# Process Reengineering for New Product Introduction at an Analytical Instrument Manufacturing Firm

by

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## Abstract page

The process of transforming Research and Development knowledge to successfully introducing new products in the market forms a key competency of an innovative company. This new product introduction process was studied at an analytical instrument manufacturing firm.

The process of commercialization spanned a number of departments and the process flow lacked functional integration. The current introduction process also lacked a number of management processes, structured feedback loops for information transfer and data metrics for process assessment and evaluation. Due to this, the information related to product knowledge was lost in the process flow creating isolated compartments which was never shared in the process flow. It was also seen that problems created earlier in the process cascaded through the flow and an amplification effect of the problems was seen later. This combined with micro-management of key processes deliverables and inadequate documentation led to a phenomenon of 'firefighting' during the product introduction process.

A new process was created for the creation of a Quality Inspection Plan, which was earlier missing. The two important deliverables were created as part of the process describing the critical dimensions and design tolerances of the new product. These documents were linked to the existing introduction process as a part of the phase gate review deliverables and would hence establish a structured method for information communication and feedback to Research and Development. These documents would also drive the creation of the Quality Inspection Plan by integrating downstream departments earlier in the process. Certain sub-process within the commercialization process were selected and the process was standardized for feedback- in terms of information as well as possible data base for metrics creation for continuous improvement initiatives. Also a set of recommendations were made to further strengthen and functionally integrate the process in order to reduce redundancies in the current commercialization process.

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# 1. Introduction

This thesis explores the process of introduction of new products or 'commercialization' at Waters Corporation. The capabilities of current processes are investigated to reduce process redundancy and an emphasis is placed on reengineering a new business process to make the New Products Introduction group at Waters more involved and responsive to the process of Commercialization. This Chapter focuses on the introduction of Waters Corporation and the market segment it caters to. A SWOT analysis is presented to highlight the competitive landscape of the market place in order to highlight the importance of the process of commercialization and why it forms the life line of the company. In the latter part of the Chapter, the involvement of the New Products Introduction Group is discussed with respect to the commercialization process.

### 1.1 The Industry and Waters Corporation

Waters Corporation is an analytical instrument manufacturer that primarily designs, manufactures, sells and services a number of different Liquid Chromatography (LC) technology systems, mass spectrometry chromatography systems as well as support systems for its instruments and software based products for interfacing its instruments. The company has two Business segments- the Waters Division and TA division. The Milford facility of Waters is primarily dedicated to designing and manufacturing the LC systems of the company. Our work concentrates on the Waters division and its business processes related to product commercialization.

The company's products are used in a number of industries- pharmaceutical, life sciences and in biochemical analysis. In the academic arena, it is used by people working in research and development, drug discovery, molecular detection and analysis, quality assurance and in laboratory applications as well.

## 1.2 Competition in the Analytical Instrument Market

The analytical instruments market is highly competitive. The company has competition from a number of manufacturers both domestic and international. Waters competes in its markets primarily based on the instrument performance, reliability and accuracy of the instrument and serviceability of the instruments. In this competitive landscape, some companies are more diversified than Waters itself and other companies are individual business units that retain the core competencies of the parent businesses.

In the markets served by the Waters division, the primary competition include- Agilent Technologies, Shimadzu Corporation, Bruker Corporation and Thermo Fisher Scientific. For the consumable LC market, it is more fragmented and the competition is more intense since it encounters competition from chemical companies that produce chemicals or specialized columns. The competitor companies in this LC segment are- Phenomenex, Supelco, Agilent Technologies, General Electric, Thermo Fisher Scientific and Merck.

### 1.3 SWOT Analysis of Waters Corporation

Table 1-1 summarizes the SWOT analysis of the company.

Table 1-1: SWOT Analysis of the Company [1]

| **Strengths** | **Weakness** |
|---|---|
| Customer centric Product Development Process (feedback driven process)<br>Dedicated R&D base for specific market segments<br>Captive Machine Shop | Lack of Upfront Planning<br>Lack of Historical Data for product introductions<br>Intuition based decision-making process in product development process<br>Decision making without input from appropriate stakeholders<br>Missing management processes |
| **Opportunities** | **Threats** |
| Growing life Sciences and Tools and Service Industry | Fierce Competition<br>Foreign Currency Exchange Rate Fluctuations<br>Government Regulations |

Waters has a broad and diversified customer base that includes pharmaceutical accounts, other industrial accounts, universities and government agencies. The pharmaceutical segment represents the company's largest sector and includes multinational pharmaceutical companies, generic drug manufacturers, contract research organizations (CROs) and biotechnology companies. During FY2012, 53% of the company's sales were to pharmaceutical accounts, 33% to other industrial accounts and 14% to university and government agencies. Waters does not rely on any single

customer or one group of customers for a material portion of its sales. During 2012, 2011 and 2010, no single customer accounted for more than 3% of the company's net sales. Hence, by serving a broad and diversified customer base the company minimizes its exposure to economic or market fluctuations experienced by any single customer segment which in turn provides competitive advantage.

Waters maintains an active research and development program focused on the development and commercialization of products that both complement and update its existing product offering. The company's research and development expenditures for 2013, 2012, 2011 and 2010 were $100 million, $96 million, $92 million and $84 million respectively as shown in Figure 1-1.

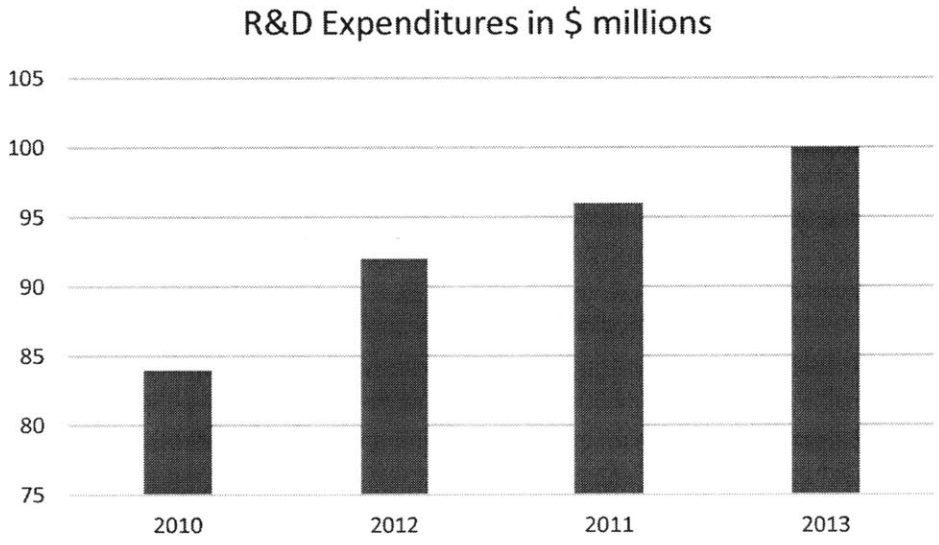



Figure 1-1: R&D expenditures at Waters 2010-2013

### 1.4 Opportunities as a Strategic Growth

Waters has a strong presence in the Analytical Instrument Market especially with respect to introduction of new products in order to expand its product portfolio. For example in June 2013, Waters introduced the CORTECS Columns, a new family of 1.6 micron solid core

UltraPerformance LC Columns. This new Ultra performance established a new standard in the column performance specifications in the industry. Also in the March 2014, Waters introduced the ACQUITY Advanced Polymer Chromatography system.

The Instrument business is an ever changing one and maintaining a strong research and development capability that could deliver new and unique customer requirements in the form of new products would be a competitive advantage for Waters highlights the importance that the commercialization process has for the company to succeed in the market.

The global life science tools and service market has seen a strong growth over the past 3 years since 2010, with an increase of 6.2% from the year 2012. Waters with its instruments dedicated for molecular detection in the pharmaceutical, life sciences, and biochemical, industrial settings can leverage its technology solutions to enhance its revenues in the coming years. Also a sustained growth in the company's key end markets would help translate into a higher growth rate. In summary, the market place that Waters caters to is a growing one, hence having a robust product introduction process can allow Waters to grow financially as well as increase its customer base.

### 1.5 New Products Introduction Group

The New Products Introduction (NPI) group provides services to the Research, Development and Engineering (RD&E) in support of the product development effort. Support to RD&E is provided by evaluating the design of the product and providing feedback about manufacturability and product reliability of the product. Also during the build stages, the support is in the form of material procurement at different development stages and physical assembly of the prototype units.

The NPI process also establishes a viable production volume production by ensuring that the design is firstly manufacturable. The NPI group is also responsible for creating product and process

stability plans, creating documents for the assembly process, creation of testing protocols and tools during the Beta and Pre-production stages of development. This process ensures that designs and materials are ready for initial full-volume production builds. Hence NPI forms the bridge from RD&E to full scale production.

The NPI group's involvement begins prior to the Specification and Planning Phase Gate review (PGR) and spreads across all the major steps involved through the Design & Engineering PGR, Alpha PGR, Beta First Customer Shipment (FCS) and the Pre-production PGR. After the Pre-production PGR, the new product transfers into manufacturing which represents the conclusion of the NPI Introduction Process.

Hence in the commercialization process flow, the information flow is from RD&E which forms the upstream department to NPI for product build, validation and testing before full scale production of the product. Hence NPI and its sub-departments form the downstream departments with respect to RD&E. NPI encompasses a number of departments. The major sub-departments within NPI are-

1. Project Management
2. Supply Chain
3. Process Development and Design Feedback
4. Production Activities

The NPI process is at the central to the commercialization process at Waters Corporation. It is an interaction between a large number of smaller groups which is supported by the department organizational structure comprising of different individuals- Development Engineers, Product Assurance Engineers, Production Engineers and Supervisors in the Machine Shop, Planners for

the Production Schedules, Test and Reliability Engineers for Product Stabilization, Quality Engineers, Commodity Mangers, Procurement Specialists and Buyers.

### 1.6 Problem Statement

The NPI group at Waters has been facing a number of issues mainly due to the interaction of a number of different stakeholders which is currently not structured. The biggest concern within NPI has been with respect to incoming parts from external vendors not meeting design specifications of Waters RD&E, hence creating a big concern in the product build stages of the commercialization process.

Also in the process of commercialization, NPI forms the downstream department and there is no formal feedback processes to link NPI to the RD&E or Inspection to RD&E.

Apart from this, many of the management processes related to design revision changes from RD&E, vendor communication, internal coordination with other departments are being micromanaged to a certain extent which indicates the severity of this problem. Also, with respect to Business processes, the current instrument development plans that Waters uses for introduction of new products is 14 years old and is obsolete with respect to the current market conditions.

The problem at hand is to study the methodology of the current commercialization process at Waters with respect to the NPI group and reengineer and implement a new business process to avoid the shortcomings of the existing process which are detailed in the later chapters of this thesis.

### 1.7 Research Motivation

With respect to the analytical instrumentation markets demographics and fierce competition in all segments, introduction of new products in a timely manner- the process of commercialization is central to the overall functioning of Waters. The instrument development plan currently used at

Waters that dictates the overall product development process is 14 years old. In these past 14 years Waters has changed its business model and now offers systems solution to customers which includes LC equipment as a part of the solution. Also, there is a certain possibility that in the near future, Waters would get into business segments that requires Food and Drug Administration (FDA) compliance.

The company is currently in the process of developing a new instrument development plan which could be used as a product development roadmap for future LC product systems and cater to the current market conditions.

In the current commercialization process, the NPI Group takes a central role. Having an effective and streamlined process within NPI could be very advantageous to Waters especially as a strategic point of view for the future for building a core competency around product development.

This would help the company in a number of ways and could in turn lead to reduction in unnecessary product development costs, reduced product development lifetime, better resource planning which can ultimately lead to a higher market share.

### 1.8 Objective

The primary objective of this project was to study and assess the current "as-is" process of commercialization- from product development to full scale production with respect to the NPI group at Waters Corporation at their Milford, MA facility. The process of study was through mapping the current process via value stream maps and performing a gap analysis with respect to Industry Best practices. The expected outcome is to re-engineer and implement a new Business Process for Waters within NPI and the design groups in order to solve the problems found during the gap analysis.

In order to achieve this, the process is divided into three main parts: Process improvement with respect to Supply Chain and Material Qualification (internal to Waters functioning) and its Interactions, Supplier Assessment and the Instrument Development Plan. Each team member is in charge of one area and delegates responsibility to other team members in his/her area based on expertise. The author of this thesis was in charge of the Supply Chain and the Material Qualification process internal to Waters as well as its system level interaction with design documents in order to link the process to the Instrument Development Plan. Shubhang Tandon [2] was responsible for a systems understanding of the Waters Instrument Development Plan and its high level understanding to the commercialization process and He Yan [3] was responsible for the Supplier Assessment and Evaluation Process.

### 1.9 Thesis Outline

Chapter 1 is the general introduction to Waters Corporation and an analysis of the analytical instrumentation business and the importance of the commercialization process for Waters Corporation. Chapter 2 of the thesis talks about the general concept of Business Process Reengineering, its necessity and the methodologies used for carrying out the reengineering process. Chapter 3 discuss the process of product development and the problems of risk that are associated with the development process. The chapter also discuss different ways of how the product development process manages risk associated in the process. Chapter 4 describes the methodology of the study and process of data collection that was done at Waters Corporation.

Chapter 5 of the thesis describes the current commercialization process at Waters within the scope of the NPI group and details the various stages in the development process. Also, the chapter outlines the systems level process map for product development and how different stakeholders interact at different stages to build and validate the instrument. The chapter highlights the people

involved and the process flow structure that allows the product development process to take place. Chapter 6 describes the problems present in the current development process at Waters based on data collection and analysis carried out. Chapter 7 is the results and discussions which describes the results of the study based on the hypothesis created in Chapter 6. It also describes the creation of the new Quality Inspection Plan process map with an attempt to bridge the problems of the existing process. Chapter 8 and Chapter 9 describes the recommendations made to the company and future works respectively.

# 2. Business Process Re-engineering

## 2.1 Introduction

In today's changing world, the only thing that doesn't change is 'change' itself. In a world increasing driven by the three Cs: Customer, Competition and Change, companies are on the lookout for finding ways to adapt themselves to this constant change [4]. In this context, "Re-engineering" has been a popular term used. Causes for change include usually an environment cause that necessitates a basic need for strategic change within an organization. In order to achieve the desired strategic change, there is often a need for fundamental structural change. Reengineering is one process by which organizations are able to achieve this fundamental strategic and structural change.

Business Process Reengineering (BPR) advocates that enterprises go back to the basics and re-examine their very roots. It doesn't believe in small improvements, instead it looks at total reinvention of the process. According to Hammer and Champy [4], the last but the most important of the four words is the word- 'process.' BPR focuses on processes and not on individual tasks or jobs or people. The following is the definition of BPR:

[Reengineering is] the fundamental rethinking and radical redesign of business processes to achieve dramatic improvements in critical, contemporary measures of performance such as cost, quality, service and speed. [4]

"A business process is a series of steps designed to produce a product or a service. It includes all the activities that deliver particular results for a given customer (external or internal) [9]". Processes are currently invisible and unnamed because people think about the individual departments more often than the process with which all of them are involved. So companies that

are currently used to talking in terms of departments such as marketing, finance and manufacturing must rather shift to giving names to the entire processes in order to express the beginning to end states of a process. This outlook allows a much better process integration rather than dividing work in functional departments. Process mapping provides tools and a proven methodology for identifying current as-is business process and can be used to provide a To-Be roadmap for reengineering business enterprise functions. It is the critical link that reengineering teams can use to understand the current process in order to significantly improve business processes and bottom-line performance [4, 5].

### 2. 2 Candidates for Reengineering

Any complex, multi-tasking organization is a potential candidate for reengineering. Potential entities can be companies from either the services or manufacturing sector. Typically, companies in need of reengineering fall into one of three basic categories:

1. Companies in deep trouble - persistent losses, higher costs, falling revenue. Needed order of magnitude improvement.
2. Trouble up ahead - current operations are fine, but management perceives approaching threats and adversity in the near future.
3. Peak performance - industry leader, no problems. Initiate reengineering to further the lead over competition. [4]

### 2.3 Methodology of Business Process Reengineering

With an understanding of the basics of BPR, there are a number of methods by which a Business Process Reengineering process could be carried out at any organization. Tables 2-1, 2-2, 2-3, 2-4 and 2-5 list the most common five different methodologies proposed by different researchers in

the field of process reengineering. This section is only a representative of a basic list of methodologies proposed by different researchers in order to present similarities between the different methodologies.

Table 2-1: BPR methodology as proposed by Underdown [6]

| Process Activity # | Methodology |
|---|---|
| Step 1 | Develop vision and strategy for BPR |
| Step 2 | Create desired culture to implement BPR by readying the system |
| Step 3 | Integrate and improve enterprise |
| Step 4 | Develop technology solutions that can bridge the gaps found for BPR |

Table 2-2: BPR methodology as proposed by Harisson, Brian and Maurice [7]

| Process Activity # | Methodology |
|---|---|
| Step 1 | Determine Customer Requirements &Goals for the Process |
| Step 2 | Map and Measure the Existing Process |
| Step 3 | Analyze and Modify Existing Process |
| Step 4 | Design a Reengineered Process |
| Step 5 | Implement the Reengineered Process |

Table 2-3: BPR methodology as proposed by Furey and Timothy [8]

| Process Activity # | Methodology #3 |
|---|---|
| Step 1 | Set Direction for BPR |
| Step 2 | Baseline and Benchmark the current processes |
| Step 3 | Create the Vision required to proceed forward |
| Step 4 | Launch Problem Solving Projects |
| Step 5 | Design Improvements across different processes |
| Step 6 | Implement Changes |
| Step 7 | Embed Continuous Improvement initiatives across processes |

Table 2-4: BPR methodology as proposed by Mayer, Richard, Dewitte and Paula [9]

| Process Activity # | Methodology |
|---|---|
| Step 1 | Motivating Reengineering |
| Step 2 | Justifying Reengineering |
| Step 3 | Planning Reengineering |
| Step 4 | Setting up for Reengineering |
| Step 5 | As Is Description & Analysis |
| Step 6 | To-Be Design and Validation |
| Step 7 | Implementation |

Table 2-5: BPR methodology as proposed by Maganelli and Raymond [10]

| Process Activity # | Methodology |
|---|---|
| Step 1 | Preparation |
| Step 2 | Identification |
| Step 3 | Vision |
| Step 4 | Technical & Social design |
| Step 5 | Transformation |

## 2.4 Consolidated Methodology for Business Process Reengineering

From these five methodologies, a consolidated methodology [11] has been used in our study process for process of studying the current process and reengineering a new process. This is illustrated in Figure 2-1.

