THE SUCCESSFUL IMPLEMENTATION OF THE "OC RECOVERY PROJECT" AT WYETH MEDICA IRELAND

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This project is the work of John T. Kenny and was submitted in February 2009 as part of the requirements for the award of the degree of MSc (Industrial Pharmaceutical Science) of the National University of Ireland

Signed by: JTKenny 26/01/09

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GLOSSARY OF TERMS

OC	Oral Contraceptives
PPU	Primary Processing Unit
WMI	Wyeth Medica Ireland
OOS	Out of Stock
LS	Low Stock
PMBOK®	Project Management Body of Knowledge
SOP	Standard Operating Procedure
QP	Qualified Person
SAP ERP	Systems Applications and Products Enterprise Resource Planning
MIR	Manufacturing Investigation Report
LIR	Laboratory Investigation Report
QA	Quality Assurance
QC	Quality Control
TCCR	Temporary Change Control Request
CCRF	Change Control Request Form
BMR	Batch Manufacturing Record
OE	Operational Excellence
SPC	Solution Preparation/Coating
DMAIC	Define, Measure, Analyse, Improve and Control
CAPA	Corrective and Preventive Actions

Chapter 1: Abstract

Projects and project management are now in widespread use across the pharmaceutical industry. Project size can range from something as simple as sourcing and purchasing a new piece of office equipment to something as vast as building a 100,000m^2 extension to an existing facility.

However, the successful execution of a project can sometimes be an arduous task. A project must be perceived as important, it must be well defined and the context well understood. It must be planned with success in mind and similarly resourced. It must be led from the front by a Project Manager (PM) who is used to success.

This work discusses the successful implementation of a matrix organisation project management model, i.e. the approach taken and the results achieved. The Wyeth Medica Ireland (WMI) oral contraceptive (OC) business generates ca. 200 million dollars net per annum in worldwide sales and is therefore an important product portfolio. The OC Recovery Project was initiated at WMI in order to rescue this multimillion-dollar business when it was unable to provide finished product to a large number of customers. In a defined timeframe of 12 months the Bulk Release Team succeeded in reducing a backlog of 32 out of stock (OOS) and 36 low stock (LS) markets to a situation where there were minimal OOS and LS markets.

A number of other project teams (known as Tiger Teams) worked simultaneously with the Bulk Release Team to implement a process improvement and sustainability plan to help improve first time product quality and subsequently maintain customer service.

The approach adopted by the OC Recovery Project was two-pronged. Firstly, the OOS markets were replenished through the action of the Bulk Release Team, and secondly, upon dissolution of this team, customer service was sustained through the process improvements made by the Tiger Teams. The matrix models that were employed in this process greatly facilitated these results.

Chapter 2: Introduction

The Project Management Process at WMI is described via SOP. To better understand the process it is necessary to review and examine current Project Management terminology and methodology. In light of this examination it will then be possible to better view the project management process and analyse the existing models at WMI.

2.1 Program Management

Program Management can be defined as "the integration and management of a group of related projects with the intent of achieving benefits that would not be realized if they were managed independently" (Lycett et al. 2004, pp.289-299). Significant tensions tend to arise between the inward-focused and task-oriented view of projects and strategy-focused and often emergent wider organizational view. There is an increasing recognition that programme management provides a means to bridge the gap between project delivery and organizational strategy.

A program exists to create value by improving the management of projects in isolation (Pellegrini 1997, pp.141-149). Thus, while they create benefits through better organization of projects, they do not in themselves deliver individual project objectives. The fundamental goals of program management can be categorized two-fold:

- Efficiency and effectiveness goals: Aspects of management that a proficient project manager should address, even in the cases where related projects are undertaken without overall co-ordination. It is believed that a general improvement in management efficiency and effectiveness can be achieved by taking an integrated approach to these particular aspects of management.
- Business focus goals: The external alignment of projects with the requirements, goals, drivers and culture of the wider organization. These goals are associated with defining an appropriate direction for the constituent projects within a program as well as for the program as a whole.

2.1.1 The interface between program management and project management

Standard approaches to program management strive to obtain an inappropriate level of detail driven by a desire to exercise an inappropriate degree of control. This tends to lead to systems of program planning and control that are complex to the point of becoming unmanageable. Two negative consequences arise as a result:

- Excessive hierarchical bureaucracy and control: It can be very difficult to achieve an appropriate balance between excessive control and insufficient control in a multi-project context (Partington 1996, pp.13-21). The negative consequences of an overly bureaucratic approach to program management are: (a) a deterioration of the relationship between PMs and program managers encouraging a culture of blame and (b) diversion of energy from value adding activities.

- Focus on an inappropriate level of detail: Large integrated plans/networks are difficult to formulate and have a tendency to become cumbersome and excessively complex. By focusing at an inappropriate level of detail, there is a real risk that program managers will fail to identify the issues that are of real significance to the program. Consequently, the focus at the program level should be on the interfaces between projects (Levene & Braganza 1996, pp.331-339). This is important given that interdependencies often become associated with issues of ownership.

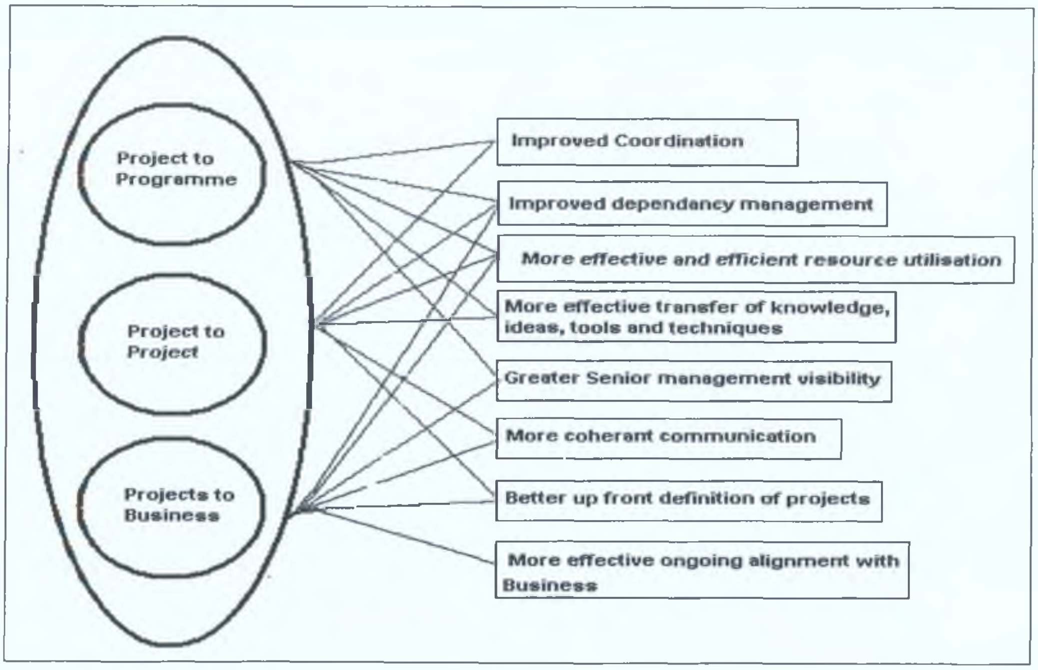

Figure 1: Key program management relationships and goals (Levene & Braganza, 1996).

Key relationships are:

(a) Between program management and project management,

(b) Individual PMs within a program and

(c) Individual projects and the goals and drivers of the wider business.

Figure 1 ties these relationships to the fundamental goals of program management.

2.2 Project Roles and Responsibilities

The Project Team: is the group responsible for planning and executing the project. It consists of a PM and a number of project team members, who are brought in to deliver their tasks according to the project schedule.

The Project Manager (PM): is the person responsible for ensuring that the Project Team completes the project. The PM develops the project plan with the team and manages the team's performance of project tasks. It is also the responsibility of the PM to secure acceptance and approval of deliverables from the project sponsor and stakeholders. The PM is responsible for communication, including status reporting, risk management, escalation of issues that cannot be resolved in the team, and, in general, making sure the project is delivered in budget, on schedule, and within scope.

The Project Team Members: are responsible for executing tasks and producing deliverables as outlined in the Project Plan and directed by the PM, at whatever level of effort or participation has been defined for them.

On larger projects, some Project Team members may serve as Team Leads, providing task and technical leadership, and sometimes maintaining a portion of the project plan.

The Project Sponsor and/or Project Director: is a manager with demonstrable interest in the outcome of the project who is responsible for securing spending authority and resources for the project. The Project Sponsor acts as a vocal and visible champion, legitimizes the project's goals and objectives, keeps abreast of major project activities, and is a decision-maker for the project. The Project Sponsor will participate in and/or lead project initiation; the development of the Project Charter. He or she will participate in project planning (high level) and the development of the Project Initiation Plan. The Project Sponsor provides support for the PM; assists with major issues, problems, and policy conflicts; removes obstacles; is active in planning the scope; approves scope changes; signs off on major deliverables; and signs off on approvals to proceed to each succeeding project phase. The Project Sponsor generally chairs the steering committee on large projects. The Project Sponsor may elect to delegate any of the above responsibilities to other personnel either on or outside the Project Team

The Steering Committee: generally includes management representatives from the key organizations involved in the project oversight and control, and any other key stakeholder groups that have special interest in the outcome of the project. The Steering committee acts individually and collectively as a vocal and visible project champion throughout the representative organizations; generally the committee members approve project deliverables, help resolve issues and policy decisions, approve scope changes, and provide direction and guidance to the project. Depending on how the project is organized, the steering committee can be involved in providing resources, assist in securing funding, act as liaisons to executive groups and sponsors, and fill other roles as defined by the project.

Customers: comprise the business units that identified the need for the product or service the project will develop. Customers can be at all levels of an organization. Since it is frequently not feasible for all the Customers to be directly involved in the project, the following roles are identified:

- Customer Representatives: are members of the customer community who are identified and made available to the project for their subject matter expertise. Their responsibility is to accurately represent their business units' needs to the Project Team, and to validate the deliverables that describe the product or service that the project will produce. Customer Representatives are also expected to bring information about the project back to the customer community. Towards the end of the project, Customer Representatives will test the product or service the project is developing, using and evaluating while providing feedback to the Project Team.
- Customer Decision-Makers: are those members of the customer community who have been designated to make project decisions on behalf of major business units that will use, or will be affected by, the product or service the project will deliver. Customer Decision-Makers are responsible for achieving consensus of their business unit on project issues and outputs, and communicating it to the PM. They attend project meetings as requested by the PM, review and approve process deliverables, and provide subject matter expertise to the Project Team. On some projects they may also serve as Customer Representatives or be part of the Steering Committee.

The Stakeholders: are all those groups, units, individuals, or organizations, internal or external to the organization, which are impacted by, or can impact, the outcomes of the project. This includes the following:

- Project Team, Sponsors, Steering Committee, customers, and customer co-workers who will be affected by the change in customer work practices due to the new product or service.
- Customer managers affected by modified workflows or logistics.
- Customer correspondents affected by the quantity or quality of newly available information.
- Other similarly affected groups.

2.3 Team Development

Regardless if one is a team leader or a team member, in order to function effectively in a team it is important that one understands that all teams progress through stages of development. The leader needs to predict what stage the team is at and then apply behaviours that will be most effective in enhancing the team's performance.

Research has shown that teams tend to develop through four stages (Tuckman, 1965) they are:

- Forming
- Storming
- Norming
- Performing

Forming Stage: The team is faced with the need to become more acquainted with its members, purposes and boundaries. Relationships must be formed and trust established. The team begins to establish ground rules by trying to find out what behaviours are acceptable with respect to both the project and interpersonal relations. This stage is complete once team members begin to think of themselves as part of a group.

Storming Stage: The team is faced with disagreements, counter-dependence and the need to manage conflict. Challenges include violations of team norms and expectations and overcoming group thinking. Focusing of process improvements, recognizing team achievement and fostering win-win relationships are needed from team leaders.

Norming Stage: The team is faced with creating cohesion and unity, differentiating roles, identifying expectations for members and enhancing commitment. The team leaders provide supportive feedback and foster a commitment to a vision.

Performing Stage: The team is faced with the need for continuous improvement, innovation, speed and the capitalization of core competencies. Sponsoring team members, new ideas, orchestrating their implementation and fostering extraordinary performance are needed from the team leaders (Gray & Larson 2005, p.344).

Figure 2 details the management skills required for high performing teams, with particular emphasis on forming, norming, storming and performing during team development.

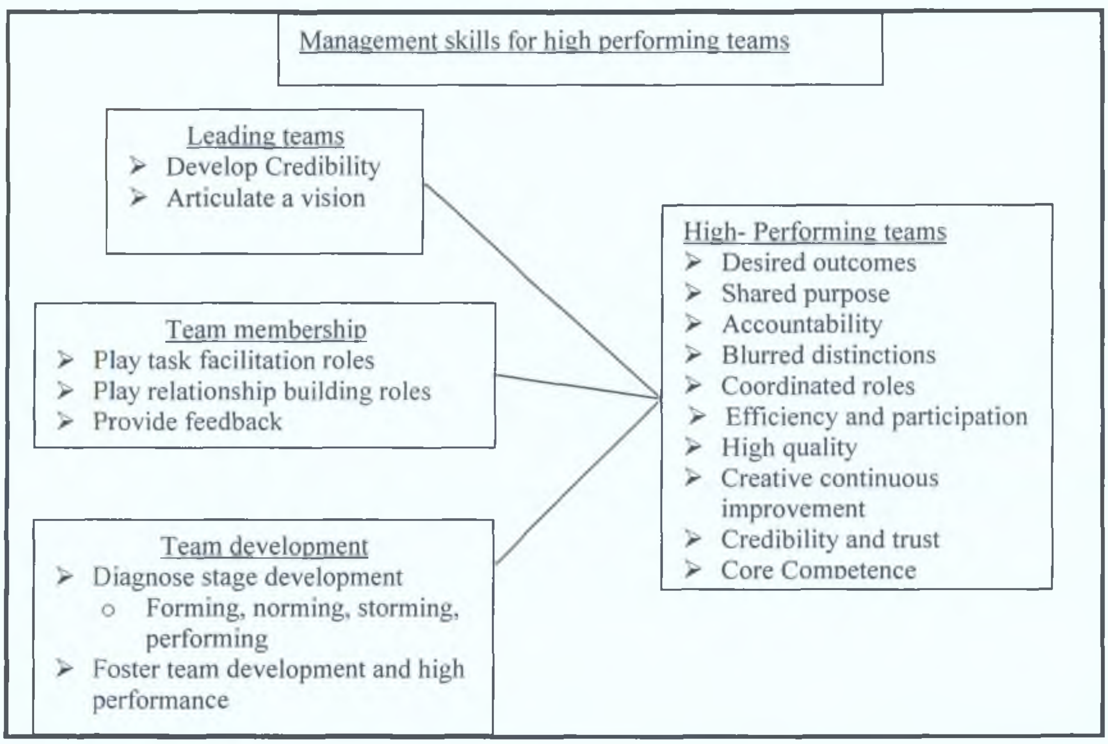

Figure 2: Management skills for high performing teams (Whetton & Cameron 2005, p.412)

2.4 The Project Lifecycle

Within a project lifecycle there are predictable changes in the level of effort and focus over the life of a project. There are many different life cycle models depicted in project management literature, most of which are specific to a particular industry. Below Figure 3 depicts a generic lifecycle by Gray & Larson (2005, p.7).

