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Assuring Product Success with ISO 9001?

Gunhild Akervold Dalen

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ABSTRACT

Several research projects have been conducted, and several reports and books have been written with the hope of finding the factors important for successful new product development. This article compares the portions of ISO 9001 related to new product development with relevant research results. These results are summarized as four main elements: Understanding customer needs and creating product advantages, a well-planned and executed product development process, available knowledge of market and technology, and management support.

The conclusion is that ISO 9001 is mainly concerned with the formal written documentation of the development process, the adherence to these documents, documentation of the results, and qualification of personnel and resources available to the project. But ISO 9001 does not include all the elements necessary for assuring a successful product development, such as customer contact, teamwork, consistent project team, authority of the team leader, or design for manufacturability.

The following advice is given to companies: Read the other ISO 9000-standards, 9000, 9004 and relevant literature about the new product development process to get an understanding of the nature and the important elements of this process. Be certain to include in the new product development process the known elements of successful new product projects not dealt with in ISO 9001.

KEYWORDS: Product development; Design for manufacturability; Customer involvement; Product design.

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Several research projects have been conducted, and several reports and books have been written with the hope of finding the factors important for successful new product development. This article compares the portions of ISO 9001 related to new product development with relevant research results. These results are summarized as four main elements: understanding customer needs and creating product advantages, a well-planned and executed product development process, available knowledge of market and technology, and management support.

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INTRODUCTION

A good process for new product development is crucial to a company. The life cycle of products is short. Harmsen (1992) indicates that about 25 percent of the revenue in North American companies comes from products that have been in the market less than three years. Cooper and Kleinschmidt (1987) estimate that roughly one third of all new products fail at launch and 46 percent of company resources devoted to new product development go to products that fail in the market or to canceled projects. The product development process itself is complicated, involving several of a company's departments, and requiring a huge range of skills and resources from these departments.

In view of this research, it should be important for a company to assure the quality of this process. This article considers the following: what are the main elements needed for success in new product development and will a new product development process according to the requirements in the International Standard ISO 9001 (ISO 9000 International Standards for Quality Management, 1993) include these success elements?

ISO 9001 is called "Quality systems. Model for quality assurance in design/development, production, installation and servicing." The current issue of the standard is from 1987, but there is a 1993 draft for a new version. Changes proposed in the new draft which affect the topic in this paper are taken into consideration. The scope of the standard is to specify "...quality system requirements for use where a contract between two parties requires the demonstration of a supplier's capability to design and supply product." There are requirements concerning organizational structure, responsibilities, processes and resources. For some of these requirements, the company has to document their intention, procedures and the result thereof. The standard is not designed as detailed instructions telling how to conduct a design process. The procedures and organization will be
different in different companies.

The standard was originally created for use in contractual situations where the supplier and customer know each other and are in discussions concerning the quality of the delivered design. This has great influence on the way ISO 9001 deals with "customer needs." In recent years, the use of ISO 9001 has expanded, and it is now widely used by companies delivering products or service to consumers. Using the standard in the context of the consumer as the customer requires careful interpretation of the statements in the standard.

This article gives a short overview of elements important for success in product development. It then describes these in more depth and gives a comparison of the findings for each of these topics with the requirements in ISO 9001.

ELEMENTS IMPORTANT TO SUCCESSFUL DEVELOPMENT PROJECTS

Several investigations have been done to define which elements are important to success in innovation and product development (Rothwell et al. 1974, Cooper and Kleinschmidt 1987, Madique and Zirger 1984, Parkinson. 1984, Womack, Jones, and Roos 1991, Harmsen 1992). Some of these use different methods of investigations and measure success either as financial pay-back, opportunity for new markets/technologies, market share or achieved original project goals. Other researchers have looked at the difference between innovative and non-innovative companies in how they conduct the new product development process (John 1984). Table 1 is a summarized listing from four research projects, of the key quality elements in the successful development of new products. Urban and Hauser (1993, 52) present a similar comparison from other investigations. The most often cited elements in their list are: "Match customer needs"; "Screened on growth potential"; "Fit internal company strength"; "Top management support"; and "Use new-product process." There seems to be overall agreement among different researchers on the elements important for successful projects. I have found it convenient to group these according to the following headlines:

