in the certification process was a determination by Merrell Dow of the critical characteristics of incoming labels. Under the agreement, Patton performs 100% inspection of labels before shipment to Merrell Dow. Merrell Dow, in turn, accepts the labels using Patton's press sheets. They are compared against the approved copy and checked for correct item code.[23]

The Customer-Supplier Technical Committee of the American Society of Quality Control (ASQC) concurs with the approach taken by Merrell Dow. The committee agrees that the successful supplier will have a "new culture" management and be very aware of the future. It will be prepared to share the customer's goals, commitment and even risks to promote a long-term relationship. The criteria established to support this, based on historical performance include having: 1) virtually no product-related lot rejections for a significant period; 2) no non-product related rejections for a stated period of time; 3) no product-related negative incidents for a stated period of time; 4) successfully

passed a recent on-site quality system evaluation; 5) agreed upon specifications; 6) a fully documented process and quality system; 7) the ability to furnish timely copies of certificates of analysis, inspection data and test results; 8) correlation and validation of laboratory results for bulk material suppliers; and 9) demonstrated statistical process control.[24]

No matter how you view it, the proof is in the product; the supplier's track record must be considered. A good quality system produces consistently good lots. When a non-conformance happens, it must be analyzed as to severity, corrective action required, and the risk of recurrence. For instance, incoming inspections and tests determine conformance to specifications, but we all know that specifications cannot possible define every aspect of the product. Any problem, even one unknowingly created by the supplier, should be resolved or seriously considered when making a certification judgment.[25]

This is the impetus for Burroughs Wellcome's program. In 1986 they introduced a new, high-speed packaging line. In moving from a slower to a faster line, Burroughs Wellcome found that the need to stay within the tighter tolerances had increased significantly, and that the efficiencies were worse than before. The problem with the new line was found to be the quality of the incoming components. The problem could not be solved by increased sampling, given the limitations of standard sampling plans. A decision was made to have the supplier use the latest statistical process and quality control techniques to control and eliminate rejectable material.

The goal of the certification program was not to eliminate all component testing at Burroughs Wellcome. Instead, the goal was to certify those firms that had demonstrated the ability to produce consistently acceptable material, so that the incoming inspection activity could be concentrated on the firms most likely to produce material out of specification.

Quality Assurance official Albert Mason of Burroughs Wellcome cautions against sole reliance on statistical control techniques in determining a supplier's eligibility for certification. He maintains that certification requires a complete auditing program capable of addressing all defectives, including attributes, and reducing them. The systems, developed to expedite the certification process, involve the classification of suppliers based on evaluation of the supplier's capabilities, service performance, and quality history.[26]

2. Historical Performance - Business

A second part of the feasibility analysis, and one that is often overlooked, is an investigation of the firm's service performance. The particular areas should include: 1) on-time deliveries; 2) responsiveness to problems; 3) effective communication; 4) total cost and 5) financial stability.

There is widespread agreement that experience is the best teacher. Selecting suppliers is of such paramount importance that if buyers have unsatisfactory experiences they are not likely to send those suppliers a second order. The efficient buyer must be certain that suppliers meet the standards of performance and

quality for which his operations have been planned. In the certification process this becomes critical. Views differ however, on whether to select the problematic or problem-free vendors in the certification effort.

Deere & Company, for example, based its supplier selection on a quality/service profile, when available, and/or on the supplier's demonstrated capability in consistently producing products meeting or exceeding all requirements, specifications, and quality goals.[27] Dorsey, on the other hand, selects both type vendors for inclusion in the certification program-those who already have a good operation and routinely produce high-quality products and those with quality problems.[28] The rationale is that if they already have the controls in place to produce quality products, then certification becomes a formality. If however, they are concerned about quality problems and willing to work with Dorsey to improve, they are considered good certification candidates.

Schering/Plough staffer Joyce Dysart, chair of the PDA task force on vendor certification, notes that the Schering program has veered away from preoccupation with certification itself. She states:

> "as there are so few suppliers out there that are really to the point where they are fully certifiable, Schering has changed the emphasis of its program to supplier improvement. Instead of approaching vendors on the basis of acceptance or rejection for certification, Schering now emphasizes forming partnerships and working with vendors to get them up to speed. Certification is the goal you are aiming to get to and in so doing you improve the vendors process."[29]

The ASQC technical committee, on the other hand, suggests that

one consider partial certification. For example, consider a supplier that makes six different materials for you. Five are perfect, but the newest one is still in the development stage - meaning, "we still haven't gotten the bugs out." Perhaps the supplier has nine contracts, but only three have produced sufficient quantities to date with data available for correlation or capability studies. By all means, have a provision for partial certification. Half a loaf can be very satisfying when you are hungry for cost savings. It is important to monitor this part carefully. One of the points to check for is trends. If the trend line projects over the control limit, call the supplier and ask if it is aware of the danger.[30]

It must be noted that the certification process will be smoother if the selected supplier is one who views service as the ability, attitude, and willingness to meet delivery dates, conforms to specifications, and render technical assistance in a timely manner. In addition, the supplier who is in a sound financial condition is more likely to be able to maintain the flow of orders over a long period of time than one whose financial condition is questionable. In essence, this supplier would likely have the resources required to participate in a certification program.

D. Assessment Process

This section describes those items which must be considered to issue an effective assessment. The sequence may vary; however, all points must be satisfied in the completion of this process.

On site assessment of the supplier by a customer's representative is imperative. In addition, a supplier visit to the customer's facility will enhance understanding of the product needs.[31]

The PMA suggests that it is important to conduct joint supplier customer meetings to better understand the supplier's process and the customer's use of the product. This would include a visit by supplier operational personnel to the customer's plant to observe how the item is used, its relationship to other parts, and its overall effect on the production process. A visit by customer operational personnel to the supplier's plant is also necessary to provide an understanding of how the component is manufactured and tested. These joint meetings will allow for a greater understanding of the required quality control criteria and the supplier's capability to meet the criteria.[32]

1. Customer's Responsibilities

Assuring the reliability of the purchased components is a "team concept approach," the PDA guidelines states. This starts at the design phase and continues through the entire manufacturing process. Both supplier and customer contribute knowledge, technical expertise and wisdom to achieve desired results.[33] Each has specific responsibilities for making the program work. The customer's responsibilities include: 1) determination of key characteristics; 2) determination of quality requirements; 3) establishments of specifications; 4) communication of use; 5) facility and process assessment; 6) establishment of partnership; 7) assessment of regulatory commitments; 8) communication of

performance; and 9) assessment of the business plan.[34]

The first step after selecting the supplier is to meet with the supplier and assure that all requirements are clearly understood and agreed upon. This clarification is accomplished by careful mutual review of and agreement on dimensional and functional specifications as well as process control points, test procedures, established quality limits, inspection requirements, data retention and submittal, defective material procedures, warranty chargeback, future design changes and so forth.[35]

Polaroid for example, which undertook a vendor certification program to eliminate the problems caused by discrepant materials believes that this approach increases the probability of long-term success. At Polaroid vendor engineering personnel review the quality history of a particular part. This part is then classified into a category based upon this history. Next, vendor engineering, along with personnel from other departments, review all specifications, drawing, and the fit-for-use requirements to assure that these criteria are realistic. Inspection and test methods are reviewed, as well as the tooling and process descriptions of the vendor's manufacturing operation.

From this review, the critical quality characteristics are determined. A plan is developed to conduct process capability studies and established process controls at the vendors.

The next step is to review with the vendor the results of this research. At this point, plans are established about how to proceed. This is also the step where the tasks of mutual interest are decided. The critical characteristics for Polaroid

may not always be the same as those for the vendor.

The final steps involve carrying out the process capability studies, which may be conducted by the vendor, by Polaroid, or by both. The results are analyzed and reviewed jointly. The capability and fit-for-use requirements must now agree. If the process cannot meet the specification, either the process must be improved or the specification must be changed.

The particular part must be monitored for a specified time as it is manufactured under the process control system. Only after this monitoring has shown satisfactory results does the part become certified.[36] The success of the program depends on an atmosphere of trust and understanding between the customer and the vendor.

Although Polaroid is not a pharmaceutical company, its approach to certification is generic and is in agreement with the guidelines outlined by the PDA and the PMA. There is one area, however, that is peculiar to the pharmaceutical industry -assessment of regulatory commitments.

The customer must evaluate the impact of a certification program on its New Drug Applications (NDA) and Abbreviated New Drug Applications (ANDA). The customer must also determine how the program will be communicated to the FDA.[37] Although it does not specifically endorse certification, the FDA generally takes a positive view of the firms that are actively trying to improve their control systems.

One FDA compliance official has commented "if I had any advice to people, it would be you better be thinking hard about vendor

certification for those products that the FDA doesn't inspect."[38]

The relationship between drug manufacturers and vendors is of particular interest to the agency right now, the FDA official noted, because of its emphasis on improving label controls. FDA activities in the labeling area may, in turn, suggest the direction the agency's compliance efforts could take in other manufacturer/vendor relationships. The company which takes the time to think through a more effective, more efficient way to organize a quality function is not the one the FDA worries about. The real concerns of the agency are those firms that do not make quality control a top priority and are making basic mistakes as a result. These are the firms that set up a quality control department because the GMP's require it and consider that their job is done.[39]

The West Company's pharmaceutical seal manufacturing plant, which is directly regulated by the FDA, for example, is experiencing some situations common throughout industry. A West staffer stated that "never before has the quality field been in the limelight as it is now. Never have so many corporate resources been available, nor has there ever been so much confusion about which way to go. Our experience with supplier certification leaves no doubt that this will be part of the quality program of the 1990's."[40]

A look at one of their processes will illustrate this point. The Clearwater plant makes about two billion pharmaceutical seals (closures, lids, or caps) per year. Three primary materials are used to make them: aluminum sheeting, plastic flip-off buttons,

and rubber sheeting. Each material is currently handled differently, and they represent the present, the near future, and the long term-term goal.[41]

The plastic flip-off buttons represent the present. They are sampled by the manufacturer before shipment to ensure they meet MIL-STD-105D AQLs, Level II, normal plan, single sample.