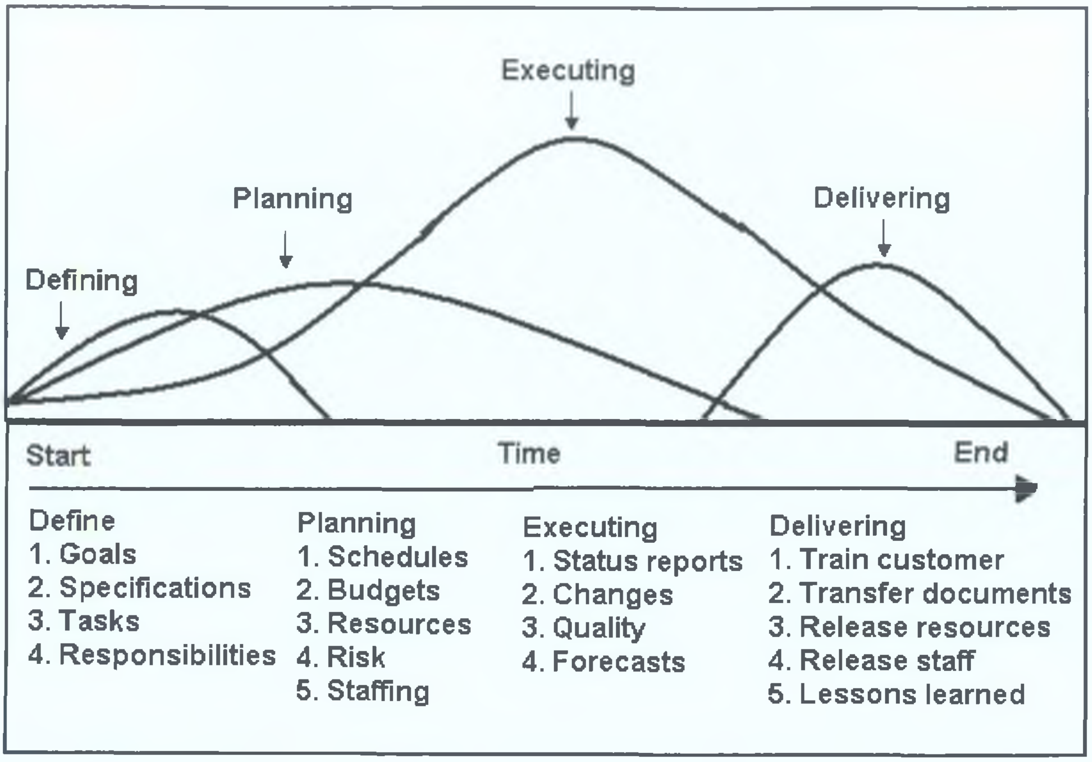

Figure 3: Project Life cycle

The project lifecycle stages:

1. Defining Stage: Specifications of the project are defined, project objectives are established; teams are formed; major responsibilities are assigned.
2. Planning Phase: The level of effort increases, and plans are developed to determine what the project will entail, when it will be scheduled, whom it will benefit, what quality level should be maintained, and what the budget will be.
3. Executing stage: A major portion of the project work takes place – both physical and mental. The physical product is produced. Time, cost and specifications are used for control.
4. Delivering stage: Includes the two activities: delivering the project product to the customer and redeploying project resources.

2.5 Stakeholder Management

The Project Management Body of Knowledge (PMBOK®) defines project stakeholders as "individuals and organizations that are actively involved in the project, or whose interest may be affected as a result of project execution" (PMBOK® 2004, p.24).

McElroy and Mills (2003, pp.99-118) define stakeholder management in projects as "the continuing development of relationships with stakeholders for the purpose of achieving a successful project outcome" To achieve a successful outcome the first step is to identify the project stakeholders. Jepsen & Eskerod (in press) describe the following process from their research that should be followed to analyze the stakeholders on a project:

1. Identify the (important) stakeholders.
2. Characterize the stakeholders pointing out their:
   (a) Needed contributions
   (b) Expectations concerning rewards for contributions
   (c) Power in relation to the project
3. Make a decision about which strategy to use to influence each stakeholder.

Andersen et al. (2004) as cited in Jepsen & Eskerod (in press), suggest presenting the results of the stakeholder analysis in an outline like the one displayed in Figure 4. The stakeholders should be listed along with their area of interest (their stake). Furthermore, necessary contributions along with each Stakeholder's expectations in the form of rewards from the project as well as their power in relation to the project should be inserted. Finally, the appropriate strategy for influencing each stakeholder and the person responsible for implementing the strategy should be added.

Stakeholder	Area of interest	Contributions	Expectations	Power	Strategy	Responsible

Figure 4: Stakeholder analysis table

The PMBOK® directs that the project management team must identify the stakeholders, determine their requirements, expectations and to the extent possible, manage their influence in relation to the requirements to ensure a successful project. Figure 5 illustrates the relationship between stakeholders and the project team (PMBOK® 2004, p.25).

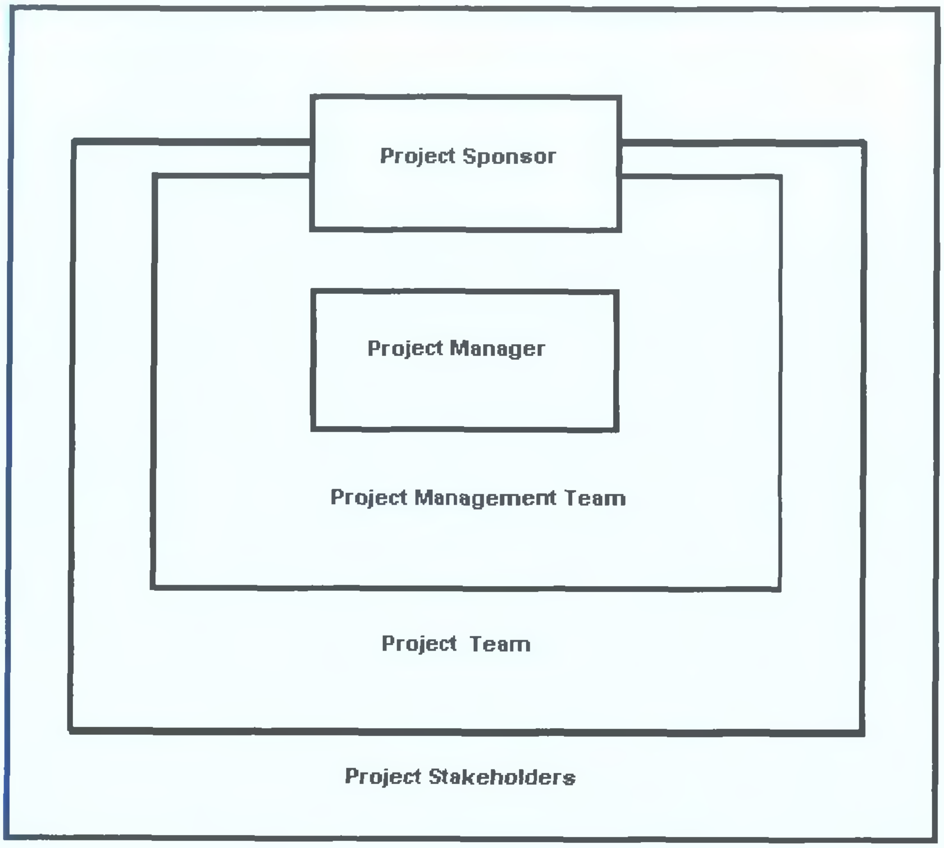

Figure 5: Relationship between stakeholders and the project

Within their article "Stakeholder Salience in Global Project" Aaltonen et al. (2008, pp.509-516) describe a process for stakeholder identification, classification, analysis and management. Stakeholder classification categorizes stakeholders according to their role in a project, such as client, contractor, customers, sponsors, local community members, media, lobbying organizations, and government agencies. Aaltonen et al. outline that a typical approach is to divide stakeholders as follows:

- Internal stakeholders are the stakeholders who are formally members of the project coalition and hence usually support the project (Winch 2004, pp.321-329).

- External stakeholders are not formal members of the project coalition, but may affect or be affected by the project. Such groups are often referred to as non-business stakeholders (Cova & Salle 2005, pp.354-359).

Many tools exist to manage stakeholders in projects. For example, there are tools to classify stakeholders through matrices such as the power/interest in the project matrix, tools to map whether stakeholders are promoting or opposing the project, and tools to categorize, visualize, and identify different stakeholder attributes such as Stakeholder Circle (Aaltonen et al., 2008).

2.5.1 Project Stakeholder Management Strategy

In his publication entitled “Commercial Project Manager” Turner (1995, p.219) describes a Project Stakeholder Management Strategy (PSMS). He states that the objective of adopting a PSMS is to curtail adverse stakeholder response while encouraging positive stakeholder response. He describes the following seven steps to produce a PSM strategy (Figure 6):

Step	Process	Main questions / issues
1	Identify Stakeholders	Who are the stakeholders? What are their stakes?
2	Investigate stakeholders	Gather information on all stakeholders
3	Identify mission	Are stakeholders likely to be supportive? Are stakeholders likely to be opponents?
4	SWOT (Strengths, Weaknesses, Opportunities, Threats)	What are the stakeholders Strengths and Weaknesses?
5	Predict Behavior	What will stakeholders do?
6	Make action plans	Formulate plans and procedures
7	Implement PSM Strategy	Make PSM a project policy

Figure 6: Steps to developing a Project Stakeholder Management Strategy

Adopting a project stakeholder management strategy will formalize the process of identifying stakeholders, evaluating likely behavior and preparing contingency action plans. This process allows the project team to act on real information and not just on rumor and will operate across changes in manpower to ensure accuracy (Turner 1995, p.222).

2.6 Risk Management

The PMBOK® describes risk management as the “Process concerned with conducting risk management planning, identification, analysis, responses and monitoring and control on a project’ (PMBOK® 2004, p.237). Risk management is a key component of project management and should be incorporated into the project from inception through to project close out. The PMBOK® outlines that the objectives of project risk management are to increase the probability of positive events, and decrease the probability and impact of events adverse to the project.

The PMBOK® describes the following Project Risk Management process:

Risk Management Planning: deciding how to approach, plan and execute the risk management activities for a project.

Risk Identification: determining which risks might affect the project and documenting their characteristics.

Qualitative Risk Analysis: prioritizing risk for subsequent further analysis or action by assessing and combining their probability of occurrence and impact.

Quantitative Risk Analysis: numerically analyzing the effect on overall project objectives of identified risks.

Risk Monitoring and Control: tracking identified risk, monitoring residual risk, and identifying new risk, executing risk responses plans, and evaluating their effectiveness throughout the project lifecycle.

A project risk can be defined as an 'uncertain event or condition that, it occurs, has a positive or a negative effect on at least one project objective, such as time, cost, scope or quality' A risk may have one or more causes and if it occurs, one or more impacts (PMBOK® 2004, p.238).

2.6.1 Use and Benefits of Tools for Project Risk Management

Within the "Use and Benefits of Tools for Project Risk Management" Raz & Michael (2001, pp.9-17) list a number of variations of Project Risk Management (PRM) processes in use. The following points list the various processes discussed within the journal:

- Boehm (1991, pp.32-41) suggested a process consisting of two main phases: risk assessment, which includes identification, analysis and prioritization, and risk control, which includes risk management planning, risk resolution and risk monitoring planning, tracking and corrective action.

- Fairley (1994, pp.57-67) talks about seven steps: (1) Identify risk factors; (2) Assess risk probabilities and effects; (3) Develop strategies to mitigate identified risks; (4) Monitor risk factors; (5) Invoke a contingency plan; (6) Manage the crisis; (7) Recover from the crisis.

- The Software Engineering Institute (Dorofee et al., 1996), a leading source of methodologies for managing software development projects, looks at project risk management as consisting of five distinct phases (identification, analysis, response planning, tracking and control) linked by an ongoing risk communications effort.

- Kliem & Ludin (1997) describe a four-phase process (identification, analysis, control and reporting) that parallels Deming's four steps for quality management (plan, do, check and act).

- Chapman & Ward (1997) outline a generic PRM process consisting of nine phases: define the key aspects of the project; focus on a strategic approach to risk management; identify where risks might arise; structure the information about risk assumptions and relationships; assign ownership of risks and responses; estimate the extent of uncertainty; evaluate the relative magnitude of the various risks; plan responses and manage by monitoring and controlling execution.

It is evident from the review conducted by Raz & Michael (2001) that there is "general agreement regarding what is included in the process, with the differences depending on variations in the level of detail and on the assignment of activities to steps and phases".

2.6.2 Risk analysis

By analyzing risks based on their potential consequences and probability of occurrence it is possible to rank/prioritize the risks that are more important. When the risks have been identified the next step is to analyze the risks. This process is "a vital link between systematic identification of risks and rational management of the significant ones" (Al-Bahar & Crandall, 1990). Once the risks have been identified and analyzed it is then possible to rank them and action those risks that are pertinent to the project deliverables.

2.6.3 Risk allocation strategy

According to Ward & Chapman (1991, pp.140-147), several conditions must be satisfied to determine whether project risks have been properly allocated or not. These conditions are:

- Risk should be allocated to the party with the best capability to control the events that might trigger its occurrence.
- Risks must be properly identified, understood and evaluated by all parties.
- A party must have the technical/managerial capability to manage the risks.
- A party must have the financial ability to sustain the consequences of the risk or to prevent the risk from occurring.
- A party must be willing to accept the risk.

These conditions must be evaluated against each owner before allocating a project risk to a particular owner. It is important to determine which party (who) has the best capabilities to accept the risk (what). The when and how factors should be considered to ensure proper risk allocation as shown in Figure 7 (Baccarini & Archer 2001, pp.139-145).