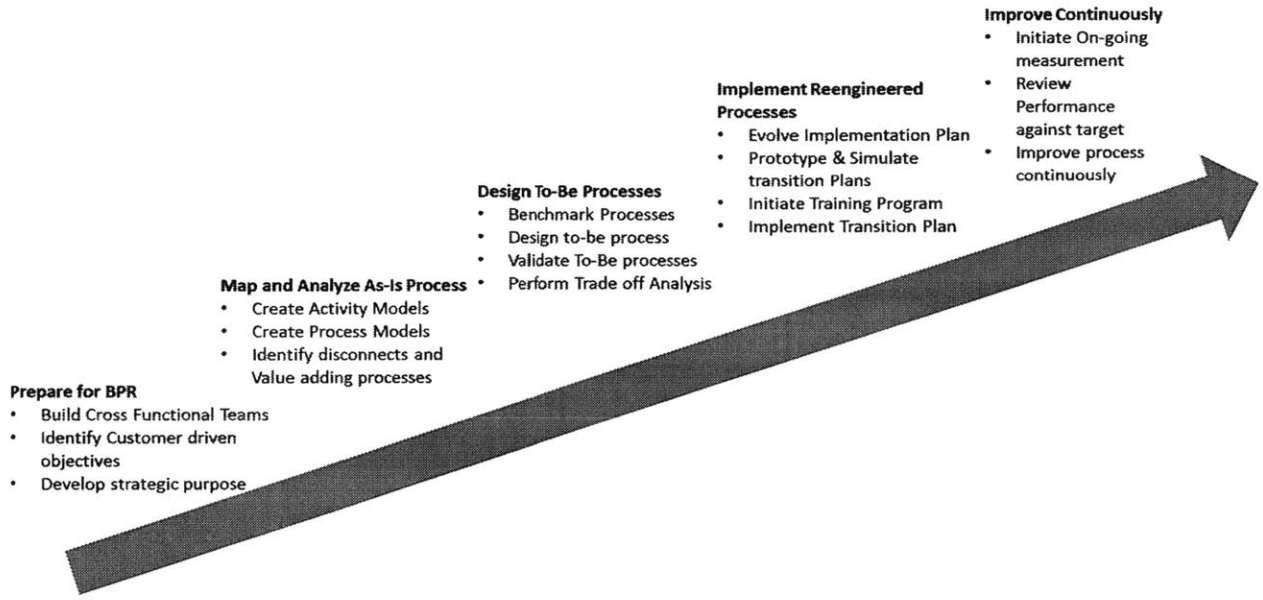



Figure 2-1: Consolidated methodology for Business Process Reengineering

The five steps in the consolidated methodology for BPR as shown in Figure 2-1 are discussed in more details-

1. Prepare for Reengineering

Planning and Preparation are the first steps for any activity to be successful and reengineering is no exception. For the process to be reengineered there needs to be a significant need. The justification of this need marks the beginning of the preparation activity [9]. At Waters, as

discussed earlier in Chapter 1 the need arises since the instrument development plan is outdated and is not suited to cater to the demands of the existing market demographics.

2. Map and Analyze As-Is Process

Before the reengineering team can proceed to redesigning of the current process, they should understand the existing process in detail. The main objective of this phase is to identify disconnects that prevents the process from achieving desired results and in particular information transfer between organizations or people [9]. This is initiated by first creation and documentation of an Activity and Process model. Then, the amount of time that each activity takes and the cost that each activity requires in terms of resources is calculated through different methods or a gap analysis is performed to find missing management processes, what the required goals and what is exactly missing or preventing from reaching the goal. The later process is the link between the Activity 2 and Activity 3.

3. Design To-Be process:

The objective of this phase is to produce one or more replacements to the current situation, which satisfy the strategic goals of the enterprise and most importantly do not compromise the overall function of the process. The first step in this phase is benchmarking. "Benchmarking is the comparing of both the performance of the organization's processes and the way those processes are conducted with those relevant peer organizations to obtain ideas for improvement [10]." The peer organizations need not be competitors or be even from the same industrial segment. Innovative practices can be adopted from anywhere immaterial of the Industry as far as the process meets the overall strategic goal of the organization.

Having identified the potential improvements to the existing processes, the development of the To-Be models is done, bearing in mind the required goals. It should be noted that this activity is an iterative process. The several To-Be models that are finally arrived at are validated. By performing Trade off Analysis the best possible To-Be scenarios are selected for implementation in the later stages.

4. Implement Reengineered Process:

The implementation stage is where reengineering efforts meet the most resistance and hence it is by far the most difficult one [8]. The environment in which the change is to be set is not as conducive as expected, rather it tries to avoid the change that is to be implemented. We could expect to face all kinds of opposition - from blatantly hostile antagonists to passive adversaries: all of them determined to kill the effort. When so much effort is spent on analyzing the current processes, redesigning them and planning the migration, it would indeed be practical to run a culture change program simultaneously with all the planning and preparation going on. This would enable the organization to undergo an easier transition. But whatever may be the juncture in time that the culture change program may be initiated, it should be rooted in our minds that winning the hearts and minds of everyone involved in the BPR effort is most vital for the success of the effort [10]. Once this has been done, the next step is to develop a transition plan from the as-Is to the redesigned process. This plan must align the organizational structure, information systems, and the business policies and procedures with the redesigned processes.

5. Improve Process Continuously

An important part in the success of every reengineering effort lies in improving the reengineered process continuously with time. The first step in this activity is to monitor the process. Two things have to be monitored – the progress of action and the results of the action. This is done by

introducing metrics in the process and these metrics are monitored time to time to indicate the health of the process.

As for monitoring the results, the monitoring aspect could include a number of different measures as employee attitudes, customer perceptions, supplier responsiveness etc. [11]. Communication is strengthened throughout the organization, ongoing measurement is initiated, team reviewing of performance against clearly defined targets is done and a feedback loop is set up wherein the process is remapped, reanalyzed and redesigned depending on the situation at hand. Thereby continuous improvement of performance is ensured through a performance tracking system and application of problem solving skills. Continuous improvement and BPR have always been considered mutually exclusive to each other. But on the contrary, if performed simultaneously they would complement each other well [12].

### 2.5 Department Structure Follows Strategy

Chandler in his book, Strategy and Structure finds that both structure and strategy go hand and hand, and are both sides of the same coin. Chandler defines structure as "the design of the organization through which the enterprise is administered..." [5]. He links organizational strategy and organizational structure by stating that structure follows strategy- "That different organizational forms result from different types of growth can be stated more precisely if the planning and carrying out of such growth is considered a strategy, and the organization devised to administer these enlarged activities and resources, a structure. The thesis...is then that structure follows strategy...." [5]

If structure is disassociated from strategy, inefficiencies inevitably result. Chandler makes this observation in the following quote- "Unless structure follows strategy, inefficiency results... If they failed to reform lines of authority and communication and to develop information necessary for

administration, the executives were drawn deeper and deeper into operational activities and were working at cross purposes."

So as a company evolves, the company's organization structure also grows over a period of time to support this new strategy. The depth and level of changes in the organization structure is directly correlated to the frequency of the company's reassessment of the market and implementation of new strategies.

By not adapting over time and not refining the strategy and structure as the market conditions change, the organization threatens to stagnate and ossify. The greater the shift in market dynamics without a corresponding shift in an organization's strategy and structure, this non-adaptability phenomenon piles up and ultimately leads to a painful transition in the company's organization in the future, else the worst case scenario the company fails as a whole.

In conclusion, for any process to take place, the company's organization structure should support the process flow, or else the entire system collapses. For a company to keep evolving with time and efficiently cater to the existing demands of the market, it needs to keep developing its process flow and hence keep developing its organizational structure to support these process changes. BPR methodologies allow companies to radically change its business processes allowing them to better adapt to the existing market conditions. From various examples of different BPR methodologies showcased earlier in this chapter, a consolidated BPR methodology was adopted for the study of the commercialization process at Waters Corporation. For aiding this process, data was collected and the methodology followed by the team is highlighted in Chapter 4.

# 3. Product Development Process

## 3.1 Introduction

Product development processes are the procedures and methods that companies use to design new products and bring them to market. Competition, technological advancement, market changes, and product life cycles all force companies to develop new products frequently [15].

A product development process is a sequence of steps or activities that an enterprise employs to conceive, design, and commercialize a product. Many of these steps and activities are intellectual and organizational rather than a physical form. Depending on the case, some organizations define and follow a precise and detailed development process, while others may not have a detailed process. Also, not the same product development process works for all organizations. Every organization employs a process slightly different from that of the other organization. A well-defined development process is useful for a number of reasons-

1. Quality Assurance

   When the phases and check points are chosen wisely, the following development process is one way of assuring the quality of the resulting product.

2. Coordination

   A clear development process acts as a master plan that clearly defines the roles of each stakeholder on the development process. It gives everyone a clear idea of the roles of each member and the process and required documentations at key phases.

3. Planning-

The development process includes milestones required for completion of each phase. The timing of each of these milestones helps to anchor the overall schedule of the development project.

4. Management

   A development process is divided into a number of phases, and hence each phase can be better managed and scheduled. Also the process is a benchmark for assessing the performance of an ongoing development effort. By comparing the actual events to the established process, problems can be easily identified.

### 3.2 Generic Product Development Process

A generic product development process is comprised of the following steps-

1. Concept Development

   In this development phase, the needs of the target market is identified, alternative product concepts are generated and evaluated and one or more concepts are selected for further development. A concept is a description of the form, function and features of the product which is accompanied with functional specifications of the product.

2. System-Level Design

   The systems level design phase includes the definition of the product architecture, decomposition of the product into subsystems, subsystem and components specifications and a preliminary design of design of key components.

3. Detail Design

   The detail design phase includes the complete specification of the geometry, materials, and tolerances of all of the unique parts in the product and the identification of all of the standard

parts to be purchased from the supplier. A process plan is established and tooling is designed for each part to be fabricated within the production system. The output of this phase is the control documentation of the product- the drawings describing the geometry of each part and its production tooling, the specifications of the purchased part and the process plan for fabrication and assembly of the product.

4. Testing and Refinement

The testing and refinement phase involves the construction and evaluation of multiple pre-production versions of the product. Early alpha prototypes are usually built with production intended parts. They are tested to determine whether the product will work as designed and whether the product meets the key customer needs. Later beta prototypes are built with vendor supplied parts and are extensively evaluated internally and are also tested by the customers in their own environment. The main purpose of testing beta prototypes is to test performance and reliability in order to identify necessary engineering changes for the final product.

5. Production and Ramp-up

In the production ramp up phase, the product is made using the intended production system to produce the required number of products. The transition from production ramp up to ongoing production is gradual. The purpose of this ramp up is to train the workforce and to work out any remaining problems in the production process.

Figure 3-1 illustrates the generic product development process with a specific example of a turbomachiner development process.

### 3.3 Design Process Problem

The development of newer product development processes over the past decade has expanded the choices for many companies as they have reached beyond staged processes in order to speed the design process and reduce costs involved in the product development process [14, 15]. In the work done by Erat and Kavadias [16], they compare older product development prototyping processes and find them to be insufficient given the current complex product architectures. Ho and Lin [17] presented an alternative product development method based on the process of concurrent engineering. Ibusuki and Kaminski [18] suggest value-engineering product development processes. However, the biggest change with respect to the traditional stage gate models are the spiral product development process. These had been development initially for software development purposes due to frequent iterations [19]. These spiral processes are more flexible since they use design cycles in their development model to manage risks associated with product development [20, 21]. In essence, the design management research has changed with the industry practice to demonstrate a variety of product development process. Given these criteria and a number of options present, selecting the ideal development process possess a challenge firstly. Apart from this, implementing one is another major hurdle.

Several companies face several risks during the new designs iteration process of new products. To meet this challenge several authors have focused on the need to develop effective risk strategies to mitigate these risks as part of product development [22, 23]. Several studies have also organized the dimensions associated with risk or categorized development risks into- primarily technical, market, budget, or scheduled risks [24]. Technical risk stems from the uncertainty about whether a new product will be able meet its own functional and design specifications laid out earlier in the

development process. Market risk stems from whether those design specifications meet customer needs; if not, a technically successful product could fail in the market [25].

The process of product development mitigates risks partially through iterations, which are controlled and are designed in a way to feedback changes to the original design. Small iterations may include minor changes to components, while large iterations may include marketing feedback that changes the overall design or even the functional design specifications. They also manage risk through phase gate reviews, which are gates or checks between development stages that are meant to confirm adequacy of the designs. Strict reviews prevent further design until early work is finalized, while flexible reviews allow more parallel work to occur [26].

### 3.4 Managing Risks through Product Development Processes

Staged process as discussed earlier were popular for a few decades because of their controlled design structure processes. These processes methodically follow a series of steps, are characterized by a few iterations and rigid reviews, and tend to freeze design specifications early. Frozen specifications helped the companies by providing stability of design, creating sharp product definitions and reducing the need for midstream corrections during the development process. Staged processes perform especially well when product cycles have stable product definitions, have high quality standards, and use well-understood technologies, as is often the case for product updates [27, 28, 26]. Freezing design specifications within the company allowed different departments to give a structure for further processes. For example freezing a design specification allowed the company's supply chain to begin sourcing of high lead time sub components early in the development cycle.

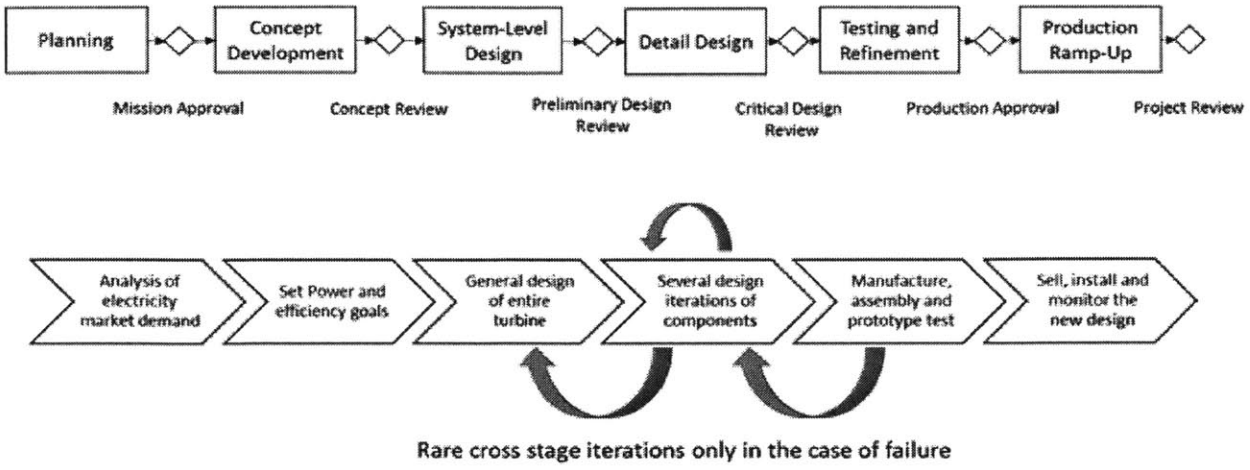



Figure 3-1: General Staged Process with a specific example of a Turbomachiner designer [13]

In Figure 3-1, first displays a general process that shows the staged nature of the product development process. Stages are generally distinct and consecutive, except for the detailed design stage, which includes several internal iterations before the prototyping of the product can begin. The staged process is called the 'waterfall' process by some researchers [29] because of its one way unidirectional nature. One of the major disadvantages of this process is that once a stage is completed, it is expensive to go back. However, there are different development process models that derive its origin from the waterfall model since at times, companies might want to revisit design issues from the previous stages. The second part of Figure 3-1 displays a case study result supporting this finding. The process and practice from Siemens- Westinghouse Power Generation makes accommodation for cross-phase as opposed to internal iterations in case of serious problems or failure. Such backward steps are rare, but it is possible.

Another important limitations of the staged model is that of rigidity and long lead times [30]. These rigid models are at times too rigid for companies in especially dynamic markets that require short development times or quick changes during development.

These insufficiencies manifest themselves in two ways. First, the staged processes can expose companies to market risk, especially if the early functional specifications or assumptions are poor. An example of market risk is when a company develops a product that meets design specifications perfectly, only to find from early prototypes or market research that the design specifications missed evolving market demands. In this case, learning about the process at the end of the development process, it is difficult to make the necessary changes in the product. Hence staged processes are sometimes difficult for projects with vague or on-the-go changing requirements. Second, staged processes sometimes have difficulty handling parallel tasks within the stages. As a result, the length of each stage may be constrained by the slowest activity within the stage, thus lengthening the development process and delaying new designs [31].

These limitations led to companies exploring other developing processes. The spiral product development process differs from the staged process because of the flexibility and feedback process laid out in the structure [32]. Figure 3-2 shows the generalized version of the spiral process developed by Unger and Eppinger [26].

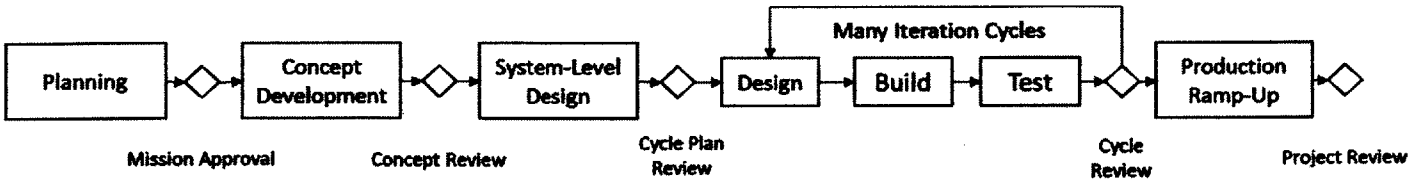



Figure 3-2: Spiral product development process [13]

The main difference between the spiral and the staged product development process is that spiral processes includes a series of planned iterations that incorporate feedback and span several phases of development. Spiral process proponents assert that it reduces burdensome and expensive rework in software, thus lowering development time and cost [32] hence it is widely used in the software industry.