<table>
<thead>
<tr>
<th>Table 1.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elements Correlating to New Product Success</td>
</tr>
<tr>
<td>Understanding customer needs</td>
</tr>
<tr>
<td>Well planned and executed process</td>
</tr>
<tr>
<td>Crossfunc. communication</td>
</tr>
<tr>
<td>Leadership</td>
</tr>
<tr>
<td>Stay close to home 1</td>
</tr>
<tr>
<td>Effective use of R&amp;D resources</td>
</tr>
<tr>
<td>Management support</td>
</tr>
<tr>
<td>Efficient marketing</td>
</tr>
<tr>
<td>Market situation</td>
</tr>
</tbody>
</table>

1 Stay close to the core business' traditional strength

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A) Understanding market and customer needs and creating product advantages

B) A well-planned and executed product development process

C) Available knowledge of market and technology

D) Management support

"Efficient marketing" is also one of these often cited success elements, but will not be discussed further in this article, because "marketing" is not a part of the ISO 9001.

A. UNDERSTANDING MARKET AND CUSTOMER NEEDS

Understanding customer needs is the key to creating a product perceived to be of high quality and high value by the customers. Some examples of wording used in the literature to describe this are: "superior product in the eyes of customer"; "higher quality than competitors"; and "a product that offers unique benefits to the customer."

To create product advantages, it is necessary to investigate the customers' expressed and hidden needs. This is best done by establishing a dialog with the customer (Bisgaard 1991). Even a supplier that produces to given specifications has to develop insight into customer needs that goes beyond the specifications (Wheelwright and Clark 1992, 171). The supplier needs insight into why the customer wants the stated specifications, and how he is going to use the product delivered. This insight improves decision making when "trade-offs" must be made in the design. Spending enough time and money to get early input from the market and frequently checking customer needs are highly recommended (Madique and Zirger 1984; Urban and Hauser 1993, 67, 173).

Understanding the market and selecting the target group is a major task for the marketing division (Drucker 1992, 74). But from the Japanese we have learned that the marketing people should not be the only ones to understand this; engineers must also understand market conditions and customer needs (Box et al. 1987, Womack, Jones, and Roos 1992, 130). Parkinson (1984, 43) studied the difference in product development between the British and West German machine tool industry. He concludes that the greater market share of the West German industry stems mainly from a higher customer interaction throughout the development process and more direct contact between the designers and potential customers. The less successful British industry was more likely to have sales or marketing departments responsible for customer contact and analyses and interpretation of customer needs and thus had little contact between customers and engineers.

THE ISO 9001 REQUIREMENTS

Table 2 compares the success elements of "Understanding customer needs" and the corresponding requirements in ISO 9001. There is almost a total lack of requirements for customer interaction in the standard's clauses.

In a typical contract situation there will be an offer and a written contract expressing the customer's requirements for product and delivery. The standard emphasizes that the supplier has to document the review of these "contract requirements." The purpose of the review is to ensure that the requirements are well defined and documented and to establish an agreement on the interpretation of the requirements across the departments in the supplier's organization. Further investigation to get a deeper understanding of customer needs is only mentioned in a note (clause 4.3).

In a situation where no contract exists, that is when the consumer is the customer, the "contract review" will have no meaning, unless it is interpreted as a kind of design review to ensure definition and documentation of product characteristics.

A review of design input requirements according to ISO 9001 could be an internal exercise without any customer interactions. The statements in the standard are very vague and allow for different interpretations. It does not clearly require customer contact. The new draft uses slightly different wording, but still does not get the issue closer to the customer.

The standard should require a closer contact with the customer in this phase. It should also state who in the supplier's company needs to understand customer needs, so that it is not just the marketing department that interprets the customers' requirements and passes its interpretation to the other departments.

The 1993 draft of the standard states in the very beginning that company's quality policy shall be relevant to "...the expectations and needs of its customers" (clause 4.1.1). If this policy is carried forward to the other clauses in the standard, the customer needs should be well taken care of. But it is yet to be seen how this statement will be used and judged by registration.