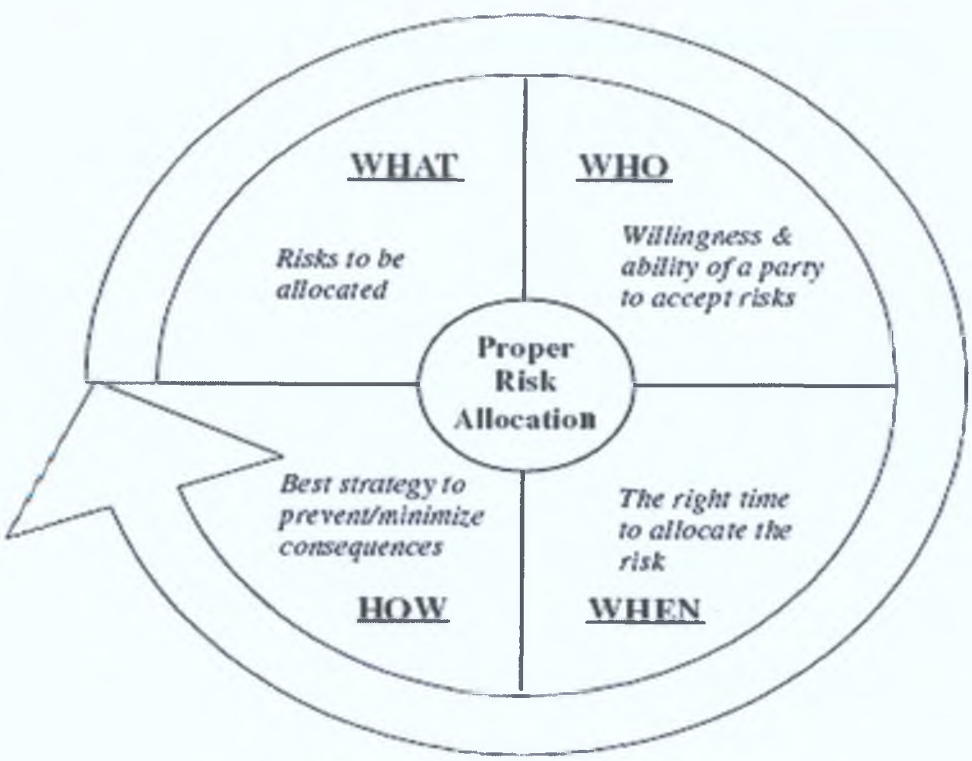

Figure 7: Risk Allocation Strategy

2.7 Project Communication Management

The PMBOK describes project communication management as the knowledge area that employs the processes required to ensure the timely and appropriate generation, collection, distribution, storage, retrieval and ultimate disposition of project information.

The Project Management Communication Process includes the following:

- Communication Planning: Determining the information and communications needs of the project stakeholders.
- Information Distribution: Making needed information available to project stakeholders in a timely manner.
- Performance Management: Collecting and distributing performance information. This includes status reporting, progress measurement and forecasting.
- Manage Stakeholders: Manage communications to satisfy the requirements of and resolve issues with stakeholders (PMBOK® 2004, p.221).

2.7.1 Performance Reporting

The performance reporting process involves the collection of all baseline data, and distribution of performance information to stakeholders. Performance information includes how resources are being used to achieve project objectives. Performance reporting should provide information on scope, schedule, cost and quality (PMBOK® 2004, p.231). Common formats for performance reports include bar charts, S-curves, histograms and tables. Earned value analysis data is often included as part of performance reporting (PMBOK® 2004, p.233).

Chapter 3: The Project Team Model

Merdith & Mantel (2006, pp.185-199) describe three major project organisational forms and how they fit in with the parent organisation.

3.1 The Project as Part of a Functional Organisation

Projects can be housed in a number of different areas within the parent organisation. One option is to make the project part of a functional division, for example, a systems installation project could be based in the Information Services Department. The major advantages of this method of housing a project are:

- There will be maximum flexibility in the use of staff with personnel being assigned to the project and re-assigned back to the normal work as and when required.
- Individual experts within the function can be used by many different projects.
- The depth of knowledge within the function can be easily accessed and used to solve technical problems.
- The function retains technological know-how even when team members leave the project.
- The functional organisation serves to encourage personnel involved in team activities by containing the normal course of advancement which the team member may pursue apart from project activity.

The major disadvantages of this method are:

- The client is not the focus of concern as the functional unit has its own routine work to carry out.
- Sometimes no individual is given full responsibility for the project leading to a lack of coordination.
- This lack of coordination can lead to slow response times to client needs.

- The project can be sub-optimised or even totally ignored as its goals may not relate to normal functional interests.

- Motivation of personnel to complete the project may be weak and project activities seen as a professional detour.

- The functional organisational approach is not holistic and does not lend itself to cross-functional collaboration.

3.2 The Project as part of a Pure Project Organisation

A pure project organisation exists at the opposite end of the spectrum from the Functional Organisation. The project is separate from the rest of the organisation and is self-contained with its own personnel. The advantages of this model are as follows:

- The PM has full authority and is basically the head of a 'department' dedicated to the project. The project is the point of focus.
- Project personnel report solely to the PM with little or no consultation required from other functional heads.
- Pure Project Organisations retain a more or less permanent group of experts who have developed much skill in certain areas, e.g., problem solving.
- The project team tends to be highly focused on and committed to the task in hand.
- The structural organisation tends to be simple, flexible and easy to understand.
- A systems approach is taken whereby the project is considered as a whole and the focus is not placed on optimisation of the project's sub-systems.

There are also some disadvantages to this system:

- Where several project teams exist there can be duplication of effort in every area thus leading to severe inefficiency.
- The PM may stockpile technical experience and equipment just in case they are needed, thus making the project very expensive to fund.
- Highly technological projects may require the services of the function most closely associated with the project but access may not be readily available due to the pure project structure.

- Normal policies and procedures may be abandoned due to urgent needs of the project but this can lead to administrative and procedural errors.
- Team members on projects can form strong attachments to the project as it grows and "projectitis" may ensue whereby there is infighting amongst project personnel and a we-they attitude pervades.
- There can be much concern amongst team members as to what happens when the project ends.

3.3 The Project as part of a Matrix Organisation

The Matrix Organisation model was developed in an attempt to couple the advantages of the functional and pure project models and avoid some of the disadvantages of each. A matrix organisation can basically take any form that lies along the spectrum between the functional and pure project models. A strong matrix organisation most closely resembles the pure project form, whereas a weak matrix organisation bears more similarity to the functional form. An almost infinite variety of organisational forms exists between the strong/weak matrix extremes.

3.3.1 The Strong Matrix Model

In this model the project team is not separated from the main organisation, as is the case with the pure project model. The PM usually reports to a Program Manager (described in Chapter 2) who is normally responsible for other projects also. It is not uncommon however for the PM to report to a manager with a particular interest in the project. Individuals are assigned to the project on either a full-time or part-time basis from their respective functional departments. Meredith and Mantel (2006, pp.185-199) emphasise that "the PM controls when and what these people will do, while the functional managers control who will be assigned to the project and what technology will be used".

3.3.2 The Weak Matrix Model

This model may only employ one full-time member, e.g., the PM. Rather than functional personnel being assigned to the project on a part-time or full-time basis, capacity to the project is devoted with the PM coordinating the activities carried out by the function.

3.3.3 Advantages/Disadvantages of the Matrix Model

The matrix approach represents a synergistic combination of the best parts of the functional and pure project models:

- The PM is responsible for bringing the project in on-time and within budget having achieved what it set out to do. The project is the point of focus, as with the pure project model.
- Because of the matrix structure, the project has reasonable access to all technologies across the functions. Also, as certain functional personnel may be involved in several projects it reduces the duplication of work that often exists in the pure project structure.
- Personnel are less concerned about post-project work as they are still part of a function.
- The response to client needs is as rapid as the pure project response while this form is also capable of response to the demands of the parent organisation.
- When several projects are simultaneously underway, the matrix model allows the company to better balance resources to meet the goals of the individual projects.
- The matrix organisation model provides a middle ground between the extremes of the functional and pure project organisational models. There is also great flexibility regarding the organisation of the project, with the parent organisation having much scope to adjust the model to suit the project needs.

The disadvantages of the matrix model mainly involve conflict between the PM and other functional managers. They are as follows:

- Within the matrix organisation there is a need for a balance of power between the functional manager and the PM. This balance is sometimes very delicate and can lead to ambiguity as to who is really leading the project this causing the project to suffer.
- The ability of the matrix organisation to balance the time, cost and performance of several projects has a flip-side. The projects require careful management with sharing of resources between projects possibly leading to political infighting.
- A strong matrix model can suffer from the same "projectitis" complaint as the pure project model with project identity being very strong and projects refusing to die.
- Problems may arise when the PM's negotiating skills are not sufficient to secure adequate resources and technical assistance from the relevant functional manager's department.

Chapter 4: Methodology And Results

Wyeth Medica Ireland (WMI) was established in Newbridge, Co. Kildare in 1992. The company currently employees over 1300 people in a facility of over 100,000m^2. WMI is considered a centre of excellence for the global and regional supply of existing products. WMI currently manufactures a range of products to over 100 markets, covering Europe, Africa, Australia, Asia and Latin America. The facility produces over 140 different product formulations packaged in approximately 800 different pack-to-market presentations.

The key products manufactured at WMI include:

- Hormone Replacement
- Oral Contraceptives
- Cardiovascular
- Gastrointestinal
- Central Nervous System
- Antibiotics

Of the products above the Oral Contraceptives (OCs) product range makes up approximately 30% of the volume manufactured on site. At present the OC product portfolio faces intense competition from its competitors; both generic and non-generic manufactures are producing the product at a reduced cost.

During the first four months of 2007 the OC Primary Processing Unit (PPU) began to encounter a number of "roadblocks" which led to the 32 OOS and 36 LS markets described in Figure 8 below. At this point a decision was made by the PPU to request the formation and implementation of a Bulk Release Team and three Tiger Teams. Many of the tools and methodologies described in the project management processes in Chapter 2 were employed as a framework for the establishment and success of the projects. The WMI SOP on project management (PPG-00025977 "Project Management Process") provided definition and guidance on the roles, responsibilities and life cycles for the projects.

OC Product	Total	OOS	LS
Minulet	14	8	6
Trinordiol	11	7	4
Nordette	11	5	6
Minesse	8	4	4
Harmonet	10	3	7
Loette	4	2	2
Adepal	3	1	2
Minidril	3	1	2
Triminulet	1	1	0
Microval	2	0	2
Stediril	1	0	1
Total	**68**	**32**	**36**

Figure 8: OOS and LS markets for WMI OC products at week 22 2007

4.1 The Bulk Release Team

4.1.1 Project Scope and Strategy

A PM was appointed by the Project Sponsor in consultation with the Executive Sponsor and Site Steering Committee, and along with senior personnel in the PPU embarked upon a fact finding mission to determine the scope of the project. The following key factors were determined:

- Batches were not being QP (Qualified Person) approved on time due to untimely closure of investigations [Manufacturing Investigation Reports (MIRs)]. It was also found that closure of Change Controls was not occurring in a timely fashion.
- Because of the recent introduction of SAP ERP, a resource planning software application, personnel were using different schedules which resulted in a disjointed approach to scheduling, with different functions prioritising different batches.

As the project could not be stand-alone from normal PPU activities due to the inherent need to progress batch release, a matrix model was chosen. This strong matrix model was chosen to allow full time team members to focus solely on the task in hand with part time team members providing a strong PPU support and knowledge base. The team consisted of five full-time personnel: 1 PM, 2 Investigative Leads, 1 Technology Specialist and 1 Compliance Specialist, along with a number of part time personnel from QA/QC and Customer Services.

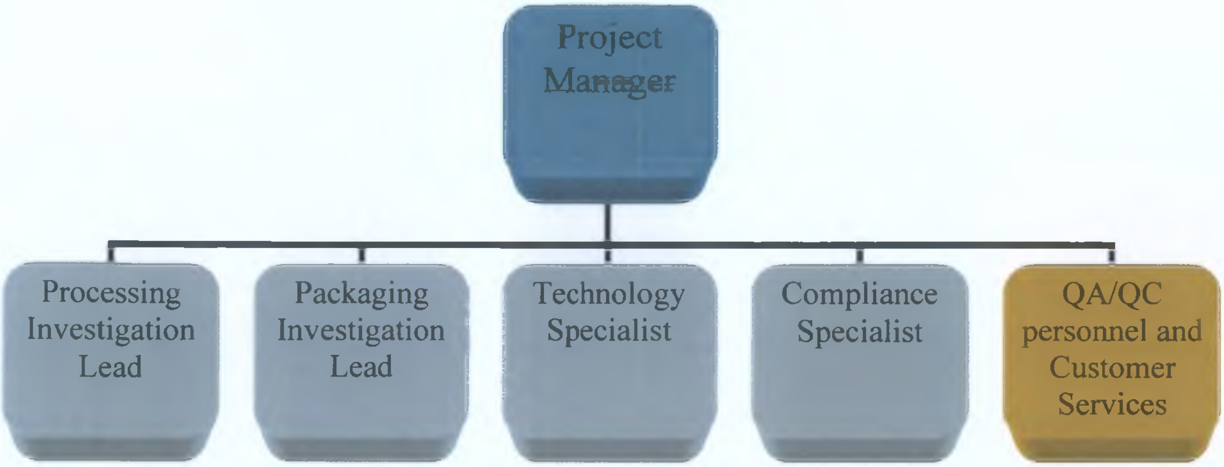

Figure 9: Reporting structure for Batch Release Team. ▪ = Full Time, ▪ = Part Time

The Investigation Leads were chosen from the Packaging and Processing Supervisor group with a remit to close all existing MIRs and also to close any newly generated MIRs within 15 calendar days, which was well within the allowed investigation closure time of 30 days from date initiated. The Processing Investigation Lead (the author) had a strong Quality Control (QC) background having spent 5 years as an analyst and group leader in the QC laboratories at WMI. This facilitated closure of Quality related MIRs that resulted from out of specification and out of trend QC results. For example, a low assay result would merit a Laboratory Investigation Report (LIR). If this LIR concluded that the root cause was not QC related then an MIR would be raised to investigate possible active loss during, for example, granulation or compression. The necessity for this type of expertise will be discussed in the next section.

The Technology Specialist was recruited on to the team to close out existing temporary change controls (TCCRs) and permanent change controls (CCRFs). As most of these change controls related to process changes/deviations and validation it was paramount that the candidate had process development and validation experience. The chosen candidate also began his career as a compression operator in OC Processing thus adding to his suitability for the role.

The Compliance Specialist role was multi-faceted and included aspects such as: general Quality oversight for project related activities, participation in discussion on LIR, MIR and change control strategy, support in the reporting of project metrics to the site leadership team and Quality liaison for the team with other functions. This candidate had previous experience in QA, QC and Processing/Packaging.

QA/QC and Customer Services personnel were seconded to work part time for the Bulk Release Team thus enhancing the general support structure around the team by facilitating LIR closure, conveying customer expectations and developing weekly schedules based on a balance between immediate customer requirements and the longer term project goals of reducing the OOS and LS backlog.