The spiral PDP is repetitive of steps that include concept development, system level design, detailed design, and integration and testing. The process is flexible; the actual number and span of loops can vary depending on the project complexity. The spiral process requires managers to assess risk early in the project, which is advantageous because major costs have yet to be incurred [33].

The spiral process also has several disadvantages. First, its complexity requires significant management consideration. Second, the lack of rigid specifications can potentially lead to delays in developing complex subsystems [34].

Also, a simple spiral process with negligible uncertainty and only a single loop would closely bear a resemblance to a stage gated process; thus, the spiral process may be overkill for ordinary projects that could use a simpler staged process [20]. Hence depending on the project complexity, it is important to decide on a product development process to maximize flexibility and reduce uncertainties in the development process.

### 3.5 Phenomenon of 'Fire-fighting' in Product Development

The metaphor of firefighting typically referring to the allocation of significant resources to solve unanticipated problems or "fires". In product development firefighting describes the unplanned allocation of engineers and other resources to fix problems discovered late in the development cycle which were initially not anticipated.

Yet, despite its high uncertain costs, the phenomenon of firefighting occurs commonly in the development of new products. Creating new products is a fundamentally uncertain task, often involving unproven technologies and processes that need to be made into a reliable product with accurate functional specifications. Further, the alternatives to firefighting, such as letting a defective product reach the market or canceling it altogether, are often even less appealing which could translate into financial or market share loss.

Firefighting imposes numerous costs on the project that requires it: Introduction dates are often slipped, reducing the chance of market success; engineers and managers sometimes work extraordinary hours, leading to fatigue, burnout, turnover, and increasing the chance of further errors; and additional people are often added to the project, thus requiring additional expense [35].

The major problems that create the need for extra resources and departures from the standard development process, although usually attributed to outside forces such as changing customer requirements and problematic suppliers, are themselves the result of past firefighting efforts [36]. Due to this, while the ability to fight fires is often viewed as a necessary skill for getting the product to the market as quick as possible, required by the messy reality of developing complex products in a competitive environment, we find that even the isolated use of firefighting can quickly spread to other projects, driving out the disciplined execution of the desired development process. Many organizations experience considerable amounts of difficulty in following the product development processes prescribed in the literature, and evidence suggests that in many organizations the desired development process and the sequence of tasks actually used to create products are two very different things [37]. Griffin [37] reports that, despite widespread acceptance in the literature, almost 40% of firms surveyed still use no formal development process. Smaller sample studies also report similar results. O'Connor [38] studies the efforts of six organizations in depth and finds

that no organization in his sample was able to gain the full benefit of a new development process, even after, in some cases, three years of continuous effort.

Also, the history of management contains numerous examples of innovations like Total Quality Management that, despite documented benefits, failed to significantly influence practice in the majority of organizations that tried to implement them [39]. To avoid a similar fate, the considerable advances in process design must be complemented with an improved understanding of the factors that contribute to effective process execution in New Product Development.

In this chapter, the generic process of product development was discussed with respective to the different steps involved in building a product. Two important product development models- the staged gate model and the spiral models were discussed in more detail and their shortcomings were highlighted. In the latter part of this chapter, the process of reducing risks associated with the design process was discussed through iteration loops and doing work upfront as well as the phenomenon of firefighting was explained. Waters currently follows a staged-gate product development process, hence it has a certain set of limitations as discussed earlier in section 3.4. The current product introduction process lacks management processes for product iteration and feedback which is discussed in more detail in Chapter 6.

# 4. Methodology of Study

The commercialization process at Waters spans across a number of departments. It involves the interaction of a number of departments- RD&E, Supply Chain, Product Reliability and Engineering, NPI etc. The development process involved a number of iterations in design which was done in consultation with other groups at Waters and depending upon the feasibility and degree of adherence to functional design specifications the development process goes forward through the different gated phases.

The approach taken by the team was to first study the commercialization process as a system level process- to understand how the entire process spans and what the key deliverables are that drive the process forward. This was further analyzed by breaking down the process to understand interactions, first the interactions between departments followed by interactions between important stakeholders within each department in the process.

The process within the different departments were further detailed out by mapping the current process and using the information to create process maps. Process Understanding was carried out in a number different ways as shown in Figure 4-1.

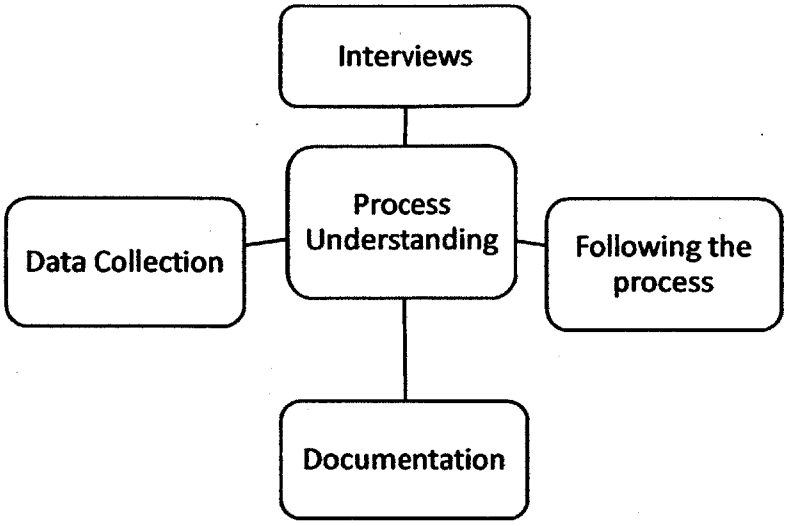



Figure 4-1: Different strategies taken to understand the process

The different strategies undertaken to study the current process-

1. Internal Project Documentation

At every key phase of the product development, different teams were assigned to create different documents as a part of the PGR deliverables such as the bill of materials list, product stability report etc. and were stored on the SAP portal (data repository). Each document milestone also had a respective document template. Each document was studied in detail and was linked to the development process in a number of ways such as by backtracking how the information flow occurred in order to write the document. Also, each document was studied as a point of interaction between different stakeholders of different departments and how each stakeholder brought their knowledge of the process to the document.

2. Interviews

Different Stakeholders were interviewed in the process to understand their view of the process. Each functional team member had different responsibilities and using the process of interview, their involvement in the process was understood in detail and more importantly the source of

knowledge creation and transfer. Also, in order to keep the process understanding objective, members with the same role and responsibilities on different functional teams were asked the same set of standard questions (see appendix A-standard questionnaire). This allowed the process of understanding the process architecture to be non-subjective.

3. Data Collection

Waters has a number of data collection tools to analyze and measure different parameters such as incoming rejects in lots, number of total parts received, number of parts ordered etc. Each department at Waters was connected through SAP modules and certain departments had localized data collection systems in place such as TrackWise and manual inputs to Microsoft Excel Sheets. Data was initially collected from all these data repositories and was first linked to the process by finding the origin of the data source and later was used to support different hypothesis created in the process of discovering different problems. Data collected was then analyzed and was used to narrow the scope of the project from the entire commercialization process to pin point problems found in the process.

4. "Following the Process"

Waters was in the process of developing a new column manager product which was set to launch by the end of last year but had been delayed. The product was first decomposed into functional components. Each functional component build was studied in detail from the RD&E source drawings to the Purchase order sent to vendor, followed by inspection of part by incoming inspection and finally to assembly of the product. The product components were studied by making some questions during the interview phase more product specific and by collecting data which was specific to the component.

5. Activities, Connections and Flow Maps

Once the Process Architecture was understood in full detail. Using the information learnt about the process, an activities, flow and connections map was created to map the entire process within the department and also at the interface between departments. Different stakeholders involved in the process were also linked to the process map. After mapping the entire process, a Gap Analysis was done to bench mark key development processes in the company and a problem list was created. The delay caused in CM-30s product introduction was also studied and the origins of the problems was traced back to the process maps created earlier and hence the origin of problem as traced back to the origin points in the process map. Different hypothesis were created to explain the problems faced by the process and were validated by the data collected in previously.

# 5. Dynamics of the Commercialization Process at Waters Corporation

This chapter explains the process that occurs at Waters within the NPI world with respect to commercialization. It highlights the process, the key deliverables and the process flow that should happen as per the Instrument Development plan. Also, the role of every stakeholder within NPI is discussed to understand the entire process architecture and process flow.

The Commercialization process at Waters includes the process from the planning stage to building a new LC equipment to finally shipping the product to the customer referred to as the first customer Shipment (FCS). The entire process is complex requiring the interplay of many different stakeholders in the process. A very high level systems view of the process is that the marketing team and the Product Feasibility team at Waters through a number of different inputs from different sources such as the end customers, technical experts decide on the feasibility both financially and technically on the development of new products referred to as the Screening Process. This process is followed by a Yes/No decision by the higher management at Waters.

Once the project is given the go-ahead, the function of the RD&E group at Waters is to oversee the feasibility of the product. Following this process, they build the alpha prototypes and detailed designs and specifications of the product. In this commercialization phase, the link from RD&E to ramp up of production to meet the market forecast (see appendix B- Milford Instrument Development Plan), the NPI group at Waters plays an important role.

At Waters, this process follows the traditional stage gate process. A stage gate system is a conceptual and operational road map for moving a new product project from idea to launch. The stage gate divides the effort into distinct stages separated by management decision gates or gate reviews as shown in Figure 5-1.

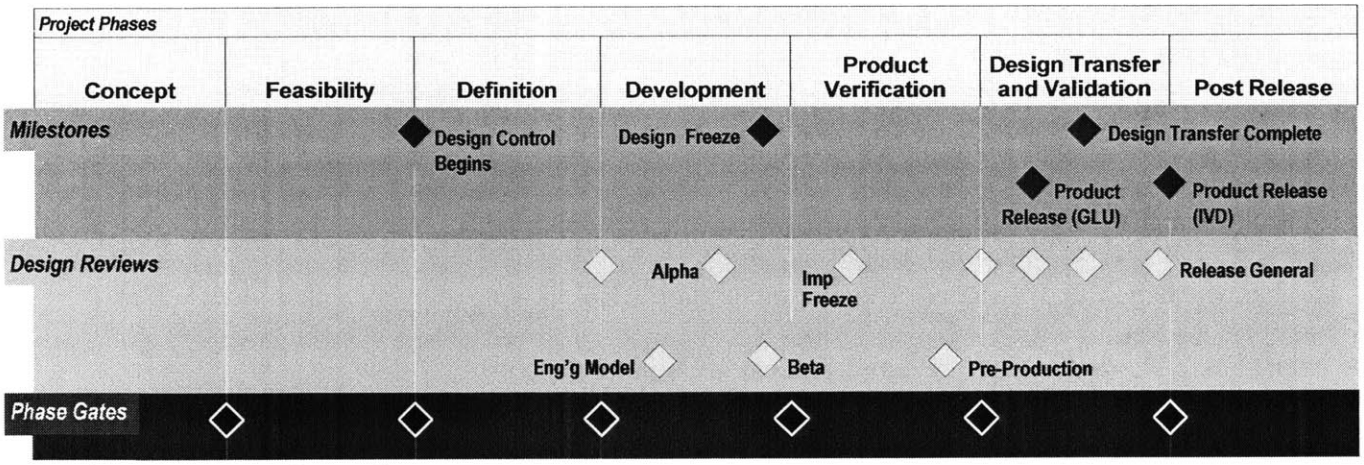



Figure 5-1: Phase Gates in the Development Process

## 5.1 Commercialization Process and NPI Group

This chapter outlines the procedure within the NPI as per the Corporate Instrument Development Plan and sets the basis of the current process at Waters within the NPI group. The NPI group provides services to RD&E in support of the product development and evaluation efforts. The support to RD&E is provided by material procurement at any stage, building prototype units and providing feedback about the manufacturability and product assurance of the product being developed. The NPI process establishes a viable volume production process by assuring the design is Manufacturable, creating assembly documents, tools, tests, and processes during the Beta and Pre-production Phases. This process confirms that designs and materials are ready for initial full-volume production builds. Formal NPI activities supporting a development project are complete when the NPI Engineer completes an Engineering Change Order changing the life cycle status of the top level assembly(s) to Release General.

Prior to NPI becoming involved in a new product introduction, RD&E requests the assignment of an NPI team to the new product. The project manager is assigned by the NPI Manger. The NPI team structure is shown in Figure 5-2.

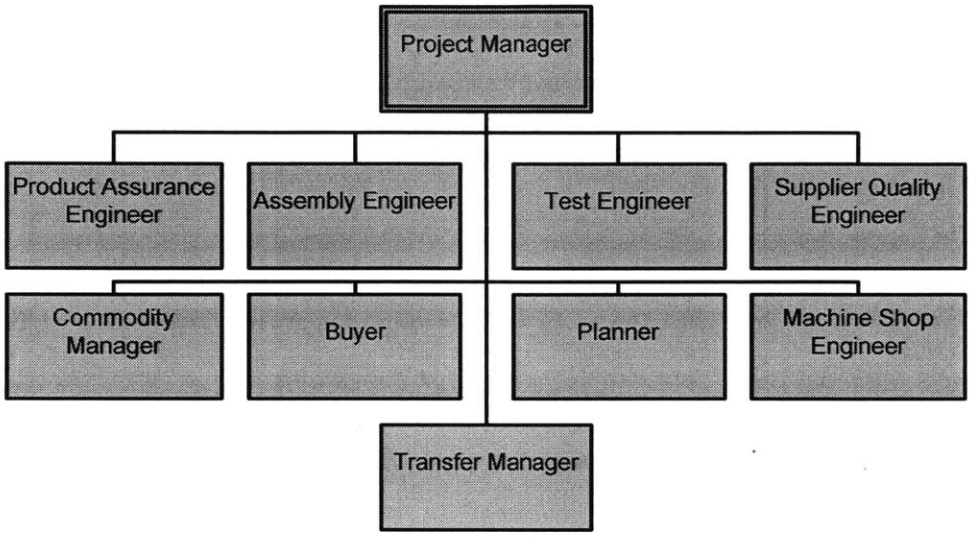



Figure 5-2: NPI Team Structure

### 5.2 Process of Commercialization –Process Flow

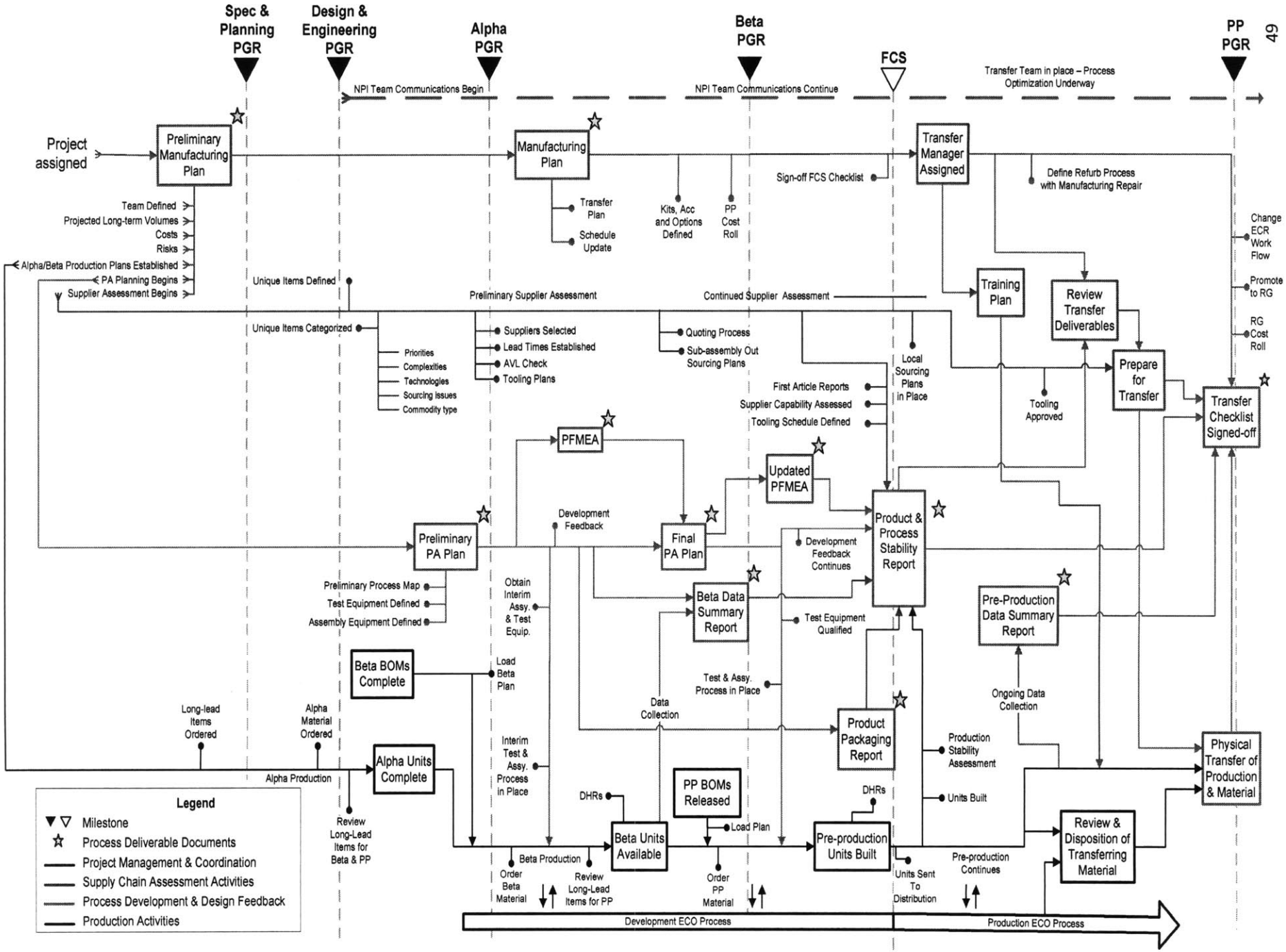
In the Specification and Planning phase, the NPI team establishes the preliminary manufacturing plan. The preliminary manufacturing plan defines the projected long term production volumes and the cost breakdown analysis and a risk analysis of the new product. At this stage, different sub teams at NPI use this preliminary manufacturing plan created as an input to create different deliverables. The preliminary manufacturing plan is an important process milestone in the specification and planning phase gate review.

