Pilot Process Development for a Medical Diagnostic Product

by

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B.S. Chemistry, B.A. Psychology
Tufts University, 1987

Submitted to the Sloan School of Management and
the Department of Materials Science and Engineering
in Partial Fulfillment of the Requirements for the Degrees of

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Abstract

As competitive pressures increase, a market-leading manufacturing firm is likely to focus on a strategy of product innovation. The rapid development and introduction of new products is often an effective way for a firm to maintain technological advantage, and thus maintain its market leadership position. Today, many firms recognize that successful product development and process development are linked.

Process development does not necessarily imply invention on the part of the manufacturing firm. In many cases, process technologies are available, external to the firm, that if correctly sourced and applied, may greatly accelerate the process development, and thus the product development effort. Nonetheless, those firms committed to product innovation often exclude a focus on process technology as part of their overall strategy.

This thesis is based on the experience of a product development team of a medical diagnostics company. Given the functional complexity of this new diagnostic product, designed experiments were applied to the process development effort. Although designed experiments identified critical process variables, interactions, and led to an understanding of design space, the question of process robustness remained. Cpk analysis was therefore used as a follow-up tool, to evaluate process robustness, and to therefore assess the overall status of the process development effort. Given that the development effort required the implementation of new process technologies, the thesis considers how a process technology strategy is linked to the company's overall strategy of product innovation.

From the research, the following conclusions were drawn:

- Designed experiments combined with Cpk analysis is an effective statistical tool for process development.
- A process technology strategy, which addresses technology sourcing, investment and implementation is a critical part of a firm's overall strategy of product innovation.

Thesis Advisors:

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Thomas W. Eagar, Professor of Materials Science and Engineering.

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I am deeply grateful to the members of the Quicksilver Development Team at LifeScan, a Johnson & Johnson Company, for the support and encouragement they showed me during my internship. In particular, I thank Karen Drexler for making the internship opportunity available, and Remy Dato, Tahir Iqbal, Mark Miller, Mike Tomasco, Deb Tuohy, and Victor Walle for their dedication and strong contributions to this project.

I am also grateful for the support of my Thesis Advisors, Don Rosenfield and Tom Eagar, who provided me not only with technical direction, but with moral support and encouragement on a regular basis.

I would like to thank Polaroid Corporation for providing my sponsorship to the Leaders Program. These two years have richened my understanding of the challenges faced by manufacturing firms, and have confirmed my desire to pursue a career in manufacturing management. I look forward to "giving back" to Polaroid beginning in June. In particular, I am grateful for the support and involvement of Herb Ahrens and Penny Bergmann. Together, I feel we pioneered a solid process for future Polaroid- sponsored fellows.

Finally, and most important, I thank my Husband, Marc Zwetchkenbaum, without whose warm support, encouragement and incredible patience the past two years could not have been possible. I know that we will always do whatever we can to insure each other's fulfillment. (I do promise, however, never to move to California again..... without you, anyway!)

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Chapter 1

1.1 Statement of the Problem

LifeScan, a market leader of home blood glucose monitoring systems in the U.S. and Canada, finds that its competitive environment is changing rapidly. As new players enter the market, and chip away at LifeScan's historic technological advantage, LifeScan's strategy for product innovation becomes critical.

The Manufacturing Decision Category Approach[1] is a technique to assess the consistency of a company's strategic vision with its actual policies. Policies are reviewed in nine decision categories, (see section 4.1). By utilizing this approach, this thesis will examine the consistency of LifeScan's current policies with its strategic mission to innovate. Emphasis will be placed on the manufacturing decision categories of Production Technologies and Processes, as well as Product Development and Organization. Specifically, the thesis proposes that a strategy for product innovation is strongly linked to a process technology strategy, i.e., a process technology strategy is essential for a firm committed to rapid new product development.

Clark and Wheelwright point out that "all too often, *development projects* means product development projects, the assumption being that process technology can be acquired easily, if and when the need for it becomes obvious. Unfortunately, such a view results frequently in the full benefits of the product technology never being realized-- the manufacturing process simply cannot deliver the quality, cost, or timeliness the product requires. "[2] In addition, Clark stresses, "It is almost impossible to work out the basic research involved in a new manufacturing process while a product development project is trying to meet a preset time schedule, performance

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[1] Rosenfield, Donald B., Notes from 15.761, Operations Management, Strategy Section, MIT Sloan School of Management, December 1992.

[2] Wheelwright, Steven C. and Kim B. Clark, Managing New Product and Process Development, New York: The Free Press 1993.

specs and resource utilization goals."[3] LifeScan's Quicksilver team has been engaged in the development of a new medical diagnostic product for the past three years. The thesis will utilize the experience of LifeScan's Quicksilver product development team to illustrate these two observations, and, in so doing, will highlight the need for a process technology strategy.

1.2 Summary of Approach

This thesis focusses both narrowly and broadly on process development at LifeScan, as is graphically depicted in figure 1.1.

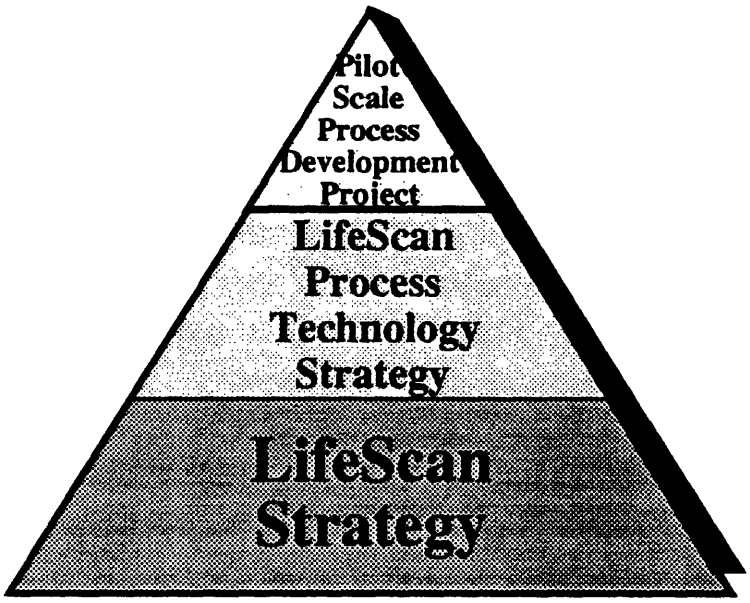

Figure 1.1 Thesis Structure

In a narrow focus, the thesis describes a series of designed experiments which were run by a small team, within the larger Quicksilver development team. Team members included the LFM intern, and three additional full-time resources. This small team was charged with developing a pilot-scale manufacturing process for a new diagnostic product. This experimental approach was intended to produce results which would ultimately be scaled up into process conditions for a production process. In a broader focus, the

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[3]Hayes, Robert H., Steven C. Wheelwright, and Kim B. Clark, Dynamic Manufacturing, Creating the Learning Organization, New York: The Free Press 1988.

thesis develops a strategy for implementing new process technologies, and presents this strategy as a critical part of LifeScan's overall strategy for new product development.

1.3 Thesis Organization

Chapter Two establishes the context for this research by briefly describing Diabetes, the Home Blood Glucose Monitoring Industry, and LifeScan's position in this industry. LifeScan's strategy is presented in broad terms. The Quicksilver development project is introduced as an example of LifeScan's emphasis on new product development.

In the context of the Quicksilver development effort, Chapter Three describes a series of Designed Experiments aimed at developing a pilot-scale manufacturing process for a new diagnostic product. Research methodology is described, as are results of each experiment. This experimental approach is intended to produce results which the team can ultimately scale-up, into process conditions for a production process.

Chapter Four utilizes the Manufacturing Decision Category approach to outline LifeScan's current policies in several areas. Certain inconsistencies are highlighted between current policies and LifeScan's strategic mission of Product Innovation. The Decision Categories of Production Technologies and Processes, Product Development and Organization are presented as they are most strongly linked to LifeScan's strategic mission.

Chapter Five utilizes the experience of the Quicksilver development team to expand on the decision categories of Production Technologies and Processes, Product Development and Organization. A Process Technology strategy is outlined.

Chapter Six summarizes all results. Based on the analysis of the Quicksilver development effort, and the Strategy for Process Technology, the thesis concludes with recommendations for future product development efforts at LifeScan.

Chapter 2

2.1 Diabetes and Home Blood Glucose Monitoring

Diabetes Mellitus is a chronic disease syndrome, resulting from an interaction of hereditary and environmental factors. It is estimated that 5-6% of the United States population, or 14 million people, have diabetes, with 650,000 new cases diagnosed each year[4]. Diabetes is characterized by an abnormal carbohydrate, protein and fat metabolism, fluctuating blood glucose levels, and a variety of end organ complications. The clinical management of diabetes has been based primarily on controlling the level of blood glucose within a range believed to be acceptable and safe from the risk of disease complications. Diabetics typically achieve control of blood glucose through a combination of dietary measures, exercise, supplementing their own body's insulin supply, and use of oral agents.[5]

Research reports have suggested that "the devastating complications of diabetes can be prevented or delayed by monitoring blood sugar levels more closely"[6]. A *mechanism* for measurement of the level of glucose in the blood is therefore central to diabetes management. Originally, measurement techniques were complex, requiring specially trained technicians in clinical laboratory settings. However, technological advances over the past fifteen years have led to the creation of a one billion dollar U.S. market for self monitoring of blood glucose (SMBG).

Today, SMBG products fall into two categories: Visually readable or Meter readable. Visually readable strips require the diabetic to prick his/her finger with a lancet, place a drop of blood on the strip, wait for a chemical reaction, wipe or blot the strip, and check for a visual color change. The ending color is then correlated off a chart to a certain blood glucose level.

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[4] LifeScan Environmental Scan, July 1993

[5] LifeScan Environmental Scan, July 1993

[6] Fisher, Lawrence M, "Diabetes Report May Lift Sales of Medical Devices", New York Times, June 15, 1993.

Meter readable products generally provide greater accuracy. The diabetic pricks his or her finger with a lancet, and feeds a drop of blood onto a strip . Through reflectance photometry, or electrochemical methods, the chemical reaction is translated by a meter to a digital output of blood glucose level for the patient.

The SMBG industry is dominated by three companies, who together account for 90% of U.S. meter and strip sales: LifeScan, Inc. (a Johnson & Johnson Company), Boehringer Manheim Corp, and Miles Laboratories. U.S. Market growth has averaged 17% (in dollars) over the past three years. An annual market growth of 10% is expected through 1995. In addition to the three market leaders, there are several meter/strip competitors, and two strip-only competitors have recently emerged.[7]

2.2 LifeScan, and LifeScan Strategy

LifeScan, acquired by Johnson & Johnson in 1986, currently leads the U.S. market in home blood glucose monitoring. In 1987, LifeScan was the first to market a "second generation" meter readable product: One Touch®[8] Blood Glucose Monitoring System. One Touch required no washing, wiping, blotting or timing of the strip by the user. Accurate readings were automatically displayed 45 seconds after placing a drop of blood on a strip pre-positioned in the meter. The meter was additionally capable of storing up to 250 readings for patient and/or physician tracking of trends in blood glucose levels. This technologically superior product allowed LifeScan to achieve significant market share by 1990. In 1991, LifeScan broadened the technological gap between itself and competitors even further by introducing One Touch II®[8] . By this time, brand awareness and a highly reputable customer service organization led LifeScan to a market leadership position in the U.S. and Canada. LifeScan currently has a 47% share of meter placements in the U.S. and has held its market leader position since October of 1991.

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[7] LifeScan Environmental Scan, July 1993

[8] One Touch ® and One Touch II® are registered trademarks of LifeScan, Inc., a Johnson & Johnson Company.

Although LifeScan currently retains its U.S. and Canadian market leadership position, the competitive environment for home blood glucose marketing has since changed dramatically. By late 1994, LifeScan's two primary competitors are expected to introduce second generation meter readable products which may essentially eliminate LifeScan's technological advantage. In addition, smaller competitors have introduced meter readable products with certain technological advantages to OneTouch. While LifeScan continues to differentiate itself through its superior customer service, product innovation has now become essential toward assuring continued market leadership.

The introduction of low cost off-brand strips by two new players in the home blood glucose monitoring market has further complicated the competitive environment. These strips may be used with LifeScan's meters, and are available at roughly 75% of the retail cost of LifeScan's strips. LifeScan maintains that these products violate their patents. At this time, the effect of legal actions taken by LifeScan to block this form of competition is unknown. In any case, lower cost off-brand strips have heightened the need for LifeScan to differentiate itself from competitors. A broader product line may enable this.