The PM had general oversight of the project team and took special responsibility for a daily morning meeting involving all team members which looked specifically at how the team would meet its primary objectives.

4.1.2 Project Execution

The Bulk Release Team began its year-long mandate in June 2007. By this time the number of OOS markets had risen to 38 and the number of LS markets was at 39, see Figure 26 in Discussion and Conclusions section. Depending on the size of particular customer orders, a number of packaging orders, e.g., 5 to 10, may be fulfilled from one bulk batch. On the other hand, if an order was large a full bulk batch (7 million tablets for a sugar coated formulation) may fulfil just a single order. With this in mind, the Investigation Leads started work on the ten open MIRs (see Figure 10) by prioritising the ones that would address the most OOS markets while also considering MIRs that were due to be raised for ongoing issues.

Figure 10 shows the unpredictable nature of MIRs for OC products at WMI during the life cycle of the project. Even though the number of open MIRs had been reduced to zero in the space of two months, this was a level that was difficult to maintain. As issues increased, investigations became more intricate, corrective actions became more relevant and more difficult to close out, and QP expectations increased.

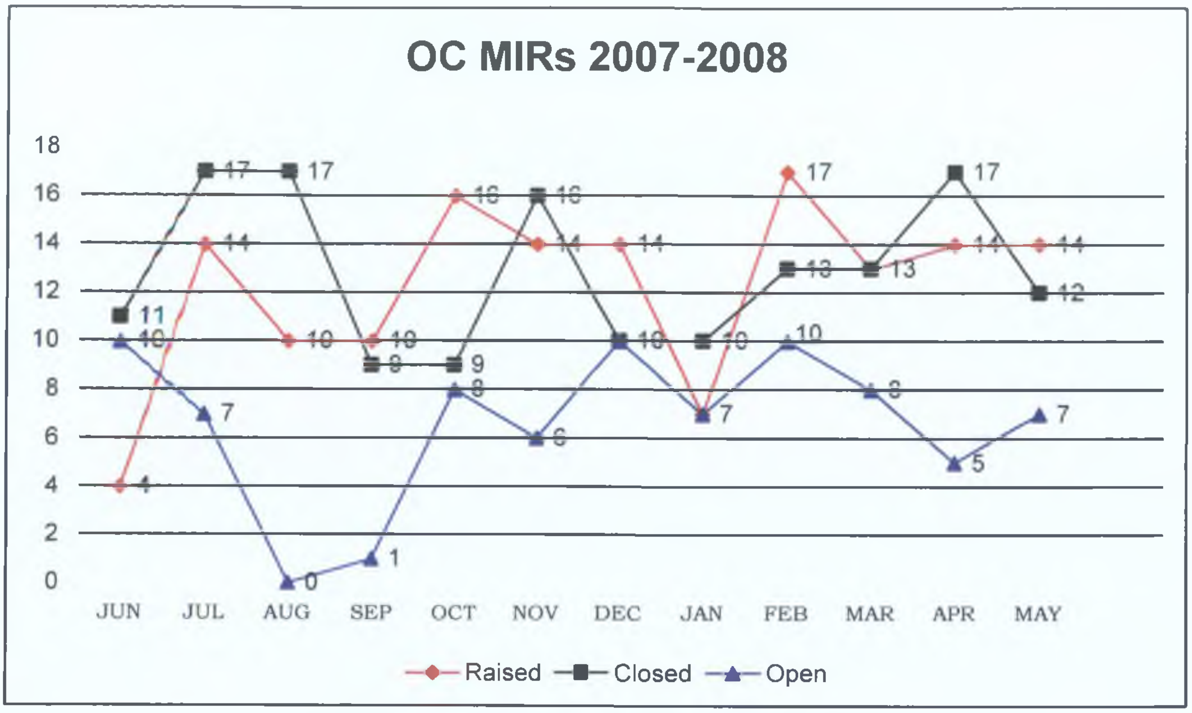

Figure 10: OC MIRs raised, opened and closed during the project life cycle

As the project progressed goals were reset and the number of open MIRs was determined to be acceptable at <10. The main priority was to target MIRs most likely to hold up priority batch release. For example, during June and July a total of 22 batches were affected by one MIR. As the investigation related to microbial contamination in the OC processing suite, the investigator had to devote two weeks solely to the MIR in question. This was necessary as part of the processing suite was out of operation and immediate corrective and preventive actions were required to prevent a recurrence of the issue. Closure of the MIR allowed the 22 batches to receive an acceptable disposition from the QP while also allowing the affected area of the processing suite to restart production.

During the course of the project life cycle temporary change controls (TCCRs) were required on an almost weekly basis to facilitate the completion of a number of batches, which contained process deviations (MIRs). Chapter 4.2 provides more detail on the nature of these deviations. Most TCCRs were required to either re-sort sugar coated formulations with %CV for weight failures or re-inspect batches of sugar coated tablets with colour variation. Figure 13 in Chapter 4.2 illustrates this fact. Although not originally within the scope of the Bulk Release Team or the Tiger Teams, the Technology Specialist set about devising a way to negate the requirement for a TCCR when re-sorting a batch of tablets. A new SOP was drafted detailing all possible scenarios that may have led to a batch re-sort and all batch manufacturing records (BMRs) were updated to include a re-sort section. Previously there had been a separate re-sort BMR.

Initially, this would have been considered a trade-off (Meredith & Mantel 2006, pp.132-133), as devising this new procedure took time and effort. However, by the start of 2008 the new procedure was in place and there was no longer any need to raise a TCCR to re-sort a batch. The advantage was that OC Processing no longer had to put a batch on hold to await TCCR approval; they could re-sort it as soon as their schedule allowed.

Appendix 1 is an excellent example of the week to week scheduling complexities encountered during the project. This snapshot is taken from the first full week in December 2007. There were 22 batches on the list with 15 required for release by week end (7th Dec.). Here are some points to note:

- The first thing to notice is that the QC lab was pulling batches forward. The first three batches in the schedule were being processed through the lab much quicker than normal.
- Some batches had LIRs for weight, LOD and assay failures, most of which progressed to MIRs.
- Four out of five of the OOS batches had an associated MIR, three of these MIRs were closed.
- 10 out of the 22 batches had MIRs.
- One batch had a TCCR to re-sort part of it and another TCCR (not mentioned) to re-inspect another part of it (C00385, C00385A and C00385AB).
- One batch was a possible reject. This batch was eventually rejected.

These points indicate a number of characteristics of the Bulk Release Team:

1. The part time support functions, such as QC, were fully behind the vision of the project even forgoing routine business to reduce the batch cycle times in the lab to almost 50% of target (30 days was the routine batch turn around time).
2. MIRs were being prioritised based on their effect on OOS, and to a lesser extent LS, markets.
3. Batches C00385, C00385A and C00385AB were all eventually released to market.
4. LIRs/MIRs/TCCRs were associated with a high proportion of batches.
5. Rejected batches for low/high assay, extreme colour variation etc. were not uncommon.

It was the PM's responsibility to constantly tweak this schedule depending on whether LIR/MIR/TCCR closure was possible, QA/QC personnel were available, customer pressure existed due to OOS markets, etc. Points 1-3 emphasise good teamwork, good prioritisation skills and a healthy realisation of the nature of the OC business. With these learnings the team progressed towards its goal of zero OOS markets and minimal LS markets with a growing confidence. Note: Points 4 and 5 were indicative of the justification for the Tiger Teams.

4.2 The Tiger Teams

To ensure sustainability of product supply following on from the work of the OC Recovery Team, it was decided to form three further project teams, known as Tiger Teams. Figure 11 details the resource allocation to each team, with the PMs reporting to a Program Manager who in turn reported to the OC PPU Director (Project Sponsor).

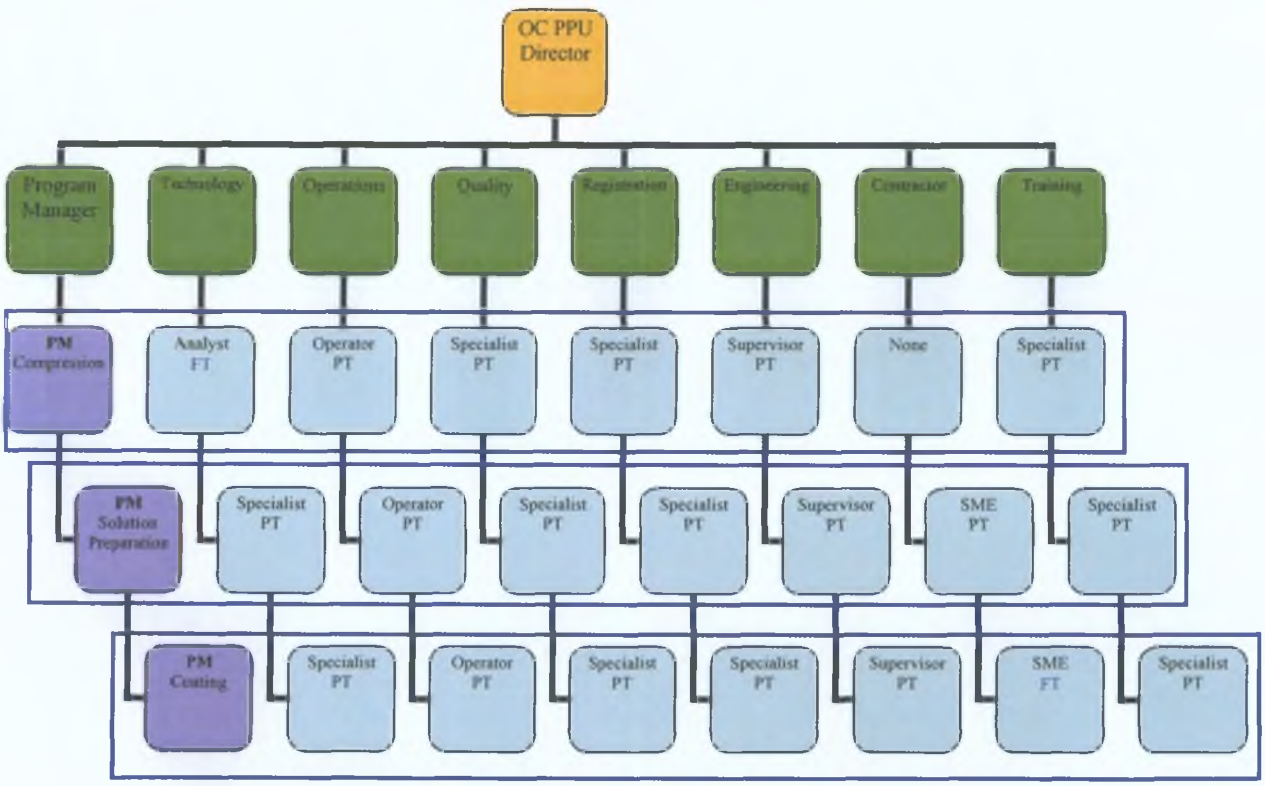

Figure 11: Matrix organisation of the OC Tiger Teams. PT = Part Time, FT = Full Time.

The matrix organisation model used for the Tiger Teams differs from the one described for the OC Recovery Team. Excluding the PMs, only two of the team members were assigned to a project on a full time basis. This structure can therefore be described as a weak or functional matrix. The structure was chosen as there was no requirement for any more full time personnel and each functional manager agreed to devote, on average, 20% of a team member's time to the project. This structure provided access to a broad knowledge and resource base while still allowing team members to engage in routine functional activities. For these three projects a Program Manager was selected who was trained in Lean Management and proficient in such approaches as Six Sigma and operational excellence (OE). Dinsmore (1993) emphasises the "lean and mean" approach for projects with the managerial difficulties of a matrix model being offset by their relatively low cost coupled with good access to broad technical support. The goal of the Tiger Teams was to address the unacceptable level of customer service and first time quality, and provide solutions to improve process robustness. They each had a relatively short life cycle of 4 months (July-October 2007) to complete their defined objectives.

The DMAIC cycle was used to form a framework around which each team could progress towards their defined objectives. In Figure 12 the acronym DMAIC describes the five phases of the cycle, namely: define, measure, analyse, improve and control.

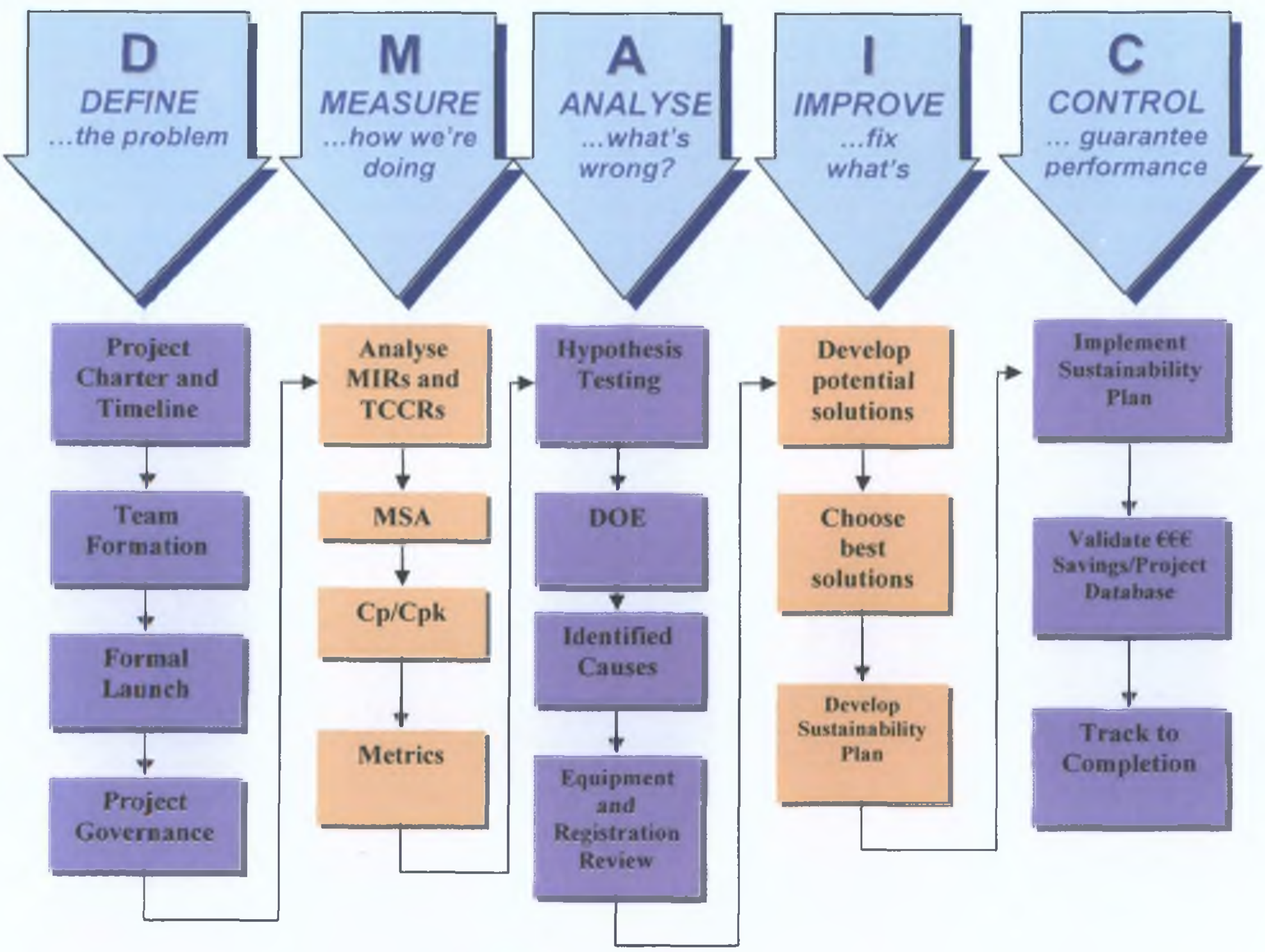

Figure 12: Methodology – DMAIC Cycle

Application of the DMAIC tool helped define the scope of the three Tiger Teams, i.e. compression, solution preparation and coating. All OC MIRs raised from the beginning of 2006 to May 2007 were reviewed to determine the key focus areas. Figure 13 shows a bar graph of the key findings, with 47% and 30% of all MIRs generated for solution preparation/coating and compression issues, respectively. The granulation and sorting statistical frequencies, when added together, did not equate to the compression frequency and were not deemed significant enough to warrant the focus of a project team.