The NPI Introduction process is described in detail in Figure 5-3. The Figure highlights four major areas within NPI-

1. Project Management

2. Supply Chain
3. Process Development and Design
4. Production Activities

## Figure 5-3 NPI Introduction Process



### 5.2.1 Project Management and Coordination

Once the Project is assigned from RD&E to the NPI. The NPI Project Manager takes over. It is the role of the project manager to manage and drive the entire process of development within NPI. Along the process, a number of key process milestones are required in order to pass through a phase gate. For example for the Specification and Planning phase gate review, the preliminary manufacturing plan is an important deliverable. Similarly, as shown in Figure 5-3 it can be seen that before the beta phase gate review, the manufacturing plan is an important deliverable. The manufacturing plan includes the transfer plan and the updated process schedule as well the accessory kits to the product being developed are defined. Also before the beta phase gate review, the pre-production cost is established as well. Depending upon the health of the project and sign off on other important milestones from other teams which are discussed later in this chapter, the product is made ready for FCS. At FCS, a transfer manager is assigned who reviews and manages the transfer process to pre-production. For the product to go into the pre-production stage, the important milestone is the transfer checklist document. In the transfer stage, training plans, transfer deliverables and manufacturing repair processes are established. Once all these documents are signed off, the product is moved into the pre-production phase.

### 5.2.2 Supply Chain Assessment Activities

The main purpose of the supply chain is to effectively source parts and sub components during this process. Using the preliminary manufacturing plan, the supply chain team at Waters begins to accesses the vendor who can make the parts as per the required dimensions. After the Design and Engineering phase gate review and when the design specifications of the product are almost certain, a new unique component list of parts and subassemblies is created for sourcing. This acts as the component list that the supply chain team would work with to effectively source in the near

future. Once the unique items are defined, it is important to categorize them into different groupings based on different priorities such as part complexity, technologies, sourcing issues and the commodity type. Using this, the vendors are selected and the preliminary supplier are selected via a quoting process. After this process, the lead times and the tooling plans are established. The Buyers and the commodity managers as a part of the supply chain team, start sending out purchase orders and sub-assembly sourcing plans to the vendors during the beta phase. Once the parts and subassemblies start arriving at Waters, they are inspected at incoming inspection based on the design specifications as per the design drawings generated earlier by RD&E. Different criteria such as the first article inspection reports from the vendor, supplier capability assessment and tooling schedules are used to create the product and process stability report which is a key milestone at the end of the beta phase gate review. This document checklist is the check document before first customer shipment.

### 5.2.3 Process Development and Design Feedback

Using the preliminary manufacturing plan, a preliminary product assurance plan is created. The preliminary product assurance plan contains the preliminary process map, the test equipment and the assembly equipment for the product being developed. This preliminary product assurance plan serves as the document checklist for the alpha phase gate review. Once completed, in the beta stage of development the process failure mode and effect analysis (PFMEA) is done and forms a major document milestone in the beta stage. This process is iterative and with development feedback and an interim assembly and test equipment strategy combined with the PFMEA forms the bases of the final product assurance plan. With continuous design feedback from the development process and from RD&E, the PFMEA is updated. Simultaneously, the product is being tested for performance in different operating environments. The product is also tested in different packaging

options which includes testing such as a drop test with different orientations and exposure to harsh environments to simulate real world issues faced during shipment. This forms the basis of the product packaging report, which is a key deliverable before first customer shipment.

A product and process stability report is created from the data gathered so far- both from the internal PFMEA process, the final product assurance plan and the information input from the supply chain in the form of first article inspection report and supplier capability assessment. This report forms the basis of how efficient and stable is the product being developed with respect to different criteria such as failure modes, supplier capability and manufacturability. The report forms the process milestone prior to first customer shipment. Also, after the transfer process occurs, the data is collected from pre-production builds and a pre-production data summary report is created as well.

### 5.2.4 Production Activities

From the preliminary manufacturing plan, the alpha and beta production plans are established. Once the plans are established, the parts and subassemblies with long lead times are ordered for the alpha production process. Once the lead times are established, the supply chain orders the alpha material. Once the part arrives at Waters, after the inspection process carried out from incoming inspection the alpha units are built and completed. Simultaneously, the bill of materials (BOM) for the beta build is completed. After the product is in the beta development stage, the beta plan developed earlier is loaded and similar to the alpha stage, the beta materials are ordered for long team times. After parts received at incoming inspection followed by the part qualification process, the beta units are built. The process occurs once again for the pre-production phase. At the end of the pre-production phase, the pre-production parts are built and after the transfer checklist is signed off, the physical transfer of the production and materials takes place.

### 5.3 Commercialization Process – Different Stakeholders

In the previous section, we have discussed the process flow in the product development process. In companies, the strategic goals should translate to the product development process and should be supported by the company's organization structure. In this section, rather than enlisting the company organization structure, I have enlisted different stakeholders in the commercialization process and discussed their role and responsibilities in detail. This would help to understand the process of commercialization as an interaction of different stakeholders based on the stage gated product development process. The different stakeholders in the commercialization process are-

1. NPI Manager

The NPI Manger ensures the compliance of the project with the procedure as per the instrument development plan. It's his main responsibility to identify and assign resources to different NPI project teams based on the work load. Also, when RD&E initially assigns a project to NPI, it is the role of the NPI manger to assign the project to a NPI project team.

2. NPI Project Manager

The main role is to Collaborate with the introduction team to define and develop the Preliminary Manufacturing Plan prior to the Design & Engineering phase gate review and publish it in the Project Room- virtual data repository through which information is shared. He is also required to collaborate with the introduction team to define and develop the Final Manufacturing Plan prior to the Beta phase gate review and publish in the Project Room. The Project manager ensures that all team deliverables are identified, assigned and completed on schedule. Signing off the FCS checklist for the NPI team is the final sign off in the entire commercialization which indicates the product is ready to ship to customer is controlled by the approval of the project manager. The

Manager also approves engineering change requests (ECRs), performs cost analysis and creates cost estimates time to time at different stages of the project cycles.

During the build phase, it is the NPI project manager's responsibility to initiate and facilitate build plans for various needs. He coordinates the design and drawing reviews with the RD&E project manager prior to the Beta phase's bill of material release. Also during the component assessment period he creates a list of product specific unique items initiating the supplier section process. Along with the Commodity Manager, he looks to identify long lead and risk buy components for sourcing of parts later in the process.

Apart from this, he is the main driver for the product and process stability report and also communicates with manufacturing engineering on the product refurbishment process. As the parts are received via the vendors, the role of the project manager is to prioritize parts through incoming inspection to support the build and pre-production plans. Also, during the transfer phase, his main responsibility to support the transfer manager as the product is transferred to steady sate production.

3. NPI Product Assurance Engineer

The role of the NPI product assurance engineer is to coordinate the development of near-term test strategies. They initially collaborate with the technical team to define and develop the preliminary product assurance plan which is a key milestone for the alpha phase gate review. They are also responsible for developing and qualifying interim test equipment and procedures with support from RD&E and Test Engineering. They release processes into SAP via ECRs prior to the end of the Beta phase. During the process of development, at every stage they provide cost estimation inputs to the NPI project manager for cost benefit analysis. Apart from these major responsibilities

in the alpha phase, they participate in development product design reviews for manufacturing, testability and serviceability.

In the beta phase, they conduct and facilitate the PFMEA meeting and drive the completion of this process. During this time, they chair test strategy meetings with appropriate engineering groups to draft test strategies for sub-assemblies and final products. They coordinate the beta test data review meetings with RD&E, Test Engineering and marketing to discuss and finalize performance specifications. Using this as input they publish the data summary report at the end of beta stage. Also, they collaborate with the technical RD&E team to define, develop, and implement the long-term production test and assembly processes and document these as part of the final product assurance plan which is a key milestone during this phase.

Along with inputs from the NPI manufacturing assembly engineer, they produce the product packaging report and monitor the product stability through all phases and drive corrective actions as needed. Using the data collected from the assembly and manufacturing operations during the pre-production phase, the NPI product assurance engineer creates the pre-production data summary report and publishes in the project room. The assurance engineer defines the process validation requirements as a part of the product assurance plan and collaborates with test engineering to complete the qualification of the automated test equipment. He supports the NPI project manager in creating the product and process stability report which is a key deliverable before first customer shipment.

4. NPI Production Engineer

The main role of the NPI production engineer is to define, document, and implement the assembly process and provide line support through successful product release. He is in charge of developing and implementing tooling requirements and communicates the manufacturability concerns to

RD&E through design review meetings. He reviews and implements the developmental engineering change orders and loads the assembly processes into SAP via ECRs prior to the end of the beta phase.

He trains the NPI assembly technicians on the interim manufacturing assembly tooling and processes. The production engineer also creates and maintains the product family tree during Beta and pre-production phases of product introduction. He coordinates with the reliability engineering team and the product assurance engineer to produce the product packaging report. Along with the product assurance engineer, he drives the completion of the PFMEA which is a key deliverable before FCS. Apart from these major roles in the product development process, he supports the transfer manager as the product is transferred to steady-state production and drives lean manufacturing practices when the manufacturing line is implemented.

5. Production Supervisor

The main role of the production supervisor is to identify and communicate resource constraints and shortfalls in the production process. He assigns resources to support the Alpha, Beta and Pre-production product builds and supports the Transfer Manager as the product is transferred to steady-state production.

6. NPI Production Personnel

The main role of is to support the NPI Assembly and Test processes and building and testing of the new products under the direction of the NPI Assembly Engineers, NPI Product Assurance Engineers and the Test Engineers. They collaborate with the NPI Engineering staff to develop assembly processes, test processes and techniques when needed. They provide feedback regarding manufacturability as well as bill of materials and documentation discrepancies to NPI Engineering

and RD&E. Apart from these major responsibilities, they also train mainstream production personnel during the Pre-production phase.

7. Test Engineer

The test engineer collaborates with the product assurance engineer to develop the test plan and test strategy sections of the preliminary and final product assurance plans. He provides test equipment cost estimates to the NPI project manager to cover the Production Test Equipment during the development process. He also provides support for the product assurance engineer with Interim Test Protocols and Interim Test equipment and participates in development product design reviews for manufacturing, testability and serviceability.

In broad terms, he develops and documents a production test strategy that aligns with the functional specifications of the product. He also provides schedule inputs to the NPI project manager for the development and implementation of the production test strategy. As a test engineer, his main role is to assess and qualify test equipment. He trains test technicians on the final test fixtures and procedure for Release General Transfer by qualifying a product for release status. He also plays an important role in supporting the Transfer Manager as the product is transferred to steady-state production.

8. Commodity Manager

The commodity manager interfaces closely with development and the procurement specialist on vendor selection for the part sourcing process. He works in order to develop the supplier sources for new designs, sub-assemblies and commodities for the product in development. He collaborates with the development engineers and the supplier quality engineers (SQE) on new supplier qualifications and supplier assessment process. He supports problem resolution activities when

they are identified within the supply chain and collaborates with the supplier quality engineer to resolve supplier quality issues.

He collaborates with the SQE, Machine Shop and Procurement Specialist in defining long-term, cost effective suppliers in order to meet product cost objectives and product sourcing strategies for the future to sustain steady state production activities. He also facilitates the tooling process for plastic molded designs and timely implementation and validation prior to the release of the product. As a long term strategy to offshore production to contract manufacturers, he identifies and recommends outsourcing for potential sub-assemblies.

9. Buyer

The buyer is mainly involved in purchasing and managing material requirements using the information generated from SAP and engineering requests made during the Alpha, Beta and Pre-production phases of the product introduction phase. They interact with the suppliers to negotiate and optimize costs for part sourcing. They also manage suppliers to ensure timely delivery of parts and collaborate with the supplier assessment team which includes the Commodity Managers and SQEs to qualify vendors. In terms of costing analysis, they provide costing information to the finance group for Beta and Pre-production costs in SAP and participate with the vendor to input the projected release status cost information in SAP. They also assure timely communication with the supply chain on design changes and coordinate re-works with the supply chain on engineering change requests.

They are involved with NPI in assisting and identifying long-lead items and risk-buy parts to circumvent potential shortage issues during the build stages in alpha, beta and pre-production. They provide suppliers with long-term inventory forecasts that provides them short-term flexibility

and ensures that internal Waters project schedules are communicated to suppliers and that parts are received timely to allow time for design verification and Inspection.

10. Production Planner

The production planner monitors the forecast, master plan, delivery, and production schedules. They interface with the master scheduling team during the pre-production phase to ensure that product availability is consistent with the forecasts. They provide product and service parts planning from early phases of product development until the release to manufacturing and at the time of release, they transfer all planning responsibilities to the sustaining planning group. They are involved in creating planning bill of materials and spares demand in SAP as requested by NPI project managers to support internal demands during beta and pre-production phases of product introduction.

In broad sense, they monitor production activity, deviations from the planned schedules and adjust the forecasted values accordingly. They drive for resolution of different issues such as shortages, resource issues, technical issues and quality issues which effect the completion of the build plan as scheduled, and communicate these issues to the NPI Project Manager involved. They collaborate with NPI, Demand Planning, Purchasing, and Production to execute production plans to meet the schedules and work together with the NPI project manager to ensure that build plans are loaded correctly and adjusted whenever necessary. They monitor, review, and react appropriately to Engineering change orders during the introduction period and manage material inventory requirements related to inventory reduction goals, end of life inventory reduction goals, and the NPI introduction forecasted cost estimates.

11. Supplier Quality Engineer

The supplier quality engineer collaborates with the commodity management and the RD&E to select and qualify the appropriate suppliers for part sourcing. They act as the liaison between RD&E, Production Engineers and suppliers to ensure optimal part manufacturability. They review the summary of new parts provided by the NPI Team and identify different failure modes and possible correlations between new parts and similar existing parts, with the goal of reducing failure trends. They ensure that appropriate and adequate controls are in place at the supplier to ensure consistently acceptable quality of parts and when necessary, develop quality and/or control plans with the supplier. In the broad sense, they ensure all parts meet design requirements prior to release to Release General Status. For this, they collaborate with suppliers up front to ensure that the incoming parts will meet design specifications and when required, they work in partnership with the commodity management to resolve quality issues and if needed change the suppliers when required.

12. Machine Shop Production Engineer

The machine shop engineer collaborates with NPI to execute expected orders on schedule and also simultaneously communicates realistic timelines for production parts. They plan accordingly for annual usage to properly route and produce parts giving real time feedback on the part production. They are involved in sourcing decisions- make parts in house versus buying parts from external vendors and communicates decisions with the team when required. They also participate in supplier assessments when requested by the commodity manager and support development Engineer change order implementation. They work together with RD&E and NPI in the developmental stages to ensure manufacturability and repeatability of the product. They work to minimize documentation changes at production level through constant communication with

RD&E and the NPI team. In a broad sense, they work on a common goal to reduce confusion among different teams once the product is in full production stage.

13. Transfer Manger

The transfer manger develops and implements a transfer plan for each product that is assigned to him. He manages critical transfer deliverables from the NPI process using regular meetings and other methods to "pull" the product into release general status so products can be sent to the customer.

He identifies and creates a transfer team and provides day-to-day direction and communication to the transfer team members to ensure that all team deliverables are identified, assigned and completed on schedule. He also creates and implements training plans as required to ensure successful transition of product during the transfer phase. During the transfer phase, he oversees and coordinates the transfer of production equipment to the receiving site and reviews and coordinates the transfer and disposition of materials during the transition phase as well. Apart from this, he coordinates Release General Cost analysis with the Finance group and trains sustaining assembly technicians on the final assembly tooling and processes required for the transfer status. He works to promote the product bill of materials to Release general status in SAP via Engineering Change Requests. And most importantly, manage the sign-off of the Transfer process checklist to the production checklist.

In summary, this chapter establishes the processes within NPI as per the Instrument Development Plan that should happen. This understanding forms the basis for chapter 6 which discusses the problems and issues seen in the current product introduction process.

# 6. Problems in the Current Introduction Process

This chapter highlights the problems seen at Waters in their current commercialization process. Firstly, the systems level map of the entire process is described. This is followed by a section on 'problem visibility' which explains why only in a particular section of the commercialization process, at incoming inspection the problems can be identified. Following this, the data collected at incoming inspection is presented and root causes of the problems are identified in detail. The root causes found are then coupled back to the systems level map to identify points of origin of the problems. Subsequently, the process of downstream amplification is explained. Finally, all problems are grouped and categorized as a part of different hypothesizes to explain the problems, which is used in Chapter 7 to build new process maps and for further improvement recommendations.

## 6.1 Process Maps- Systems Level Understanding

Figure 6-1 is representative of the Systems level understanding of the commercialization process within the scope of NPI.