2.3 The Quicksilver Product Development Effort

Recognizing the importance of product innovation in maintaining competitive advantage, in May of 1991, LifeScan formed its first cross-functional development team, code-named "Quicksilver". The team was charged with developing a new diagnostic product in a "fast" time frame. The development effort was estimated to last eighteen months. LifeScan would be the first to market this type of product, which would broaden its current product line, open up new markets, and help to maintain LifeScan's image as a technological leader in home blood glucose monitoring.

To date, the Quicksilver team has been together for about three years, and a reliable process has yet to be developed. (Fortunately for LifeScan, no competitive product has been introduced during this time-frame.) Several factors have contributed to this delay in product introduction:

Only a few months after its formation, the team discovered that successful development of this product would require LifeScan to learn about and integrate new process technologies. The technology of LifeScan's current product was essentially non-transferable. Further, as a one-product, one-process company, LifeScan had no formal strategy in place for connecting itself with and/or importing new process technologies.

The Quicksilver team's challenge was increased by the fact that this new product is functionally more complex than LifeScan's current product. Consistent product performance relies on a complex chemical interaction between materials properties and coatings applied. Product performance is sensitive to a large number of process variables relating to coating method, drying method, materials and coating formulations. In addition, the team's experience to date strongly suggests that interactions between variables are present.

Pressure for the fast cycle team to rapidly develop this product caused the project to advance prematurely from an R&D phase to a production phase. Decisions to purchase production equipment were made prior to really understanding the process. Tied to production equipment that may not be optimal, the team's process development efforts over the past year have primarily involved one-factor-at-a-time experimentation, or arbitrary selection and manipulation of process variables *suspected* to significantly affect desired responses. Although many relationships between process variables and responses were suspected, as were many interactions between responses, (estimated to be 1000's),these relationships had not been quantified or formally demonstrated. While pressure to introduce the product increased, many questions remained as to how to develop a reproducible process.

Chapter 3

3.1 Introduction

The thesis project presented an opportunity to take the process back to the lab; to a controllable environment, where the effect of multiple process variables and interactions could be measured and understood. While a portion of the team was dedicated to developing a manufacturing process on production equipment, the thesis project allowed for a pilot scale focus on process development.

3.2 Overview of the Manufacturing Process

Prior to discussing the designed experiment approach to pilot process development, it is helpful to provide an overview of the manufacturing process steps for this new diagnostic product:

1. Coating and drying of Membrane

The coating process involves multiple steps. For each, a porous membrane substrate is coated with a chemical formulation. The membrane is subsequently dried.

2. Lamination of Polyester to Membrane

A polyester substrate is laminated to the coated membrane.

3. Strip Assembly

Additional layers of polyester are laminated onto the coated structure. For these experiments, the assemblies are cut into cards.

4. Slicing

Individual strips, which represent the finished product, are sliced apart.

Of the four manufacturing process steps, **coating and drying of the membrane** was suspected by the team to be most critical, in terms of its effect on end product performance, and sensitivity to a large number of process variables. The pilot process development effort, therefore, focused on this step only.

3.3 Experimental Methodology

Experimental Design was the chosen scientific approach toward process development. For this application, Response Surface Methodology (RSM)[9] was chosen over Taguchi Experimental Design. Although Taguchi methodology has several strengths, it incorporates certain assumptions which render it inappropriate for this particular application. First, the structure of Taguchi arrays assumes that no unintended interactions exist between input parameters. As mentioned previously, several interactions were suspected, but not known to exist in this system. Second, the Taguchi approach is limited in its ability to identify the optimal. A Taguchi Design's ability to identify optimal conditions is limited by the experimenters up-front knowledge of the process. In other words, it is impossible to extrapolate optimum conditions from experimental data. The optimum conditions in a Taguchi experiment must be a combination of the exact parameter levels used as inputs. The implicit assumption in Taguchi Design is that the process is fairly well understood from the onset of experimentation. This was clearly not the case for the Quicksilver development effort.

Alternatively, Response Surface Methodology assumes very little understanding of the process up front. "The pragmatic use of Response Surface Methodology puts a high priority on sustaining a better understanding of the process system as well as estimating optimum conditions.[10]" Unlike with Taguchi design, the determination of optimum conditions with RSM is not limited by up-front knowledge of the process. Response Surface Methodology provides a sequential approach toward process development and optimization, and can be used to effectively answer the following questions:

"1. How is a particular response affected by a set of variables over some specified region?

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[9] Hogg, Robert V. and Johannes Ledolter, Applied Statistics for Engineers and Physical Scientists. New York: Macmillan Publishing Company, 1992.

[10] Myers, Raymond H., Andre I. Khuri and Geoffrey Vining,"Response Surface Alternatives to the Taguchi Robust Parameter Design Approach", The American Statistician, May 1992, Volume 46, #2.

2. What settings of the variables will give a product or process satisfying desirable specifications?
3. What settings of the variables will yield a maximum (or minimum) response, and what is the local geography of the response surface near this maximal (or minimal) value?"[11]

The following general RSM path was applied to this process development effort:

1. A First Order Screening Design, Linear Model.
Even though the linear model is not likely to provide an adequate description of the system, it usually provides a good starting point for the analysis. Variables are evaluated for significance. Non-significant variables may be eliminated in the next round of experimentation. Trends are identified, as are starting point ranges for the subsequent higher order experiment.

2. A Second Order Design, Quadratic Model. This model will lead to surfaces that describe minima or maxima. Contour plots are a convenient format for interpreting results. Lack of Fit indicates the need for transformation of data, additional runs and/or use of a different model. With no lack of fit, response surfaces can be identified for each response. Overlapping design space may then be determined: settings for each variable are identified which yield satisfactory levels across all responses.

3.4 Overview of The Pilot Scale Designed Experiments

The process development project consisted of several experiments designed by the team, summarized in table 3.1. The team utilized a hand-coating method in the first two experiments to simulate the production process. Two major limitations to the hand coating method included variability introduced

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[11] Myers, Raymond H., Andre I. Khuri and Geoffrey Vining,"Response Surface Alternatives to the Taguchi Robust Parameter Design Approach", The American Statistician, May 1992, Volume 46, #2.

by the operator, and the inability to create the positioning of coatings required for full functionality of the end product. To overcome these limitations, and to improve the pilot process development effort, the team designed and built a bench top pilot coater. The bench top pilot coater's purpose was to automate the hand-coating process. The team designed this equipment to greatly reduce variability, to have the capability to produce fully functional end-product, and to allow for the flexibility to evaluate alternate coating techniques. The first two hand-coated experiments were run while the bench top pilot coater was being built. The team initiated protocol testing with the bench top coater immediately upon its arrival. Subsequent to the internship, remaining team members utilized the coater in the third designed experiment. **Although the thesis will describe the design of this third experiment, results will not be included.**

Experiment	Purpose	Model	Process Method
Designed Experiment #1	Screening	Linear	Hand-Coating
Designed Experiment #2	Optimization	Quadratic	Hand-Coating
Protocol Testing	Debugging, testing for consistency.		Pilot Coater
Designed Experiment #3	Optimization	Partial Cubic	Pilot Coater

Table 3.1: Series of Designed Experiments for pilot process development.

3.5 Designed Experiment #1

Selection of Response Variables (Outputs)

The response variables for this new product were chosen to represent the responses by which the customer bases product performance. Knowledge of responses for the current product, as well as information from customer focus groups (held by the team's marketing manager) led to identifying the following response variables:

Reaction Time
Elapsed time from application of blood to generation of a blood glucose measurement.

Color
A quantitative measurement of the degree of color change, corresponding to a particular blood glucose value.

Hemolysis Time
Elapsed time from application of blood to breakthrough of red blood cells, and thus an appearance of red color.

Hemolysis Degree
A quantitative measurement of the degree to which hemolysis occurs, i.e. how severe is the breakthrough of red blood cells, or how much is the color affected?

Spread of Data was included as an additional response variable to assess the variability of the hand-coated process, and any changes to that variability between cases. (This response was included to assure that the level of variability of the hand-coating process was low enough to yield meaningful results.)

Selection of Process Variables (Inputs)

As mentioned previously, a critical portion of the manufacturing process for this new product (in terms of effect on end product performance) is the coating and drying of the membrane. Based on the team's experience to date, the following process variables were suspected to significantly influence product response: (Note that certain parameters are disguised due to proprietary reasons.)

- solids concentration of the first coating applied.
- membrane characteristic
- percentage of solvent in subsequent coatings.
- drying conditions.

• coating parameter, denoted as X
• whether chemical parameter, denoted as Y, was contained in the first or in a subsequent coating.

Each of these process variables was therefore included in the screening designed experiment.

Inputs and Outputs of Designed Experiment #1 are graphically depicted in Figure 3.1

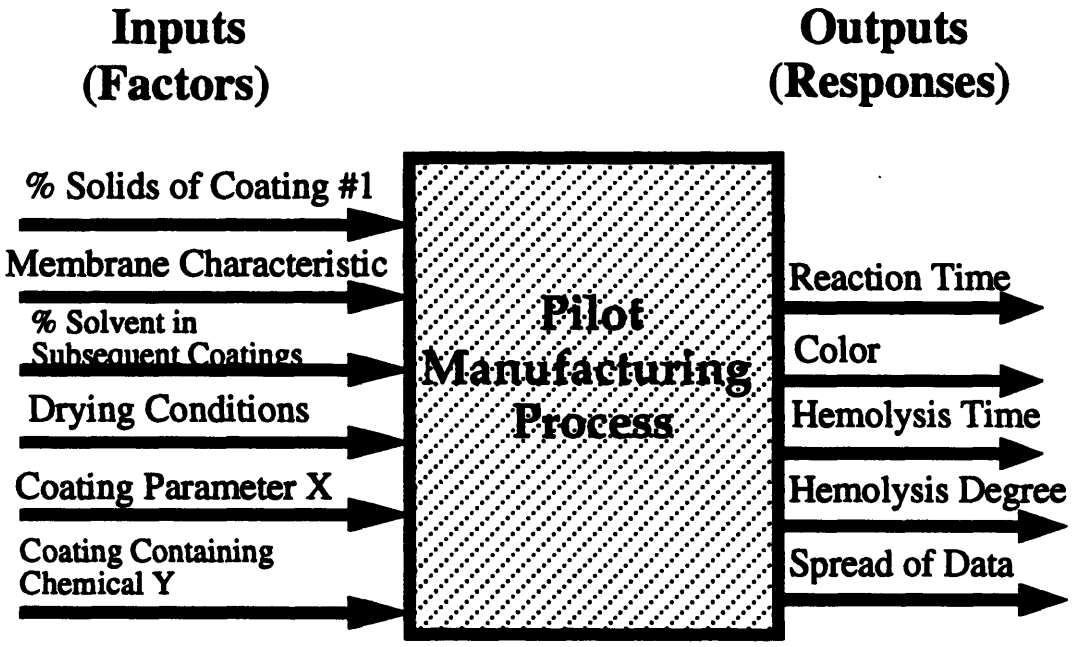

Figure 3.1 Inputs and Outputs of Designed Experiment #1

Selection of Levels

Of the five process variables chosen, three are continuous and two categorical. The continuous variables were analyzed at three levels, based on the team's experience to date. Levels for each input are summarized in Table 3.2.

	Input	Level 1	Level 2	Level 3
Continuous	% Solids of Coating #1	40	60	80
	Membrane Characteristic	1500	2000	2500
	% Solvent in Subsequent Coatings	10	20	30
Categorical	Coating Parameter X	1	2	
	Drying Conditions	Low	High	

Table 3.2 Input Levels for Designed Experiment #1

Note: The process variable "Coating Containing Chemical Y" was not included in the experimental matrix. For this categorical variable, each trial was run at each of three settings, or "coating protocols":

Coating Protocol A:	First (and only) coating:	Contains Chemical Y
Coating Protocol B:	First coating:	No Chemical Y
	Subsequent coating:	Contains Chemical Y
Coating Protocol C:	First coating:	Contains Chemical Y
	Subsequent coating:	No Chemical Y

Testing/Sample Size

For each coating protocol, four cards were made, i.e., 12 cards per experiment. Six strips were tested per card. All strips were tested with the same glucose level blood.

Analysis of Data

E-Chip Experimental Design Software was used to analyze all data. Consistent with an RSM approach, a linear with center point model was chosen for this screening experiment.

Results of Designed Experiment #1

Highlights of the results of this experiment, and corresponding conclusions may be summarized as follows:

• Each variable exhibited a high level (99.9%) of significance for at least one of the response variables. Several variables exhibited a 99.9% significance level across multiple response variables.