The receipt of aluminum represents a transitional step to the future. This material is accepted with a "certificate of analysis," available on each lot from the suppliers. Identity and chemical tests for functionality of a lacquer on the metal are performed via MIL-STD-105D, Level S-I.

The third material, rubber is accompanied by a "certificate of compliance," as most material will have to be in the 1990's. The difference between a "certificate of analysis" and a "certificate of compliance" is that the former contains test data from the actual batch in question, while compliance means that the lot is certified to comply with all agreed-upon specifications. To achieve the confidence required to accept a certificate of compliance, West went through a logical progression that took several years. The product went from MIL-STD-105D normal to reduced plan. It then was taken to skip-lot sampling - from one in two to one in eight lots. As they decreased sampling they worked with the vendor to match test methods, procedures, and specifications.[42]

West Quality Assurance manager Ed Nelson notes that his company has taken an aggressive approach toward certification by drug manufacturers. Nelson describes West as "pro-active" in

helping drug manufacturers to determine what is needed to achieve certification and is setting up a workable program. West currently has more than a dozen certification agreements in place involving metal seals, rubber stoppers and glass vials. According to Nelson, experience in certification and the willingness to work with drug manufacturers in developing their programs gives West a competitive edge.[43]

2. Supplier's Responsibilities

In addition to the customer's responsibilities there are certain requirements for which the supplier is responsible. Since certification is a cooperative program, the first requirement is an agreement by the supplier to participate in the vendor certification program.

The success of the program requires the corporate commitment of the nominated supplier. Agreement must be secured from those persons in the supplier's organization who have the authority and responsibility for sales, manufacturing, product engineering and design, and quality control/assurance. As part of the agreement, selection of both product and manufacturing site to be certified is essential.[44]

Other responsibilities include: 1) confirmable process capability; 2) the ability to provide documentation to the customer; 3) a demonstration of financial stability; 4) demonstrated technical capability; 5) documented change control procedures; 6) price structure; and 7) control of purchased material.

Kathrina Fahlin, Dorsey Lab's supervisor of in-process control, says "we try to work with vendors who already seem to have a good operation going and who are routinely turning out high-quality packaging. If they already perform the various quality control checks, certification can be just a formalizing of what they're already doing. Or we'll choose a firm that we're really having quality problems with." If they're concerned about the problem and willing to work with Dorsey to improve, they're a good candidate for certification.[45]

Dorsey conducts vendor audits consisting of one or more visits from Dorsey purchasing and process control personnel to verify that the agreed upon procedures are being implemented and documented. Each of the plants supplying Dorsey receives an audit, and additional visits may be scheduled if major machinery changes are made. Dorsey's policy regarding the certification process, procedure for implementation, and complete directions for vendor process control are in formal written form. Each vendor has complete directions for complying with Dorsey's program, from correct machine settings to filling out the proper inspection records.

"Although the packaging vendor certification process is rigorous and the follow-up requires substantial paperwork, more and more vendors are actively seeking certification from pharmaceutical packagers," says Dorsey. For suppliers who can meet the stringent requirements of pharmaceutical packaging quality, the benefits are many. Vendors generally emerge with a better understanding of their own processes, assurance of

continued high-volume business from the drug packager as long as quality levels remain high, and a major selling point when soliciting orders from other pharmaceutical firms.[46]

3. Combined Responsibilities Customer/Vendor

A key ingredient of any Certification Program the industry guidelines state, is better cooperation with suppliers in the quality control effort. According to the PMA guide, the basic premise is that when the customer and supplier work together to establish the proper product design characteristics, specifications and test criteria, and process controls, the results will be a product that is consistently fit for use and free of defects. In general, the supplier must play an equal role with the purchaser in the certification effort.

In order to ensure compliance with CGMPs the association guidelines emphasize the importance in the certification process of defining and agreeing upon the documentation required to produce and evaluate the product. It recommends that the supplier provide to the purchaser a lot-specific certificate of process compliance stating that the product was manufactured in accordance with approved procedures, using approved materials, and meets all approved process control criteria and specifications. It is the customer's responsibility to define the exact documentation and/or test criteria required.[47]

The ASQC technical committee recommends that these joint responsibilities are spelled out at a commitment meeting. Here you gather all the representatives of all concerned departments from

both organizations. Purchasing, design engineering, and QA are the minimum from the customer side. Others might be materials management, production, and equipment specialists. Representing the suppliers would be management, QA, sales/service, and perhaps the production manager.

This meeting should open with a historical view of the supplier's performance-quality, delivery and cost records. A review of the goals, expectations, and requirements from both the company and the supplier should be discussed and agreed to. The meeting should end with an agreed upon time to begin the verification process.[48]

E. Verification Period

Over a reasonable period of time that includes several different lots of material from the supplier, the two firms review and compare Statistical Process Control (SPC) and/or test data and service performance. If discrepancies in material services or data arise, an evaluation of the data in question should be initiated. When a suitable number of lots of material have been successfully reviewed and the material used successfully then the supplier is considered certified.[49]

1. Handling Discrepancies and Evaluation

When discrepancies arise or if in process material failure occurs, the purchaser should advise the supplier using the previously established communication system (see D.1). When the discrepancy or failure occurs, the certification process proceeds

along one of the following three paths: 1) the supplier certification process continues because the impact of the problem is minor, 2) the supplier certification process is interrupted while both firms review the problem to determine where corrective actions(s) should occur, or 3) the certification process is stopped due to the results of the review, findings serious discrepancies that cannot be resolved.[50]

2. Certification Ceremony

At the completion of a successful verification period, certification is confirmed. The certification of a supplier is a major accomplishment. Wall plaques or certificates are awarded to the supplier in recognition of this accomplishment. Appropriate management representatives are present during the certification ceremony.[51] The reason for this ceremony is three-fold: 1) it allows both parties to recognize their mutual achievement; 2) it shows top management that the objectives were accomplished; and 3) it gives impetus for continued success.

F. Decertification

Certification is manufacturing site, production process, product material requirements and end use specific. It demands a joint commitment to the quality concepts supporting the program. A change in any one or more of these parameters requires a reevaluation of the supplier's certification status. The extent of the change is the determining factor for the minimum requalification necessary to reestablish certification.[52]

1. Suspension

Immediately upon establishing that a change in any one of the specifics has or may have occurred, the purchaser suspends the supplier's certification. Incoming inspection and testing are instituted. The supplier is advised of the suspension. Requalification of the supplier sufficient to meet the original qualification is required.[53]

2. Requalification

During any period of requalification, the purchaser may continue to do business with the supplier, relying on traditional incoming testing and inspection. The methods originally followed by the purchaser in awarding certified supplier status are applied again in recertification. Failure of the supplier to meet the requirements for recertification is cause for decertification.[54]

3. Voluntary Termination

Either purchaser or supplier may elect to discontinue certification with or without cause. Upon decertification or discontinuance of the certification program, purchaser and supplier may continue to transact business under a basis relying on some form of traditional incoming testing or inspection. In summary, ending certified supplier status does not automatically end the business relationship between purchaser and supplier.[55]

G. Maintenance

After the certification of a supplier is established it is

still necessary to monitor quality programs and product quality. There must be a program to assure ongoing compliance and continual improvement of mutual objectives. The monitoring program can be conducted using any one or a combination of the following:

- **Data correlation** - periodically test a shipment(s) of material and compare results to supplier's data.

- **Periodic Visit** - Visit the supplier on a scheduled basis for an assessment of the certified systems and to identify improvement opportunities.

- **Confirmation of Product Performance** - The certification committee makes internal inquiries as to the supplier's performance to all departments involved with the supplier: Manufacturing, Quality Assurance, Purchasing, Accounting, Engineering, R&D, etc. Questions should also be directed externally to field performance.[56]

H. Conclusion

As stated at the beginning of this Chapter, the road to vendor certification is long and sometimes rocky. Yet those companies willing to take the risks have reaped rewards.

West, for example, documented savings for the quality department of 40 labor hours per week. This has significant impact in a department with five hourly workers. No jobs were lost; workers were able to spend more time auditing the process.[57]

At Polaroid approximately 35% of the target parts from 40% of

the vendors selected for the program have been certified to date. Their goal was to have the program completely in place by mid 1980 and they were on schedule.[58]

Similarly, Dorsey Laboratories reported savings of $12,000 per year in inspection costs alone. Schering's savings since 1984 have totalled more than $1 million. Both firms stress, however, that the program's greatest benefits are in better efficiency, faster line speeds and fewer rejects.[59]

Burroughs Wellcome has thus far targeted about sixteen packaging suppliers as certification candidates, six of which have already been audited. The firm is very close to completing certification in at least two cases.[60]

These firms and others have laid the foundation. Other firms with similar characteristics can build on this foundation.

Chapter III

Survey Results

III. Survey Results

A. Background of the Survey

In the search of the literature, the author was able to find only a few pharmaceutical companies who have implemented or are in the process of implementing vendor certification programs. Only one of those companies was in New Jersey the area where survey information was gathered.

A three page questionnaire was sent to eighteen pharmaceutical companies in New Jersey. Ten of the questionnaires were addressed to a specific Quality Control or Quality Assurance Manager. Eight were addressed to the Purchasing Manager with no specific name. Out of the 18 mailings, eleven were returned for a response rate of 62%. This response rate is considered mediocre for purposes of analysis, but better than average for mail questionnaires. It should be noted that eight of the ten addressed to specific individuals were returned, whereas only three of the eight addressed to the department were returned. This would suggest that people tend to respond when addressed personally.