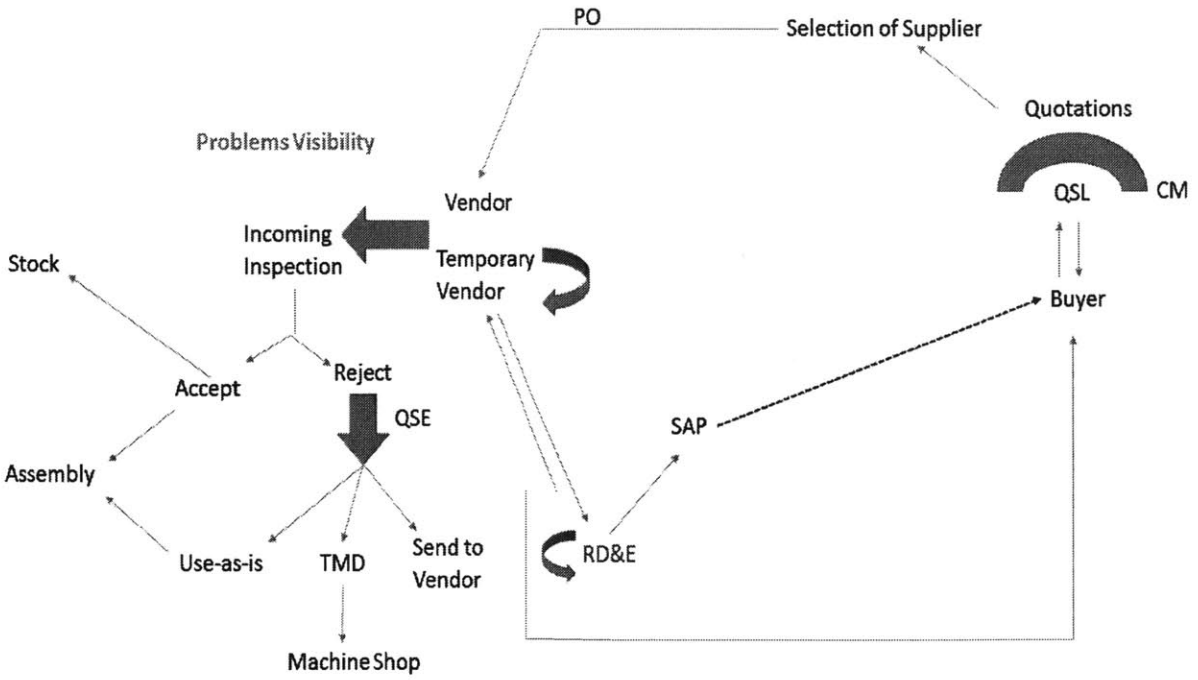



Figure 6-1: System Level Flow Map within NPI

Referring to Figure 6-1, we see that RD&E does a number of iterations on the design specifications based on the functional specifications list. During the designing phase, RD&E is in contact with external temporary vendor to understand the manufacturability of their design. The term temporary has been used to differentiate between the vendors from which vendor would ultimately would get the business contract. The vendor at his end also does a number of design reviews to assess if he can physically build the part using his equipment specifications. This process allows design increments back and forth between the vendor and the RD&E team for part manufacturability. The result of this RD&E design iterations is the design drawings and specifications of different sub components and sub-assemblies for the product that has to be released. These design drawings are then loaded onto SAP. The buyer accesses the SAP to use the design drawings for the procurement process. The Buyer, on looking at the drawing classifies the sub-assemblies into different categories such as mechanical, electrical etc. based on the expertise of different commodity

managers. After consulting with the commodity manager and assessing the supplier using the Qualified Vendor list, quotations are sent out to different external vendors for price quotes. The Qualified Vendor list is a data base of all external vendors who have been audited by the supply chain team and are capable of manufacturing and meeting Waters specification. After the quotes are received and evaluated, the external vendor is selected to make the part based on a number of criteria such as established lead time, price per part, past relationship with Waters etc. Once the supplier is selected, the Buyer sends out the purchase order attached with the design drawings. The vendor manufactures the part and sends it to Waters, which is received at receiving area and passed onto incoming inspection for part inspection. At incoming inspection, the part received is either accepted or rejected. When the part is accepted, it is a dock –to-stock process i.e.it would be used for assembly operations when the part is required. When the part is rejected, the process of disposition occurs. During the disposition process, since the part is rejected, a team is put together to investigate the non-conformance reason for the part rejection. Depending on the case, the following actions take place-

1. Information of 'part rejection' is communicated to the Vendor and the part is physically sent back.
2. A temporary manufacturing deviation plan is generated and sent to the Waters internal machine shop to work on the rejected part in order to fix the issue so that it could be used later. This is termed as 're-work' during the disposition process.
3. "The rejected part is used directly in the assembly operation. This is referred to as the 'Use-as-is' case and frequently occurs at Waters. When the use-as-is case occurs, in the disposition process, the disposition reason is noted and used for future reference. This data is collected by TrackWise and used by the supplier quality engineer on a regular basis.

Figure 6-2 below indicates the disposition of non-conformance due to supplier liability by quantity and by cost.

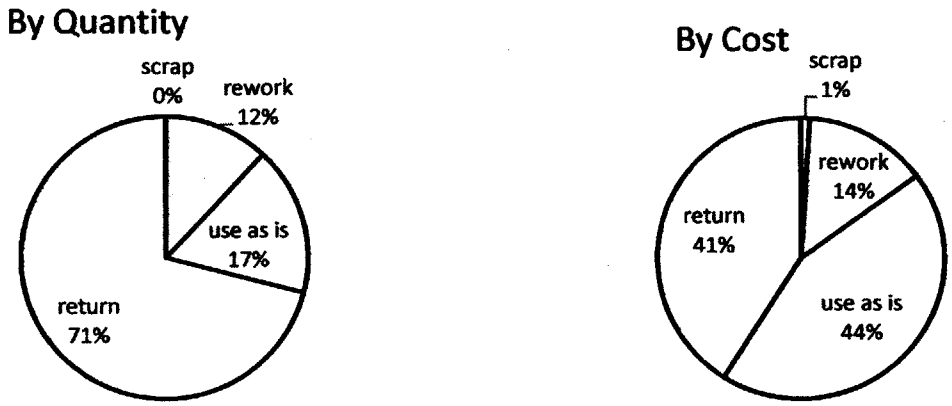



Figure 6-2: Quantity and Cost wise disposition data for non-conformance due to supplier liability

**6.2 Problem Visibility**

From Figure 6-1, the process flow of information occurred in such a way that all the problems created at the upstream RD&E stage, vendor sourcing issues at supply chain, inspection communication issues were all visible only at incoming inspection. The process of inspection allowed the verification of the design drawings to the physical part received from the vendor and hence it was an objective decision of part acceptance or part rejection- showcasing the problem.

It was seen that the problems originating upstream were micromanaged and resolved temporarily in such a way that the problem actually amplified as it progressed downstream, and finally showcased itself at incoming inspection. Due to the process of 'firefighting', the problems were temporarily fixed initially without the proper stakeholders and hence created larger issues later downstream, for example at incoming inspection due to part rejection.

This process at incoming inspection was further analyzed to trace the point of origin of the problem and the effects of amplification which has been discussed later.

### 6.3 Data Collection at Incoming Inspection

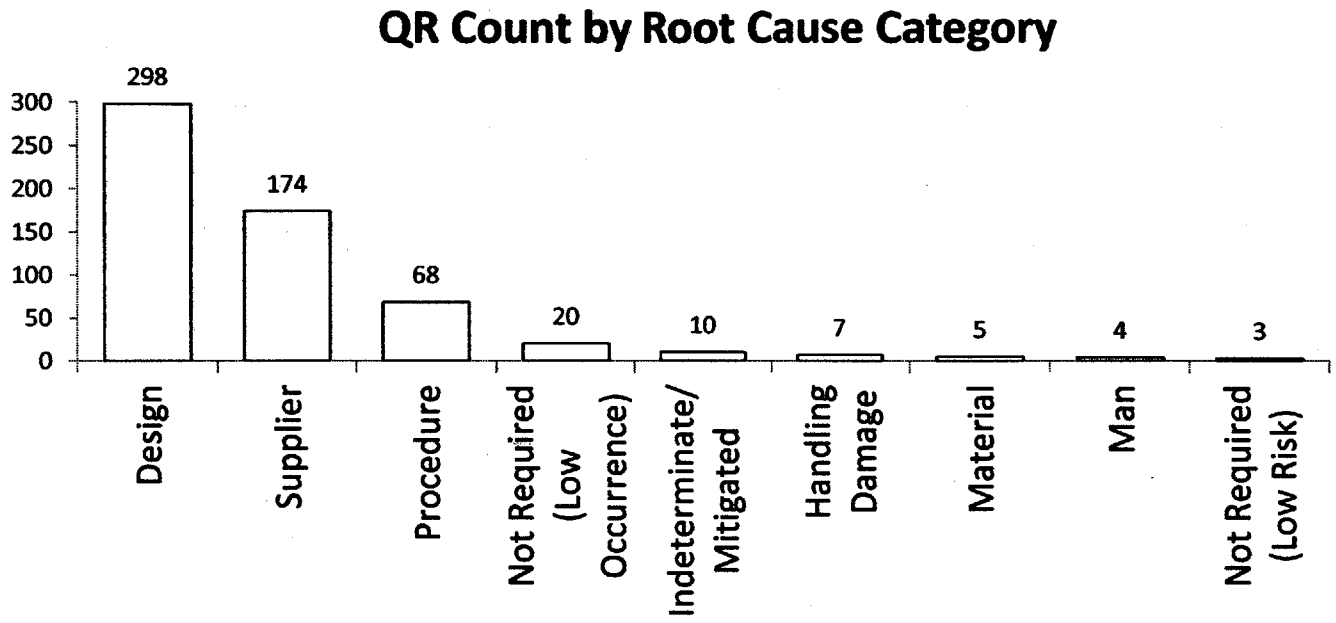



Figure 6-3: Quality Rejections at Incoming Inspection by root cause category

Since the problem created upstream is visible only at incoming inspection, a root cause analysis was done for the data collected during the quality reject disposition process. During this process, any part rejected was assigned considerable resources to identify the root cause of the problem. Figure 6-3 illustrates the problems seen at incoming inspection and classifies the quality rejects based on the root cause category for a period during the study period (data analyzed for Jan 2013 to June 2014). It can be seen that the maximum quality rejects is due to the category of design, followed by supplier and the category of procedure that refers to the process followed after dock to stock. Other categories were considerably lower by magnitude and were not studied further. The

classification of class 'not required' in Figure 6-3 is representative of scrapping of the component. It includes two separate classes for scrapping i.e. low occurrence and low risk.

The problems caused by the 'design' root cause category is much higher than the problems caused by Supplier and Procedure combined together. Due to this reason, the problems caused by design were further analyzed. The pie chart in Figure 6-4 represents the further categorization of design problems that was done by the Waters Supply Quality Engineering team during the disposition process.

One of the major issues in the disposition process that identifies root cause categories is that it was done only by a team which comprised of– SQE, Inspection and Manufacturing and did not include a representation of the RD&E at any point, which could represent a process of wrong categorization.

According to the disposition process, the current process identifies a total of 47 root causes as shown in Figure 6-4. However the problem seen was that all 47 root causes were representative of a general category of problem rather than a specific category. Also, due to this, it was difficult to pin point problems specific to the drawings. Having a specific categories would allow easier and quicker way to pin point the problem in order to solve it.

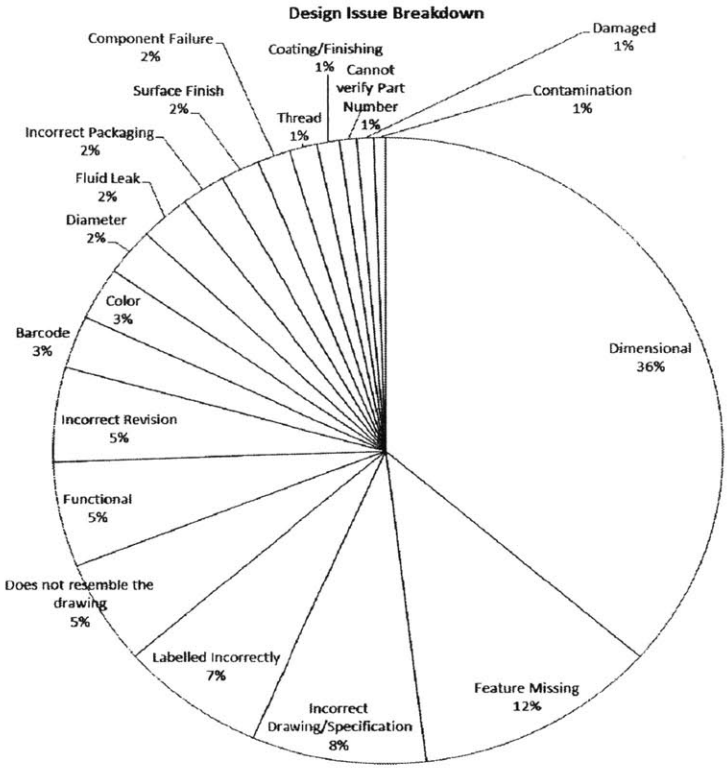



Figure 6-4: Design Issue Break Down from the disposition process

Since the categorical break down during the current disposition process were not specific hence not representative of the real problem, we analyzed the disposition data related to design at incoming inspection and categorized them into 8 workable categories as shown in Figure 6-5 that pin point the problem created during design process in greater detail.

Figure 6-5 is representative of this categorization and it was seen that the biggest contributor to the design root cause category was dimensional issues that includes dimensional tolerances on design drawings (see Appendix C-drawing 1 has a specific example of dimensional issue).

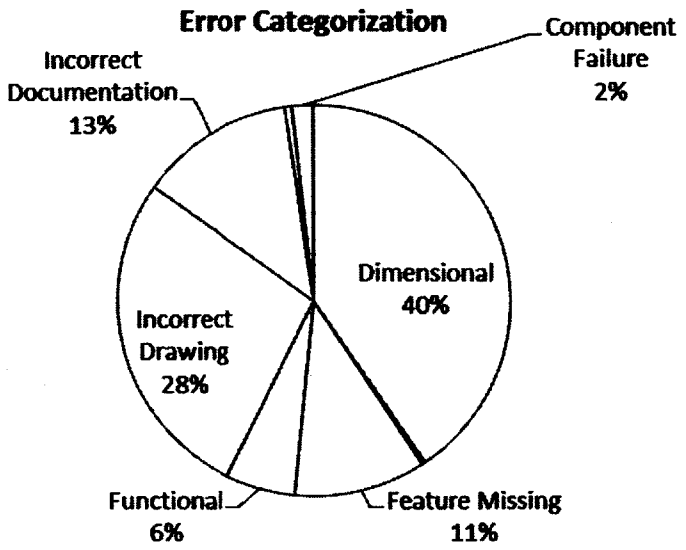



Figure 6-5: Factors contributing to Design related problems leading to part rejection at inspection

The other top three categories of incorrect documentation, incorrect drawings and incorrect part functionality in Figure 6-5 were further analyzed and broken down.

Figures 6-6, 6-7 and 6-8 represent individual breakdowns of problems contributing to incorrect documentation, incorrect drawings and incorrect part functionality respectively.

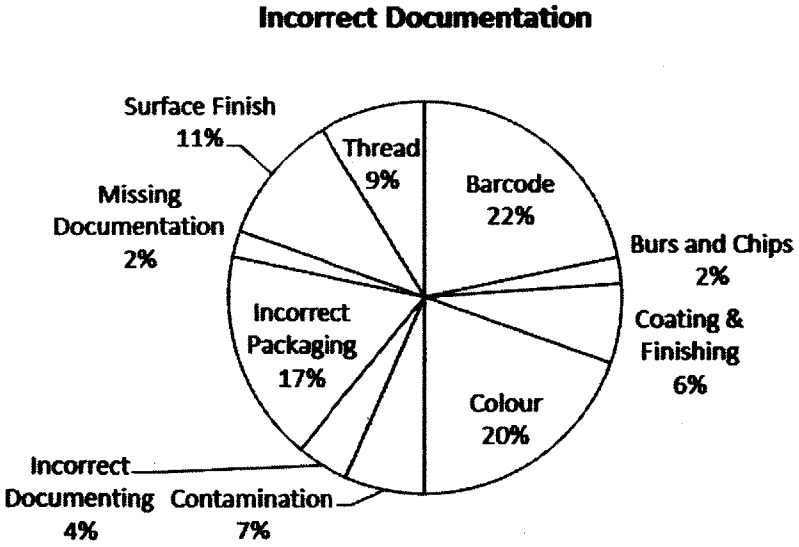



Figure 6-6: Factors contributing to Incorrect Documentation

(See Appendix C- drawing 2 has an example of incorrect documentation and dimensional error)

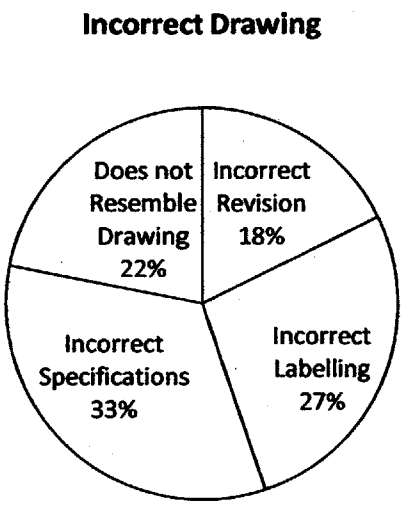



Figure 6-7: Factors contributing to Incorrect Drawings

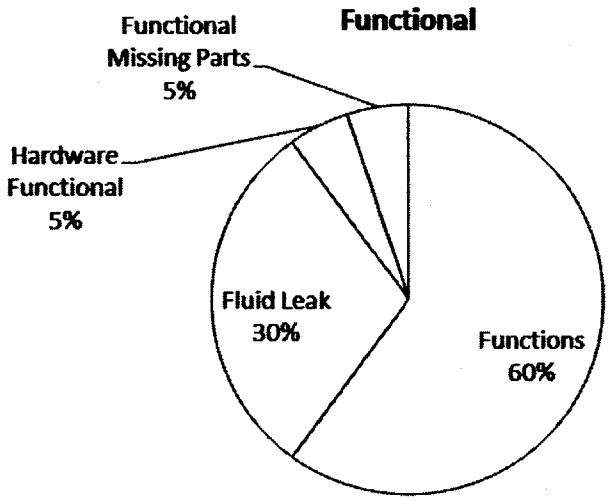



Figure 6-8: Factors contributing to incorrect part functionality

From all the three Figures, one of the main conclusions was that the not one major problem within the design categories were contributing to the part rejection but rather a number of processes together equally represented the problem of the entire system. This meant that working to improve

a single sub process within RD&E was not the way forward but rather it was required to build an entire system that ensured such problems identified did not occur and moreover the problem did not flow downstream. [2]

After establishing the different categories of problems based on root cause category, the point of origin of these problems were pin pointed to trace back the problem to the point of origin in the simplified activities connections and flow map as shown in Figure 6-9. This allowed us to identify the location where the problem originated and causes of why the problem originated.