Conclusion: The team selected the "right" process variables for this first designed experiment. Chances are, however, that not *all* relevant variables were included.

• Across all coating protocols, variables ranked as follows in their effect relative to all responses:

1. % Solids in Coating #1
2. Membrane Characteristic
3. % Solvent in Subsequent Coatings
4. Drying Condition
5. Coating Parameter X.

Conclusion: % Solids and Membrane Characteristic appear to be the two most significant process variables.

• Coating protocols B and C showed similar significance for all variables relative to all responses.

Conclusion: It is still unknown whether chemical Y should be included in the first or the subsequent coatings.

• For all coating protocols, coating parameter X , level 2, was consistently reported as significant.

Conclusion: Future experiments should eliminate this variable; level 2 of coating parameter X should always be incorporated.

• Adding subsequent coatings, (from coating protocol A to C), increased the overall significance of drying conditions across response variables.

Conclusion: The next experiment should examine drying conditions more closely, by separating this process variable for coating #1 vs. subsequent coatings.

• For all coating protocols, drying condition "high" was consistently reported as significant.

Conclusion: Future experiments should examine a range of drying conditions built around "high".

• Several trade-offs exist between variables and responses. Specifically:

Reaction time favors a 40% solids level in coating #1.
Color favors an 80% solids level in coating #1.

Reaction time favors a Membrane Characteristic of 2500.
Color favors a Membrane Characteristic of 1500.

Reaction time favors a 40% solvent level in the subsequent coatings.
Hemolysis time favors an 80% level of solvent in the subsequent coatings.

Conclusion: The team has successfully identified these relationships, i.e. trade-offs, and has quantified their magnitude relative to one another. However, the team must conduct future experiments to determine the particular settings, (if any), of process variables that are required in order to satisfy *all* responses.

3.6 Designed Experiment #2

Consistent with the RSM approach, the team utilized a quadratic model in the second, optimization Designed Experiment. The goal of this experiment was to generate response surfaces, interpreted from contour plots, which would define optimal settings for each process variable across all responses.

Based on results of Designed Experiment #1, the team incorporated the following input and output parameters into this designed experiment:

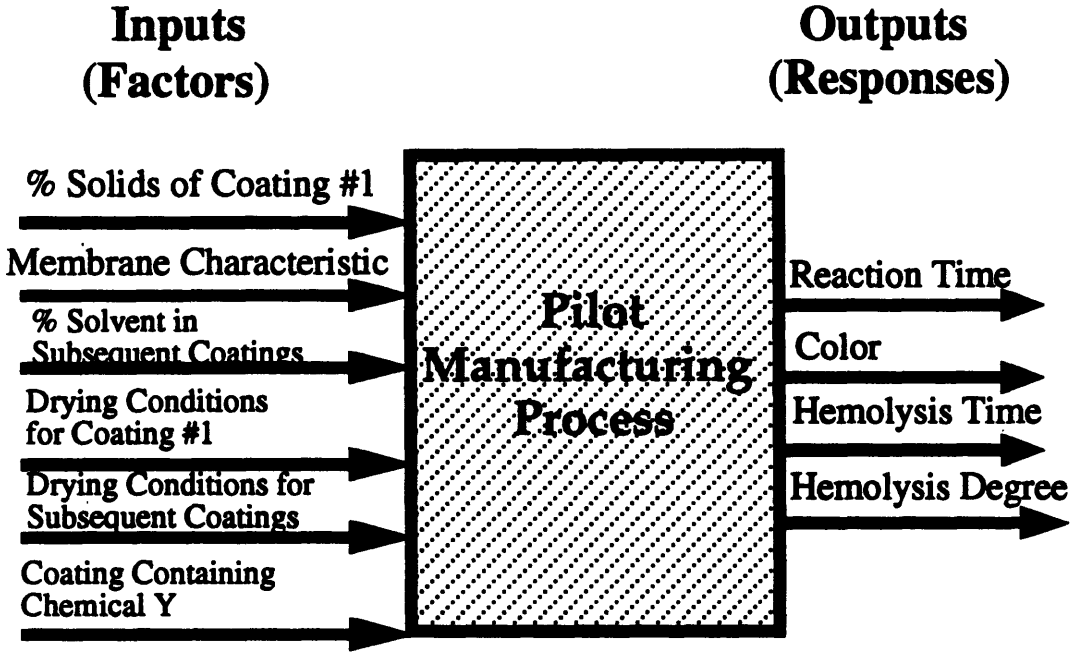

Figure 3.2 Inputs and Outputs for Designed Experiment #2

Selection of Responses

The same response variables, (i.e. end product performance measurements), measured in Experiment #1 will be examined in Experiment #2. Spread of Data was dropped, as it revealed no significance in the first experiment. (All cases were identical in terms of this response, suggesting that the level of variability of the hand-coating process was low enough to yield meaningful results.)

Selection of Process Variables

Based on results of Designed Experiment #1, the team selected the following process variables for this experiment:

- % Solids in Coating #1.

- Membrane Characteristic .
- % Solvent in subsequent coatings.
- Drying conditions for coating #1
- Drying conditions for subsequent coatings.
- Coating containing Chemical Y.

Two of the above process variables, Drying Conditions and Coating containing Chemical Y, warrant further comment:

- **Drying Conditions**

Designed Experiment #1 indicated that the effect of drying conditions changed in moving from one to multiple coatings (from coating protocol A to C). Designed Experiment #2 will therefore treat Drying Conditions of the first coating and Drying Conditions of the subsequent coatings as individual process variables. Given the significance of drying condition "high" in the first experiment, this experiment will focus on a range of drying conditions surrounding the high level for each coating.

- **Coating Containing Chemical Y (First vs. Subsequent)**

This experiment will once again attempt to address the team's question as to whether to add Chemical Y to the first or the subsequent coatings. (Results of experiment #1 did not provide clear direction for this process variable.)

Selection of Levels

All five process variables for Designed Experiment #2 were continuous. Variables were analyzed at three levels, as shown in Table 3.3.

	Input	Level 1	Level 2	Level 3
Continuous	**% Solids of Coating #1**	50	60	70
	Membrane Characteristic	1500	2000	2500
	% EtOH in Coating #2	10	20	30
	Drying Conditions, Coating #1	5	15	25
	Drying Conditions, Coating #2	5	15	25

Table 3.3 Input Levels for Designed Experiment #2

As in Experiment #1, the process variable "coating containing Chemical Y" was not included in the matrix. Each trial was run with two coating protocols:

Coating Protocol A:	Chemical Y contained in first coating.
Coating Protocol B:	Chemical Y contained in subsequent coatings.

Testing/ Sample Size

For each coating protocol, two cards were made; i.e. four cards per experiment. Three strips were tested per card. Strips from each case were tested with two blood glucose levels.

Analysis of Data

The team utilized E-Chip Experimental Design Software to analyze all data. Following the RSM path, the team chose a quadratic model for this experiment. Given that results identified Membrane Characteristic and % Solids in Coating #1 as the two most significant variables, the team generated contour plots in the following format:

Primary Axes:	Membrane Characteristic, % Solids
Off Axes:	% Solvent, Drying Conditions for Coating #1, Drying Conditions for subsequent coatings.

Design Analysis Approach

The team followed a four step approach in analyzing data from Designed Experiment #2, as shown below:

Step 1: Generate contour plots in the format described above for each case across all four response variables.

Step 2: Identify a "design window" for each variable: Determine a range of Membrane Characteristic and % Solids which yielded "acceptable" response levels for each response variable.

(Table 3.4 lists "internal specifications" for each response variable which were used to identify design windows.)

Step 3: Within one coating protocol, identify any overlap in design windows across all response variables. (Theoretically, this range of Membrane Characteristic and % Solids would yield acceptable levels across all response variables.)

Step 4: Select the coating protocol corresponding to the largest design space as representative of the most robust process.
(See Figure A.1 for comparative design space of protocol A vs. B.)

Response	Internal Specification
Color	> 125 gray scale units.
Reaction Time	< R seconds
Hemolysis Time	> H seconds
Hemolysis Degree	< 25

Table 3.4 Criteria for Defining Design Window

Results of Designed Experiment #2
Highlights of the results of this experiment, and corresponding conclusions may be summarized as follows:

• E-Chip results indicated a Lack of Fit in all cases. (Lack of fit indicates discrepency between actual and predicted results given the chosen model.)

Conclusion: Lack of fit may be explained as due to any of the following scenarios:

1. The wrong model was chosen, i.e. a quadratic model can not accurately describe this system.
2. An insufficient number of experiments were run.
3. Certain relevant process variables were missing from the analysis.
4. An inability to control the process tightly enough and thus prevent large amounts of scatter in resulting data.

In any case, "lack of fit" results precluded this experiment from yielding optimal settings for process variables. For the purpose of this analysis, ranges of process variables were identified which yield acceptable responses. A third experiment, utilizing the pilot coater, will be run subsequent to the internship, to determine optimal settings. Consistent with the RSM approach, an alternate model to quadratic (partial cubic) will be utilized, in effort to better describe this system and to attempt to avoid lack of fit. It is unknown, at this time, whether the benefits of a more accurate model for this system would outweigh a suspected inability to control the process tightly enough. In other words, "lack of fit" results may repeat themselves in the third (optimization) experiment due to poor process control, despite the use of this alternate model.

Note that the implications of "lack of fit" for this experiment are not severe, in that the team could still learn much from the results. The "lack of fit" results may be viewed as an inability to optimize the hand-coated process, which is not capable of manufacturing fully functional product. In attempting to optimize the pilot coating process, which is capable of making fully functional product, avoiding a lack of fit result is more critical. (i.e. At this stage of the experimental path, we are more interested in confirming trends and defining general ranges of process variables. We're not making fully functional product, therefore we are not yet ready to optimize)

• The team confirmed the existence of the trade-offs between variables and responses that were identified in Experiment #1, and identified additional trade-offs as well. Such trade-offs include:

Reaction time favors the 50 % solids.
Color, Hemolysis Time, Hemolysis Degree all favor 70 % solids.

Reaction time favors a membrane characteristic of 2500
Color, Hemolysis Time, Hemolysis Degree all favor a membrane characteristic of 1500.

Reaction time favors a Drying condition level of "25" for Coating #1.
Hemolysis time favors a Drying Condition of "5" for Coating #1.

Conclusion: Competing Responses are present in this system.

• Although these trade-offs exist, there do appear to be ranges for membrane characteristic and % solids which yield acceptable response levels across all responses.

Conclusion: Design windows are present. It is important to next relate the existence of these design window to process robustness. In other words, is the process capable of consistently satisfying the criteria as described by design windows, given naturally occurring variability, etc.? Section 3.9 will specifically consider the Design Window in terms of process robustness.

• The majority of significant responses identified by this experiment were interactions. (See Figure A.2, describing response type by significance.)

Conclusion: Experimental design is an essential tool for identifying and quantifying interactions present in this system. The "one at a time manipulation of process variables" previously employed by the team is an unacceptable scientific approach for this system.

• Coating Protocol B, including Chemical Y in subsequent coatings, yields the largest design window. (See Figure A.1, comparing design windows for coating protocols A and B)

Conclusion: Including Chemical Y in subsequent coatings rather than in coating #1 results in a more robust process.

• The 70 % Solids level is preferable across all responses.

Conclusion: In the next experiment, the range of % Solids should be built around 70%.

• For Membrane Characteristic, a tighter range surrounding the 2000 level is preferable across all responses, but testing was done with one hematocrit level only.

"Hematocrit" is a measure of the concentration of red blood cells in a sample of blood. Typical blood hematocrit levels range from 35 to 55. All testing to date has been with average hematocrit level: 45. The team's experience to date has shown that hematocrit level can influence the performance of the strip; i.e. a 35 hematocrit blood and a 55 hematocrit blood with the same level of glucose can yield a different response from the strip. (The difference in response is most likely due to a difference in flow characteristics of blood with varying concentrations of red blood cells.) This phenomena is referred to as "hematocrit effect". Note that Designed Experiment #2 used one hematocrit level only when testing. The team chose to optimize the hand-coating process around the nominal level, 45, as a first step. The pilot coater optimization experiment, Designed Experiment #3, will be evaluated with three different Hematocrit levels.

Conclusion:
The team's experience to date has shown that a very low membrane characteristic, (below the range explored in this experiment, i.e., below 1500), seems to minimize hematocrit effect. Therefore, membrane with this very low characteristic, (1000), will be included in the next experiment. In order to study hematocrit effect, blood hematocrit level will be added as a process variable.