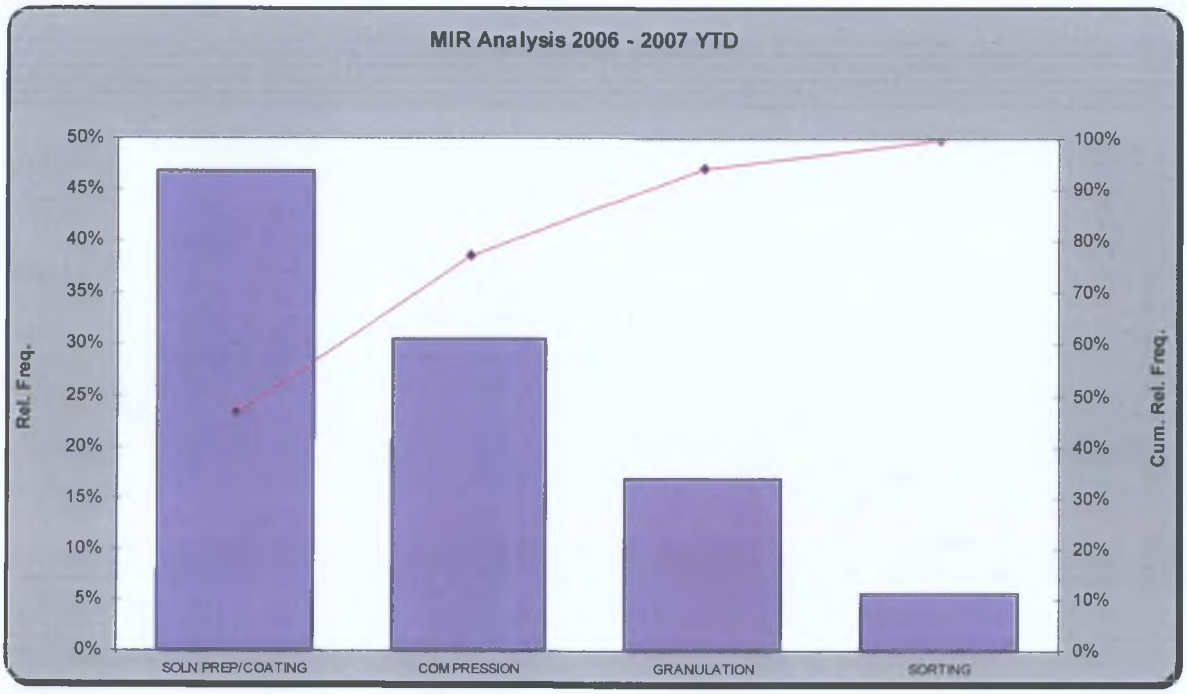

Figure 13: OC MIR analysis 2006-May 2007.

The Tiger Team project charter consisted of the following elements:

- Project Objectives
    1. Eliminate identified "showstoppers" in OC Processing.
    2. Provide solutions to ongoing colour and weight failures in OC Coating – issues already highlighted earlier in this chapter.
    3. Provide solutions to improve process robustness in OC Compression.
    4. Improve operator knowledge in OC Coating and Compression.
- Financial Opportunity: Savings from rejected batches, rework costs, late delivery penalisation costs and extra inventory costs.

- Business Impact: Reduce compliance risk and improve customer service.

Each PM reported to the Program Manager on a weekly basis with the Program Manager reporting to the Project Sponsor (OC PPU Director), Executive Sponsor, Site Steering Committee and stakeholders on a biweekly basis.

Note: From the commencement of the Tiger Team mandate, the Training Dept. worked with the Operations personnel and PMs of the three teams to create a formalised on-the-job training assessment kit.

4.2.1 The OC Compression Team Findings

The OC Compression Team, using the DMAIC tool, began by defining the problem. The four goals of the Compression Team were defined as follows:

- Reduce MIRs related to compression issues.
- Reduce downtime caused by these issues.
- Improve the compression process and equipment.

The OC MIR review (Figure 13 above) indicated that compression issues contributed to 30% of the MIRs raised during the defined time frame. From this collection of MIRs a Pareto analysis (Figure 14) was performed to identify key focus areas.

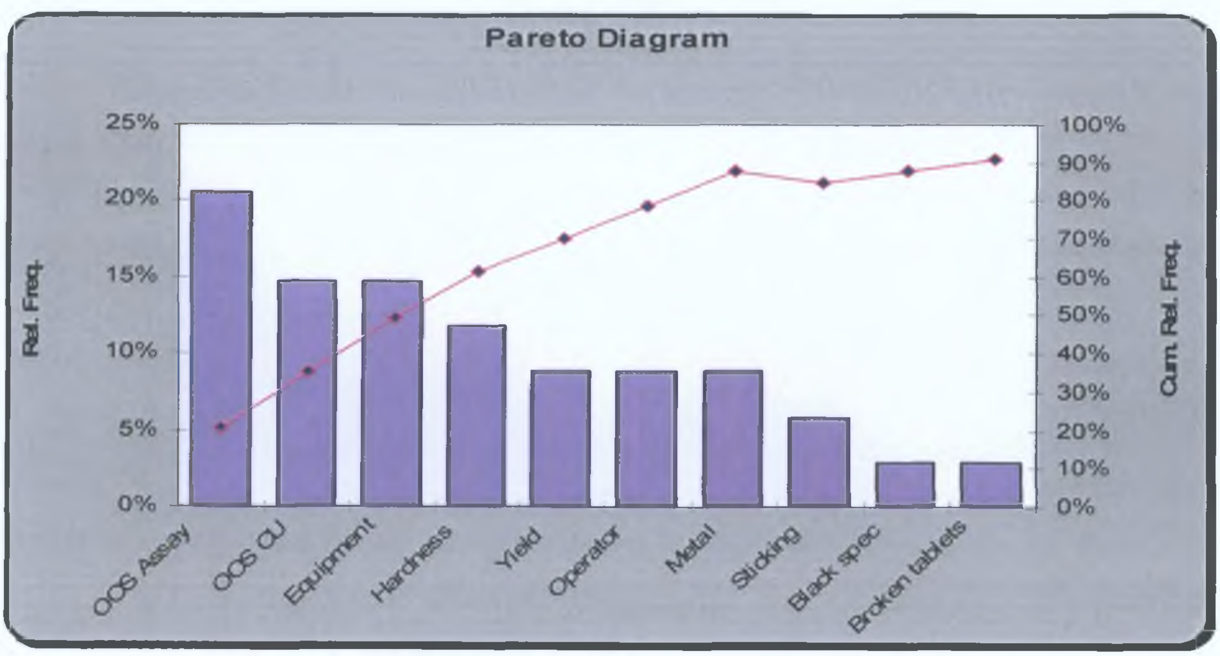

Figure 14: Pareto analysis of compression MIRs

As a result of the Pareto analysis the Compression Team decided to focus on two key areas: equipment issues and out of specification assay/content uniformity results.

4.2.1.1 Equipment

A review of the equipment MIRs revealed that a large number of them were related to tooling, e.g., broken punches, excess rejects, etc. A comparison of tablet thicknesses between Q4 2005 and Q1 2006 yielded the results shown in Figure 15.

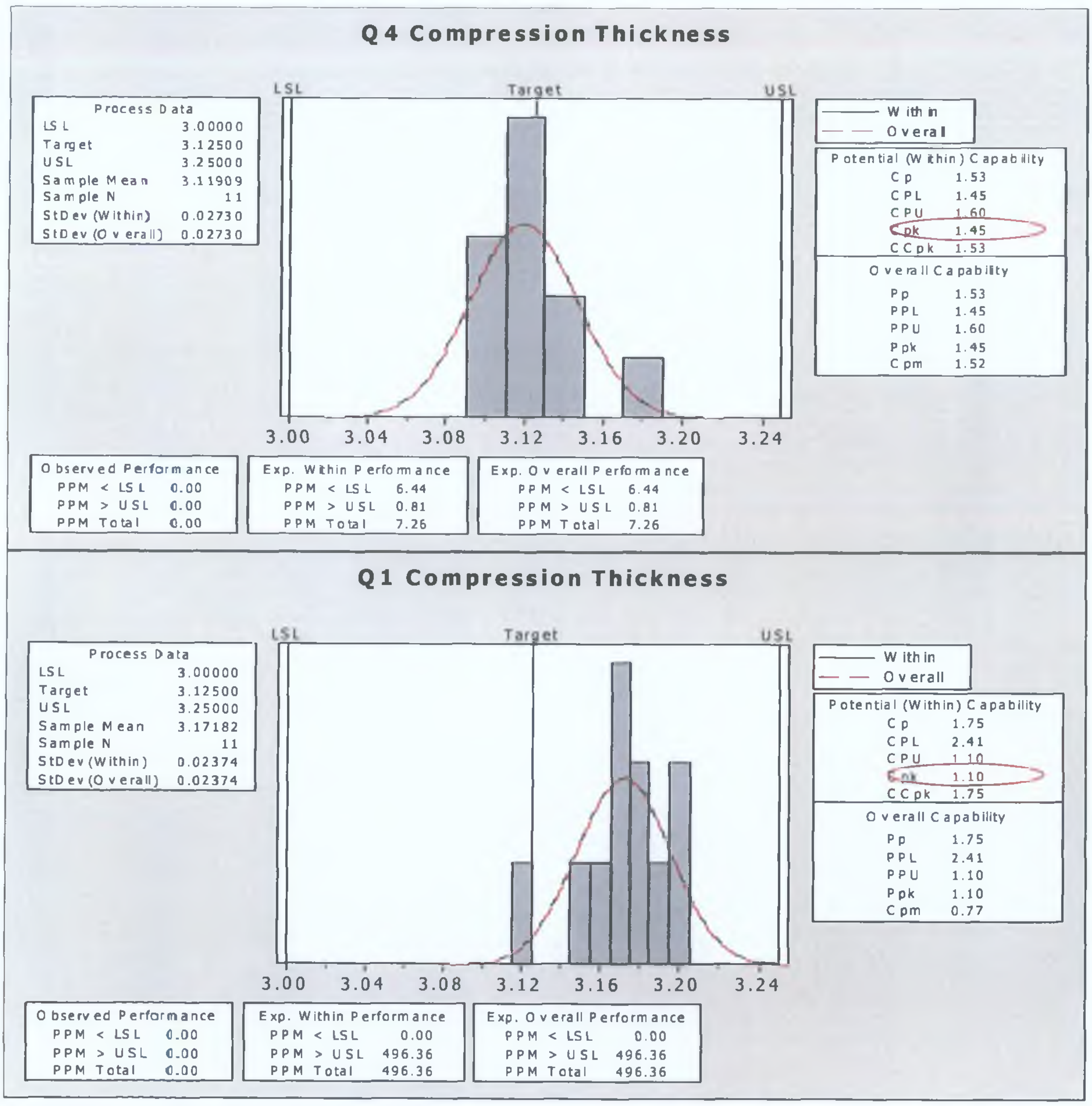

Figure 15: Process capability for tablet thickness at compression.

Note: Cpk is an index (a simple number) that measures how close a process is running to its specification limits, relative to the natural variability of the process. The larger the index, the less likely it is that any item will be outside specification. A value above 1.33 indicates a centred and capable process.

The Cpk value for Q4 2005 was 1.45 indicating that the process was centred and capable. However, the Cpk value of 1.10 for Q1 2006 demonstrated that the process was capable but no longer centred. When the tooling supplier was contacted it transpired that the tooling geometry had been revised at the end of 2005 without informing WMI (this was a once off occurrence). The change in tooling geometry resulted in an average tablet thickness increase of 0.1 mm. This change would have also resulted in an increase in the level of tablet sorting rejects.

Having analysed the change in tablet thickness a new vendor was commissioned to produce a set of tooling to the required specifications. Figure 16 details the process capability achieved with the new set of tooling.