B. THE DEVELOPMENT PROCESS

In one of their later reports, Kleinschmidt and Cooper
Table 2

The Element "Understanding Market"
Compared to the Requirements in ISO 9001

<table>
<thead>
<tr>
<th>KEY ELEMENTS</th>
<th>ISO 9001 (*)</th>
<th>ISO 9001 REQUIREMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Understand market and customer needs</td>
<td></td>
<td>4.3 &quot;Each contract shall be reviewed to ensure...the requirements are adequately defined and documented; any requirements different from those in the tender are resolved...&quot;</td>
</tr>
<tr>
<td>- Early input from market</td>
<td>O</td>
<td>4.4.3 &quot;Design input requirements...shall be identified, documented and their selection reviewed by the supplier for adequacy.&quot;</td>
</tr>
<tr>
<td>- Frequent dialog with the customer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Insight beyond the specifications</td>
<td>Δ</td>
<td></td>
</tr>
<tr>
<td>- Engineers market-contact</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Prioritizing of customer needs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Agreement on target market</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* The connection between the element and requirements in ISO 9001:

@: Required in ISO 9001

O: Partly required in ISO 9001

Δ: Weak connection between requirement and this element

If nothing, the element is not addressed at all

(1991) conclude that one of the largest causes of failure in product innovation is failure in the development process. As success elements they mention a process with clear phases and listed activities, project reviews, multifunctional development team, stable project group throughout the process and management's go/kill decisions and resource allocation. The four strengths of the Japanese design process given by Womack, Jones, and Roos (1991) are leadership, teamwork, communication and simultaneous development. Madique and Zirger (1984) say that the planning and coordination of the new product process is important to success. However, they provide little details about this process. To give a more detailed description, the elements of the development process are divided into four subgroups: clear phases with criteria for moving forward; leadership, teamwork and communication; consensus on product concept; and efficient design. A comparison of the success elements for the new product development process and the requirements in ISO 9001 is given in Table 3.

CLEAR PHASES WITH CRITERIA FOR MOVING FORWARD

Mørup (1992) states that there are needs for structured models and procedures for product development. The process should have clear phases with criteria for moving forward, and has to be understood by the management and all involved (Wheelwright and Clark 1992, 163). A study by Johne (1984) of innovative firms compared to non-innovative firms showed that the more innovative firms have a higher level of written procedures and standardized control procedures in their new product development process than the non-innovative firms.2 Another case-study by Graves et al. (1991) shows improvement in product development by creating a procedures manual which explains each phase in the process and what is needed to proceed to the next phase. Project reviews were also implemented to give feedback for improving the development process. Project reviews are also mentioned by

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2 Innovative is defined by percentage of sales income from new products
### Table 3
The Element "Well Defined and Executed New Product Development Process" Compared to the Requirements in ISO 9001