3.7 Pilot Coater Protocol Testing

Upon arrival of the Pilot Coater, the team initiated protocol testing. The process conditions for this protocol testing were derived as indicated in Table 3.5.

Process Condition	Derived From
1 A high level for Drying Conditions	Experiment #1
2 Coating Parameter X, Level 2	Experiment #1
3 Chemical Y in subsequent coatings.	Experiment #2
4 70% Solids concentration in Coating #1	Experiment #2
5 Laminating Membrane to Polyester after coating #1	Ability to more closely simulate product process than hand coating allowed.
6 Membrane with very low membrane characteristic . (1000)	Ability to test hematocrit effect, since end product is now fully functional.

Table 3.5 Pilot Coater Protocol Testing Process Conditions

Results of Protocol Testing

Protocol testing yielded strips that were highly consistent in performance, as measured by color, reaction rate, hemolysis time and hemolysis degree. Strips had excellent color, reacted in the required time, and exhibited zero hemolysis within an acceptable time frame. With the exception of hematocrit effect, (which, at this point, remained an unknown), these strips come very close to satisfying final product requirements.

The team repeated protocol testing one week later. Resulting strips performed identically.

3.8 Next Step: Designed Experiment #3:
Pilot Coater Optimization Experiment.

Although protocol testing yielded consistent strips, with functionality approaching final product requirements, the team agreed that it was important to identify whether a design window did indeed exist which would yield fully functional product. (Note that the Design Window identified by Experiment #2 did not yield fully functional product, since the hand-coating process was employed.) The team also agreed that hematocrit effect must be considered when defining this design window. The team therefore planned a Pilot Coater Optimization Designed Experiment to address these issues. Inputs and Outputs of this experiment are shown in Figure 3.3.

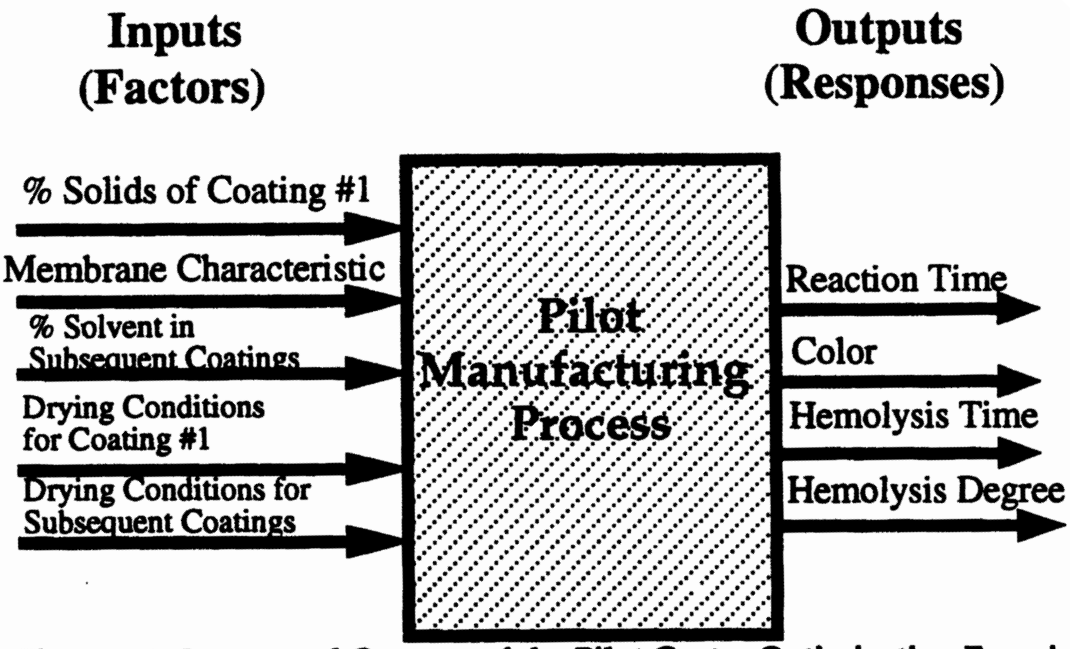

Figure 3.3 Inputs and Outputs of the Pilot Coater Optimization Experiment

The team actually initiated the Pilot Coater Optimization experiment subsequent to the internship period. "Post-internship", team resources were dedicated to completing this experiment, and analyzing the results, which will not be included in the thesis.

Overall, the trends which the team identified by the Pilot Process Development effort were consistent with those trends observed by those Quicksilver team members who were working with the production process. It is likely, therefore, that the design window ultimately identified by the Pilot Coater Optimization Experiment will be translate into process conditions that are applicable for the production process.

Section 3.9
Beyond Designed Experiments:
Cpk as a Tool to Analyze Robustness of the Process

Figure A.1 illustrates particular results of Designed Experiment #2. Specifically, the design window for Coating Protocol B shows that a Membrane Characteristic range of approximately 1500 to 2000 yields satisfactory results across all responses. These results suggest that LifeScan only incorporate membrane satisfying this criteria into the manufacturing process. Such a recommendation next raises the question of whether this Membrane Characteristic may be controlled tightly enough to satisfy this requirement. Or, alternatively, the question arises as to whether or not LifeScan's manufacturing process for this new diagnostic product is too sensitive to variability that naturally occurs in the Membrane Characteristic.

Cpk is a statistical tool by which assess process capability. Specifically, "the Cpk index was designed to compare the variability of some quality characteristic (Membrane Characteristic), based upon the lower specification limit, (LSL) and the upper specification limit (USL) while assuming the average membrane characteristic (X) is equal to the desired target value."[12] The concept behind the Cpk calculation is that process variability must be small relative to the acceptable range limits.
The formula for Cpk is shown below:

$$\text{Cpk} = \text{minimum of } \frac{(\text{USL}-\bar{x})}{3\,(\text{std dev})} \text{ or } \frac{(\bar{x}-\text{LSL})}{3\,(\text{std dev})}$$

Interpretation of Cpk
"According to acceptable standards in industry, Cpk values of less than 1.00 are unacceptable, values between 1.0 and 1.33 are marginally acceptable, and values greater than 1.33 are desired." (A higher Cpk value indicates a higher level of process robustness.) "Today, many quality oriented companies such

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12 Box, George E.P, William G. Hunter and Jay Stuart Hunter, Statistics for Experimenters ,New York: Wiley & Sons, 1978

as Ford Motor Company and Motorola are now requiring Cpk values greater than 2.0."[13]

Cpk for Membrane Characteristic

Using the range of acceptable "Membrane Characteristic" as determined by the second Designed Experiment, (1500-2000), and calculations for mean and standard deviation based on data from multiple lots of Membrane, the resulting Cpk was determined to be .87. This low Cpk value strongly suggests that the manufacturing process is not robust enough to handle the variation in Membrane Characteristic that can be expected to naturally occur.

Note that the third Designed Experiment will expand the low side of the range of Membrane Characteristic X down to 1000, due to the ability to now study hematocrit effect (see section 3.6). Should the entire expanded range , (1000-2000), yield acceptable results across all responses, the Cpk would increase to 1.4, a "marginally acceptable value".

Implications for LifeScan

At this time, it is unknown whether Designed Experiment #3 will result in an expanded range of Membrane Characteristic X, which would lead to increasing the Cpk to a "marginal accept level". **LifeScan must be sensitive to the fact that a Cpk value below 1.33 strongly suggests that their manufacturing process may not be robust enough to be profitable.** LifeScan must therefore consider techniques to increase process robustness. Such techniques include:

- investing in improving the membrane manufacturing process at the supplier in an effort to decrease naturally occurring variation of Membrane Characteristic .
- experimenting with the impact of a product design change on robustness of the process. (Would an alternate, simpler yet still functional, product design

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[13] Box, George E.P, William G. Hunter and Jay Stuart Hunter, Statistics for Experimenters ,New York: Wiley & Sons, 1978

result in an expanded range of Membrane Characteristic which would satisfy product requirements?)

• relaxing the product specifications to a certain degree, which will not be objectionable to the customer. (Increasing acceptable reaction time, decreasing acceptable color, etc.) In so doing, the range of Membrane Characteristic satisfying these new product requirements would be expanded, leading to an increased Cpk.

The three options listed above represent trade-offs in cost and product performance. Nevertheless, proceeding with a manufacturing process which is too sensitive (not robust enough) to naturally occurring variability in this Membrane Characteristic is likely to result in extremely low yield rates, and therefore, increased costs to LifeScan.

Chapter 4

4.1 The Manufacturing Decision Category Approach

The Manufacturing Decision Category Approach[14] is a technique to assess the consistency of a company's strategic vision with its actual policies. This approach assumes that consistency of policies and strategic mission is essential to carry that mission forward. Inconsistencies render a strategic mission a "surface mission" only, without the structure and/or infrastructure to support it and make it happen. The technique is based on a "four level fit" of policy and strategy. Specifically, the analysis focusses on the four levels of corporation, business, function and finally category.

This approach reviews a broad range of policies, by focusing on each of nine "decision categories" listed in table 4.1. Any inconsistencies that are identified between strategic mission and policy are then tracked to a specific category, highlighted, and hopefully targeted for modification.

Manufacturing Decision Categories

1. Facilities	5. Work Force Management
2. Capacity, Distribution	6. Logistics Planning and Materials
3. Vertical Integration	7. Organization and Incentives
4. Production Technologies and Processes	8. Product Development
	9. Quality Programs

Table 4.1: The Nine Manufacturing Decision Categories

[14] Rosenfield, Donald B., Notes from 15.761, Operations Management, Strategy Section, MIT Sloan School of Management, December 1992.

Section 4.2 of this chapter emphasizes LifeScan's strategic mission. Section 4.3 then reviews LifeScan's policy for each of the nine decision categories. Inconsistencies between specific policies and the company's strategic mission for product innovation are identified in Section 4.4. The three Manufacturing Decision Categories highlighted as having the most impact on LifeScan's strategic mission will be explored further in chapter five.

4.2 LifeScan's Strategic Mission: Past and Present

The 1993 Strategic Plan states LifeScan's strategic vision as follows: "LifeScan will acquire, develop, manufacture and market products world-wide to improve the quality of life for people with diabetes." As its competitive environment changes, LifeScan can no longer remain market leader as a one product company. LifeScan can no longer differentiate itself through current product technology. Product Innovation is recognized as key toward maintaining market leadership. In this sense, LifeScan's strategic mission may be interpreted as one of **Product Innovation, or New Product Development.**

A strategy of Product Innovation is not entirely new to LifeScan. Innovation in the form One Touch, the industry's first meter readable product that required no wiping, washing, blotting or timing by the user, launched LifeScan to the market leadership position it now enjoys. This product represented a significant technological advance in home blood glucose monitoring. LifeScan furthered the One Touch Innovation in 1991, with the introduction of One Touch II. This more advanced version of the meter clinched LifeScan's technological superiority in the market, bringing them to a market leadership position that same year.

Post 1991, a lack of new product introduction suggests that LifeScan's market leadership position perhaps led to a feeling of decreased urgency for product innovation. This is a classic trap for a market leader; the competitive environment changes, its former technological product advantages have been matched by competitors, sometimes at a lower price. The need for product innovation surfaces as critical toward retaining market leadership. This description applies to LifeScan. In 1994, with competition beginning to erode

its market share, LifeScan is compelled to once again differentiate itself through innovative new products.

4.3 LifeScan's Policy for each Manufacturing Decision Categories

1. Facilities

While LifeScan "facilities" exist in Milpitas, Puerto Rico, Canada and throughout Europe, Manufacturing is split between Milpitas (primarily coating, limited converting and packaging) and Puerto Rico (converting). Further, LifeScan Milpitas is the sole manufacturing facility for the company's primary product: One Touch Test Strips (Puerto Rico manufactures a sub-assembly only.)

LifeScan in part recognizes that an alternate manufacturing site to Milpitas is necessary as contingency to insure non-interruption of test strip production. While LifeScan is willing to consider leasing, not purchasing, off-site facilities to increase space, (an ongoing surveillance effort is in place to scout buildings available for lease in the Milpitas area which satisfy manufacturing requirements) the issue of contingency planning remains largely unaddressed.

2. Capacity and Distribution

Capacity:

Capacity currently leads demand, but "as LifeScan concentrates on growing its European Market, demands on LifeScan U.S. for manufacturing capacity will continue to escalate."[15].

LifeScan has a zero-backorder strategy for capacity, and utilizes a back-order metric to track performance. In order to counteract poor forecasting and cyclical demand, production generally builds in a 30-40% buffer.