### 6.4 Point of Origin of Problem

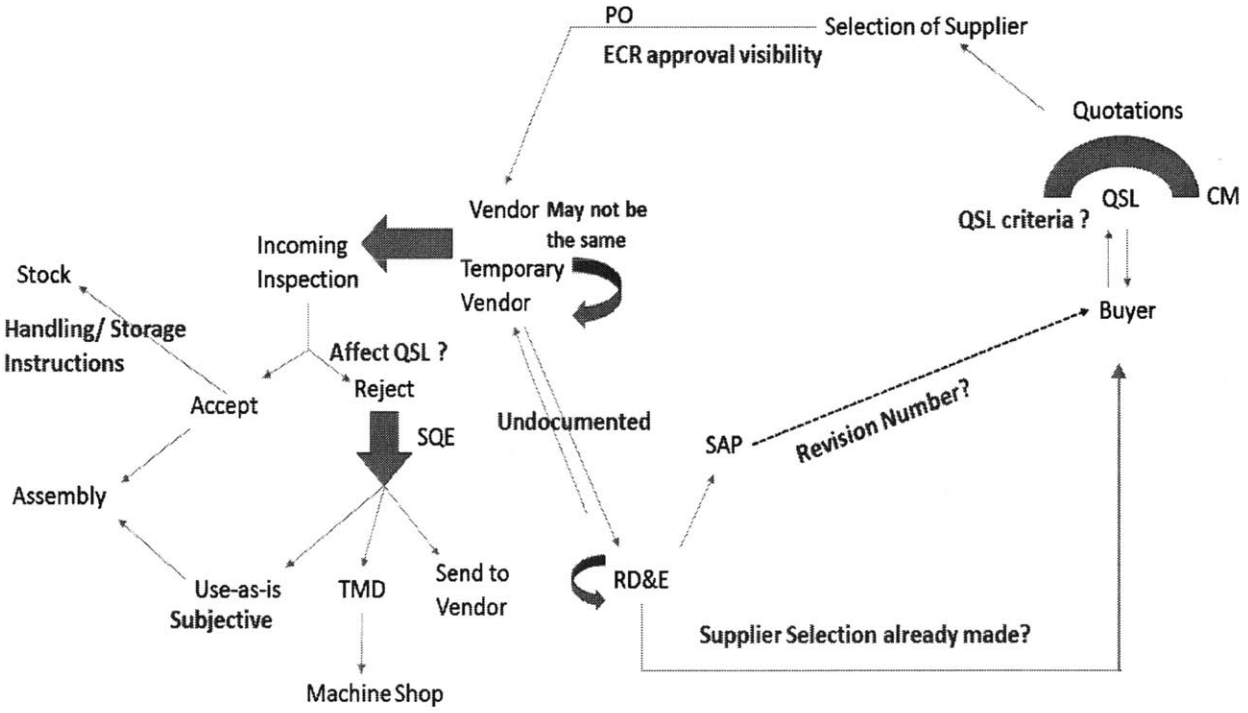



Figure 6-9: Point of Origin of the problems on the activities and connections map

In Figure 6-9, the point of origin of the problem are depicted in the systems level map of the process. The following points highlights the origin of a specific problem that leads to part rejection at incoming inspection.

1. Undocumented Design Changes

The point of contact between RD&E and the temporary vendor is the first source of issue in the process. The process of communication is highly undocumented. For example out of 10 examples noted, in 7 cases RD&E spoke directly to the external vendor on the phone and approved many designed changes such as critical tolerances, functional details, materials selections etc. and this was not followed up by formalizing these changes in the design drawings. Since the process was micromanaged and also the design drawings were not updated in a timely manner, the external vendor sent in the updated parts based on changes approved by RD&E informally, but were rejected at incoming inspection since the received parts did not match the design drawings.

2. Temporary Vendor Interaction with RD&E

At times, RD&E directly contacted the temporary vendor and this resulted in the temporary vendor also providing design feedbacks to the RD&E. The vendor used his expertise based on his previous work with Waters, his machinery, processes, process controls for giving a design feedback through Design for manufacturability-DFx reports delivered to Waters. This expertise given by the vendor was not documented in the development process resulting in the similar issue as discussed earlier of design drawings not being updated and hence the parts at incoming inspection are rejected. Due to the process of selecting a temporary vendor by RD&E, the entire process of selecting and assessing the external vendor was not done which required the involvement of the supply chain team. This resulted in a number of issues. Firstly, the contracts were given to vendors who were not on the qualified supplier list. In two examples, there were instances that the vendor did not even have the basic equipment and capability to make the parts. Secondly, RD&E assessed the vendor without involving the supply chain team thereby bypassing the entire assessment and evaluation process of the external vendor.

3. Communication with Supply Chain and RD&E

An extreme example of this case was that, there was an instance of RD&E requirement of material source control i.e. the material was supposed to be sourced from a very specific supplier (DuPont) and the requirement was of a very specific material. However, this was not communicated to the supply chain team. The supply chain team followed the process for price quotation, evaluation of vendor and material sourcing. Hence the business contract for this material was given to a different supplier. This problem was only found during the product assembly stage.

This is indicative of communication problems at the interface between RD&E and Supply chain and an example of how information is lost in the process flow leading to problem amplification downstream.

The Buyer in the development process works with a non-updated drawing from RD&E, and he has no knowledge of any drawing updates. The drawings are visible to the Buyer only on the SAP portal. Since the drawings are not an updated revision, the entire process of sending quotations, assessing suppliers are based on old drawings which creates a problem when the part is rejected at incoming inspection.

4. Qualified Supplier List (QSL) issues

The Supply Chain group at Waters has some major issues with the QSL criteria. The supply chain does not collect real time data to assess the external vendors. The time lag between the data collection to the time the QSL is effected is a minimum of 3 months. The reason for this lag is that after the part is rejected at incoming inspection, the process of investigation in the disposition process creates a time lag- since the vendor liability is to be assessed. This represents the lag period problem. During this lag period, the vendor could be issued other business contracts.

Another major problem is that there are vendors that do not have the potential in terms of expertise and equipment to make the part as per the requirements of Waters, however have been approved and are a part of the QSL.

5. ECR approval visibility issues

Once the purchase order had been sent out to the external vendor to make the part, it was seen that RD&E did engineering changes on the part drawings. The problem with this process was that the ECRs done on the parts were not communicated to the buyer and hence the supplier was not informed of this engineering change. This is due the problem that the ECRs raised by different teams were not effectively communicated to the Buyer and the Buyers were caught unaware of these changes since the ECR approval process was not visible to the Buyers. This represents another specific problem with respect to communication break down at the interface between RD&E and Supply Chain.

6. Quality Inspection Plans

Once the part was received, incoming inspection inspected the part. There are two main issues with respect to the inspection process.

Firstly, the process of inspection was done by inspecting all the dimensions on the part (both critical and as received rather than inspecting only critical to function dimensions. Also, the process of inspection by creating quality inspection plans (QIPs) were done only when the parts were received at the receiving bay. Also there currently does not exist any process of creating quality inspection plan documents and also if created for complicated parts, it was done in a localized manner by not consulting the design team. Hence stakeholder ship for creation of QIPs does not involve the RD&E engineers.

Due to these major problems of not having a formal procedure of creating of QIPs and inspecting all dimensions on a part, incoming inspection has had a backlog of more than 300 parts (21st June 2014).

7. First Article Inspection Report

The external vendor is required to provide Waters with a First Article Inspection Report (FAIR) which represents the data collected from the inspection of the parts manufactured by the vendor. The data from the FAIR report can be used by incoming inspection at Waters to validate the inspection done by the external vendor. However, at Waters only 1 in every 10 parts received are accompanied with a FAIR. The Inspection team rather than validating the FAIR report, does not use the FAIR provided by the vendor and hence inspects every dimension on the part. Also, it was seen that the Supply Chain does not mandate the external vendor to send the FAIR and the vendor is neither penalized for it. In any case, if the vendor does not send the FAIR, it does not affect his supplier assessment scores in the future.

8. Handling and Storage Problems

After the part is accepted at incoming inspection, the part is dock-to-stock so that it could be used for assembly later on. However, there were a number of instances when the handling and storage of the part post inspection created the part to be rejected at assembly. For example, in a number of instances the LCD screens used by the LC equipment produced, due to problems created during handling and storage were found of have scratches on the screen. This caused the part to be rejected at the assembly operation. The investigation team took more than 3 months in this case, to determine the reason for the scratches and was finally found to be a Waters liability issue rather than a vendor liability. This was due to the lack of handling and Storage Instructions.

9. Use-as-is case disposition process

After the part rejection, the process of use-as-is was very subjective. The decision to use the part was determined by different stakeholders at different instances of time. There were instances of project managers, reliability and test engineers, production engineers making the decision to use the part in the assembly process without consulting the primarily stakeholder and making the decision for part use. Also the disposition reason for documentation purposes given during the use-as-is was highly distributed across teams and were non-technical. No single team gave a precise reason for the part use.

These problems discussed earlier contributed to the process of snowballing downstream in the process flow. The next section explains this with a specific example of design being tolerance. It also highlights the resources required downstream to fix the problem.

## 6.5 Downstream Amplification and Cascading Effects

Figure 6-10 shows a specific example of downstream amplification effects due the problem of design being over tolerance.

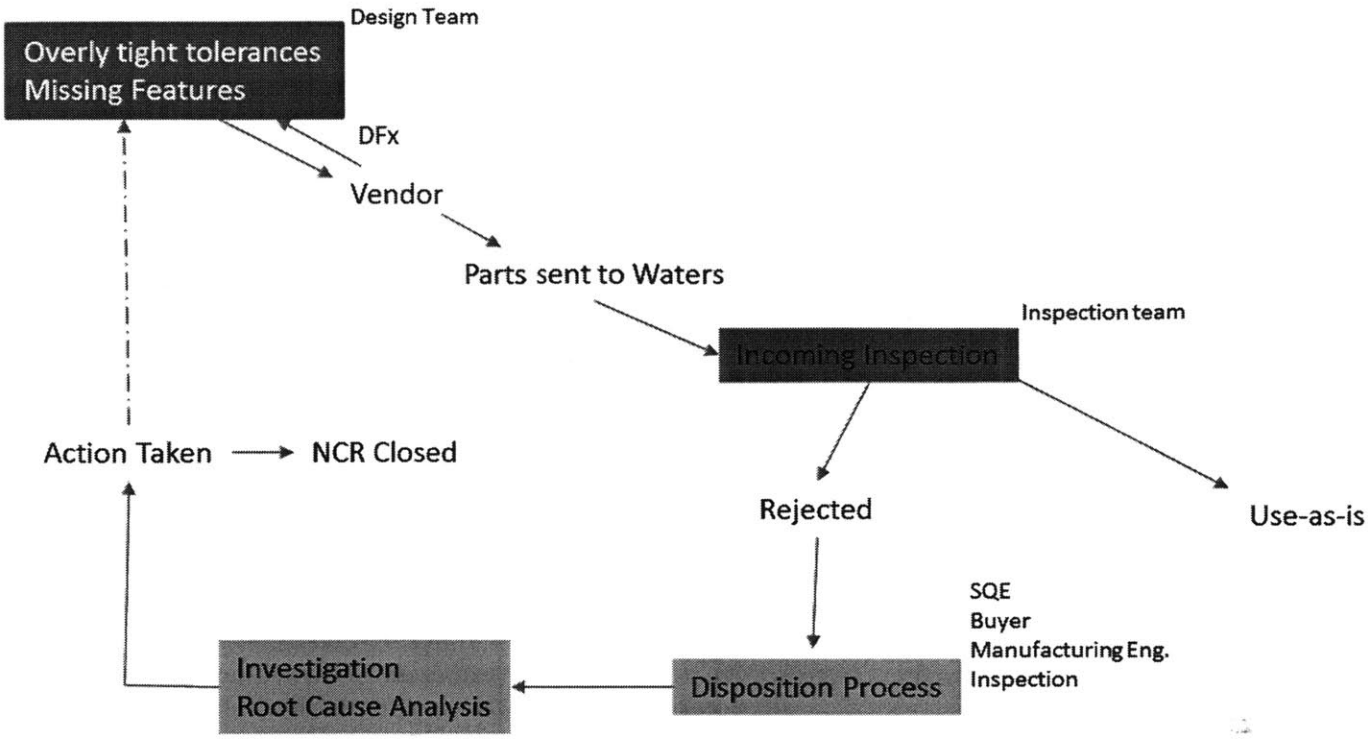



Figure 6-10: Downstream Amplification and Cascading effect

During the process of 'following a part', when the design from RD&E was too tight for manufacturing and the design review process upstream was not able to pin point this problem, this issue cascaded to different departments downstream. After the design review process, depending on the vendor, the vendor at times caught this tolerance issue and sent this as a feedback to Waters in the form of the DFx document. If this was not caught by the vendor, the parts with incorrect tolerancing were sent to Waters. Incoming Inspection rejected the part and during the deposition process, the error was analyzed. In terms of resource utilization, at the disposition process, the stakeholder ship changes to include the SQE, Buyer from the Supply Chain Group, Manufacturing Engineering and the person in charge from Inspection. These Stakeholders start the investigation process to ascertain the root cause of the problem, create a nonconformance report (NCR) and decide on the action to be taken. In this case an ECR is made to RD&E to open up the tolerances.

Once the ECR is approved and completed the NCR is closed. Table 6-1 gives specific examples of the time taken from the creation of the NCR to closing of the ECR which is representative of the time required to solve the problem found.

Table 6-1: Time taken for the disposition process to effective corrective action being taken

| SL No. | ECR# | NCR open date (mm/dd/yy) | ECR open date (mm/dd/yy) | ECR close date (mm/dd/yy) | No. of days from opening of NCR to closing of ECR |
|---|---|---|---|---|---|
| 1 | 9181454 | 7/19/2013 | 7/22/2013 | 7/31/2013 | 9 |
| 2 | 9185815 | 10/18/2013 | 1/17/2014 | 4/1/2014 | 118 |
| 3 | 9184575 | 11/12/2013 | 11/14/2013 | 3/27/2014 | 98 |
| 4 | 9184220 | 12/24/2013 | 10/31/2013 | 3/10/2014 | 55 |
| 5 | 9184760 | 3/17/2014 | 11/21/2013 | not yet closed | - |
| 6 | 9188875 | 4/11/2014 | 5/20/2014 | 6/4/2014 | 39 |
| 7 | 9183005 | 4/15/2013 | 9/19/2013 | 10/17/2013 | 134 |
| 8 | 9189311 | 6/3/2014 | 6/10/2014 | not yet closed | - |
| 9 | 9178840 | 2/12/2013 | 4/16/2013 | 4/22/2013 | 50 |
| 10 | 9185860 | 3/15/2014 | 1/20/2014 | not yet closed | - |
| 11 | 9176192 | 3/2/2013 | 1/7/2013 | 11/1/2013 | 175 |
| 12 | 9180487 | 3/20/2013 | 6/13/2013 | 7/2/2013 | 75 |
| 13 | 9175044 | 4/5/2013 | 11/7/2012 | 4/29/2013 | 17 |
| 14 | 9180779 | 1/16/2013 | 6/24/2013 | 6/28/2013 | 118 |
| 15 | 9176624 | 1/21/2013 | 1/24/2013 | 2/12/2013 | 17 |
| 16 | 9177316 | 2/8/2013 | 2/20/2013 | not closed yet | - |
| 17 | 9178840 | 2/12/2013 | 4/16/2013 | 4/22/2013 | 50 |

From Table 6-1, it can be seen that the time required to solve the problem depends on the category of the problem. Certain problems can be fixed easily whereas majority of the problems take considerably a long time, hence consuming much more resources downstream. Hence creating systems for finding problems early in the process is very helpful both in terms of time and resource utilization.

On more detailed analysis, it was found that the NCRs classified the problem into different categories. There are two main issues with the current categories. Firstly the number of categories

created are too broad and subjective in nature and these categories have been created without the involvement of the design engineering team. Also, it was seen that there is no RD&E involvement in the disposition process. Since the categories are not very broad, there is considerable amount of time lost in back tracking and finding the appropriate stakeholders upstream in RD&E.

### 6.6 Problem Hypothesis

Based on the problems discussed earlier, all of them were grouped together within each major category and was used as a starting point for building a new process map to address these major issues.

1. Lack of Functional Integration between departments

   This was the biggest problem seen within NPI. By various departments here, it also includes various sub groups such as incoming inspection, RD&E, supply chain, manufacturing engineering etc. A common sign of this problem that was seen was that people downstream were caught unaware of any actions taken upstream. As discussed earlier, upstream RD&E actions were not visible across downstream departments such as supply chain and incoming inspection. As a part of the activities, connections and flow diagram, it was seen that information and product knowledge was lost in the process flow due to lack of formal communication channels.

   Between phase gates, the phase gate documents acted as a transfer document from one phase to another phase, was found to be inadequate and did not document all the product and process knowledge. Due to this, small gaps which could be fixed upstream actually end up cascading in the process and hence the problems amplified downstream as explained earlier.

Since the entire product introduction process involved the stakeholder ship of different departments and the process flow was not well integrated. This resulted in information loss at the interfaces.

2. Inadequate IT Integration

   Waters uses a number of IT tools for managing the product development process and for product management. One of the biggest issue seen was that across departments, every department used a specific IT software/ tool. This was not uniform across departments, and instances were seen that due to this information was not shared across departmental verticals. If the IT integration was done well, it would make the product introduction process more streamline by helping integrate different stakeholders in the process.

   Waters uses an enterprise resource planning (ERP) software by SAP which is commonly used by all departments. With SAP, it was seen that a number of stakeholders did not have access to the required SAP modules needed for communication and information transfer. Also, with respect to Quality Management, it was seen that Waters in spite of having purchased the SAP module, it was not being used by any department.

   As a result of this there was no synergy across verticals, hence the decision making process also was not data driven, which also contributed to the problems as a whole.

3. Lack of Feedback process

   For any process to be functional, the process should allow two way transfer of information- both outwards and inwards. As discussed earlier, at different instances such as the interface between RD&E and Supply chain, RD&E and Incoming inspection, RD&E and NPI, Incoming Inspection and Supply Chain there was no feedback process in terms of communicational channels. Due to this, each department worked as an independent unit.

Also, due to not having a feedback process, there was no way to measure if the actions taken initially were correct or wrong, for example whether the action taken downstream solved the problem or created or escalated an existing problem.

This ensured the process was not robust enough and restricted information flows leading to greater redundancy in the process flow.

4. Lack of Involvement of Appropriate Stakeholders

As cited earlier with a help of a number of specific examples, it was seen that decisions were taken without the involvement or consultation of the appropriate stakeholders in the process. This lead to problems related to downstream people being unaware of the pressing issue or the actions that were taken upstream. Also, due to this the expertise of different engineering teams do not end up reflecting in the product and hence lead to a larger number of unplanned iterations. Due to this problem, the faults were found too late in the process and hence unplanned iterations are more expensive and time consuming.