The survey was organized in four sections, each with a different focus:

Section I: General Data, describes the respective vendor certification programs and summarizes the administrative aspects of the certification process.

Section II: Implementation, summarizes the implementation process: vendor selection, training, documentation and the length of time required to implement.

Section III: Results, summarizes the success of the program.

Section IV: Company Profile, identifies the companies by size and number of sites.

B. Survey Results

Of the eleven returns, six have fully implemented vendor certification programs, two are in the infancy stage of implementation, meaning that the implementation team has been formed and they either have or are in the process of developing objectives. Three do not and have no immediate plans to implement the program.

Although the two respondents who are in the beginning stages of implementation did not complete the questionnaire, they did provide information which was useful to the study. For instance, one respondent indicated that during internal evaluation it was found that there were areas in their operation that required major improvements if the certification program were to be successful. Their focus was on improving quality, reducing lead times and reducing costs. To meet these objectives required 1) reducing the existing vendor base which was far too large; and 2) improving the scheduling and forecasting areas.

The other respondent indicated that the certification team was not full time, that in addition to the certification process function, they performed their normal daily functions. At this rate it was expected that it would require at least a

year to certify their first vendor. This company has decided to select a supplier who is already involved with vendor certification for two reasons: 1) the company's certification team would be able to use the expertise of the supplier to learn the certification process, and 2) it would shorten the time required to certify a supplier and in doing so would provide results which could be used as a performance metric for other suppliers.

Both of these companies are following the recommendations of the PDA (Chapter II) and are taking the precautions described in the literature. Certification procedures can be carried out by a drug manufacturer on its own internal operations. The real test of a company's readiness to embark upon a vendor certification program is identifying the ability of its own operations to conform to the established criteria. Following are the responses of the other companies who completed the questionnaire.

1. General Data

With respect to the administrative part of the questionnaire, 33% of the programs were initiated by a joint team made up of representatives from Quality Assurance, Quality Control and Purchasing; 50% were initiated by Quality Assurance and 17% by a joint team from Quality Control, Purchasing, and Materials Management. Similar results were noted in response to a question regarding the departments involved in the certification process.

All of the respondents (100%) include the Quality Control, Quality Assurance and Purchasing departments. In addition to these departments, other departments include Materials Management (50%), Regulatory (50%), Production (33%), Engineering and Statistics (17%). Statistics was a write-in response under "other". Apparently, some companies have separate statistics departments. However, this does not seem to be the norm. These responses are similar to the recommendations stated in the literature - that is, the team approach is the right approach.

In the survey, respondents were asked to rank the reasons for implementation. The most important reason was given a 1 and the least important a 5. Table 1, entitled "Reasons For Implementation: Priority Ranking" shows the overall response.

TABLE I: REASONS FOR IMPLEMENTING: PRIORITY RANKING

REASON		RANKING 1	2	3	4	5
Improve Quality	RESPONDENTS	3	1	-	-	2
Reduce In-House Leadtime		1	2	1	1	-
Reduce Inspection Costs		1	2	-	2	-
Reduce Inventory		1	-	3	-	-
Improve Vendor Leadtime		1	1	-	1	1

The numbers across the top of the chart (1, 2, 3, 4, 5) represent the ranking of the reasons given. A dash (-), represents no ranking assigned for the particular reason.

This table indicates that quality improvement was the most important reason for a majority of the respondents. Three companies said quality improvement was their most important reason for implementing the program. One company said that this was the second most important reason, and two said it was the least important. One company listed both quality improvement and reduced inspection costs as most important. The other reasons - reduce in-house lead time, reduce inspection costs, reduce inventory and improve vendor lead time - were each most important to one respondent. It should be noted that not all respondents ranked all five reasons.

There were several questions concerning inventory relative to the number of parts and the types of inventory included in the program. In response to the question on how many parts were in inventory, the responses were:

Raw material:

less than 500 parts	33%
501 - 1000 parts	33%
1001 - 2000 parts	17%
more than 2000 parts	17%

Primary components (those in direct contact with product)

less than 500 parts	67%
501 - 1000 parts	17%
more than 2000 parts	17%

Secondary components

less than 500 parts	50%

501 - 1000 parts	17%
1001 - 2000 parts	17%
more than 2000 parts	17%

If we were to categorize the companies based on inventory size, 17% would be considered small with less than 500 parts in each inventory category; 17% would be considered large with more than 2000 parts in each category and 66% would fall somewhere in between since the number of parts in each category ranged from less than 500 to more than 2000 parts.

All three inventory types are included in the vendor certification programs. Table II shows the distribution of particular types of inventory parts in the program.

TABLE II: WHAT TYPES OF MATERIALS ARE IN YOUR VENDOR CERTIFICATION PROGRAM? CHECK ALL THAT APPLY

	ITEM	PERCENT
Raw Materials	Active Ingredients	33
	Excipients	67
Primary Components	Bottles/Vials	83
	Stoppers	50
	Caps	50
	Films/Foils	67
Secondary Components	Folded Cartons (printed)	33
	Folded Cartons (unprinted)	67
	Roll Labels	33
	Cut Labels	17
	Cut Labels	33

From the chart you can see that 83% of the respondents have glass bottles/vials in the program. This was the largest single group in the program. The next largest groups were excipients, films/foils, and unprinted cartons. Active ingredients and secondary components were included in only 33% of the programs. Cut labels were included in only 17% of the programs. This is understandable since there have been numerous FDA recalls resulting from label mix-up with cut labels.

On the question of how many vendors and items are involved in program categories, two of the respondents (33%)

indicated that the question was unclear. Consequently, they did not respond to it. Table III summarizes the results of the others.

TABLE III: HOW MANY VENDORS AND ITEMS ARE INVOLVED IN YOUR PROGRAM FOR EACH CATEGORY?

CATEGORY	NUMBER OF VENDORS	NUMBER OF ITEMS
RAW MATERIALS	5	8
PRIMARY COMPONENTS	11	213
SECONDARY COMPONENTS	6	318

To summarize, 17% of the respondents have only excipients (3 items, 2 vendors) in the program, 17% have primary components (200 items, 5 vendors), active ingredients (5 items, 3 vendors), and secondary components (200 items, 5 vendors). Seventeen percent have only primary components (11 items, 5 vendors), and secondary components (118 items, 1 vendor) in the program. Seventeen percent have only primary components (2 items, 1 vendor) in the program. All (100%) of the respondents began the program with existing vendors.

From the literature search it is evident that vendor certification in the pharmaceutical industry is fairly recent. The survey confirmed this. All of the programs were less than three years old. Sixty-six percent of the programs have been in effect for two years, 17% for two and a half years and 17% for one year.

2. Vendor Selection and Training

The process of selection of a vendor may vary according to the focus of the individual company's program. This section of the survey attempted to summarize this process.

"What factors were involved in your selection of the initial vendor?" was one of the questions asked. The respondents were asked to check all that applied. The responses were:

Good performance	100%
Large volume supplier	66%
Vendor initiated	17%
Statistical Process Control (SPC) Program	17%

All of the surveyed companies selected vendors who had performed well. This was anticipated given the number of items certified (section 2.1) in the short time that programs have been in effect. Surprisingly, 17% responded that the vendor initiated the action. This is very positive for the company in that the cooperative commitment is from the vendor. The SPC program was not on the questionnaire but was given as a write-in for "other". This response correlated with the answers in Table I where improved quality and reduced inspection costs were primary reasons for implementing the program. SPC is one method used in quality improvement programs.

The answers concerning the materials involved in the initial implementation were also as expected. Sixty-seven

percent began the program with primary packaging components and 33% with raw materials. These are the categories that fall under FDA regulations.

Several questions were asked relative to vendor training. One question asked for the type of training developed with the vendor. The respondents were asked to check all types applicable. Sixty-seven percent of the respondents did not develop any training programs. Thirty three percent developed training programs in these areas:

Statistical Process Control	33%
Good Manufacturing Practices	33%
Testing	33%
Measurement	17%
Process	17%
Housekeeping	17%

Again, the results are as expected for the pharmaceutical industry, for during the verification period of the certification program SPC and test data are reviewed and compared in order to determine if the program should continue. (See Section E, Chapter II).

Although 33% of the respondents developed programs with the vendors, none of the respondents actually provided training for their vendors. All (100%) did however, bring the vendor's operating personnel into the company to see the process and the end use of the product. The PDA guidelines suggest that this is an important step in that it ensures that

personnel understand why the characteristics must be controlled.

In addition to establishing training guidelines with the vendors, the PDA guidelines suggest that the vendor be included in component design and specifications. Eighty-three percent of survey respondents included vendor input, 17% did not. This is the 17% that has only excipients certified at this point. The questionnaire did not ask for explanations for negative answers therefore we do not know why this group did not include vendor input. It is likely that since excipients are inactive ingredients with standardized formulation for purity and strength and are available as stock items complete with certificates of analysis and/or certificates of compliance, customer input is not necessary.

Since documentation is required for regulatory compliance, the respondents were asked what type of data is supplied with each lot. Fifty percent received a certification letter and test data. Eighty-three percent received only a certification letter. The total is greater than 100% because 33% of the respondents use either/or depending upon the item.

Finally, the managers were asked how long it took to implement their program. The answers ranged from nine months to two years. Thirty-three percent said it took nine months - 17% of these said it is still in process, 17% said two years, 17% said one and a half years, and 33% said one year. Table IV summarizes the vendor certification programs in our survey.