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15 LifeScan Strategic Plan, 1993

LifeScan's Puerto Rico site has space available for expansion of current manufacturing. However, issues regarding work force skill level and environmental concerns, (high external humidity levels with limited humidity control, and a humidity sensitive product) have, to date, precluded this option.

Distribution:

LifeScan's world-wide distribution occurs primarily through its Milpitas warehouse. LifeScan ships U.S. products to wholesalers who then ship to retail locations. European distribution is accomplished by shipping products from Milpitas to LifeScan Distributors throughout Europe.
LifeScan's Customer Service Department's *eastern* U.S. shipments of warranty products presents an exception to the Milpitas warehouse distribution system. A Customer service Warranty Parts Bank is handled by Federal Express in Memphis.

LifeScan is currently considering the establishment of an east coast distribution site. Possibilities include converting an underutilized eastern J&J company, or, as does customer service, utilizing a Federal Express parts bank in Memphis.

3. Vertical Integration

LifeScan has a low degree of vertical integration; almost all components are outsourced. LifeScan's policy is to maintain this low level, or to decrease it further through establishment of supplier partnerships.

4. Production Technologies and Processes

The manufacturing process for LifeScan's primary product is robust enough such that a "satisfactory" manufacturing process (i.e. one that results in a fairly high yield of functional, consistent product) can be achieved by a low level of technology. To date, no attempt has been made to upgrade this technology.

LifeScan realizes that investment in production technologies and processes is required for new product development.[16]

5. Work Force and Management

LifeScan's wage policy is to pay competitively with the medical diagnostic, and other high tech industries. The pay plan is undergoing a transition from pay for performance to pay for skill in certain areas.

LifeScan recognizes a deficiency in the number of technical employees. An increased amount of University recruiting is planned to raise the number of technical hires. LifeScan also utilizes professional recruiters to scout specific technical talent.

A significant percentage of LifeScan employees are temporary. A high level of job security exists for regular employees. (In order to reduce headcount, the number of temps can be reduced in lieu of lay-offs.)

The current organizational structure is fairly hierarchical. Approximately six levels exist for engineers/scientists and management tracks.

6. Logistics Planning and Materials

Inventory Policies

LifeScan utilizes a safety stock policy for its primary product, the One Touch Test Strip. If LifeScan ever runs below safety stock, LifeScan holds its meter shipments. LifeScan's policy is to forego growth of new customers for satisfying the demand of strips for current customers. Approximately three months of inventory exists in the distribution channel.

A separate inventory exists exclusively for customer service, (in a Federal Express Parts bank in Memphis for eastern U.S., and in Milpitas for western U.S.).

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[16] LifeScan Strategic Plan, 1993

Vendor Relations/Vendor Development

LifeScan places high emphasis on establishing supplier partnerships. Potential vulnerability from a single sourcing policy is viewed as less important than establishing true supplier partnership. LifeScan's preferred strategy is to build relationships with suppliers that will lead to their investment in duplicate manufacturing lines dedicated to LifeScan. LifeScan also lessens potential vulnerability by identifying alternate suppliers for single-source materials in advance.

In 1990, LifeScan implemented a Supplier Quality Assurance Program. A Supplier Certification Program is in place to move suppliers up a scale of process control/quality, to the point where certified materials are inspected at the supplier only, and are received by LifeScan directly onto the factory floor. A "Supplier Recognition Day" occurs annually, to formally recognize suppliers' contribution to LifeScan's business.

7. Organization and Incentives

Structure, Degree of Centralization

LifeScan is primarily functionally organized, and highly centralized. Recognizing that new product development can best be accomplished by cross-functional teams, LifeScan formed it first team, Quicksilver, in mid 1991. This team crossed a hierarchy of levels and functions. Although members are 100% dedicated, they technically retain formal reporting relationships to functional managers, and report indirectly to the team leader. LifeScan has formed one additional autonomous cross-functional team modeled after Quicksilver. When the development activity ends for these teams, it is possible that management will fold members back into functional departments.

Reward System

LifeScan's current incentive system is pay for performance. A bonus program exists for hourly, salaried and management employees. LifeScan recognizes that it's incentive system "must change to reward risk taking; and that

execution should not necessarily be rewarded without consideration of risk."[17] As mentioned previously, a pay for skill pay plan is in the process of being implemented.

Costing Systems:
LifeScan is capable of tracking costs within a particular department only. No *project* accounting system exists. Product development teams cannot track costing. All projects are lumped together under any given functional support group; costs cannot be effectively broken out by project. An initial attempt to implement Activity Based Costing (ABC) was unsuccessful. (The current incentive system led centralized, functional resources to overstate the number of hours spent supporting product development teams.) LifeScan continues to explore how to successfully implement ABC accounting.

8. Product Development

New product development at LifeScan occurs through one of three organizational structures: The functional R&D department, a cross-functional product development team with part-time dedicated members, or an autonomous, fully dedicated cross functional team. Only two such autonomous teams exist at LifeScan. **Primarily, product development remains a functional activity.**

The Quicksilver product development team contains 100% dedicated resources from R&D, Operations, Marketing, and Quality Assurance. Team members report directly to functional managers, and indirectly to the team leader. Members are classified as core team members, and non-core team members. Core members, the most senior representative of each function, are evaluated based on their own performance *and* team performance. Non-core members are evaluated based on their own performance only.

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[17] LifeScan Strategic Plan, 1993

While on the team, the responsibilities of team members are tailored to skills rather than strict function from where they came. Functional responsibilities are intentionally blurred.

Core team members are responsible for assessing technical challenges and establishing schedule accordingly. Core team members are responsible for the ultimate release of the product.

9. Quality Programs

LifeScan has implemented a Quality Improvement Program (QIP). QIP training of all employees is mandatory, and Quality Improvement Teams exist throughout the company. LifeScan's Quality Improvement Program includes an extensive internal course offering.

4.3 Inconsistencies between LifeScan Policies and a Strategic Mission of Product Innovation

Table 4.2 reviews LifeScan's policy for the manufacturing decision categories for consistency with a Product Innovation strategy. This table classifies categories as either inconsistent or consistent with LifeScan's strategic mission.

Manufacturing Decision Category	Consistency with Strategic Mission	
	Yes/No	Explanation
1 Facilities	No (in part)	"Stated" strategy to expand is consistent with supporting new product lines, however, no action to date.
2 Capacity	No	No clear strategy for expansion, unclear if current capacity can support new product lines.
3 Vertical Integration	Yes	Low degree of vertical integration provides manufacturing flexibility required for new product development.
4 Production Technologies and Processes	No	Low level of technology is inconsistent with strategy for product innovation
5 Workforce	No (in part)	Workforce is fairly hierarchical. Several layers of Engineering, Scientists and Management is not conducive to new product development.
6 Logistics Planning and Materials	Yes	Inventory Policy seems capable of supporting new product lines. Emphasis on Supplier Partnerships consistent with supporting new product development.
Distribution	Yes	Plans for East Coast Distributor consistent with supporting new product lines. However, these plans currently on hold.
7 Organization and Incentives	No	Organization remains, in large part, functional and highly centralized. This structure is not conducive to new product development. Pay plan does not reward risk taking or team-work.
8 Product Development	No (in part)	Product development remains primarily a functional activity.
9 Quality Programs	N/A	Quality Improvement Program at LifeScan does not specifically address new product development.

Table 4.2: Consistency of Manufacturing Decision Category Policies

4.4 Conclusion: Categories to Target

The decision category of Production Technologies and Processes seems to be in greatest conflict with LifeScan's strategic mission. Because Manufacturing Decision Categories represent both structure and infrastructural policies, certain decision categories are linked. Targeting inconsistencies in a structural category may not be effective if inconsistencies in a related infrastructural category are allowed to continue. For example, the category of Production Technologies and Processes requires an infrastructure as described by the categories of Workforce, Organization and Incentives, and Product Development. Inconsistencies in these areas must therefore be targeted as well.

Chapter 5

5.1 Structural and Infrastructural Inconsistencies

A Structural Inconsistency at LifeScan:
Production Technologies and Processes.

For the past three years, LifeScan has led the U.S. market in home blood glucose monitoring with One Touch. When LifeScan first introduced One Touch in 1987, the product represented a major innovation in home blood glucose monitoring. LifeScan clinched market leadership with the introduction of One Touch II in 1991, furthering its original innovation and its technological advantage over competitors. From 1991 to the current time, LifeScan has introduced two significant variations of One Touch technology. However, during this period, LifeScan has not introduced a product constituting a new technology platform. The image of "LifeScan as an innovator" began to slow with the 1991 introduction of One Touch II. Since this time, LifeScan's competitive environment has changed dramatically:

- Competitors are closing the gap on One Touch product technology. Diversification, within, and outside of the Home Blood Glucose Monitoring Industry, is recognized as key toward maintaining market leadership. LifeScan recognizes that investment in production technologies and processes is critical for new product development.

- The recent market entrance of off-brand strips, a low cost alternative to LifeScan's current test strips, requires that LifeScan invest in production technologies and processes to increase efficiency and lower costs.

A major structural inconsistency exists relative to LifeScan's current policy for production technologies and processes and its strategic mission of new product development. Namely, LifeScan's lack of investment in new technologies seems entirely inconsistent with the company's critical need to rapidly develop and introduce new products.

Infrastructural Inconsistencies at LifeScan:
Workforce, Organization and Incentives, and Product Development.

Inconsistencies between current policies and strategic mission also exist in the infrastructural categories of Workforce, Organization and Incentives, and Product Development. A strategic mission of product innovation demands an organizational support structure. Clark and Wheelwright strongly suggest that autonomous, cross functional work teams are most conducive to new product development[18]. If managed successfully, such a team structure eliminates the frustration, delays, political and beaurocratic issues associated with product development across strong functional boundaries and several hierarchical levels. Theoretically, an autonomous team promotes communication between functions, and intentionally blurs functional responsibilities. Team members grow beyond their traditional functional responsibilities, and take ownership for the product development process. An appropriate incentive system would reward skills required by an effective team member, such as team work, risk-taking, and accountability. A costing system would aid in promoting accountability, by accurately tracking project costs across functions.

A Manufacturing Decision Category analysis of current policies reveals that LifeScan's organization is primarily functional, highly centralized, and fairly hierarchical (6 levels of engineering and management). While two autonomous, cross-functional, new product development teams exist, Product Development remains primarily a functional activity. LifeScan's current incentive system does not reward risk-taking or team-work, nor does it promote accountability. Finally, LifeScan's current costing system is incapable of tracking total project costs, across functions.

If LifeScan is serious about its strategic mission for product innovation, changes to each of these policies , structural and infrastructural, are required.

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[18] Wheelwright, Steven C. and Kim B. Clark, Managing New Product and Process Development, New York: The Free Press 1993.

5.2 The Quicksilver Development Effort: An Example of Structural and Infrastructural Inconsistencies

Quicksilver is one of two autonomous, cross functional new product development teams at LifeScan. The Quicksilver development experience may be used to highlight how certain infrastructural and structural inconsistencies can delay new product development; i.e. can prevent LifeScan from achieving its strategic mission of product innovation.

The QuickSilver Development Effort: Evidence of a Structural Inconsistency

The Quicksilver product is functionally more complex than LifeScan's current product, One Touch. The manufacturing process demands a significantly higher level of process technology. LifeScan's lack of investment in this process technology forced Quicksilver to start from scratch. This *process* development effort occurred during the critical path of *product* development, and slowed the development effort significantly. As Clark and Wheelwright point out: "It is almost impossible to work out the basic research involved in a new manufacturing process while a product development project is trying to meet a preset time schedule, performance specs and resource utilization goals."[19]

The QuickSilver Development Effort: Evidence of Infrastructural Inconsistencies

Team Structure

Although Quicksilver is LifeScan's first autonomous, cross-functional development team, a support structure *seemingly* consistent with strategic mission, there are factors related to the team structure which are inconsistent

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[19] Wheelwright, Steven C. and Kim B. Clark, Managing New Product and Process Development, New York: The Free Press 1993.

with a strategic mission of Product Innovation. Such factors are likely to have contributed to a delay in product introduction.

For example, the team employs a "light weight management structure".[20] With this structure, team members report indirectly to the team leader, and directly to functional managers. At times, conflicting objectives between functional managers and the team leader render the team more of a "collection of juxtaposed functions" than a true team. The light-weight management structure demands much external lobbying on the part of the team leader, to assure that functional managers share the team's vision.