Specific examples discussed earlier include no RD&E involvement in Quality Inspection plans, No source control information from RD&E to Supply Chain and no involvement of RD&E in the part disposition. From all these examples, it can be seen that each process forms the interface between two departments and due to this, the integration across the product introduction process is not present.

5. Lack of Generational Learning

Due to lack of historic data of previous product introductions, it was difficult for the managers to learn from the previous problems faced. For a process to be mature and evolving in nature, it is required that the number of unplanned iterations from project to project decreases, which translates into resource optimization and better resource

forecasting. However, with Waters, across all project teams, there was no such document or data metric that was present which would allow such a continuous learning process to happen.

6. Lack of Organized and Structured Data-

   Waters lacks a comprehensive feedback mechanism for continuous improvements activities across all departments. Also for monitoring any process or for the purpose of decision making, we found that the process was not data driven and instead rested on intuition or the 'gut' feeling of the person involved. It was seen that data was collected during the process but was not organized in order to provide a feedback for measuring process productivity or data metrics for evaluating the process. As discussed earlier, in RD&E, there was a lack of data metrics for evaluating design and design changes and lack of data for evaluating process within NPI.

   Also, in a particular case, data was organized after the disposition process with respect to number of acceptance/rejects category wise but was not feedback to RD&E for process evaluation or process improvement initiatives.

7. Missing Management Processes

   There were a number of processes that occurred which were not supported by the organizational structure of both RD&E and NPI. It was seen that for a fully integrated process, a number management process were lacking at departmental interfaces. Due to this, functional overlap was not seen and each department functioned as a secluded sub unit. As explained earlier, a process for creation of quality inspection plans was missing. Apart from this, lack of management processes also meant having no formal processes for information transfer or formal feedback processes.

# 7. Proposed Process Map

This chapter discusses the new process map for creation of quality inspection plans based on the requirements and the constraints for the purpose of implementation. Changes to the current process of inspection and disposition have been discussed as well for improved efficiency.

## 7.1 Process Map Creation for QIP Implementation

The main purpose of creating new processes is that it should allow iterations to take place quickly and efficiently, reduce the overall time taken and reduce redundancy in the process flow [30, 31].

For this it was important to create interaction points in the process flow from where information can be shared between departments especially between downstream NPI departments and RD&E [22, 23].

A key constraint for creating the new process was that Waters should be able to use them. This meant that the new process was not supposed to be change the existing process dramatically instead a small change should allow dramatic improvements in process efficiency. Also this would allow the suggested process to be readily implemented since considerable resources would not be required for implementation.

As discussed earlier the incoming inspection team currently acts as a single isolated entity without any connections with any departments either upstream or downstream. The only connection is the process of disposition that occurs after the part is rejected after inspection.

The main aim of the creating a process map was to create a new set of documentation that can drive newer processes and allow better functional integration between RD&E and NPI.

### 7.1.1 Quality Inspection Plans

For the Inspection to carry out inspection of the incoming parts, it is required to create Quality Inspection Plans (QIPs) that detail out the process of part inspection. As discussed earlier, incoming inspection currently inspects all part dimensions on the incoming part immaterial of the dimension being a critical or non-critical part. Due to this inspection strategy, time taken per part is very high, which is wasteful as well. Also inspecting non-critical dimensions repeatedly is not effective with respect to resource efficiency.

The new improved process is illustrated in Figure 7-1 proposed aims to solve these problems which were discussed in the earlier chapters.

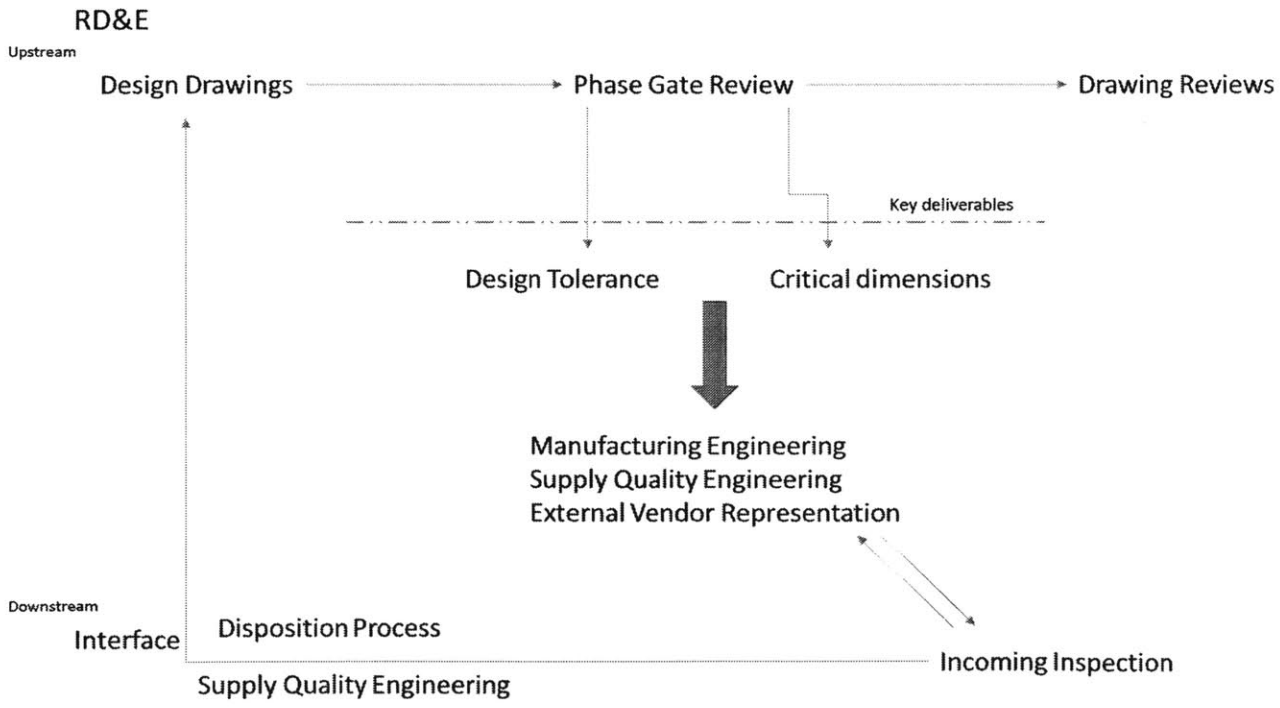



Figure 7-1: Process Map for Quality Inspection Plan

As a part of the new process map, during the Phase Gate Review process, we add three extra deliverables. The templates are attached in appendix B. The three deliverables proposed are-

1. Stakeholders Involvement

The document should include names of all key personnel involvement, their key responsibilities during the design phase. This helps to establish accountability in the process [5]. Also, if problems are found, this document would help to find the appropriate stakeholder for fixing the problem [5].

2. Critical Dimensions

The critical dimension of a part documents all the important dimensions of the part with respect to the following:

- Critical Dimensions for Process Control
- Critical to Function dimensions
- Critical to Inspection dimensions
- Critical to Change Dimensions

This document would be the key driver for the quality inspection plan. As explained earlier in section 3.3, this check point would serve as a product evaluation in the early stages and can be used for product planning.

3. Engineering Tolerances

The main purpose of this document is to give a list of all permissible limit or limits of variations in the physical dimension of a part that has to be engineered. This would allow firstly, a second review of the design by a different stakeholder such as the NPI manufacturing engineering team. Based on the inputs from different departments, it would allow a second review of the engineering tolerances and can be used as a point of feedback. Using this second review as a feedback point from NPI to RD&E can keep mitigate risks associated with product development earlier in the process [22, 23].

The use of this document is specific to getting design for manufacturability feedback for the design team and include NPI earlier in the product development process. This could be given by in-house expertise via the manufacturing engineering team or even by the external vendor who has to make the part. This document would allow the process to finding if tolerances are too restrictive early in the product development process.

### 7.1.2 Process Flow

The main idea of creating these two deliverables upstream is because design already has these information since it is required for the product design process. Hence in terms of resource utilization creation of these documents upstream is very low. Also, creation of these two deliverables upstream are relatively simple as compared to document creation downstream due to the presence of appropriate stakeholders such as design engineers [5].

This is followed by two meetings to discuss each document in more detail with the following stakeholders- NPI manufacturing engineer, supply quality engineer and the representation of the external vendor or a Waters commodity manager dealing with the vendor closely.

The agenda for the first meeting would discuss all the engineering tolerances with the purpose of giving a design for manufacturability feedback. This comes in the form of in-house expertise by the manufacturing engineering group and from outside Waters by the Vendor who has to finally 'make' the part. Design tolerance reviews allow the tolerance to be reviewed in terms of process to build the part and also gives RD&E an opportunity to review the tolerance values in case the tolerance is too tight for manufacturing. Also with the representation of the external vendor and the supply quality engineer, it is possible for both stakeholders to prepare themselves based on the design specifications and provide expertise as well. This would ensure no stakeholder involved is

caught unaware of the changes and also information to be communicated across departments [4, 5].

The main purpose of the second meeting is to establish all the critical dimensions with respect to different categories with the help of RD&E. The critical dimensions establish the most important parameters on the design specifications and hence building inspection plans around them allows the inspection team to inspect only critical to inspection dimensions and not all dimensions. Also, establishing critical to function and critical change dimensions would allow downstream departments with the required information for sustaining development efforts mainly required for on-field cost cutting exercises. Establishing these critical dimensions and having the external vendor as a part of the process, would allow both RD&E and incoming inspection to direct their expertise to the vendor and establish standardized protocols for inspection that would be required. Using this information of critical to inspection, incoming inspection and the supply quality engineering group would build procedural protocols for the inspection process. This would create the quality inspection plan for incoming inspection to follow in the future.

This would allow NPI Engineers to start planning and working upstream and hence better manage the transfer phase from RD&E to NPI [4, 5].

Another key aspect of this process map is that the Supplier Quality is the representative of the External Vendor. This means that the FAIR that is sent to Waters is received by the SQE and shared with incoming inspection to verify the validity of FAIR [3].

### 7.2 Process of Inspection

With respect to the process of Inspection, the first inspection that incoming inspection carries out is to inspect all dimensions on the part sent by the external vendor. This is followed by a report

that is an acceptance or reject report based on the inspected dimensions which is cross-verified with the FAIR sent by the external vendor.

If the FAIR is deemed wrong, the information is feed back to the supplier quality engineer and the corrective action is taken by affecting the supplier performance [3]. The subsequent parts sent to Waters, are inspected only for critical dimensions and not a complete inspection of all parts are carried out. The certificate of analysis sent by the vendor would be audited to determine all other dimensions. This would make the inspection process more efficient.

After the third lot, the dock to stock process occurs. The inspection process after the third lot should be based on a random sampling criteria, the incoming lots are inspected for verification after they have been docked to stock.

### 7.3 Disposition Process

With respect to the disposition process, the main purpose is to include the involvement of right stakeholders within RD&E. The QIP process map developed earlier would document a list of all lead design engineers and their responsibilities through the first Stakeholder deliverable. Based on the assessment of the Supplier Quality Engineer (SQE), the key personal involved in the RD&E would be included in the disposition process.

Also, the data that is currently inputted to TrackWise, has to be first standardized by RD&E by creating a list of standardized root cause categories. Also this list of categories has to been jointly approved by the SQE, RD&E and incoming inspection.

This data compiled from TrackWise has to be sent to RD&E Project Managers evaluating the ongoing development process. Since RD&E currently lacks data metrics, this feedback in the form

of reports can be used for finding problems with respect to RD&E design drawings and over a period of time, these can be reduced via continuous improvement initiatives [12].

# 8. Recommendations

As discussed in the earlier chapter, the proposed process map for QIP would allow help solve a large number of issues with respect to functional integration between NPI and RD&E, formal communication channels and create a new process which has been missing. Hence it is highly recommended that the company should implement this proposed process.

As discussed earlier, the standardization of the disposition process with RD&E as a major stakeholder, is highly recommended.

Apart from these, other suggestions are included below, these have been categorized as departmental recommendations from upstream to downstream in the order of process flow-

## 8.1 Research, Development and Engineering

1. The process of data collection at different stages and data analysis as a part of the post-project performance should be performed. Also, a creation of all project-learnings document should be made that documents all the unseen problems faced and steps taken. This can be used in the future for planning and forecasting resources. So, after FCS, every team can share and present their learnings during their project to different teams within NPI. This would help to share process knowledge across teams which currently remains localized.
2. Having appropriate stakeholders at Drawing Reviews has to be reviewed once again [3]. The process of drawing reviews currently seems disorganized. A 'divide and conquer' approach would help Waters. The design review can be broken down into a number of different drawing meetings at component level based on commodity such as sheet metal, machined parts etc. and at a systems level assembly and review meetings can be held.

Hence for each meeting, proper participation can be accessed easily based on commodity type and design corrections can be made quickly.

3. The process of design reviews should occur earlier in the product development process. Also, designs should be made rigid and the required work should be done earlier and not postponed for later [3].
4. The Data taken from TrackWise should be used for continuous improvement initiatives within RD&E. From our study it was seen that the performance variation between teams was high, and using the data provided from TrackWise for design mistakes would pin point deficiencies in different teams. Using this, appropriate training can be given to the Engineering teams [9].
5. During RD&E discussions with the temporary vendor, the lead design engineer should take the responsibility for updating all the drawings. In case the drawings are not found updated later, he should be held responsible. Also he should be responsible for updating the SAP database with the latest drawing revision number.
6. Projects should be categorized based on the level of technology. Most of the products released range from a minimal engineering changes to new technology based products. This would help systematic resource allocation for different projects.
7. Establishing new metrics for importance of sub-components in a product should be carried out, and this should dictate resource allocation. This would ensure important components are designed and engineering up to the required specifications.

### 8.2 Supply Chain Interface with External Vendor and RD&E

1. Currently there is no process map for receiving any documents such as Inspection reports and process control plans from the external supplier. Making the Supplier Quality Engineer responsible for the receiving of the documents by interfacing with the external vendor after the contract has been sent out would solve this problem.
2. The supply chain should be responsible for making the vendor liable for sending in the following reports- FAIR, Certificate of Compliance, Certificate of Analysis, Process followed at Supplier for making the part, Statistical Process Control data and other important information about the manufacturing of the part. The vendor can be made liable by downgrading the supplier's performance score card. A specific section based on these criteria can be added onto the score card and appropriate weights can be assigned based on the criticality criteria of the supplier. This subsection can be used to access the degree of response of the supplier to Waters.
3. Also, for evaluating a new supplier, it is important to evaluate the supplier on the basis of the degree of response. Similar to the previous idea, the subsection can be added to for assessing new supplier for the QSL. A separate section can be added which details questions regarding the following reports-FAIR, Certificate of Compliance, Certificate of Analysis, Process followed at Supplier for making the part and Statistical Process Control data. It can be used to establish standard communication practices of Waters with the Vendor by asking the vendor to provide the prerequisite documents discussed before [2].
4. Process of downgrading the vendor should be visible to the Buyers as well. This historical data should be used to decide on the external vendor and the decision should not be based on 'intuition'.

5. In the cases where ECRs were made after the business contract was given out, implementing a joint ECR signoff process would be beneficial to both RD&E and the Supply Chain team. A joint ECR signoff process means that unless both RD&E and the buyer from the Supply chain don't sign off, it is not approved by the system. This would ensure, that both stakeholders understand the changes made during the ECR and hence it can be communicated to the external vendor.

### 8.3 Incoming Inspection

1. Use of the Quality Management SAP software tool across different departments. The QIP process map can use this module to save all the required documents and access can be given to the all the stakeholders who are a part of the QIP creation process.
2. Incoming Inspection should do a 'dock to stock' process based on the handling instructions received from the vendor. This would help reduce problems caused by handling procedures.
3. Incoming Inspection should inspect part dimension based on the inspection plans rather than inspecting based on the design revision as a part of the traveler. Also in the process of inspection, incoming inspection should recheck on the latest design revisions and use the same in the process of inspection.

### 8.4 Disposition Process

1. RD&E should standardize the symptom codes for the problems found at disposition related to root cause category 'Design'. Also, they should have a representative from RD&E in the disposition process.

2. The SQE should standardized the 'use-as-is' process by standardizing different root categories of 'use-as-is' with appropriate stakeholders. This would ensure that the 'use-as-is' reasoning process is not subjective. Also, in the near future, the process of 'use-as-is' should be minimized.
3. This could be used as data base for creating data metrics for product evaluation. For example metrics such as – percentage of problems related to incorrect drawing, percentage of problems related to over-tolerancing, percentage of problems related to incorrect documentation etc. Also, the metrics could include trend lines indicating number of specific design related errors and could be monitored for project management.

# 9. Future Works

This section overviews areas of work that could be pursued by Waters to further improve the process of Commercialization.

### 9.1 Product Decomposition for New components Designed

For a large number of a new product releases, it was seen Waters only engineered a small set of new sub-components and used the previous sub-components from already existing products for the final product.

Due to this, for new products introduction, a system level decomposing to sub-components and subsequent identification of new components could yield a number of benefits. One of the key benefits is that, resource allocation can be done better by allocating more resources to new sub-parts rather than allocating resources for already existing sub-components.

Also, in case of component level testing, more stringent testing requirements for newly engineered components and can be created. The information of new sub-components can produce a number of benefits at systems level testing as component level interaction can be mapped easily. A methodology for this, could be an initial document from RD&E which establishes the components type. This could be share with other downstream departments such as incoming inspection, testing and reliability engineer for better resource planning and optimization.

### 9.2 Product decomposition for Component specific Process Map

Waters currently follows a generic process map for product introduction without taking into account the type of material involved. By this we mean that, the process map for handling ceramics

is the same as that for handling sheet metal, electrical components or even plastic components. Due to the nature of each component, having a generic structure for handling all of them is not very efficient.

Hence each component should have a specific process map for the product introduction process. The process map could be very useful for internal processes for incoming inspection and Supply chain. Currently at Waters, firstly no such data collection system exists and neither does a system to track how much time a sub-component spends in each process exist.

### 9.3 Commodity Specific Production Part Approval Process

This system is used by the automotive industry for establishing confidence in component supplier and their production processes by demonstrating that all specifications requested by the customer are properly understood by the vendor and that the supplier has the proper process to consistently meet those requirements. The result of this process is a series of documents that are called the "PPAP Package" which are formally approved by the vendor and Waters. Waters currently uses this process for the plastics components, but the percentage of acceptance of plastics parts is only 83 % [3].