TABLE IV: SUMMARY OF THE VENDOR CERTIFICATION PROGRAMS SURVEYED

Age of Program (Months)	Number of Vendors Certified	Number of Items Certified	Implementation Time (in months)	Category of Material in Implementation
30	2	3	24	Raw Materials
24	13	405	12	Raw Materials
24	6	129	18	Primary Components
24	1	2	9	Primary Components
24*	-	-	9	Primary Components
12*	-	-	12	Primary Components

*These respondents did not answer the question concerning number of vendors per item category.

As you can see they are as varied as the reasons for implementing the program. It shows that there is no one way to do it but that it can be done.

3. Results

The managers were asked to rate the success of the programs, to indicate if there were procedures to deal with defective material and if there were written agreements detailing notification of process changes. On the question rating the program's success, the responses were:

medium	66%
low	17%
high	17%

These responses correlate to the answers to the question on reducing or eliminating incoming inspection for the affected items as a result of the program. Fifty percent saw a 0-25% reduction, 17% a 76-100% reduction in inspection. Needless to say, this 17% rated the program as highly successful.

All (100%) of the respondents have a procedure to deal with material received under the certification program that is found to be defective. Similarly, all have an agreement with the vendor on notification of process changes. Sixty-seven percent include this agreement as part of the specification and 33% have a written contract covering notification of a process change.

4. Company Profile

Different size companies were represented in the survey. Half (50%) had between 500 and 999 employees, 33% had more than 2000 employees, and 17% had 1000-2000 employees. In 33% of the responses the data submitted were based on single sites; in the remaining 67% data came from multiple sites where purchasing was handled at the central level.

C. Summary

Despite the problems with collecting data, the survey suggests some important relationships. The failure of 34% of the respondents to answer the question relating to the percentage of vendors and number and types of items in the

program leaves a gap in the overall interpretation of the programs' success. On the other hand, there was enough data to relate to positions of the pharmaceutical companies discussed in chapter two.

For instance, a comparison of the characteristics of a company with a highly successful program versus one with medium success (Table V) indicates that neither the size of the company nor the number of parts in inventory had any real influence on the success of the program. There is, however, an indication that by starting a program with an existing vendor with a history of good performance some degree of success will be noted within two years. The same holds true for involving the vendor in the development of training programs.

There appears to be a relationship between the rate of success and participation by all operating departments within the company. The most successful respondents included purchasing, production, engineering, quality control/quality assurance, materials management, regulatory and statistics departments in the certification program. There also appears to be a relationship between the type of material and the success of the program. Ninety-nine percent of the items certified were packaging components and sixty-one percent of the vendors certified were suppliers of packaging components (see Table III). This is not unexpected since they are not easily affected by changes in temperature and humidity during transit.

TABLE V: PROFILE: MEDIUM VS. HIGH SUCCESS COMPANY

Characteristics		Success Rating Medium	High
Percent Reduction in Inspection		0-25	76-100
Number of Employees	R	500->2000	1000-2000
Number of parts in inventory	E	1000->2000	>2000
Average Number of Months to Implement	S	15	18
Number of Months in Program	P	24	24
Main Criteria for Vendor Selection	O N	Performance	Performance
Existing Vendor	D	Yes	Yes
Type(s) of Material in Program	E N	Packaging Components Raw Materials	Packaging Components
Training Developed with Vendor	T	Yes	Yes
Number of Departments Involved	S	3	7

Based on these findings one can conclude that with total management involvement and the right selection of both vendor and materials, it is possible for a mid-sized pharmaceutical company to successfully implement a vendor certification program. The next chapter will compare the companies in our survey to Company X and the literature.

CHAPTER IV

CASE STUDY

IV. Case Study

A. Introduction

In Chapter II we outlined the important steps which were required in order to implement a vendor certification program and how industry leaders have successfully implemented programs. Chapter III brought the concept closer through a profile look at pharmaceutical companies within the State of New Jersey who have or are in the process of implementation with varying degrees of success. In both instances, the focus was quality improvement. Likewise in both instances, the message was clear: a quality improvement program of this magnitude is not a one man job. It requires team involvement.

Some of the most highly respected leaders in the field of quality assurance support this concept and have strongly advocated that any real positive improvement must start "at the top" to be effective. Crosby, for instance, has stated that only top management can institute the corporate cultural changes necessary to implement such positive improvements.[61]

This chapter will evaluate the current operations and prioritize the actions required for Company X to implement a vendor certification program. This in-depth look at one company may be useful to other companies as well. The analysis and recommendations will draw upon the procedures and data obtained in the search of the literature and the survey. Supporting data will include the results of the supplier survey.

B. Background of Company X

Company X is a medium size pharmaceutical company located in Northern New Jersey. It manufactures prescription parenterals and oral products which are used in hospital settings. The Company markets approximately seventy different products. Approximately 500 parts are used in the manufacture of these products. These parts include raw materials (both active ingredients and excipients), primary components (bottles, caps, stoppers) and secondary components (trays, labels, cartons - printed and unprinted, inserts, etc.).

Approximately 65% of the raw material actives are purchased from overseas. Excipients are purchased from distributors and/or major manufacturers. Components are purchased from approximately fourteen different suppliers. Stated lead times (from the time the order is received in purchasing until it arrives on the dock) range from ten days to six months. In-house lead times range from ten to thirty days.

The Company is in the final stages of transferring from a manual to a computerized Materials Requirement Planning (MRP) system. The modules currently used include the Bill of Materials, Inventory Control, Tracker (for lot traceability), Purchasing and Master Scheduling. The Shop Floor Control module is only used for labor reporting. Capacity planning is done manually.

The Company has a reputation for providing quality products to its customers. However, like any other successful

company, in many cases this was achieved only after extensive testing, inspection and correction of material deficiencies after receiving. A concentrated effort is needed to formulate a more comprehensive quality program with emphasis on prevention rather than detection of errors if it is to maintain its competitive advantage in the marketplace.

C. Analysis of Current Operation

The previous sections of this study illustrated the multifaceted nature of vendor certification. In this analysis, all of the functional areas - management, purchasing, planning and inventory control, quality control, quality assurance, and engineering will be reviewed.

As previously indicated one of the keys to success is program administration and management support. This requires a participative team approach with clear goals and objectives for each member group of the team. In addition it requires a consensus that quality management is not the sole responsibility of the quality control/assurance department. Company X generally operates in an autocratic fashion. However, there is informal collaboration. The structure of the organization is such that department managers report to directors who in turn report to the president (see organization chart: Appendix C). Reporting to department managers are supervisors or other staff personnel. The functional responsibilities are such that all of the managers' time is consumed in day-to-day operations. In conversations

with these managers, they have indicated that there is no time left to administer a vendor certification program. A similar response was heard from one of the companies in the survey. For that company, the approach was to begin slowly with a realization that the process might take longer.

All of the successful companies agreed that it is the total commitment from upper management that ensures that resources are allocated and that policies are in place to support such a program. Like any other project, it must be included in the strategic planning of the company.

1. The Team Approach

Both the PDA and the PMA stress the need for the establishment of a team that represents all disciplines involved in the certification program. All of the benchmark companies and all of the survey respondents used this approach in their implementation process. This was one of the major differences between the highly successful companies and those noting medium success in the survey. The teams were responsible for assuring that the internal operations were ready for the program in addition to performing the assessment and training required of the supplier. Company X already has in place many of the recommended tools required.

Quality Assurance has in place a document control system which tracks review dates for all standard operating procedures. This assures that procedures are reviewed and updated periodically. Another part of the same system is used

to maintain and update the listing of current specifications flagging those pending revision. In addition, there is an internal and external audit procedure. All primary and secondary component suppliers, contract packagers, and selected raw material suppliers are audited every two years for GMP compliance. To adapt the current procedures to meet the requirements for vendor certification would entail, 1) expanding the audit to include process capability, in-process control, and quality control test procedures, and 2) more in-depth auditing of the vendors' training procedures. Consequently, additional personnel would be required to support the audit function.

Although only 17% of the responding companies included engineering as part of their implementation team, it was included in all of the benchmark companies. Its function on the team is to ensure that product design and specifications are consistent with requirements. This function is the responsibility of the packaging engineer with input from the related functional departments. There are well designed specifications for all components and standard operating procedures detailing how changes are handled. In some instances the suppliers will provide suggestions/ recommendations relative to their ability to meet the specifications. This is a very positive element in a vendor certification program. For example, all of the benchmark and 83% of the surveyed companies required supplier input in component design and/or specifications. In addition to

providing specifications the supplier must know how the item is used and how key characteristics will affect the safety, purity, and effectiveness of the product.[62] This area would require more attention up front rather than when problems arise in a certification program. Unlike the surveyed companies, Company X does receive input from a small percentage of the suppliers of raw materials.

Quality Control's position on the team is perhaps the most visible of all the team members, due in part, to the fact that they are the ones who must bear the bad news of non-conforming parts. In addition, it is this group that is responsible for testing incoming materials for fitness for use or for stopping production if non-conforming parts are discovered during processing.

At Company X, there are detailed specifications and standard operating procedures covering the receipt and testing of all incoming materials. There are also procedures for dealing with non-conforming parts. In addition there is a Materials Evaluation Review Committee, chaired by the manager of quality control, to address specification changes, material deviations and new product requirements. The members of the committee include all of the functional areas which would be involved in a vendor certification program.

As the overseer of incoming and in-process quality, and direct cost savings from a vendor certification program would most likely be seen here. There is some type of testing/ inspection on all incoming material. Any reduction in these

areas would reduce the personnel requirement in this area, personnel which could be used in other areas to support the vendor certification program. As one of the benchmark companies found, a labor reduction of 40 person hours in inspection was used in the audit function. This reduction is supported by the data from the surveyed companies where 67% saw some reduction in incoming inspection. One company, after two years in the program, had a reduction of 76-100% for the affected parts.