Furthermore, given that Quicksilver is LifeScan's first autonomous project team, external focus is also required by the team leader to assure management that a break from an historically functional organization is indeed supporting LifeScan's mission of Product Innovation.

The time the team leader must spend as "external obstacle remover" may detract from time required to remove "internal obstacles", (such as distinct functional barriers between engineers and scientists). Such an external focus may also detract from a required internal *operational* focus: such as time required to pull together the team's technical efforts, and to enforce a system of accountability for technical assignments.

Incentive System and Costing System

Although the team leader does have significant influence in the review process, (especially of core team members), LifeScan's incentive system remains geared toward a functional organization of individual contributors. Finally, as a cross functional team, the absence of a costing system has prevented Quicksilver from accurately tracking project costs. As product introduction continues to be delayed, and costs continue to accrue, management's need to understand Quicksilver's development costs grows.

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[20] Wheelwright, Steven C. and Kim B. Clark, Managing New Product and Process Development, New York: The Free Press 1993.

Implications of this inconsistency extend to other project development teams at LifeScan, attempting to learn from Quicksilver's experience.

Summary of Manufacturing Decision Category Analysis

In summary, the Quicksilver experience evidences both structural and infrastructural inconsistencies with LifeScan's strategic mission of Product Innovation. The structural inconsistency is evidenced by a lack of prior investment in coating technology. The infrastructural inconsistencies were evidenced by team structure, incentive system and costing system. While the Quicksilver team does represent a change to LifeScan's organizational policies that is "more consistent" with mission, a truly autonomous team, with members reporting directly to team leader, may enable the internal focus required for a product development effort to advance. In addition, a strategic mission of new product development demands an incentive system consistent with this team structure, as well as a method which will allow the team to accurately track project costs.

5.3 A Process Technology Strategy

A process Technology strategy guides the firm in acquiring, developing and applying technology for competitive advantage. It is a critical element of a firm's development strategy.

A process technology strategy is based on the premise that "when (process technology) invention is included in a development project, it invariably causes delay, backtracking, and disappointment. However, when done in advance, so that its results are available for application, new technology development may contribute significantly to project success."[21] Basically, a process technology strategy separates invention from application, by taking process technology development off the critical path of product development.

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[21] Wheelwright, Steven C. and Kim B. Clark, Managing New Product and Process Development, New York: The Free Press 1993.

This thesis proposes that a process technology strategy will allow LifeScan to directly address those structural and infrastructural inconsistencies between current policies and a strategic mission of product innovation. Specifically, a Process Technology Strategy will focus LifeScan on policy changes required in the categories of Production Technologies and Processes, Organization, and Product Development.

There are three components to a firm's process technology strategy:

1. Focus

define those technologies where the firm seeks to achieve mastery or superiority relative to competitors.

2. Sourcing

Should technology be sourced externally, or developed internally to the firm?

3. Implementation

A. Which individual or function is responsible for finding the technology, and bringing it inside the firm?

B. Which individual or function is responsible for implementing the technology inside of the firm?

Table B.1 describes the numerous choices available to a firm in a process technology strategy. Choices are classified as "Finders of technology" (Individual or function responsible for finding the technology, and bringing it inside the firm) ", External Sources of Technology", and "Method of Incorporating Technology". The following section, which describes elements of process technology strategies at other companies, highlights several of these choices.

5.4 Elements of Process Technology Strategies at Other Companies

Hewlett Packard

Hewlett Packard's development strategy is described in Figure B.1[22]. Hewlett Packard allows business and functional strategies to drive "promising technological opportunities." Advanced development projects are then initiated around those technologies. A bank of proven technologies ("pizza bins of proven technologies") is established, from which product development teams may draw. In this manner, Hewlett Packard successfully separates invention from application, and pulls process technology development off of the critical path of product development.

Hewlett Packard's relatively short product development cycles and the efficiency of its product development process serve as a model in the industry.[23] A significant part of Hewlett Packard's success no doubt revolves around the company's emphasis on a process development strategy.

Baxter Scientific

Baxter's strategic mission is "product innovation primarily through external development"[24] To achieve that mission, Baxter has established a "technology scout" function. The technology scout's role consists of identifying external technologies consistent with Baxter's strategic initiatives, and subsequently selling those technologies internally. The Scout categorizes technologies by a "pyramid of needs". The top of the pyramid consists of technologies with the highest probability of adoption, in that they directly

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22 Wheelwright, Steven C. and Kim B. Clark, Managing New Product and Process Development, New York: The Free Press 1993, 95.
23 Ibid, 102.
24 Wolff, Michael F., "Scouting for Technology", Research-Technology Management, Jan-Feb 1992, Vol 35, #1.

address current project development needs at Baxter. The middle of the pyramid consists of alternative technologies or extensions of closely matched technologies. Finally, technologies at the bottom of the pyramid bear some relevance to Baxter's business, however no direct fit is apparent. As the technology scout points out, the "sell job" becomes more difficult when moving down the layers of the pyramid. The scout cautions, however, that although risk of investment increases when moving from the top to the bottom of the pyramid, technologies in the bottom level may provide companies with a quantum leap in technology required to maintain market leadership.

Financial Data (available through 1991)[25] suggests that this process technology strategy has allowed Baxter to remain competitive (i.e. meet the industry average financial performance) in the medical diagnostic industry.[26]

Westinghouse

A Corporate Science and Technology Center at Westinghouse is a centralized function servicing all business units with process technology development. The Center shares the experience of Baxter's scout, however, in that selling an investment in process technology to risk-averse business units is at times difficult. With a product obsolescence rate of 50% over a five year period, Westinghouse was aware that investment in new technologies is critical toward maintaining competitiveness. Westinghouse realized, therefore, that it must directly address the business units' reluctance to invest.

Westinghouse established a "Business Unit Alliance Program"[27], to encourage investment in new process technologies by dividing financial risk between the Corporate Science and Technology Center and the business unit. The alliance program featured a "revolving loan fund", whereby the Center

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25 Annual Report, Form 10K, Baxter Scientific 1991

26 Industry Norms and Key Business Ratios, Dun & Bradstreet Credit Services, New York, 1992-3, Medical Diagnostics Industry, 74.

27 Barpal, Issac R., "Business-Driven Technology for a Technology-based Firm", Research-Technology Management, Mar-April 1992, Vol 30, #2.

would pay up to 75% of process technology development costs for up to two years, with the business unit funding the remaining 25%. If objectives of the project are met, the business unit repays 150% of the loan to the Center over a three year period. If objectives are not met, the business unit repays 50% of the loan over a two year period. Repaid loans are then used to fund the next process technology development project.

The program also features 100% dedicated "dual program managers", one from the business unit, and one from the center. The two program managers agree on objectives up front, and work together during an initial period of applying the new process technology to a product development effort.

Westinghouse's process technology strategy helps to remove the risk that typically hinders companies from investing in new technologies. The high product obsolescence rate faced by Westinghouse is clearly the driving force behind these investments; the company's survival is dependent on finding, investing in, and successfully applying new technologies. Aware of its competitive environment, and the implications of not investing in new technologies, Westinghouse depends on its process technology strategy to encourage investment, and thus to maintain its competitiveness.

Polaroid

Polaroid recently implemented a new process technology, automated presentation of small parts, into its camera manufacturing process. Over the course of finding and applying this technology, Polaroid's initial interest in automating camera manufacturing turned into a core competency of automated small parts presentation; a competency that has since been tapped by other industries on a consulting basis. In other words, Polaroid has achieved competitive advantage by mastering a particular process technology. Although Polaroid had no formal process technology strategy in place, several factors that contributed to their success do represent critical elements of such a strategy. These factors may be categorized as follows:

Pre-implementation Factors

• *CEO support:*

In the early 1980's, Polaroid's CEO expressed "we need to change the way we build cameras", and was willing to provide resources and investment capital required.

• *Ability to translate the investment in process technology into efficiency gains and thus dollars saved.*

• *Creating a philosophy emphasizing "process".*

The camera manufacturing manager asked his team to imagine Polaroid five years into the future. He expressed to team members that while he felt confident Polaroid would be in the hardware manufacturing business, they may not be manufacturing cameras. With this response, he asked employees to focus on process; to concentrate on being the best in the industry at "automated presentation of small parts". Focusing on process, this manager felt, would allow Polaroid the flexibility required to survive in a rapidly changing competitive environment.

• *Hiring an Automation expert, 100% dedicated, to manage the program*

• *Knowing what to ask for at a trade show; i.e. how to source technology successfully.*

In an effort to source process technology, the automation expert hired to manage the program attended a trade show. At the Sony Robotic booth, the manager ignored the robots on display, and asked to look "behind a curtain" leading to the presentation of small parts to the robot. It was the automated technology "behind the curtain" which was directly applicable to Polaroid's needs. The trade show attendee, therefore, was knowledgeable enough about the technology and Polaroid's needs, to successfully discover a source.

Factors During Implementation

• *Linking development and manufacturing engineers during the implementation process.*

Overlapping responsibility of the developers and the users of automation assured a smooth transition, leading to successful implementation and adoption of the process technology.

• *Designing the product for automation.*
Polaroid focused on process first, product second. The camera product utilizing this new process technology was designed for automation. The process was not retro-fitted into an existing product.

Post-implementation Factor
• *New process technology attracted engineering talent to the manufacturing site.*
Engineering talent attracted by cutting edge process technology was hired to successfully sustain and/or creatively improve upon the process technology and its application.

Vistakon

Vistakon recently implemented a new process technology, in the form of an automated pilot assembly line, into its contact lens manufacturing facility.[28] Vistakon is known throughout Johnson & Johnson for its strong emphasis on process technology, and the resulting benefits on product development. Vistakon's investment in this process technology has resulted in the development of a contact lens manufacturing process with efficiencies unmatched by industry competitors. In other words, investment in process technology has provided Vistakon with a clear competitive advantage. In many ways, Vistakon's experience has echoed that of Polaroid, as evidenced below:

Pre-implementation Factors
• *Management support*
• *Ability to quantify (estimate) efficiency gains, translating to a reduction in product cost, ahead of investment.*
• *Actual demonstration of efficiency gains, one piece of the process at a time*
Vistakon separated the overall manufacturing process into modules, and, through a lab bench approach, demonstrated to management the gains of one process module at a time. In this manner, Vistakon successfully fueled (i.e.

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[28] Vistakon Plant Tour and Meeting with LifeScan, November, 1993.

funded) investment in that piece of the process, and investigation into the next piece.

• *Dedicated team for Sourcing and Implementing Technology*

Vistakon provided the organizational structure required for successful implementation: Full time, members with backgrounds in the current manufacturing process and/or automation.

• *COSAT'S Involvement*

Vistakon utilized J&J's Corporate Office of Science and Technology to facilitate sourcing of Japanese automation equipment. COSAT's prior experience with Japanese technology sourcing saved Vistakon time associated with finding the source, and also helped to reduce cultural barriers.

Factors During Implementation

• *Self-directed work teams formed to implement technology*

Vistakon provided the organizational structure required to implement technology.

• *Linking development and manufacturing engineers during the implementation process.*

(Similar to Polaroid, to assure "smooth hand-off" of process technology.)

Summary of Companies Experiences with a Process Technology Strategy. Why is it important?

Hewlett Packard's process technology strategy contributes largely to reduced product development times. A process technology strategy has led Baxter and Westinghouse to find, invest in, and to successfully apply new technologies required to remain competitive in their respective industries. An analysis of Polaroid's and Vistakon's experience with sourcing, investing and applying new process technologies suggests that the development of a generic process technology strategy would increase the chances of these successful experiences repeating themselves, with alternate technologies and products. In other words, a process technology strategy could capture the critical elements that made these technology investments successful, and could serve as a model for future technology investments.

Each of these companies shares with LifeScan the need to rapidly develop and introduce new products; the need for technological innovation. These concrete experiences and their resulting positive impact on each company's competitiveness strongly suggest that LifeScan would benefit from a process technology strategy.

5.5 Recommended Process Technology Strategy for LifeScan

An outline of a process technology strategy for LifeScan is shown in Figure 5.1.