<table>
<thead>
<tr>
<th>KEY ELEMENTS</th>
<th>ISO 9001 (*)</th>
<th>ISO 9001 REQUIREMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>The development process</td>
<td></td>
<td>4.4.1 &quot; &quot;establish and maintain procedures to control and verify.&quot;</td>
</tr>
<tr>
<td>- Clear phases with criteria for moving forward</td>
<td>O</td>
<td>4.4.5 &quot;...holding and recording design reviews, undertaking qualification tests and demonstrations.&quot;</td>
</tr>
<tr>
<td>- Written procedures/manual</td>
<td>@</td>
<td></td>
</tr>
<tr>
<td>- Project reviews</td>
<td>@</td>
<td></td>
</tr>
<tr>
<td>- Discipline to the process</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leadership and teamwork</td>
<td>Δ</td>
<td>4.4.2 &quot;...identify the responsibility for each design and development activity.&quot;</td>
</tr>
<tr>
<td>- Strong project leader</td>
<td></td>
<td>4.4.2.2 &quot;Organizational and technical interfaces between different groups shall be identified and the necessary information documented, transmitted and regularly reviewed.&quot;</td>
</tr>
<tr>
<td>- Cross-functional team</td>
<td>Δ</td>
<td>4.1.2 &quot;The responsibility, authority and the interrelation of all personnel who manage, perform and verify work affecting quality shall be defined.&quot;</td>
</tr>
<tr>
<td>- Consistent team throughout the project</td>
<td>@</td>
<td></td>
</tr>
<tr>
<td>- Project-members commitment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Well defined product concept</td>
<td></td>
<td>4.3 &quot;Each contract shall be reviewed to ensure.. the requirements are adequately defined and documented; ..any requirements different from those in the tender are resolved...&quot;</td>
</tr>
<tr>
<td>- Translating customer needs to measurable product characteristics</td>
<td>@</td>
<td>4.4.3 &quot;Design input requirements...shall be identified, documented and their selection reviewed by the supplier for adequacy. &quot;</td>
</tr>
<tr>
<td>- Prioritizing product characteristics</td>
<td>@</td>
<td></td>
</tr>
<tr>
<td>- Agreement on &quot;what the product should be and do&quot;</td>
<td>@</td>
<td></td>
</tr>
<tr>
<td>Efficient design</td>
<td>Δ</td>
<td>4.4.2 &quot;..plans that identify the responsibility for each design and development activity. The plans shall describe or reference these activities...&quot;</td>
</tr>
<tr>
<td>- Good communication between marketing, R&amp;D, manufacturing</td>
<td></td>
<td>4.4.5 Design verification...&quot; qualification tests and demonstrations, alternative calculations, comparing with similar proven design...&quot;</td>
</tr>
<tr>
<td>- Supplier integration</td>
<td></td>
<td>4.4.4 &quot;Design output shall be documented and:</td>
</tr>
<tr>
<td>- Design for manufacturing &amp; robustness</td>
<td></td>
<td>- meet design input requirements</td>
</tr>
<tr>
<td>- Creating product with high benefit-to-cost ratio</td>
<td>Δ</td>
<td>- contain acceptance criteria</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- conform to regulatory requirements</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- identify characteristics crucial to safety.&quot;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.6.2 &quot;...select sub-contractors on the basis of their ability to meet sub-contract requirements, including quality requirements</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.20 Statistical techniques &quot;Where appropriate....&quot;</td>
</tr>
</tbody>
</table>

* The connection between the element and requirements in ISO 9001:

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others as a method for proving the completeness of each phase in the process and to make go/kill decisions (Cooper and Kleinschmidt 1987; Chase 1986; Bisgaard 1991).

Discipline in this process is crucial. There are a lot of examples, even in the best companies, of projects that failed because steps in the product development process were skipped (Urban and Hauser 1993, 48).

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ISO 9001 requires established procedures and description of activities for design and development of new products. The word "activities" can mean major phases in the process, or it can mean individual tasks. The purpose of the procedures is to control and verify the design, so although the description of the total process is not explicitly mentioned in the standard, it must be a natural part of the implementation.

In the current version, design reviews and qualification tests are suggested as tools for design verification, but there are no recommendations for when to have design reviews, or for setting criteria for moving forward. Requirements for design verification are intended to compare the end results to the original design input requirements. The standard also requires that the product conforms with regulatory requirements, even if this is not mentioned in the specifications given by the customer. The 1993 draft of the standard requires an additional design validation to ensure that the design meets the defined user needs/requirements. The new draft requires formal documented reviews and verification of how output meets the input requirements at appropriate stages in the design process. The new draft does a reasonably good job of assuring that the design process has "clear phases with criteria for moving forward."

LEADERSHIP, TEAM-WORK AND COMMUNICATION

The SAPPHO-study from 1974 (Rothwell et al. 1974) gives "The seniority and authority of the responsible managers" as one of the success criteria in product development projects. Womack, Jones and Roos (1991,112) describes how development projects are conducted in the Western and Japanese automobile industries. In the West, there was typically a coordinating leader who had to get project members from several departments as the project went on. The project was pushed from department to department according to the topic under investigation which caused a major delay in the development schedule. In Japan, a multifunctional project team was established, with a strong, experienced leader, and with representatives from marketing, R&D, and manufacturing. The team members followed the project from beginning to after market launch. The time used for developing a new car was extremely short in Japan, 46.2 months, compared to the 60.4 months used by the auto makers in the USA. Also Box et al. (1987) and Bisgaard (1991) mention the impact of the strong team leader and the cross-functional teams in Japanese product development processes.