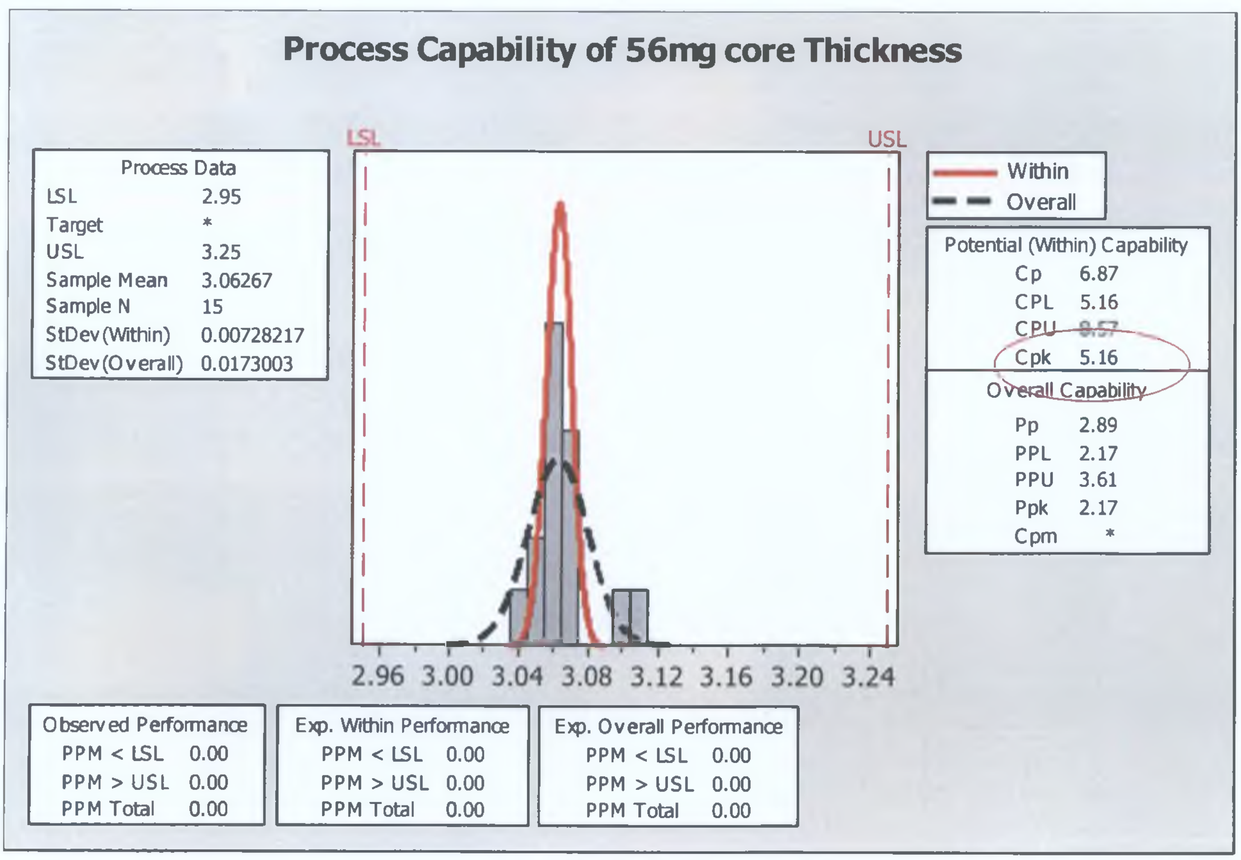

Figure 16: Process capability with new vendor tooling.

The new tooling produced a Cpk value of 5.16 thereby demonstrating a capable and centred compression process.

Controlled drawings were put in place by the Engineering Department and a Quality agreement was entered into with the new vendor to ensure adequate tooling quality for future orders.

4.2.1.2 Assay/Content Uniformity

A review of the assay/content uniformity MIRs identified a number of issues:

- A small number of out of specification results were caused by blending and segregation issues.
- Previous Technology reports established assay loses via dust extraction.
- One particular formulation (69E/F) regularly failed for high assay, i.e. the process was not centred.

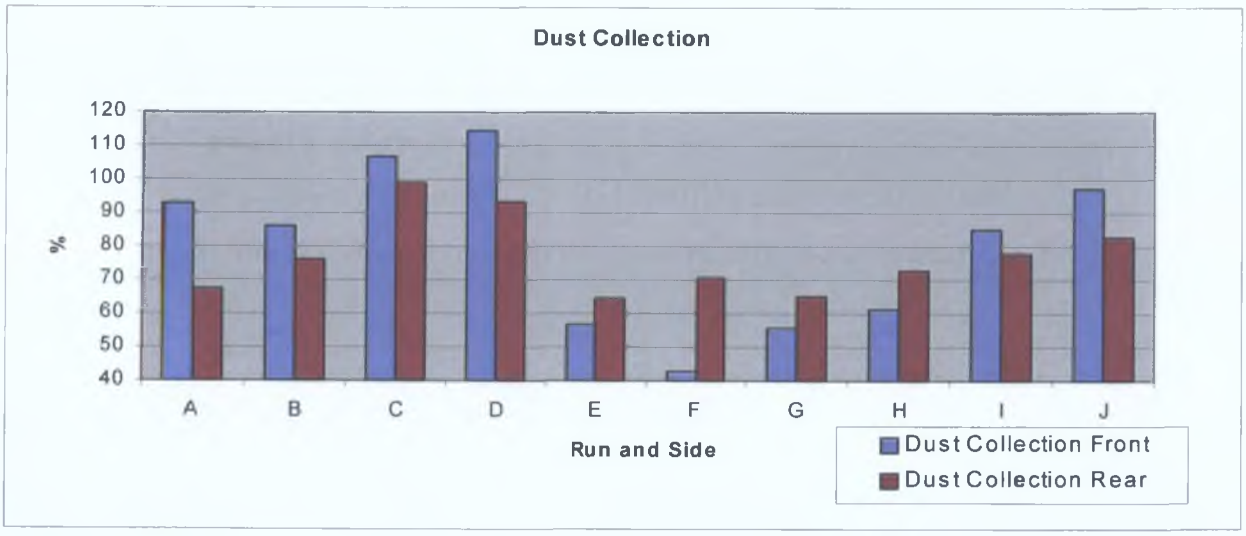

Figure 17: Dust collection active indicators for 10 compression runs.

Figure 17 shows an analysis of the quantity of active found per unit sample in the dust collection unit of an OC press for 10 separate runs. Runs A, B, C, D, I and J all had the dust extraction unit on. For each run the quantity of active was considerably higher at the front of the dust collection unit than at the rear. For runs E, F, G and H the dust extraction unit was turned off resulting in less active at the front of the unit than at the rear and an overall reduction in active being extracted.

As the dust extraction system on the OC presses was not previously monitored or controlled, each press was subsequently installed with an air velocity indicator. The levels of extraction were monitored to determine the optimum setting for the dust collection unit.

An analysis of the 69E/F high assay issue resulted in the implementation of an Overage Reduction Project. This project was a sizable undertaking and is outside the scope of this thesis. A reduction in the quantity of the two actives contained within this formulation was introduced in 2008 resulting in a substantial reduction in MIRs for out of specification/high assay results.

4.2.2 Findings of the OC Solution Preparation/Coating Teams

OC sugar coated tablets are routinely coated in a Pellegrini coating pan (see Figure 18) via a set shot strategy. A shot is applied via a "jig" (see Figure 23) and the tablets are then rolled and dried and the process repeated until the desired tablet weight is achieved. The more complex technological aspects of sugar coating are beyond the scope of this thesis.

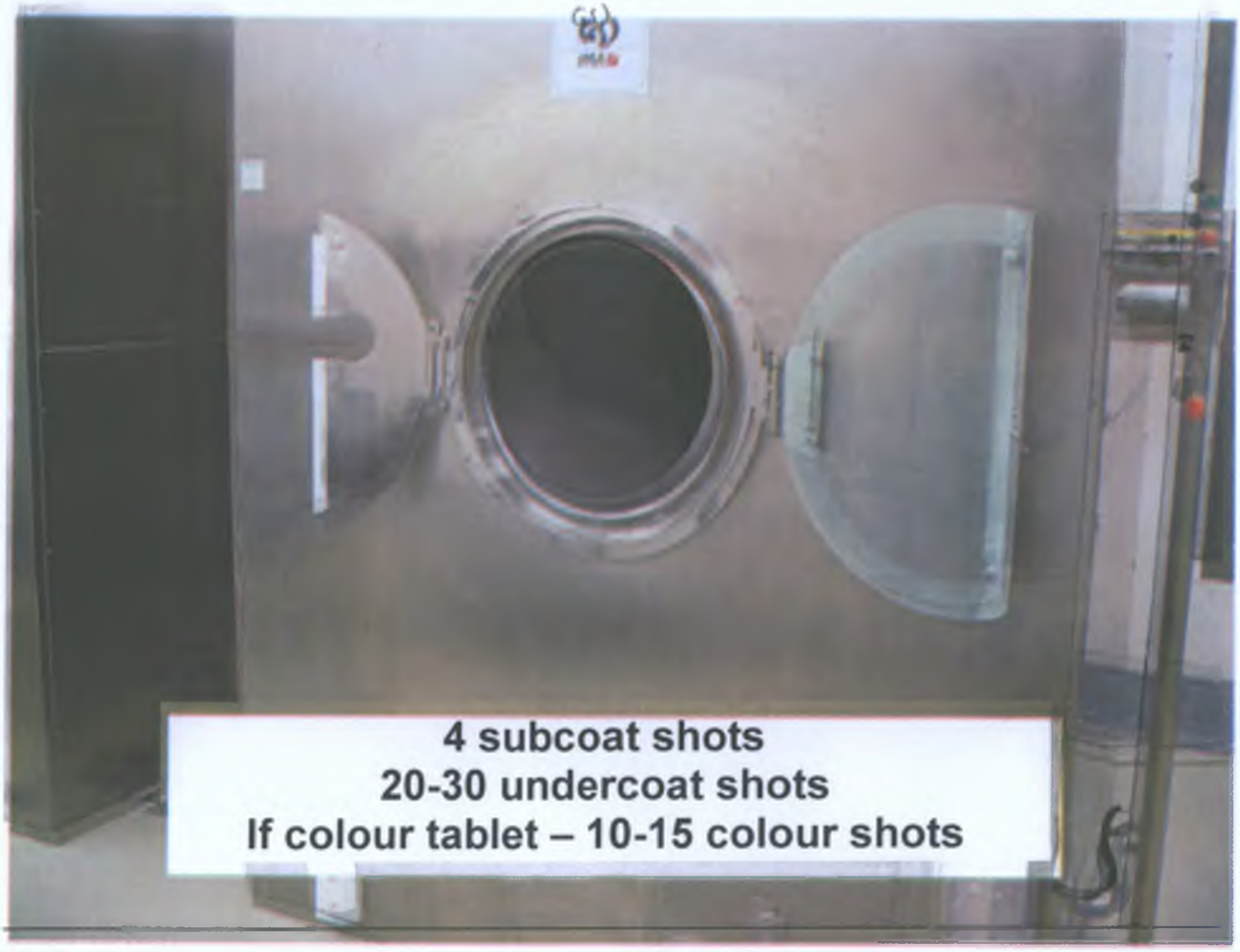

Figure 18: A Pellegrini coating pan used to coat OC sugar coated tablets.

As the preparation of coating solution and the application of the solution to coat the tablets are inherently linked, the progress of the two teams will be addressed together. The OC Solution Preparation/Coating Teams (SPC Teams), again using the DMAIC tool, began by defining the problem. The three goals of the SPC Teams were defined as follows:

- Reduce the number of weight and colour variation related MIRs.
- Provide sustainable fixes to eliminate future weight and colour variation MIRs.
- Improve the understanding of the sugar coating and solution preparation processes.

The OC MIR review (Figure 13) indicated that solution preparation/coating issues were responsible for 47% of the MIRs raised during the defined time frame. As with the compression MIRs a Pareto analysis was performed to identify key focus areas, see Figure 19.

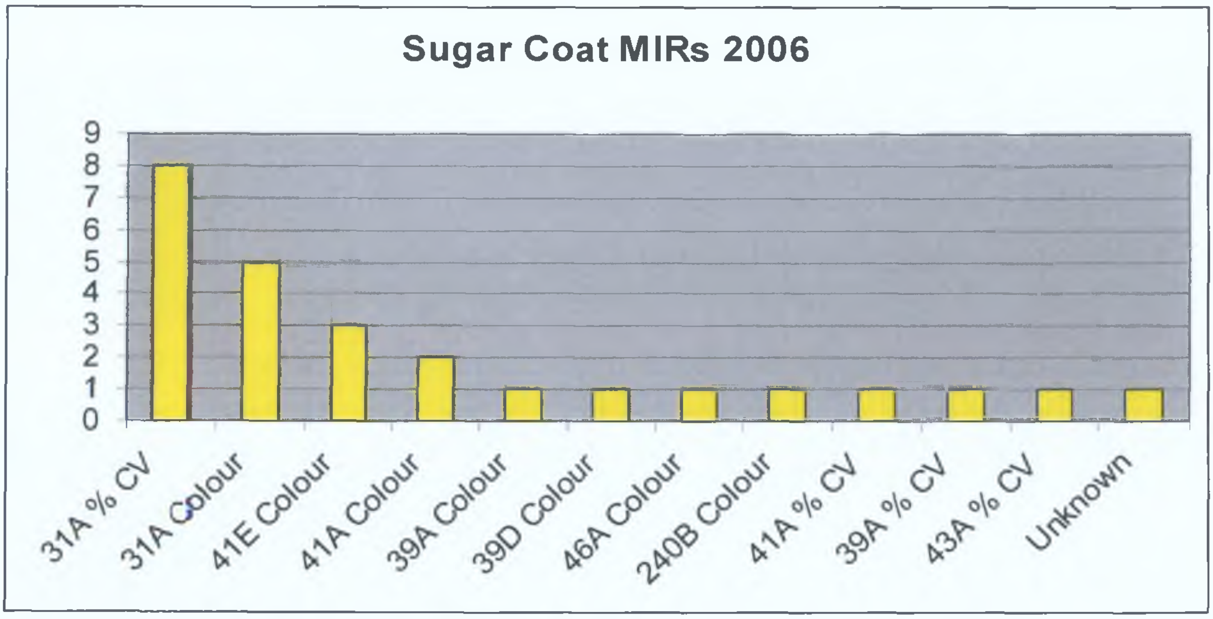

Figure 19: Pareto analysis of solution preparation/coating MIRs per formulation-issue.

From the analysis it was clear that %CV for weight and colour variation deviations for the 31A formulation were responsible for a large proportion of MIRs generated in 2006. The team decided to compare the two most common sugar coated OC formulations, 31A and 31B. These two formulations are identical except that the 31A is pale yellow and the 31B is white. The following was discovered:

- 31A accounted for 21% of volume share and 50% of weight and colour MIRs.
- 31B accounted for 10% of volume and 0% of weight and colour MIRs.

Both 31A and 31B used the same core tablet, coating equipment, operators etc. and 31B was white so colour variation was not an issue. But, analysis of the 31B data showed that none out of more than 200 batches analysed failed the %CV for weight specification.