The last functional group required on the team is purchasing/materials management. All of the surveyed companies included purchasing as part of the vendor certification team and 50% included materials management. The literature provides an explanation for this inclusion.

> The vendor performance analysis report may mislead a company into believing some of its vendors are not in compliance with its quality and delivery performance standards. Before the company can substantiate that the vendor is the culprit, it must take care to ensure that the company supplier non-support environment is not making it impossible for the vendor to successfully perform.[63]

Company X's purchasing is a part of the materials management group. It has a computerized MRP system including purchasing. The master production schedule is fed from a twelve month marketing rolling forecast which is updated monthly. Because of the nature of the business however, changes in the master production schedule may occur more frequently. In addition, since completed manufacturing work

orders are batch processed instead of on line while inspection and final assembly work orders are processed more frequently, inventory accuracy becomes questionable and expediting begins. Another critical area which must be addressed in a respect for lead times. Even though lead times are set for both supplier and in-house inspection and testing, approximately 50% of all parts are either expedited through the supplier's processes or in-house quality control inspection. The result is a rippling effect throughout the procurement, quality control production cycle. For every expedited item something must be delayed. Usually the delayed item is just as critical as the one expedited with the next schedule change. Expediting becomes "King of the Hill". Quality is compromised in favor of getting the product out on time.

One of the respondents indicated that it was necessary to reduce the vendor base before beginning a vendor certification program. This concurs with the literature findings. For Company X, this would not present a problem. Most raw materials are currently single sourced with a concerted effort being made to select backup sources. Glass vials and ampuls are also single sourced. All labelled components and most secondary components have a primary and a secondary supplier. The suppliers are generally long-term (have serviced the company for a number of years). The relationships between the functional departments and the suppliers are generally mutual respect and cooperative. However, like most companies, when problems arise, the adversarial approach sometimes prevails.

If a vendor certification program is going to work, there must be a good relationship between the company's certification team and the supplier, and problems, when they arise will have to be worked out with the supplier as a team member instead of as an adversary.

D. Supplier Survey

The feasibility study of a vendor certification program would not be complete without a determination as to whether there were suppliers willing to participate in such a program. In order to obtain data to support this study a two-page questionnaire was sent to eighteen suppliers who service the pharmaceutical companies within New Jersey. The selection was taken from the list of primary and secondary component suppliers for Company X. There were ten questions aimed at gathering information relative to their participation in a certification program. All of the questionnaires were sent to the area representative for each firm with instructions to forward it to the individual within the company who could best complete the questionnaire.

Out of the eighteen mailings, twelve were returned for a response rate of 67%. This response rate is considered mediocre for purposes of analysis, however, it is considered better than average for mail questionnaires.

1. Survey Results

Of the twelve respondents, ten are currently participating in a vendor certification program, two are not. Nine out of ten are involved in programs with other pharmaceutical companies. This means that these nine suppliers are familiar with the requirements for a regulated industry - a plus for a company like Company X.

Like the companies surveyed, all of the suppliers said that quality control/quality assurance (QC/QA) were involved in their vendor certification programs. In addition to QC/QA, 70% also included purchasing; 70% included production, 40% included materials management; and 20% included engineering. Two write-in departments, sales 20%, and packaging development, 10%, were included. It is obvious that the suppliers are following the recommendations of the PDA and PMA guidelines by including members from support groups in the administration of the program.

Similarly, when asked if the company provides input in developing component design and specification for the customer, all of the respondents replied "yes". This is important in that it ensures that the process is capable of producing components which will meet specifications.

Two questions concerning training for the customers were asked. In response to the question of providing training for their customers, 90% of the respondents did provide training. A question on training types received responses which would be

expected for a quality improvement program. The types of training and the frequency of the responses are:

Process	100%
Measurement	100%
Statistical Process Control	80%
Testing	60%
GMP	40%
Housekeeping	30%

In order to ensure compliance with CGMPs the PMA emphasizes better cooperation with suppliers in the quality control effort. In order to meet this requirement the procedures and equipment to be used for measuring and testing should be thoroughly evaluated by both the customer and the supplier to assure they are suitable for their intended use. These evaluations should cover test method validation studies with emphasis on accuracy and reproducibility.

Similarly, the supplier must be able to demonstrate that a process is under control and consistently produce products that meet customer specifications. The customer on the other hand must know the limitations of the process in order to determine if the specifications can be met. To accomplish this, SPC methods should be employed to measure and control variation in the process, determine process capability, and improve quality performance.

According to the literature, vendor selection is one of the customer responsibilities and the selection process may vary from one company to another. Based on this one might

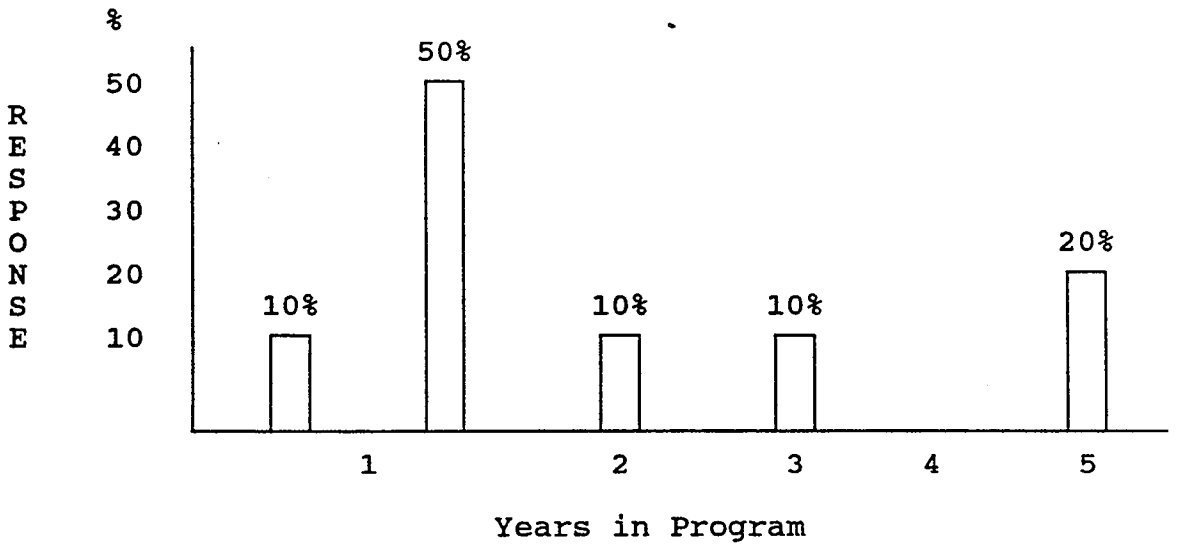
assume that it is the customer who initiates the vendor contact for participation in a program. To test this assumption we asked what factors were involved in initial participation in the program. The respondents were asked to check all that applied. The responses were:

Customer initiated	90%
Large volume customer	30%
Improved scheduling	10%
Supplier initiated	10%

This confirms the assumption above. It is also interesting that both the respondents from the companies and the suppliers indicated that the volume of business was an important consideration for inclusion in the program. One reason for this might be that in-house inspection and testing is directly proportional to quantity. The larger the certified volume, the less in-house inspection and associated costs. Consequently, the success would be more visible.

In order to determine experience in a vendor certification program, the suppliers were asked how long they had been involved in such programs. A summary of the responses are given in Chart I.

CHART I: SUMMARY - YEARS IN PROGRAM



Fifty percent of the suppliers have been involved from 1-2 years; 20% for 5 years; 10% for 3 years; 10% for 2 years; and 10% for less than a year.

Just as the amount of time in a program varies so does the success of the programs. Forty percent of the suppliers rate the program as highly successful. Another 40% consider the program as medium, 10% low and 10% indicated that it was too early to tell. Eleven out of the twelve respondents would be interested in participating in a program with a company similar to Company X.

Should Company X decide to implement a vendor certification program, there are vendors available who have both experience and proven success and are interested in participating in a program with the company.

E. Conclusions

Implementing a prevention-oriented quality program is a strategic business activity which cannot be expected to provide immediate improvement in defect rates or quality costs. By using the techniques and procedures of the companies in the survey and of the industry leaders as a measure of performance in implementing a vendor certification program, it is possible to expedite the actions needed to get the program started even while waiting for the tangible results. Patience and fortitude are required even then since the implementation process can take from nine months to over two years based on our survey.

While the PDA and PMA guidelines should help the company organize for action, it is extremely important to recognize the need to have in place all the pieces to support the program. The size of the company has no effect on the success of the program provided that the internal organization is strong and the guidelines are followed.

Management commitment and support are required to build a structure within the organization that will not only support team efforts, but will create a total quality organization. Top management must understand the need for improvement and must take an active role in its achievement.

Further, a superior quality program within the customer's plant is critical to success, for without that internal condition, constant quality problems will lead to disruption of schedules, and the need for emergency replacements. All

the internal systems; production and inventory control, quality control, engineering change, purchasing, and production must be consistent with the vendor certification philosophy or needless delays, excessive expediting, excess inventory and volatile schedules will result.

The literature indicates that implementing vendor certification produces substantial benefits representing drastic economic improvements for companies that had formerly used traditional quality/purchasing practices. In terms of tangible benefits from vendor certification, the survey confirms that the greatest degree of improvement appears in product quality, reducing the need for in-house inspection. It is also apparent from the survey that a company should begin with an existing supplier with good performance. In addition, it seems that the implementation process is faster when dealing with primary and secondary components rather than raw materials.