The importance of good communication in the development process is supported by Madique and Zirger (1984) who found that one of the success criteria was coordination of marketing, manufacturing and design functions.

ISO 9001 REQUIREMENTS

Managing a project is certainly one of the most important activities in moving the project along. The ISO 9001 does not specifically mention the project leader or project team, but there are requirements for definition of responsibility and authority (clause 4.1.2.1). It is however possible to have a "moving" responsibility for a new product development project, and still work according to the requirements in ISO 9001. A design and development process pushed from one department to another according to the list of responsibility for each activity comes to mind when reading the text. The concern in the standard is to ensure that everybody who has a responsibility in the project is dedicated to take this responsibility, that all involved get information regularly and that there will be no arguing of how to cooperate. This does not necessarily create teamwork or good communication.

Thus the standard falls short of requiring good
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leadership, teamwork and good communication.

CONSENSUS ON PRODUCT CONCEPT PRIOR TO DEVELOPMENT

The expression "product concept" is used in different ways in the literature. Here I prefer the definition according to Cooper and Kleinschmidt (1987): product concept is "what the product should be and do." In their study, one of the success criteria found was "well-defined product concept prior to development," and an agreement on the product concept and the target market early on.

Urban and Hauser (1993 p. 164) introduce the "CBP, Core Benefit Proposal" as a necessary requirement. The CBP specifies the basic benefits that the new product has to deliver to the customers and the customers’ potential trade-off within these benefits. The CBP also gives the customers’ evaluation of competitors’ products on these benefits. Early consensus on CBP prevents communication problems in the project team in later design phases.

Mørup (1992) stresses the importance of separating the activities of choosing objectives, synthesis and verification. Choosing objectives, that is defining the concept, should be the first activity. Delatore, Prell, and Vera (1989) report significant benefits at the AT&T Bell Laboratories from introducing written "requirements to designers" according to customer inputs.

THE ISO 9001 REQUIREMENTS

The element "Consensus on product concept" prior to design is best addressed in the standard by the requirements of identification and documentation of the "design input requirements" and a review of the selection of those. The review, if done jointly by involved departments, will result in a consensus on the product concept.

EFFICIENT DESIGN

Since high performance-to-cost ratio is one of the success elements (Madique and Zirger, 1984), the objective of the design process is to create a product that fulfills customer needs in a cost-efficient way. The new product has to give the customer more value at same price, or the same value at a lower price, than the competitors’ products.

The design process has to build quality into the product, to create a product that is robust to the likely variations in the ways the customers will use the product. Parkinson (1984, 96-97) found that the more successful West German industry spent more time testing and evaluating prototypes, and was more likely to do this under real conditions than the British companies. This surely resulted in a more robust product.

The design process should also include the design of the manufacturing process. Wheelwright and Clark (1992, 9-12) give a case study of a design process that was slow and required a great deal of rework, because the product design and the process design were accomplished in isolation as two different tasks. The costs of delay and rework will be reflected in longer development time and higher product price, and thus the idea of creating more value at the same price will be hard to fulfill. The idea of concurrent engineering is to have good cooperation and to design the product and process at the same time. Womack, Jones, and Roos (1991, 116) also conclude that manufacturability is one of the success elements in the Japanese automobile industry, and this is due to simultaneous design of product and manufacturing process.

Supplier-integration also seems to be important in this phase (Chase 1986; Womack, Jones, and Roos 1991, 146). The suppliers often have a better understanding and technical knowledge of the special task or product they are going to deliver. The company can therefore benefit a great deal from using this knowledge by passing functional specifications instead of detailed dimensions to the suppliers (Wheelwright and Clark 1992, 290). Supplier integration can also help speed up the design process. It is just another point of view of a previous statement: the supplier has to get an understanding of customer needs that goes beyond the specifications delivered.

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Verification of manufacturability is not required. According to the definition in another International Standard, ISO 8402, design review includes a capability study of the design which encompasses manufacturability, maintainability, reliability, safety etc. Design reviews are optional and ISO 9001 only requires documentation of the results concerning "...safe and proper functioning of the product." Documentation of the manufacturability will perhaps be a part of design reviews as required in the new draft of the standard. Evaluation of robustness of the product could also be a part of the same design reviews.