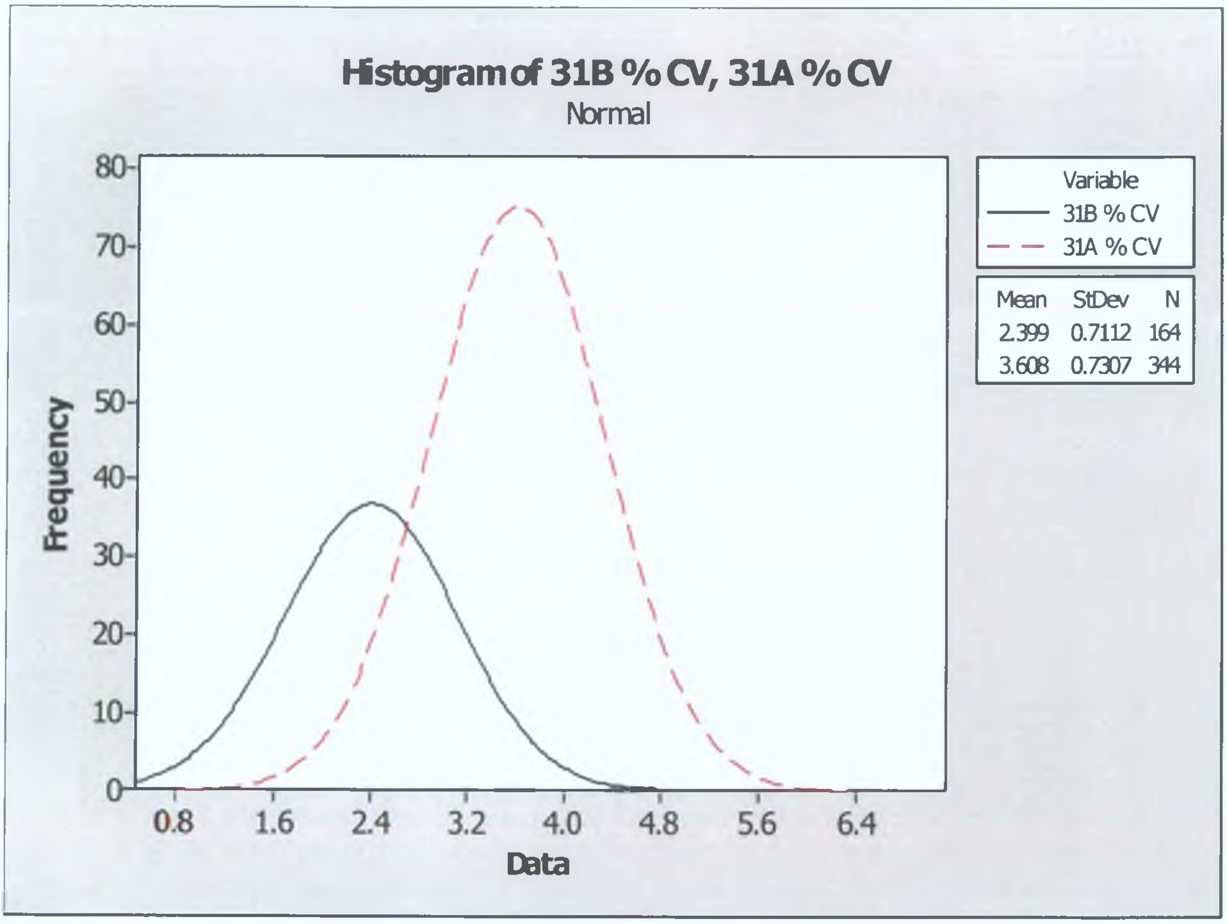

Figure 20: Plot of %CV for weight of 31A versus 31B formulations.

From the comparison of %CV for weight in Figure 20, the mean %CV for weight for the 31B formulation was ca. 2.4%, whereas the mean for the 31A formulation was much higher at ca. 3.6%.

Figure 21 shows the process capability analyses of %CV for weight for the 31A and 31B formulations. The Cpk value of 1.29 showed that the 31B coating process was a more capable and centred process than that of 31A (Cpk=0.68).

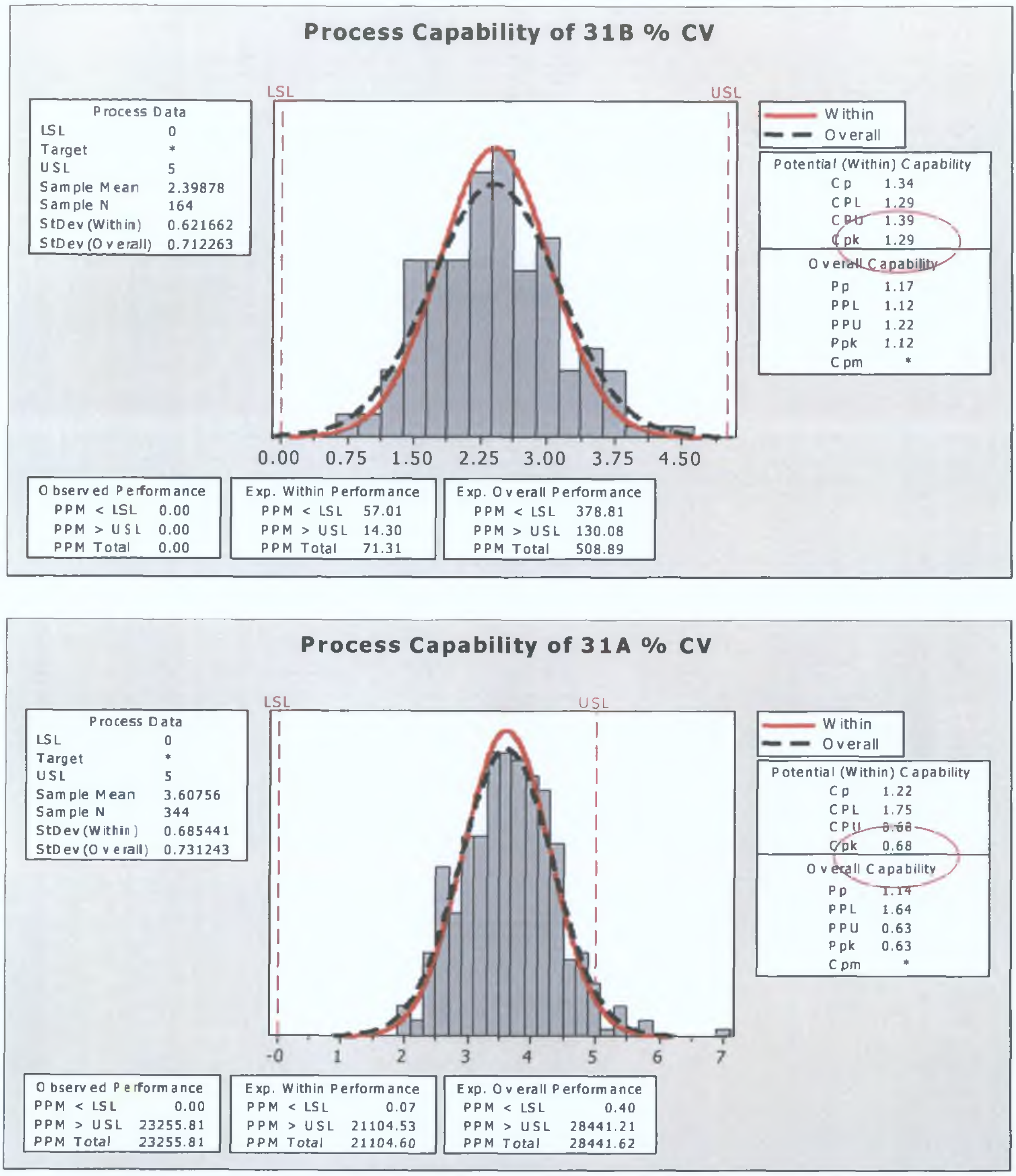

Figure 21: Process capability of 31A and 31B formulations for %CV for weight.

The teams examined the excipients of the two colour solutions and the mean flow rates for the undercoat solutions (most of the coat is composed of the undercoat solution). They found that the % solids of the two undercoats were very similar at 73.3% for the 31A solution and 74.4% for the 31B solution.

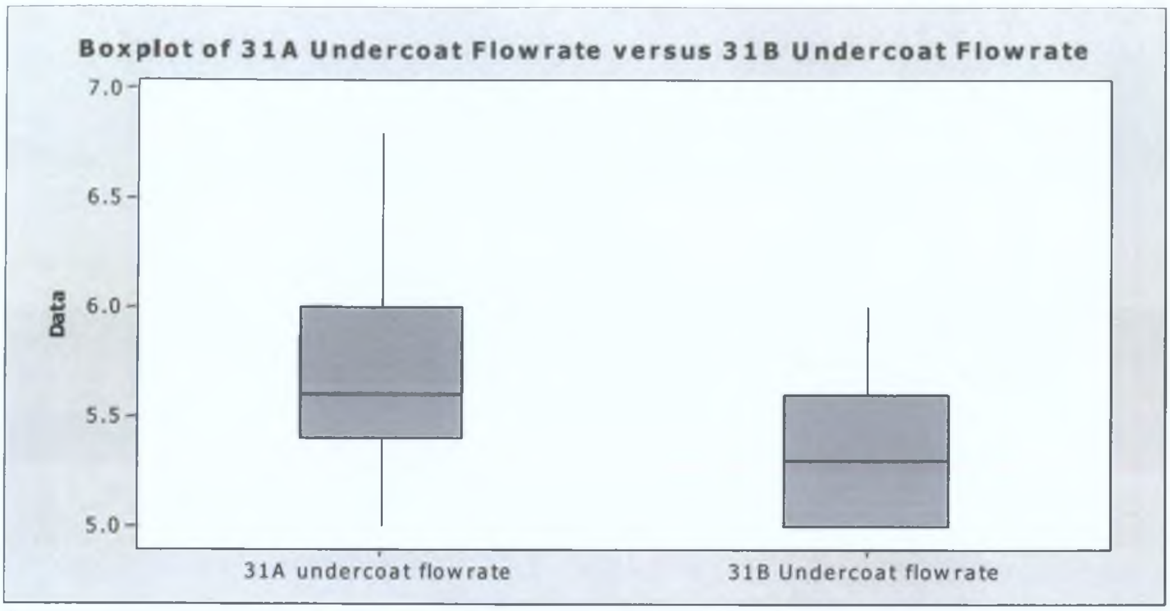

Figure 22: Box plot of 31A undercoat flow-rate vs. 31B undercoat flow-rate.

Figure 22 is a simple box plot demonstrating mean flow-rates of 5.7 ml/s and 5.3 ml/s for the 31A and 31B formulations respectively, where n=30. The viscosity of a coating solution can greatly affect tablet coverage during shot application.

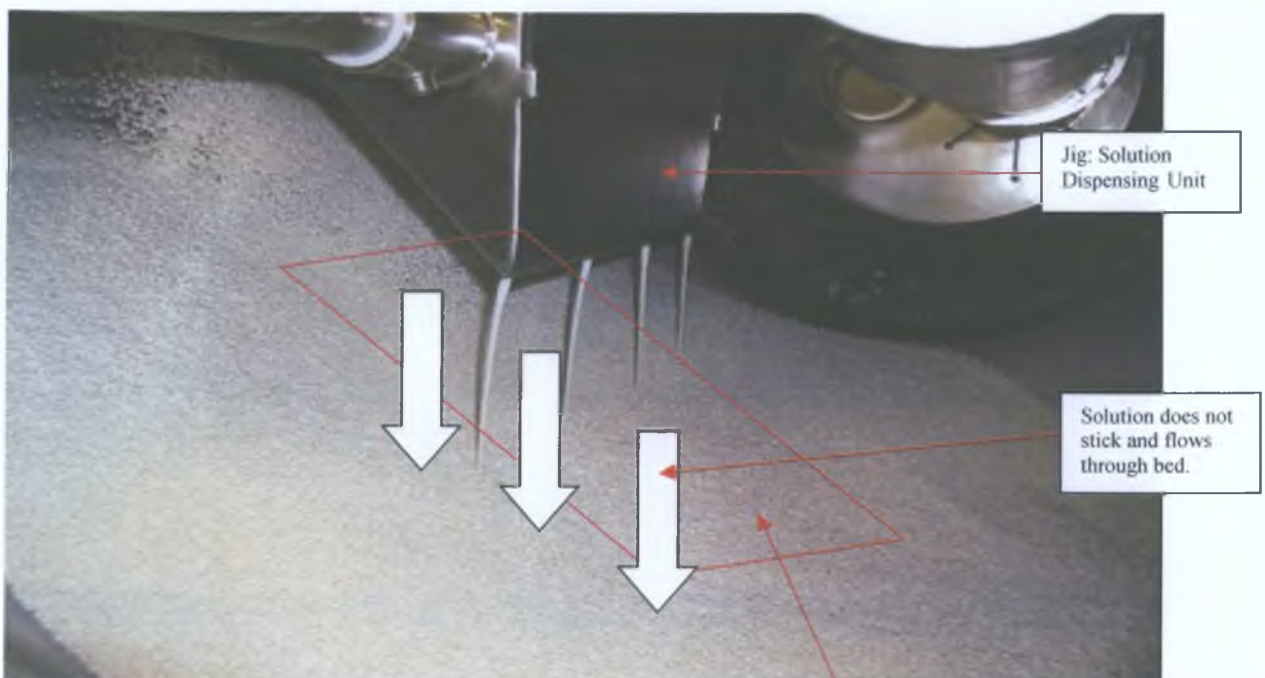

Figure 23: Coating solution shot application.

Figure 23 shows how the coating solution is applied. An aliquot of coating solution is placed in the jig and applied to the tablets in the coating pan over a specified period of time. If the solution is not viscous enough, i.e. the flow rate is too high, the coating solution will flow through the tablet bed and not be evenly distributed.

In light of the lack of deviations associated with the 31B formulation the teams prepared a trial undercoat solution with 5 kg less water than usual so that the viscosity of the problematic 31A solution would match the viscosity of the non-problematic 31B solution. This solution was then used to coat a 31A batch of tablets.