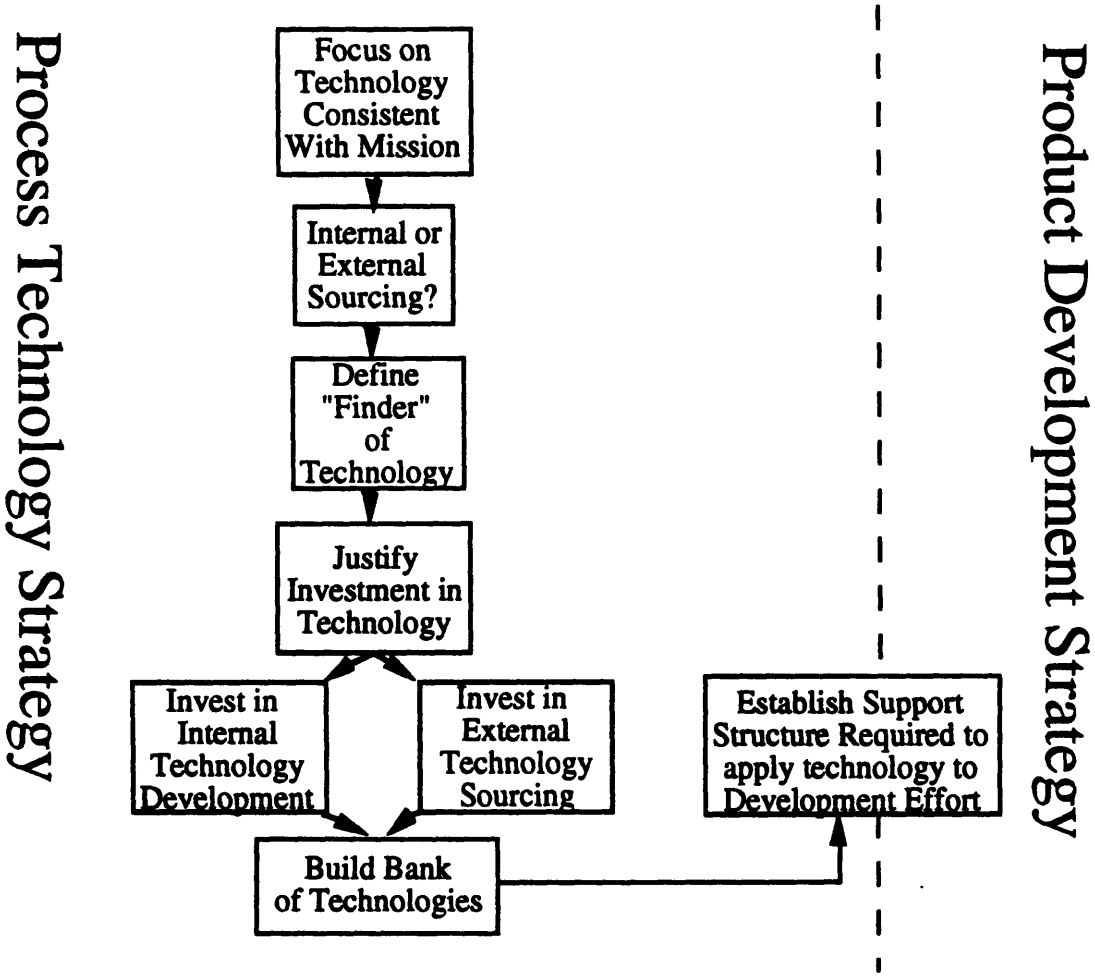

Figure 5.1: A Process Technology Strategy for LifeScan

This Process Technology strategy, as detailed below, is based on the Quicksilver product development experience.

I. Focus on Technology Consistent with Mission

The Quicksilver product development effort points toward coating/converting technology as the relevant process technology for LifeScan's investment.

II. Internal or External Sourcing?

Internal development of technology was the chosen direction for Quicksilver. This decision will be discussed further in Chapter 6.

III. Define Finder of Technology

Given the decision to source technology internally, significant resources are required for process technology development. An Advanced Process Function, consisting of a team of technology scouts, is recommended. This function would be staffed by members with extensive backgrounds in coating/converting technology, who remained well connected to the industry. The Advanced Process function would be responsible for connecting LifeScan to sources of the technology, bringing the technology in house, and developing/customizing it to the point where it could be used in future product development efforts.

IV. Justify Investment in Technology

Given that coating/converting technology is not as conducive to quantified benefits as is automation technology, a model of shared risk is recommended. Financial risk for the investment would be shared between the advanced process development function and the product development team.

V. Invest in Technology/Build Bank of Proven Technologies

Once feasibility is proven, this technology would then be "stored" in a bank of proven technologies. Future product development efforts would draw from this bank as required.

VI. Establish Support Structure Required to Apply Technology to Development Effort.

As discussed earlier, the preferred product development support structure is an autonomous team with 100% dedicated members reporting directly to the team leader. Integrating the technology scout with this team during the initial implementation phase would assure a smooth transition from process technology *invention* to *application* in the product development effort. Figure 5.1 illustrates that, at this particular step, the Process Technology Strategy becomes joined to the Product Development Strategy.

Chapter Six

6.1 Summary of Results of Thesis

In summary, the thesis utilized the product development experience of the Quicksilver team to focus on Process Development, and a Process Technology Strategy for LifeScan. In so doing, the thesis directly addressed each of four primary factors contributing to a delay in the Quicksilver product introduction:

1. Increased complexity of Quicksilver product vs. current product.
2. Influence of a new organizational structure on product development.
3. Premature advancement of the project from an R&D to a production phase.
4. Inability to leverage current product technology, One Touch technology, in the development effort.

The pilot process development project addressed factor 1, in that it allowed for better understanding of the complexities of the Quicksilver product. Contributions of this project are summarized in table 6.1.

Factor's 2, 3 and 4 were addressed by the Manufacturing Decision Category Approach as follows: Primary inconsistencies between LifeScan's current policies and its strategic mission of Product Innovation were found to occur in the infrastructural category of Organization and Incentives, and in the structural category of Production Technologies and Processes. The Production Technologies and Processes inconsistency was then rectified by proposing a process technology strategy for LifeScan.

Factor 2 was specifically addressed by reviewing LifeScan's current policies for organization, as well as organizational issues faced by the Quicksilver product development team.

Factors 3 and 4 were addressed by formulating a process technology strategy. A process technology strategy would allow process technology invention to

occur in advance of the development effort, to be stored in a process technology bank, and subsequently to be withdrawn and applied to a product development effort.

A major portion of Quicksilver's development time was spent on the invention of process technology. If done in advance, as dictated by a process technology strategy, the proven technology would have been called upon by the team, and applied directly to the development effort. Time saved by separating invention from application may have eliminated time pressure to advance the project prematurely from an R&D to a production phase. In addition, per a process technology strategy, a bank of proven technologies would provide LifeScan with several options for leveraging technology; and would not limit LifeScan to its ability (or inability) to leverage One Touch technology.

Contributions of the Pilot Process Development Project

• Suspected relationships between process variables and responses were confirmed.

• Trade-offs between variables and responses were identified.

• Suspected interactions between process variables were confirmed, the effect of which was shown to largely out-weigh the effect of single process variables.

• For the hand-coated process, a range of process variables, (a design window), was identified yielding acceptable levels across all response variables.

• Cpk calculations applied to this design window raised concern regarding lack of process robustness. Implications of LifeScan's proceeding with a non-robust process as well as suggestions for increasing process robustness were outlined.

• A bench top pilot coater was designed and built, providing the basis for pilot process development, (i.e., the ability to test several process variables in a controlled environment), and the potential to manufacture functional product in the lab.

• The Pilot Coater process was shown to be reproducible, and capable of manufacturing consistently performing strips, (as measured by color, reaction time, hemolysis time and hemolysis degree).

• Protocol testing on the Pilot Coater yielded strips that surpassed the performance of all previously manufactured strips, (as measured by color, reaction time, hemolysis time and hemolysis degree). This process was confirmed to be reproducible.

• Experimental results to date have led to designing a Pilot Coater Optimization Experiment, to identify the design window for functional, reproducible strips, to assure a satisfactory level of process robustness through Cpk calculations, and, if satisfactory, to transfer process conditions to the production process.

Table 6.1 Contributions of the Pilot Process Development Project

6.2 Recommendations for Future Product Development Efforts at LifeScan.

The focus on a process technology strategy at LifeScan in the context of the Quicksilver team's experience translates to specific recommendations for future product development efforts at LifeScan. Such recommendations may be categorized as technical recommendations, specifically derived from the Quicksilver technical development effort, and strategic recommendations, derived through applying the manufacturing decision category approach.

Technical Recommendations

• Continue to Utilize Designed Experiments and Cpk Calculations as Effective Tools for Process Development.

The Quicksilver product is technologically more complex than any product previously introduced by LifeScan. The existence of multiple interactions between process variables renders "one factor at a time" experimentation completely ineffective. Only through Designed Experiments can significant process variables be identified, and their individual and combined effects be measured and understood. Designed Experiments can lead to the identification of a design window, (a range of process variable settings that will yield acceptable response levels), as well as optimal settings for process variables. However, while Designed Experiments may lead to defining a range of process variables, an assessment of process robustness is a critical next step.

Cpk calculations provide a measurement of process capability, and thus process robustness. A Cpk calculation may be applied to the upper and lower specification limits, as determined by the Designed Experiment's resulting design window. The resulting Cpk value will provide a clear signal as to whether the manufacturing process is robust enough (Cpk>1.33) to be profitable. Very low Cpk values indicate that, despite the existence of a design window, naturally occurring variation in the properties of the process variable are likely to reduce yield to a point of significantly decreased, or possibly negative profits. An extremely low Cpk value suggests the process "can't get there from here"; i.e., investments of one type or another are

required to increase process robustness. Such investments may include working to reduce naturally occurring variation in a relevant process variable. Such reductions in variation are not always possible, or may be cost prohibitive. Alternative investments to increase process robustness therefore include changing end product design, (to a less stringent design), and/or relaxing product requirements.

In any case, Cpk is a diagnostic tool to assess process robustness, to alert a company that additional investments may be required to improve process robustness, in order to assure the development of a profitable manufacturing process.

Strategic Recommendations

- **Form Truly Autonomous Project Teams.**

To support a strategic mission of new product development, LifeScan should continue to break from a functional, highly centralized organization by continuing to form cross-functional product development teams. However, the "functional break" should be clean; i.e. the team should be truly autonomous with members reporting directly to the team leader. This structure will give the team its best chance to act as a team, not merely as juxtaposed functions. In addition, this structure would enable team members and the team leader to focus to the highest degree possible on the technical development task at hand.

- **Add an Advanced Process Function to Separate Process Invention from Application.**

LifeScan should support the addition of an Advanced Process function, or equivalent function, to connect itself with external process technologies, and/or to enable internal development of process technologies required for new product development. Members of this function would work to establish a bank of proven process technologies from which product development teams could draw.

• **Consider External Sourcing of Process Technologies.**

LifeScan should consider external sources of process development. While LifeScan promotes partnerships with external suppliers of product (raw materials), partnerships with external suppliers of process seem to be dismissed as not feasible. The chosen direction for Quicksilver was clearly one of internal process development. During the Quicksilver development effort, an external process supplier with expertise in printing, coating and converting was dismissed as a possible partner, primarily due to the proprietary nature of the product and a desire for LifeScan to retain complete ownership of process. This argument may be valid. However, assuming this external supplier's process expertise was directly applicable to Quicksilver's needs, the trade-off in deciding to develop technology internally is one of internal control and ownership of the process vs. time.

For future product development efforts, especially those where the timing of product introduction is critical, external sourcing of process technology should not necessarily be immediately dismissed. The trade-off between ownership of process and expediting the development time should be weighed; external sourcing of process technology should be viewed as potentially viable.

• **Invest in Process Technologies**

The issue of investment in process technology should be pushed with LifeScan management. Granted, return on investment in process technologies, especially those not involving automation, is difficult to quantify. A model of shared financial risk, between the Advanced Process Function and the product development team is preferable. However, a "non-quantifiable" justification to counteract a reluctance on management's part to invest in process technologies consists of two concepts:
A. Linkages. The linkage between process technology investment and new product development may be demonstrated by citing examples from other companies that have successfully achieved LifeScan's strategic mission of product innovation.

B. Alternatives. Without investment in new process technologies, LifeScan will remain a one-product company. Given a rapidly changing competitive environment, where LifeScan has lost differentiation by technological advantage, a lack of process technology investment will hand market leadership over to a competitor.

Further complicating LifeScan's competitive environment is the entrance of lower priced, off-brand strip manufacturers. This fuels the need for LifeScan to invest in process technologies for two reasons:
1. new process technologies will improve the efficiency of the current manufacturing process, leading to lower product costs.
2. new process technologies will lead to a broader product line, and will renew LifeScan's image as technological leader in the home blood glucose monitoring industry.