The suppliers are required to obtain approval from the customer whenever a new or modified component is introduced into production or when a manufacturing process is changed. Below are a list of 17 key PPAP elements [41] that are jointly reviewed by the customer and the vendor in case of the automotive industry.

1. Design Records
2. Authorized Engineering Change Documents
3. Engineering Approval

4. Design Failure Mode and Effects Analysis (DFMEA)
5. Process Flow Diagram
6. Process Failure Mode and Effect Analysis (PFMEA)
7. Control Plan
8. Measurement System Analysis Studies (MSA)
9. Dimensional Results
10. Records of Materials / Performance tests
11. Initial Process Studies
12. Qualified Laboratory Documentation
13. Appearance Approval Report
14. Sample Production Parts
15. Master Sample
16. Checking Aids
17. Customer Specific Requirements

Having this generic PPAP process modified for Waters could help Waters deal with the issue of whether the vendor can actually make the part physically. The documents could be delivered in two stages. Documents 1 to 7 indicated above can be used for communication by Waters to the Vendor during the quotation phase for the purchase order followed by the other Documents from 8 to 11 after the first production run by the supplier.

The modification to this process could be made in terms of making this part approval phase being made specific to each commodity type such as sheet metal, ceramics etc. For every commodity, the 17 PPAP elements discussed, could be decided based on a priority list and can be used for the part approval process in the two phases. Among the 17 documents, a set of them can be made

specific for every commodity for which the vendor is responsible. This would make the PPAP process commodity specific.

### 9.4 Modular Product architecture

The product architecture of the products released could be redesigned to make it a modular based product. Certain low technology modular sub parts could be procured as an already assembled product. This implies that the vendor would carry out the assembly process and this would shift the problems faced during assembly from Waters to the vendor side. To carry out this, two main requirements would be to first create a modular architecture of the product and establish low key risk and low technology sub modules that could be outsourced out of Waters. High Innovation sub modules can be still built and assembled within Waters to ensure key technology know-how remains in-house and is not lost.

### 9.5 Data Enabled Decision Making and continuous Improvement Initiatives

NPI and RD&E lacked project metrics and performance metrics across different stages of the product development process. The lack of metrics directly translate into the lack of data and data collection systems. Traditionally, Waters has relied on intuition based decision making rather than based on numeric data collected earlier on different aspects such as quality, risk buys etc.

Making the use of historical data for decision making would help Waters tremendously. For this, firstly, within the process flow it is important that certain sub-processes are required to collect data and analyze them for root causes and reasons that lead to creation of problems. Big data can unlock substantial significance by making information transparent across departments and usable at much

higher frequency for appropriate stakeholders. Having a common product management software across departments would help integrate processes better.

This would also translate into continuous improvement initiatives that could help increase the overall efficiency. Also, this data collected could be analyzed and presented in the form of reports to the concerned departments and act as feedback loops.

# Appendix A

## A-1 Standard Questionnaire Used

### Standardized questionnaire for interview

What is your name and designation?

**Duties & Responsibilities**

1. What are your key responsibilities at the –
    a) Alpha stage of the development process
    b) Beta stage of the development process
    c) Pre-production stage
2. At what stages of the development process are you (**actually**) involved?
3. How many projects at any given time are you involved with?
4. What key deliverables are being driven by you and require your input?
5. Do you feel projects are always coming through at a breakneck pace and there is always a time-crunch?
6. Are you aware of the stage at which you are involved in the development process?
7. Are you happy with the stage at which you get involved in the project? Is it too early or late or just right?

**Communication Channels**

1. How is the information communication to you (with regards to documentation) from-
    a) RD&E
    b) Supply chain (buyers, procurement people, commodity managers, etc.)
    c) Incoming Material Audit
    d) External vendors (if required)
2. Are you involved in the drawing or design reviews?
3. What are your thoughts about the current drawing and design reviews?

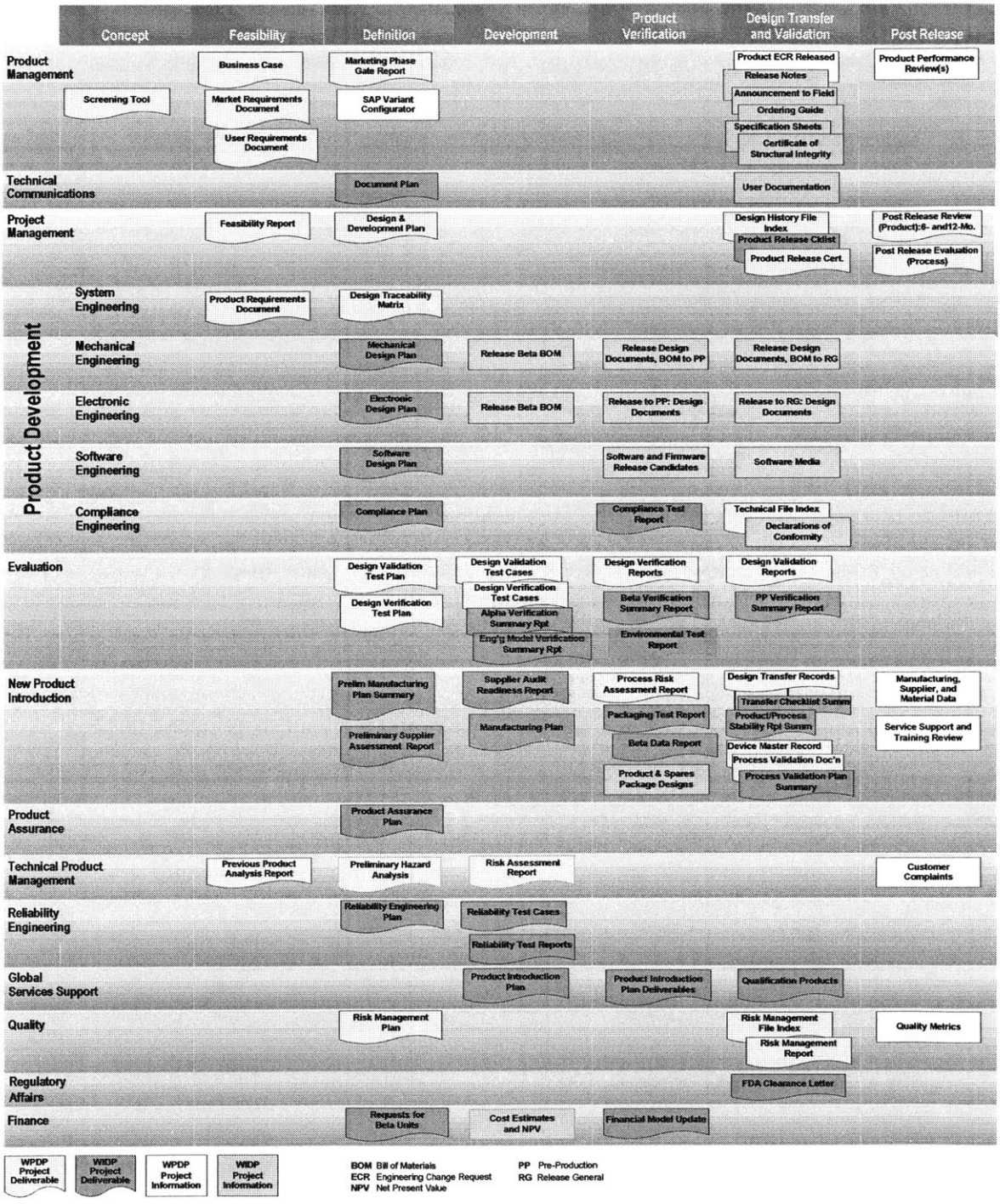
**Tools and SAP Integration**

1. What tools (including modules of SAP) do you use to aid in your daily tasks? Are there any such tools that you wish were available to you?
2. Do you feel that you get adequate information that would aid your responsibilities?

**Data Metrics for Decision making and Evaluation**

1. What sort of assessment process are you involved with for your work? Are there any metrics for such an assessment?
2. Are there any metrics that are focused on with regards to the product development process?
3. Are there any data metrics that aid or guide you in fulfilling your responsibilities?

# A-2 Milford Instrument Development Plan



# Appendix B

Document templates-

B-1 Stakeholder Details

| Project Details and Part Details | | | |
|---|---|---|---|
| | | | |
| **RD&E** | | **Waters Part Details** | |
| Project Manager | | Waters Part Number | |
| Project Lead | | Revesion Level | |
| Component Specific Leads | | Part Description | |
| Drafting In-charge | | Part Type | |
| **NPI** | | **Details (if needed)** | |
| Project Manager | | | |
| Manufacturing Engineer | | | |
| Supply Quality Engineer | | | |

B-2 Critical Dimension Details

| Critical Dimensions | | | |
|---|---|---|---|
| Dimension Code | C/D = Critical For Process Control<br>C/SU = Critical For Start up<br>C/F= Critical For Function<br>A= Aesthetics<br>C/I= Critical For Inspection<br>C/C = Critical For Change | | |
| Item No. | Dimension Code | Critical Characteristics | Details (if needed) |
| 1 | | | |
| 2 | | | |
| 3 | | | |
| 4 | | | |
| 5 | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| *Attach design drawings at the end of this sheet | | | |

## B-3 Tolerance Detailing

| Tolerance Detailing | | | | | |
|---|---|---|---|---|---|
| **Waters Part No.** | **Part Description** | | | | |
| Item No. | Characteristic Dimension | Tolerance Value | Production Method | Reason for value | Details (if required) |
| 1 | | | | | |
| 2 | | | | | |
| 3 | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
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| | | | | | |
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| | | | | | |
| *attach drawings at the end with this sheet | | | | | |

## B-4 Quality Inspection Plan

| Quality Inspection Plan | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Waters Part No.** | **Part Description** | **Revision Number** | | | | | |
| Item No. | Characteristic Dimension | Inspection Methodology | Fixture (Yes/No/Type /Fixture Number) | Supplier Sample Size | Supplier Inspection Methodology | Is Supplier methdoology and Waters Methodology same ? | Sampling Frequency |
| 1 | | | | | | | |
| 2 | | | | | | | |
| 3 | | | | | | | |
| 4 | | | | | | | |
| | | | | | | | |
| | | | | | | | |
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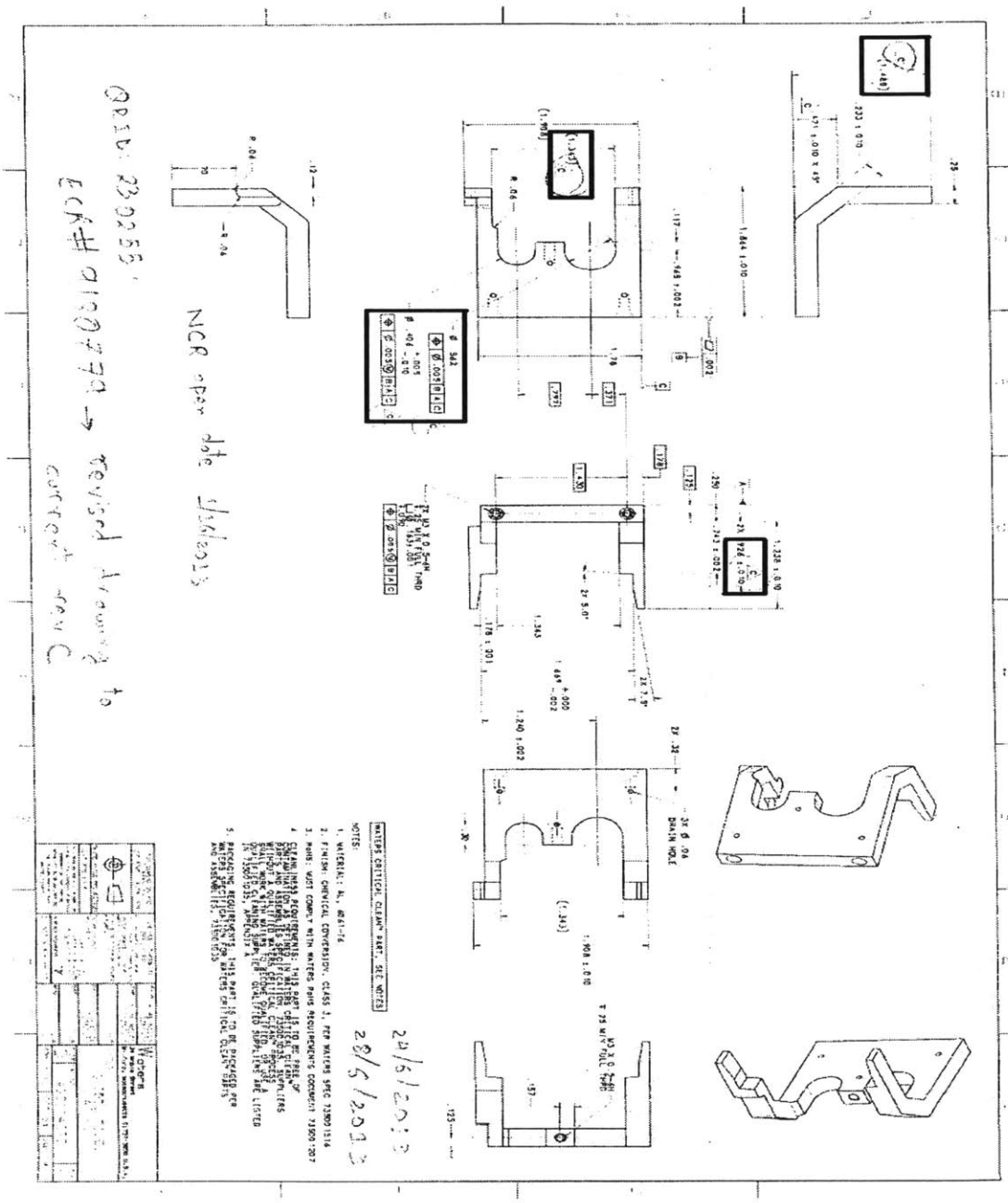
| | | | | | | | |
| *attach drawings at the end with this sheet | | | | | | | |

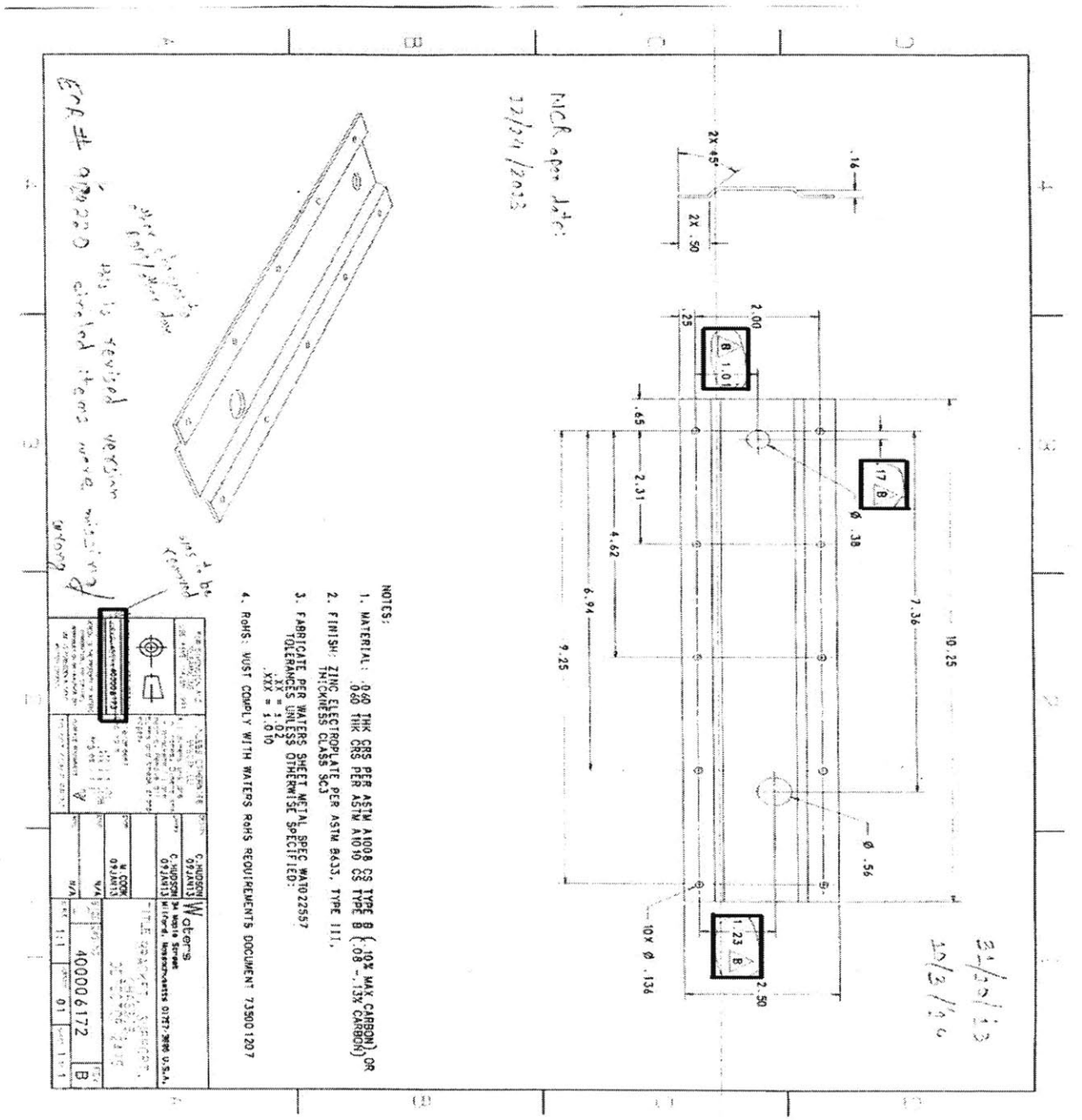
# Appendix C

## Design Drawing Error

1. The design drawing attached below lacks basic dimensions (highlighted in black in the drawing). The drawings also lacked tolerance and a feature control frame. This is was categorized as a 'dimensional' error.



2. The design drawing attached below lacks basic dimensions and also a case of incorrect documentation (highlighted in black in the drawing). This error belongs to both the 'dimensional' error category as well as 'incorrect documentation' error category.



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