An almost necessary tool when designing products is statistical techniques. Use and

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documentation of statistical techniques is only required if the company finds it appropriate. The current version of the standard does not assure that manufacturability or robustness are taken care of or documented. It has yet to be seen if the design review requirements in the new draft will include these as mandatory elements.

Suppliers are dealt with in the context of purchasing, requiring evaluation of suppliers’ quality systems as a basis for selection. Supplier integration into the design process is not mentioned at all. A requirement for integration of supplier’s design efforts in the total design would be adequate.

C. AVAILABLE KNOWLEDGE OF MARKET AND TECHNOLOGY

The most high-risk projects are those where both the technology and the market are new to the company. Cooper and Kleinschmidt’s study (1987) shows that an important success element is synergy with the existing technology and current market and management skills and resources. Madique and Zirger (1984) also found that new products would more likely be a success if they benefit significantly from existing strength of the development unit. This is often called the “stay close to home” criterion.

In contrast the SAPPHO-study (Rothwell, Jones, and Roos 1974) gives another success criteria: effective use of outside technology and external scientific communication. This is supported by Parkinson’s study (1984, 96-97) of the British and West German machine tool industry. Contact with universities and research institutes was more extensively developed in the West German industry, than in the less competitive British industry.

When the market or technology is new to the company, it is important to consider the needed skills and resources for the project, give more attention to these topics, and to communicate well with outside experts. It seems to be more important what resources and knowledge are available and used in the project, than whether these are from inside or outside the company.

THE ISO 9001 REQUIREMENTS

A comparison of the success element and the requirements in ISO 9001 is given in Table 4.

This is one of the themes where the standard is specific, requiring the development unit to have qualified personnel and necessary resources to complete the activities. The company has to consider whether they have the capability for meeting the contractual requirements. The standard requires that personnel performing specific assigned tasks shall be qualified either by education, training or experience. On this element the standard’s requirements closely match the success element “available knowledge”.

D. MANAGEMENT SUPPORT

Top management’s support from the start of development to product launch is crucial to project success (Madique and Zirger 1984). This support is necessary to give the project and the project team the time and tools they need to do a good job in each phase of the process. Management support is also important for process reviews, with management assuring that project teams realize that the work from each phase must be clear and completed before beginning the work scheduled to follow (Box et al. 1987, Urban and Hauser 1993, 608). It is also found that project leaders of successful projects have more support from management than unsuccessful project leaders (Harmsen 1992).

Managers’ support depends on their understanding of development activities and the nature of the development process. Managers in the competitive West German machine tool industry paid greater attention to engineering skills than financial expertise as a qualification for management. They also put more resources and staff into development and design. The British management gave considerable emphasis to financial objectives and did not seem to have perceived the link between product development and long-term financial success (Parkinson, 1984, 103). Wheelwright and Clark (1992, 220) argues that the role of the general managers is to build capability and create effective processes. Detailed understanding of the development process will put the managers in a much better position to evaluate the potential and the progress of projects under development. This understanding will also encourage support of the existing development process (Urban and Hauser 1993). However, this does not mean that the process itself should not be revised and improved.

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A comparison of the criterion “Management support” and the requirements in ISO 9001 is given in Table 4. Management’s overall responsibility is to
### Table 4
The Quality Elements "Available Knowledge" and "Management Support"
Compared to the requirements in ISO 9001