6.3 Conclusion

The Quicksilver development effort has provided many lessons transferable to future product development teams at LifeScan. The team's process development effort has shown that proper application of the right statistical tools can accelerate process development, and thus prevent unnecessary spending. While Taguchi Design is applicable when an up-front understanding of the process is available, Response Surface Methodology, which assumes little to know up-front process knowledge, is the more appropriate Experimental Design choice. Experimental Design, however, cannot stand alone as a process development tool. Any "design window" determined by designed experiments must be evaluated in terms of process robustness. Cpk analysis, is therefore a critical follow-up. Only when Cpk is large enough to render the design space valid is Experimental Design an effective process development tool.

On a broader level, the Quicksilver experience has demonstrated the need to integrate a process technology strategy with a product development strategy. The Quicksilver development effort has lasted three years thus far. This extended product development time is largely attributable to the fact that the invention of process technology was forced to occur during the critical path of

product development. With an intensifying competitive environment, LifeScan cannot afford a three+ year development cycle.

A process technology strategy, which promotes process invention in advance of application to a development effort, can fuel LifeScan with the bank of technologies needed for product innovation. By providing several examples, the thesis has shown that those companies who have focused on process technology and an associated strategy have benefited through shortened product development cycles, have remained competitive in their respective industry, and/or have attained competitive advantage purely from mastering a particular process technology.

In 1994, LifeScan's market leadership position holds, but this hold is by no means guaranteed to last. In fact, recent (within the last two years) market entrants have already gained significant market share (close to 10%) by presenting what appears to be equivalent product technology at a lower price. LifeScan's history teaches that innovation can lead to market leadership. LifeScan's competitors are also well aware of this fact. From LifeScan's perspective, investing in new process technologies is not without risk. However, the intensifying competitive environment dictates that the degree of risk of investing is far outweighed by the risk associated with not investing. In other words, a status quo product development strategy, which excludes a process technology strategy, is an invitation for competitors to innovate first, and to severely threaten LifeScan's market leadership position.

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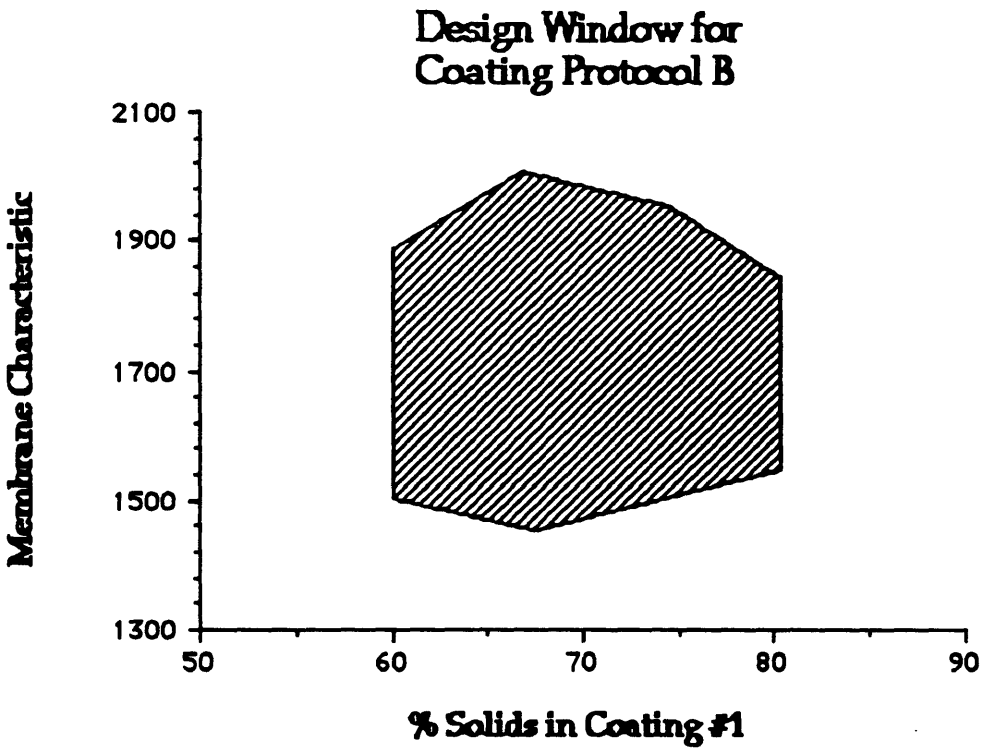
Appendix A

Additional Results: Pilot Process Development



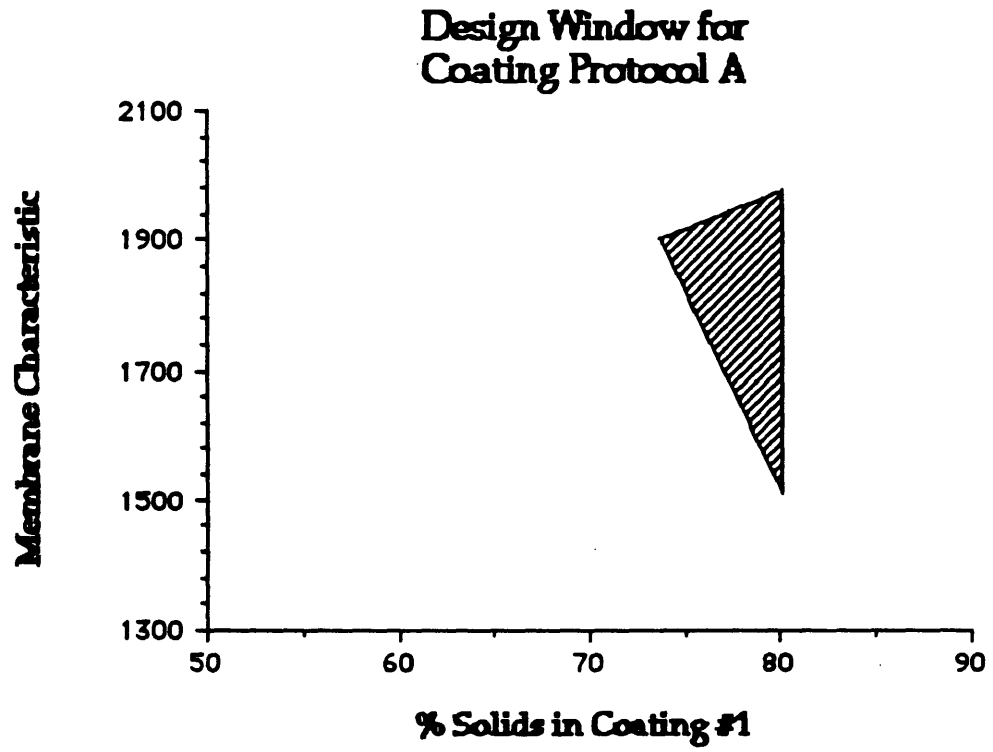


Figure A.1 Comparison of Design Windows Coating Protocol A vs. B

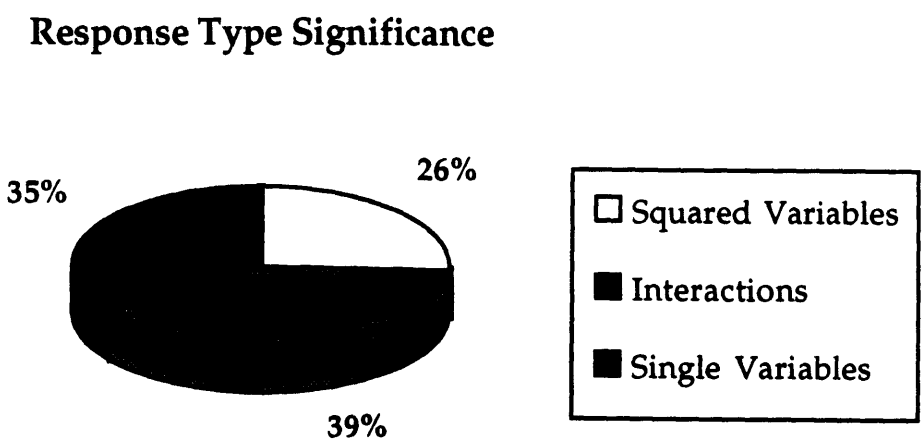


Figure A.2: Response Type Significance

Appendix B

Supporting Documents: Process Technology Strategy

Finders of Technology	External Sources of Technology	Method of Incorporating Technology
Technical Scout	University Research Labs	University Grants, Contracts
Advanced Process Function	Federal Labs	Joint Ventures
	Conferences	
R&D	Research Consortia	Partnerships
Centralized, Corporate Function	Supplier Labs	Pressure Suppliers to Innovate
Technical Specialist	Trade Shows	Persuade Customers to Share or Suggest Innovation.
Consultant		

Table B.1 Choices in a Process Technology Strategy

Development Strategy at Hewlett Packard

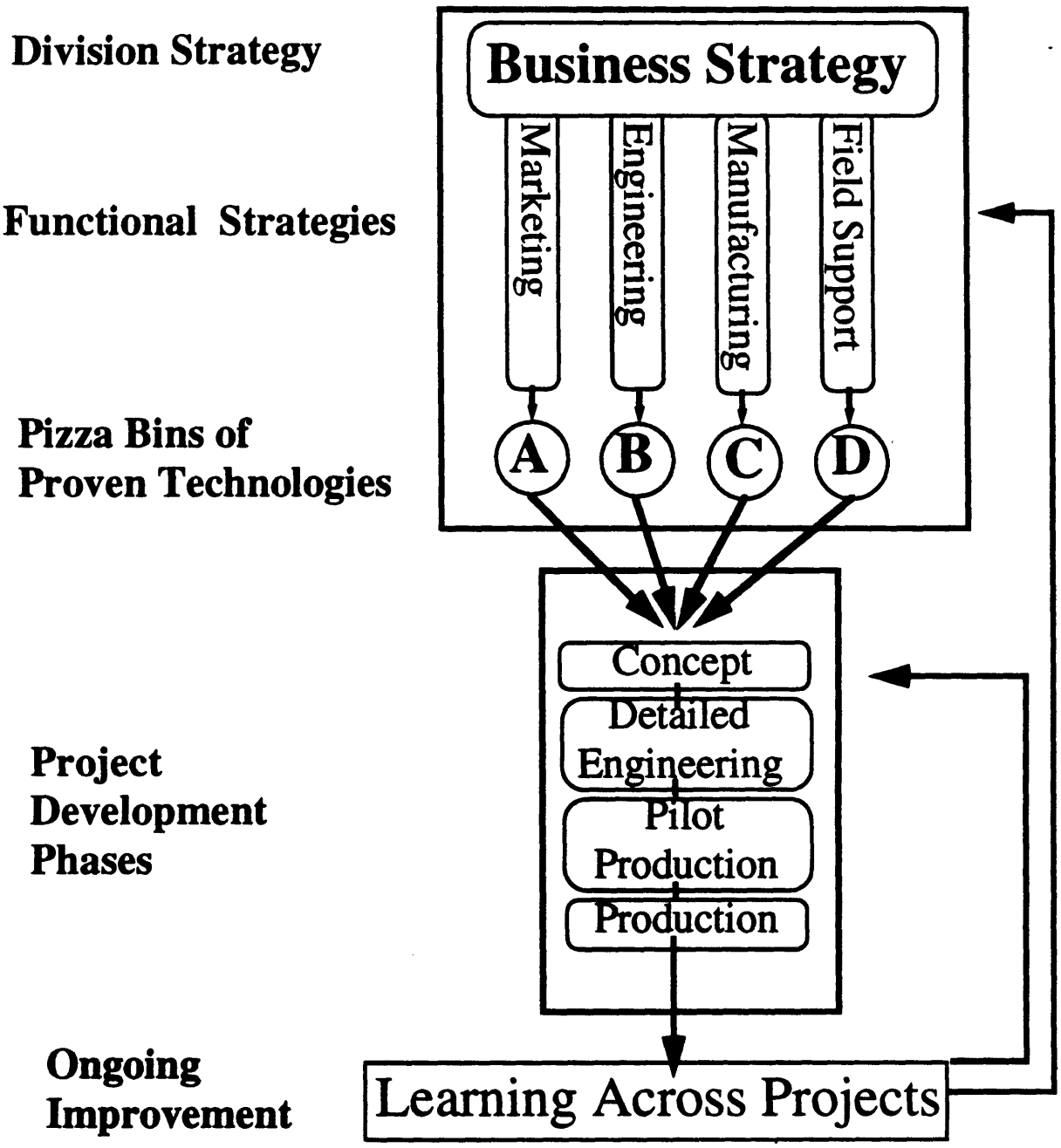


Figure B.1 Hewlett Packard Development Strategy