Certification is based on the ability of the supplier to control a given process at a given site within desired tolerances. To achieve this, the program recommends extensive use of statistical quality control techniques.[62] For raw materials the controls and testing are generally much more involved than for components, due to the nature of biological materials. In addition to interbatch variability biological material is more easily affected by environmental conditions such as temperature and humidity. As a result, procedures may have to be developed between the company and the supplier that

are more precise and with tighter specifications than those of components which are more stable.

The idea that vendor certification would be beneficial to pharmaceutical companies in general and to pharmaceutical companies in New Jersey in particular has been confirmed. It is feasible that Companies like Company X can successfully implement such a program. Recommendations for achieving successful implementation follow.

F. Recommendations

There are several things that a company must do prior to implementation to have any hope for success. For example, a company must get its own house in order. This means that the company must be ready to accept change as a way of life. There must also be a commitment to provide the required resources to manage the program.

Functional changes may require a reduction of the supplier base. This contributes to the good working relationships that are required in a vendor certification program. With a smaller number of suppliers, trust and confidence can be established between purchaser and supplier more easily.

Another area critical to successful supplier relations is stable scheduling. The company must assure that manufacturing plans do not overload manufacturing resources. The Master Production Schedule (MPS) must balance manufacturing resource demand with resource availability. It can never be "front

loaded" and/or "overloaded". This means that the MPS must have simulation and rough-cut capacity planning capability. this will allow for playing "what if" games that result in an achievable plan prior to activating the actual plan. Similarly, the MPS must have established "time fences". This provision guarantees that any demand adjustments will take place outside the time frame where changes will not create many close-in schedule priority changes and therefore, not result in a "catch-up" condition that creates unacceptable quality.

A similar scheduling problem which will affect supplier relations is purchase/manufacturing lead times. If lead times are understated, the purchase orders and/or work orders will be released too late. Expediting will be required to try to make up the lost time and quality will be compromised. If the lead times are overstated, the manufacturing plan will incorrectly state a need for resources not required.

Finally it is recommended that to start the program the company choose suppliers who, in addition to having good performance, are close to the manufacturing site geographically. Geographic location is important because the closer the supplier is to the point of use, the less chance there is for disruption of supply. Working sessions are much easier with nearby vendors, and associated travel expenses are reduced. The savings in shipping costs can also be reduced, producing tangible savings associated with the program implementation.

A study should be made in detail to determine the detailed requirements for each individual company anticipating beginning a vendor certification program. Concurrent with this study, a master plan should be undertaken for the implementation process. This master plan needs the commitment from the top if it is to succeed.

ENDNOTES

[1]L.P. Sullivan, "Reducing Variability: A New Approach to Quality", Quality Progress, July 1984, p. 15.

[2]Sullivan, p. 17.

[3]Office of the Federal Register, 21 CFR 201.1, 1988, p. 75.

[4]21 CFR 211.22, p. 78.

[5]"Supplier Certification - A Model Program", Journal of Parental Science and Technology, July - August 1989, p. 151.

[6]Pharmaceutical Manufacturers Association, "PMA Guidelines for Vendor Certification", Draft #6, October 3, 1988, pp. 1-2.

[7]Richard A. Maass, "Supplier Certification - A Positive Response to Just-In-Time", Quality Progress, September 1988, p. 76.

[8]21 CFR 211.84, p. 83.

[9]Maass, p. 75.

[10]Cynthia Lane Westland, "Avoid the Just-In-Time Terrors", Quality Progress, October 1988, pp. 69-70.

[11]PMA Guidelines, p. 3.

[12]F-D-C Reports, "The Gold Sheet", Volume 23, No. 1, January 1989, p. 1.

[13]"The Gold Sheet", p. 1.

[14]"The Gold Sheet", p. 4.

[15]Maass, p. 75.

[16]"Supplier Certification - A Model Program", p. 152.

[17]PMA Guidelines, p. 6.

[18]Maass, p. 77.

[19]Melissa Larson, "Certification System Cuts Downtime", Packaging, February 1988, p. 40.

[20]Maass, p. 77.

[21]"Supplier Certification - A Model Program", p. 153.

[22]Mary Lou Kotecki, "Quality Through Certification", ASQC Quality Congress Transactions, March 1984, p. 161.

[23]"The Gold Sheet", p. 5.

[24]Maass, p. 75-76.

[25]Paul A. Ware, "A Cooperative Approach to Vendor Certification", Quality Progress, November 1984, p. 36.

[26]"The Gold Sheet", p. 4-6.

[27]Kotecki, p. 158.

[28]Larson, p. 40.

[29]"The Gold Sheet", p. 8.

[30]Maass, p. 77.

[31]J.V. Cherry, "Vendor's Viewpoint: Quality Response, and Delivery", Quality Progress, November 1984, p. 41.

[32]"PMA Guidelines for Vendor Certification", p. 8.

[33]"Supplier Certification - A Model Program", p. 152.

[34]"Supplier Certification - A Model Program", p. 154.

[35]Ware, p. 36.

[36]"Supplier Certification - A Model Program", p. 154.

[37]"The Gold Sheet", p. 3.

[38]"The Gold Sheet", p. 3.

[39]"The Gold Sheet", p. 3.

[40]Earl E. Nelson, "Life Cycle Expert", Quality Progress, November 1987, p. 42.

[41]Nelson, p. 41.

[42]Nelson, p. 42.

[43]Nelson, p. 41.

[44]Ware, p. 37.

[45]Larson, p. 40.

[46]Larson, p. 39.

[47]Maass, p. 77-78.

[48]"Supplier Certification - A Model Program", p. 156.

[49]"Supplier Certification - A Model Program", p. 156.

[50]"Supplier Certification - A Model Program", p. 157.

[51]"Supplier Certification - A Model Program", p. 157.

[52]"PMA Guidelines For Vendor Certification", p. 17.

[53]"Supplier Certification - A Model Program", p. 158.

[54]"Supplier Certification - A Model Program", p. 158.

[55]"Supplier Certification - A Model Program", p. 159.

[56]"Supplier Certification - A Model Program", p. 159.

[57]Nelson, p. 42.

[58]Ware, p. 37.

[59]Larson, p. 40.

[60]"The Gold Sheet", p. 6.

[61]L. Ferris Bell, "Quality Improvement Through Management Involvement", ASQC Quality Congress Transactions, March 1984, p. 97.

[62]Richard D. Martel, "A Switch From Traditional Thinking", American Production & Inventory Control Society 1988 Conference Proceedings, p. 290.

[63]Martel, p. 290

APPENDIX A

429 Wilden Place
South Orange, N.J. 07079

November 17, 1989

Dear Colleague,

I am currently doing reasearch for my Master's Thesis on Vendor Certification in the Pharmaceutical Industry at NJIT.

This survey intends to provide insight into the feasibility of implementing such a program for a mid-sized pharmaceutical company in this area. In particular I am interested in the type of products covered in the program, the time required to implement the program and the success of the program.

The questionnaire is divided into four parts and is designed to gather information from companies who do not yet have a program as well as those that do. Therefore, please send me a questionnaire even if partially completed. You may pass the survey on to your colleagues to complete some areas.

Your individual response will be strictly confidential. All responses will be reported in tabulated form only. The purpose of the identification number in the upper right-hand corner of the questionnaire is merely to enable a follow-up of the nonrespondents.

Thank you for your cooperation. Please return the survey by December 21, 1989.

Sincerely,

Clarice P. Johnson

VENDOR CERTIFICATION QUESTIONNAIRE

I. GENERAL

1. Do you currently have a Vendor Certification Program in Place?

   [ ] Yes [ ] No
   (If Yes, skip #2 and go to #3. If No, go to #2).

2. Do you plan to institute such a program?

   [ ] Yes [ ] No
   (If No, please go to Section IV).

3. Was the Certification Program Initiated By

   a. Quality Assurance _____
   b. Quality Control _____
   c. Purchasing _____
   d. Materials Management _____
   e. Other (Specify) _____

4. What Departments are involved in the Vendor Certification Program? (Please check all that apply).

   a. Purchasing _____
   b. Production _____
   c. Engineering _____
   d. QC/QA _____
   e. Materials Management _____
   f. Regulatory _____
   g. Process Development _____
   h. Other (Specify) _____

5. What was your primary reason for implementation? (Please rate in order of importance 1 = Most Important, 5 = Least Important).

   a. Reduce In-House Inspection Costs _____
   b. Reduce Inventory _____
   c. Reduce In-House Lead-Time _____
   d. Improve Product Quality _____
   e. Improve Vendor Lead Time _____
   f. Other (Specify) _____

6. How many parts do you inventory in each category?

   a. Raw Material

   [ ] Less Than 500, [ ] 501 - 1000,
   [ ] 1001 - 2000, [ ] More than 2000

   b. Primary Packaging Components (Components In direct contact with the product).