<table>
<thead>
<tr>
<th>KEY QUALITY ELEMENTS</th>
<th>ISO 9001 (*)</th>
<th>ISO 9001 REQUIREMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Available knowledge</td>
<td></td>
<td>4.4.2 &quot;The design and verification activities shall be...assigned to qualified personnel equipped with adequate resources.&quot;</td>
</tr>
<tr>
<td>- Strong fit between project needs and the company's skills and resources in marketing, engineering and manufacturing</td>
<td>@</td>
<td>4.18 &quot;Personnel performing specific assigned tasks shall be qualified on the basis of .....&quot;</td>
</tr>
<tr>
<td>- The product benefits from existing strengths in technology and market</td>
<td>@</td>
<td>4.3 &quot;...Each contract should be reviewed to ensure .the supplier has capability to meet contractual requirements.&quot;</td>
</tr>
<tr>
<td>- Efficient use of outside experts</td>
<td>∆</td>
<td></td>
</tr>
<tr>
<td>Management support</td>
<td></td>
<td>4.1.1 &quot;...management shall define and document its policy and objectives for, and commitment to quality.&quot;</td>
</tr>
<tr>
<td>- Support throughout the project</td>
<td>O</td>
<td>4.17 &quot;...planned and documented internal audits to verify whether quality activities comply with planned arrangements and to determine the effectiveness.&quot;</td>
</tr>
<tr>
<td>- Management involved in project reviews</td>
<td>Δ</td>
<td>&quot;...The management personnel responsible for the area shall take timely corrective action...&quot;</td>
</tr>
<tr>
<td>- Management go/kill decisions</td>
<td>O</td>
<td>4.1.3 &quot;Note - management's assessment of the results of internal quality audits...&quot;</td>
</tr>
<tr>
<td>- Authority of responsible managers</td>
<td>O</td>
<td></td>
</tr>
</tbody>
</table>

* The connection between the element and requirements in ISO 9001:

@: Required in ISO 9001

O: Partly required in ISO 9001

Δ: Weak connection between requirement and this element

If nothing, the element is not addressed at all

assure that the company meets all the requirements in the standard and that management can document their commitment to quality. In this context the design project should have management's support for getting the resources and tools for the activities. More detailed suggestions for management's involvement in decision-making and project-reviews are not mentioned in the standard. To assure this important success element, it could have been a requirement that management be involved in major decisions such as design-input requirements and design reviews.

Management's review of the total new product development process is taken care of by internal quality audits. Audit of the development process is a natural part of internal audits. This requires planned arrangements to determine the effectiveness of the quality system. The standard requires that managers responsible for the audited area shall take action on the results from the audit and improve the process.

### Conclusion

Tables 2 - 4 give a picture of how ISO 9001 meets the requirements for a successful new product development process as described in this article. ISO 9001 addresses many of the success criteria for new product development, - especially documentation of the process and capability to do the design. The requirement of design reviews and design validation at appropriate stages in the design process is a good improvement in the new draft.

To become an even better tool for assuring success in development of new products some changes are suggested. The most important would be
to require more customer interaction, to reflect, throughout the standard, a policy of meeting "...the expectations and needs of its customers." As an example, there could have been a requirement to do the contract reviews in close contact with the customers and to establish channels for interface with the customer's organization. It should also be a must that design requirements (clause 4.4.3) are selected and conflicts are resolved by communication with the customer.

Requiring a description of the total process with clear phases and criteria for moving forward would be an improvement. It should also be mentioned that it's the responsibility of the managers to ensure that the process is understood by those involved.

It would have been appropriate to require documentation of responsibility and authority of the project leader. Clear recommendations for team work and communication would also have been a major improvement. Although the standard seldom requires specific methods it would not be a contradiction to the general voice of the standard to require "...a plan for regular communication and cooperation between involved departments."

Verification of manufacturability could have been one of the required documented design outputs listed in clause 4.4.4. Assuring this throughout the development process could have been taken care of by requiring close communication between design and manufacturing groups and use of proper design reviews.

The ISO 9001 standard is one of several standards on quality assurance. ISO 9000, which gives guidelines for use of the standards, states as a principal concept of quality assurance: "The organization should achieve and sustain the quality... so as to meet continually the purchaser's stated or implied needs." One of the others, ISO 9004 "Quality management and quality system elements - Guidelines", includes some of the elements we miss in the ISO 9001 requirements, especially in assessing customer needs. The ISO 9000 and 9004 are not contractual documents, but are worth reading when interpreting the requirements in ISO 9001.

Although ISO 9001 has some weaknesses concerning the assurance of a successful new product development process, it has to be mentioned that there are no statements in the standard that prevent the implementation of the missing elements in a company's New Product Development Process.

The recommendation to the managers responsible for product design should therefore be: The requirements in ISO 9001 are not sufficient to assure project success. It is, however, worthwhile to study the general standards in the ISO 9000-series and the key quality elements of success projects as described in literature and including those in the New Product Development Process.

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