   [ ] Less than 500, [ ] 501 -1000,
   [ ] 1001 - 2000, [ ] More than 2000

   c. Secondary Packaging & Labeling

   [ ] Less than 500, [ ] 501 - 1000
   [ ] 1001 - 2000, [ ] More than 2000

7. What types of materials are in the program? (Check all that apply).

Folded Cartons (Printed)	_____
Folded Cartons (Unprinted)	_____
Roll Labels	_____
Cut Lables	_____
Cut Inserts	_____
Films/Foils	_____
Bottles/Vials	_____
Stoppers	_____
Caps	_____
Active Ingredients	_____
Excipients	_____
Other (Specify)	_____

8. How many vendors and items are involved in your program for each category

	Raw Materials	Primary Components	Secondary Components
a. How many Vendors	_____	_____	_____
b. Apprx. percent of Vendors	_____	_____	_____
c. How many items	_____	_____	_____

9. How long have you had a Vendor Certification Program?

   _____ Years

10. Was your program begun with a new supplier or with an existing supplier?

[ ] New [ ] Existing

II. IMPLEMENTATION

1. What factors were involved in your selection of the initial vendor in the program? Please check all that apply.

a. Problem Vendor _____
b. Good Performance Record _____
c. Sourcing Problem _____
d. Vendor Initiated _____
f. Large Volume Supplier _____
g. Other (Specify) _____

2. What category of material was involved in your initial implementaion?

[ ] Raw Materials
[ ] Primary Packaging Components
[ ] Secondary Packaging Components

3. Have you provided training programs for your vendors?

[ ] Yes [ ] No

4. What types of training did you develop with your vendors? Check all that apply.

a. Housekeeping _____
b. Process _____
c. Statistical Process Control _____
d. GMP _____
e. Testing _____
f. Measurement _____
g. Other (Specify) _____

5. Did you bring the vendor's operating personnel into your facility to see the end use of their product?

[ ] Yes [ ] No

6. What data does the vendor supply with each lot?

   a. Certification Letter _____
   b. Certification Letter & Test Data _____
   c. Other (Specify) _____

7. Do you include vendor input in developing your component design and specifications?

   [ ] Yes [ ] No

8. How long did it take to implement your program?

   _____ Months, _____ Years

III. RESULTS

1. Have you reduced or eliminated your incoming inspection as a result of this program on the affected items?

   a. No Reduction _____
   b. 0 - 25% Reduction _____
   c. 26 - 50% Reduction _____
   d. 51 - 75% Reduction _____
   e. 76 - 100% Reduction _____

2. How would you rate the success of your program?

   a. Unsuccessful _____
   b. Low _____
   c. Medium _____
   d. High _____

3. Does your program have a procedure to deal with material received under the certification program that is subsequently found to be defective?

   [ ] Yes [ ] No

4. What is the basis of the agreement with the vendor on notifications of process changes?

a. No Agreement _____
b. Written Contract _____
c. Purchase Order Statement _____
d. Part Of Specification _____
e. Vendor Questionnaire _____

IV. COMPANY PROFILE

1. How many are employed at your company?

[ ] Less Than 200, [ ] 200 - 499,
[ ] 500 - 999 , [ ] 1000 - 2000
[ ] More Than 2000

2. The data is based on

[ ] Single Site, [ ] Multiple Sites

3. If the data includes multiple sites, is purchasing handled at the local or central level?

[ ] Local [ ] Central

APPENDIX B

429 Wilden Place
South Orange, N.J. 07079

November 17, 1989

Dear Supplier;

I am currently doing a research for my Master's Thesis on Vendor Certification in the Pharmaceutical Industry at NJIT.

In particular, I am interested in your experiences in a vendor certification program and/or your willingness to become part of such a program.

The questionnaire is designed to gather information from companies who do not yet have a program in addition to those that do. Therefore, please send me a questionnaire even if partially completed. You may pass the survey on to your colleagues to complete some areas.

Your individual response will be strictly confidential. All responses will be reported in tabulated form only. The purpose of the identification number in the upper right-hand corner of the questionnaire is merely to enable a follow-up of the nonrespondents.

Thank you for your cooperation. Please return the survey by December 21, 1989.

Sincerely,

Clarice P. Johnson

VENDOR CERTIFICATION QUESTIONNAIRE

VENDORS

1. Are you currently participating in a Vendor Certification Program?

   [ ] Yes [ ] No

2. Are Pharmaceutical Companies included in your program?

   [ ] Yes [ ] No

3. What Departments are involved in your current Vendor Certification Program? (Check all that apply).

   a. Purchasing _____
   b. Production _____
   c. QC/QA _____
   d. Materials Management _____
   e. Engineering _____
   f. Other (Specify) _____

4. Does your company provide input in developing component design and specification to the customer?

   [ ] Yes [ ] No

5. What types of training was developed with you and your customer? (Check all that apply).

   a. Housekeeping _____
   b. Process _____
   c. Statistical Process Control _____
   d. GMP _____
   e. Testing _____
   f. Measurement _____
   g. Other (Specify) _____

6. What factors were involved in your initial participation in the program? (Check all that apply).

   a. Customer Initiated _____
   b. Large Volume Customer (Value/Quantity/Space) _____
   c. Pareto Analysis _____
   d. Improved Scheduling _____

7. Have you provided Training for your customers?

   [ ] Yes [ ] No

8. How long have you been involved in a Vendor Certification Program?

   _____ Years

9. Do you consider your program a success?

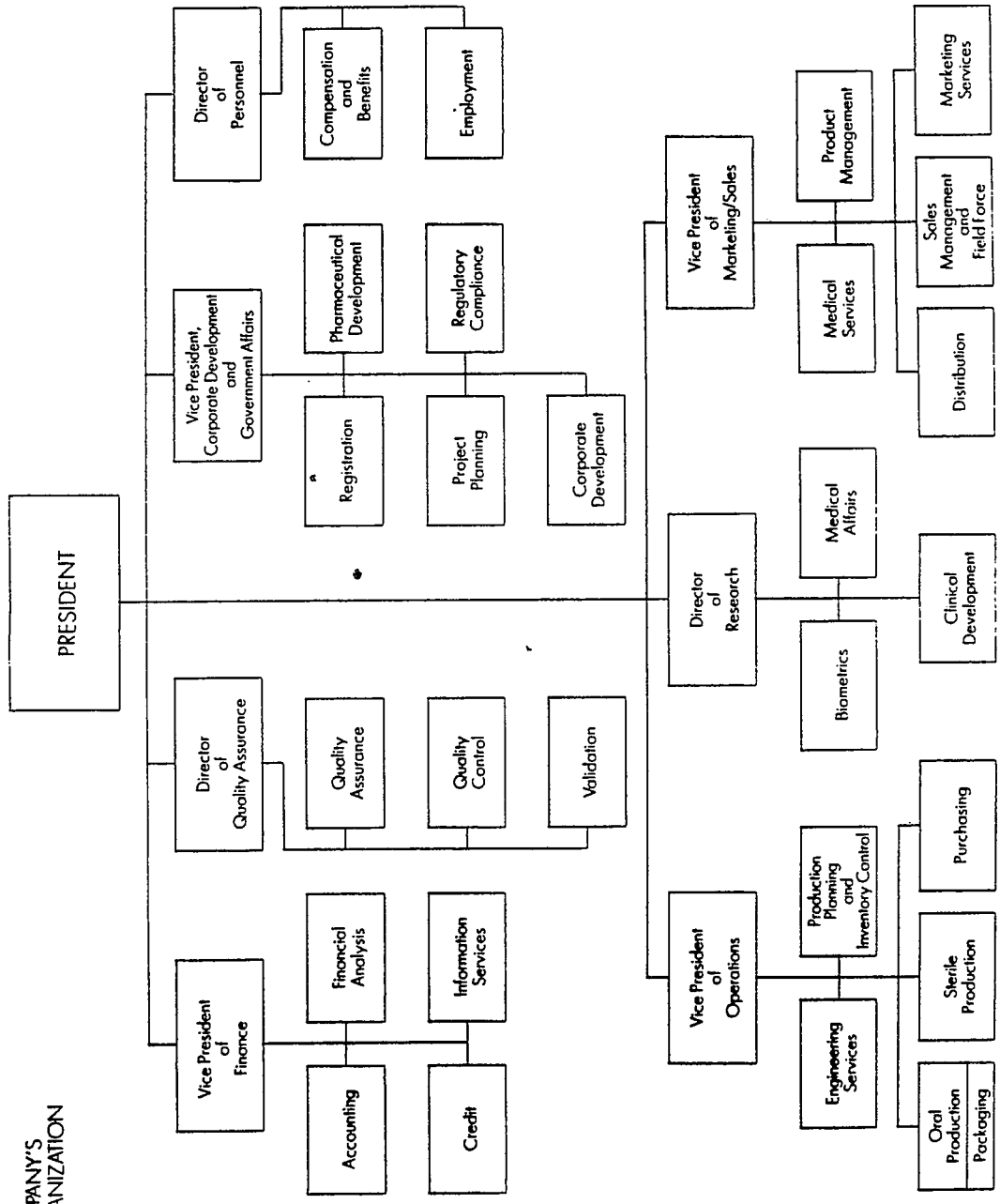
   [ ] No, [ ] Low, [ ] Medium, [ ] High

10. Would your company consider participating in a Vendor Certification program with a mid-sized pharmaceutical company in New Jersey?

    [ ] Yes [ ] No

APPENDIX C

THE COMPANY'S ORGANIZATION



APPENDIX D

As used throughout these guidelines:

(a) The terms "vendor" and "supplier" are used interchangeably in these guidelines to refer to the manufacturer of the purchased item and no differentiation between terms is implied. The term "Vendor Certification", however, is used exclusively because of the established recognition of that term.

(b) The term "drug product component" means any ingredient intended for use in the manufacture of a drug product, including those which may not appear in such drug product. (Ref. CGMP)

(c) The term "drug product" means a finished dosage form, e.g., tablet, capsule, solution, etc. that contains the active drug ingredient(s) generally but not necessarily in association with inactive ingredients. (Ref. CGMP)

(d) The term "bulk pharmaceutical chemical" means any substance which is intended for use as an active ingredient component in drug products, or a substance which is repackaged or relabeled for drug use. Such chemicals are usually made by chemical synthesis, by processes involving fermentation, or by recovery from natural material. (Ref. PMA Guidelines for Bulk Pharmaceutical Chemicals.)

(e) The term "raw material", as applied to bulk pharmaceutical chemicals, means any substance (such as botanicals, animal tissues, chemicals, filter aids, solvents, diluents, catalysts, fermentation media, etc.) intended for use in the production of bulk pharmaceutical chemicals, including those which are not intended to become part of the finished bulk pharmaceutical

chemical. (Ref. PMA Guidelines for Bulk Pharmaceutical Chemicals)

(f) The term "just-in-time" (JIT) refers to a management philosophy whose goal is to closely link production to current demand by producing only the minimum necessary units in the smallest possible quantities at the latest possible time. JIT aims at achieving this goal by streamlining the production process and increasing flexibility through the reduction of lot sizes, lead times, set-up times, raw material and work-in-process inventory levels, and waste throughout the manufacturing process.

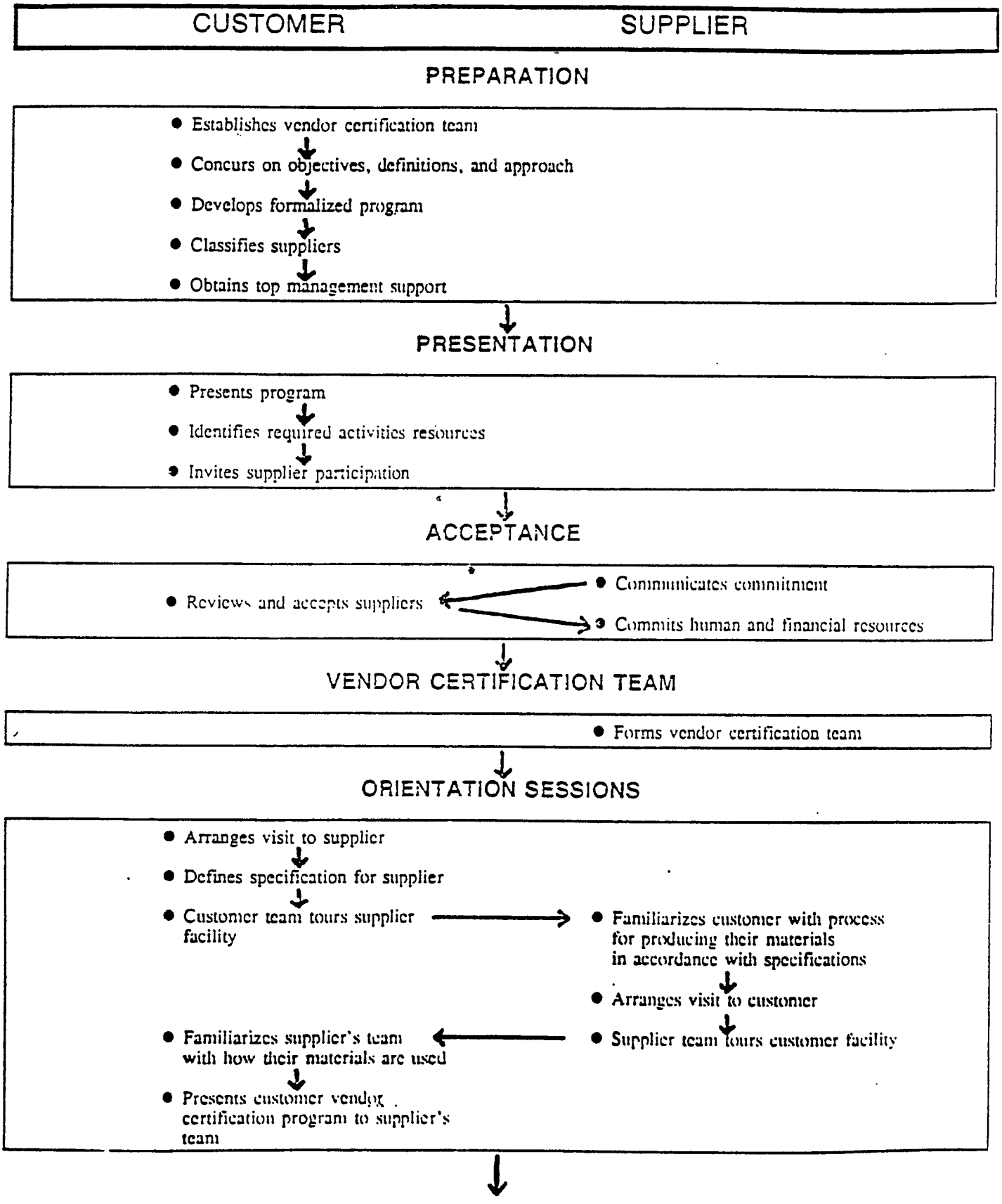
(g) The term "statistical process control" (SPC) refers to methods for improving and controlling a process by using statistical techniques during manufacturing to assure products conform to specifications as they are produced.

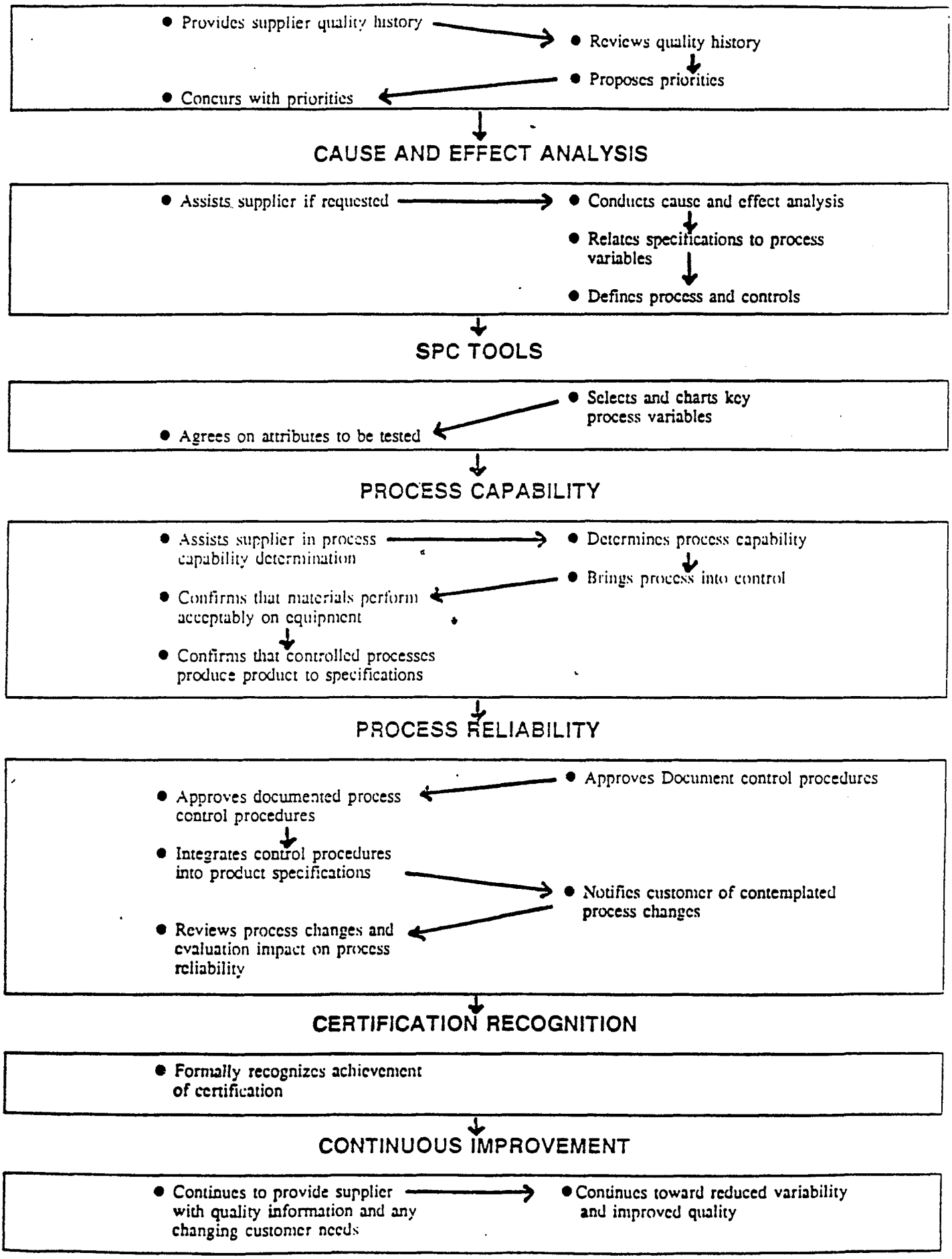
(h) The term "controlled process" means a documented process run in strict accordance with procedures and one in which sources of variation are identified, monitored and controlled using statistical process control and other techniques to ensure that the process produces a product within defined limits.

(i) The term "statistical quality control" (SQC) refers to the use of appropriate statistical methods to measure, evaluate, and/or control quality.

APPENDIX E

VENDOR CERTIFICATION FLOW CHART




• Provides supplier quality history
• Reviews quality history
• Proposes priorities
• Concurs with priorities
CAUSE AND EFFECT ANALYSIS
• Assists supplier if requested
• Conducts cause and effect analysis
• Relates specifications to process variables
• Defines process and controls
SPC TOOLS
• Selects and charts key process variables
• Agrees on attributes to be tested
PROCESS CAPABILITY
• Assists supplier in process capability determination
• Determines process capability
• Brings process into control
• Confirms that materials perform acceptably on equipment
• Confirms that controlled processes produce product to specifications
PROCESS RELIABILITY
• Approves Document control procedures
• Approves documented process control procedures
• Integrates control procedures into product specifications
• Notifies customer of contemplated process changes
• Reviews process changes and evaluation impact on process reliability
CERTIFICATION RECOGNITION
• Formally recognizes achievement of certification
CONTINUOUS IMPROVEMENT
• Continues to provide supplier with quality information and any changing customer needs
• Continues toward reduced variability and improved quality

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