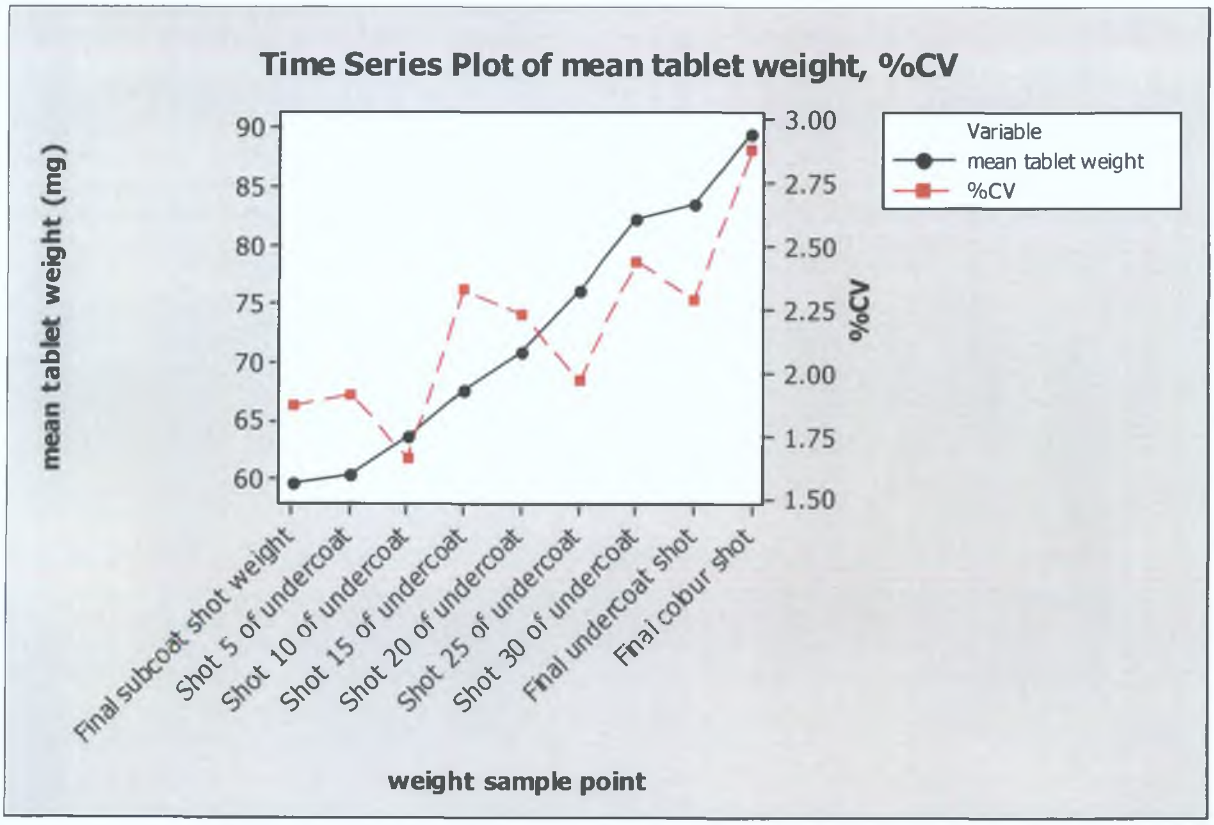

Figure 24: Time series plot of mean tablet weight/%CV for weight

Figure 24 shows the weight/%CV for weight correlation throughout the coating process. At the final tablet weight of 90 mg the %CV for weight was 2.9% compared to a typical value of 3.9%.

The team members from the Registration Dept. performed an analysis of the registered testing requirements for all markets supplied with the 31A formulation. They discovered that there were weight testing requirements for most markets with some exceptions. One of these exceptions was Brazil which had no weight requirements. As depicted in Figure 25, over 30% of the volume of 31A tablets produced at WMI is supplied to the Brazilian market.

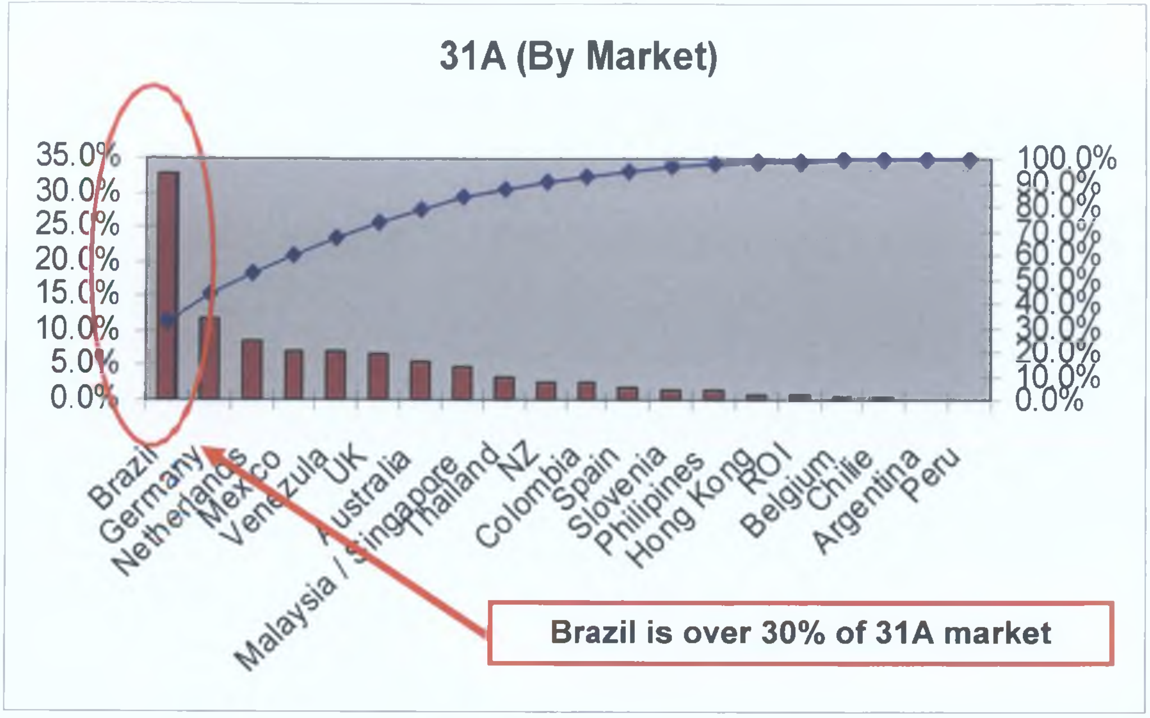

Figure 25: Market supply metric for 31A formulation

The discovery of this non-requirement for Brazil meant that the QC lab could forego weight testing for all 31A batches scheduled for shipment to Brazil. This was termed as a "quick fix" as over 30% of all 31A batches would not require weight testing. This would in turn lead to quicker batch turnaround times in the QC lab., less MIRs for weight failure and quicker supply to the market.

The use of OE tools such as DMAIC, Cpk index, Pareto analysis, box plots, etc. provided the Tiger Teams with the means to pinpoint the pivotal processing issues in the OC PPU. The collaborative efforts of the Tiger Teams provided a springboard of knowledge, based on statistical fact, which would serve to ensure the sustainability of the favourable stock situation achieved through the efforts of the Bulk Release Team. Chapter 5 will discuss and conclude on the implications of the findings of the OC Recovery Project teams.

Chapter 5: Discussion And Conclusions

WMI is a "functionally" orientated organisation, that is to say that personnel operate comfortably within their functions, with very few people having occupied a position in two or more functional groups. A Processing Operator will very rarely move to Packaging and a QC analyst will rarely traverse to Processing. In Six Sigma terminology, this could be classified as a "silo" mentality, where people in one functional group do not know what is happening in other functional groups. However, it does encourage personnel to pursue a particular career in a chosen discipline and serves to create a large pool of subject matter experts (SMEs).

The OC Batch Release Team had a project life cycle of 12 months. It required core personnel who would be given solely to the goals and objectives of the teams. Therefore there was a requirement for full time personnel. However, because of the nature of the work, e.g., cross-functional knowledge requirements, the Site Steering Committee decided that the team members must have the necessary experience if the project was to succeed. These factors ensured that the project model adopted was a strong matrix model where the four core team members were specially chosen because of their cross-functional experience and they worked full time for the team with the support of a number of part time personnel from QA/QC and Customer Services.

The objective of the Bulk Release Team was very clearly communicated to the functional managers of the full time personnel on the team, however there were occasions when the functional manager asked a team member to do some routine functional work. This created some friction between the PM and functional manager and brought to light the importance of the true project management abilities of the PM within the matrix model. The PM was very clear in reminding the functional managers of the paramount importance that the project had in ensuring continued success of the OC business at WMI.

As mentioned at the end of Chapter 4 the Registration Dept. discovered a "quick fix" for the 31A weight failure issue. This however would be better classified as a trade-off, as the Technology Specialist had to raise a TCCR each time a 31A batch was released to Brazil. Weight testing was a routine test. Therefore, to negate this test was a planned change in the testing regime for a 31A batch, which required a TCCR. This strategy was implemented at the start of 2008 which was around the same time that the Technology Specialist had implemented the new procedure for re-sorting batches that failed weight testing. This new procedure negated the requirement to raise a TCCR to re-sort a batch. To summarise, no sooner had the Technology Specialist devised a method to reduce TCCRs was he subsequently asked to raise more TCCRs to help the Tiger Teams implement a "quick fix". This could have resulted in in-fighting among the project teams as one team's recommendation resulted in another teams work load increasing. However, there was a good holistic sense of common purpose amongst the teams with frequent sharing of information and expertise. This served to dispel any "we-they" attitude that could have existed and frequently does when "projectitis" sets in; as discussed in Chapter 3.

Figure 26 illustrates the OOS/LS OC market trend during the life cycle of the OC Batch Release Project.

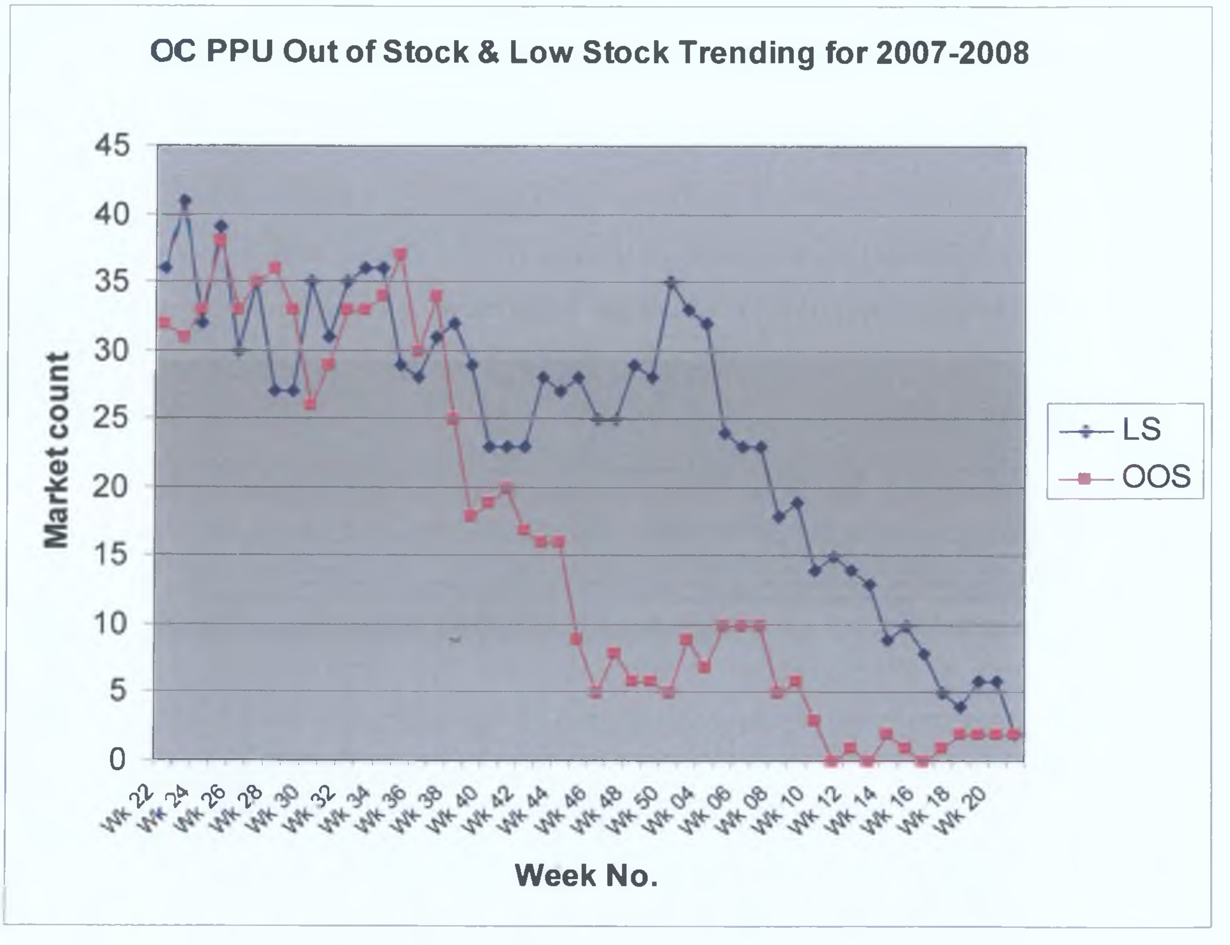

Figure 26: OOS/LS Trend Data for 2007/2008

Analysis of the trend data shows the phenomenal success of the OC Batch Release Team and is a clear justification of the use of the matrix model. From a peak of 38 OOS and 39 LS markets in week 25 of 2007 the team achieved a week 21 2008 result of 2 OOS and 2 LS markets. The OOS metric declined quicker than the LS as more emphasis was placed on supplying OOS markets than LS ones. This was an obvious course of action as an OOS market is a much more serious situation than a LS one. Both metrics can be seen to increase at the start of 2008. This was a natural occurrence and was due to the holiday period when supply stopped but demand still existed. The situation recovered by the middle of February whereupon further progress was made and the metrics declined further to give a favourable end result. The following statement appeared in a general WMI communication on 13/08/08 "OC recovery is complete. Any low stock or out of stock in the markets are due to over-sales. There is no constraint of supply or demand."

As well as reducing the OOS and LS markets to minimal levels, the OC Bulk Release Team was also responsible for the following by the end of the project life cycle:

- Increasing approved bulk status from 60 million tablets in June 2007 to 170 million tablets in May 2008.
- The re-sorting procedure was formalised thus resulting in more efficient and timely schedule attainment and a reduction in TCCRs.
- Closing out 72% of all OC MIRs within 15 days of initiation; 30 days were allowed for MIR closure.
- An average of 90% schedule adherence was obtained at final QP release. This metric was below 10% at the beginning of the project.

Upon termination of the Bulk Release Team in May 2008 the OC PPU sought to embed the Bulk Release Team activities into day-to-day operations. Of the two Investigation Leads, one was promoted and the other resumed work as a Packaging Supervisor in the OC PPU. The PPU created a Lead Investigator position to sustain the specific task of opening and closing investigations and implementing appropriate corrective and preventive actions (CAPA). The Compliance and Technology Specialists were absorbed back into the OC PPU were they resumed routine duties but also gained the experience and knowledge associated with having been on the project team. This knowledge base was retained and utilised in the OC PPU.

Having achieved stock recovery in a sizable number of OC markets a new challenge arose. How would the OC PPU sustain the current stock situation? The Tiger Teams were introduced (July 2007) shortly after the OC Recovery Team started. Their task was to improve process robustness in order to sustain the situation achieved by the Recovery Team. Following the termination of the Tiger Teams in October 2007, weekly "decision forums" were held in the OC PPU to agree implementation of identified solutions. The factors considered were: timelines, cost, product volume projections and resources required. By the end of 2008 the following identified solutions had been implemented as a result of the work of the Tiger Teams:

- Compression tooling of a high quality had been sourced and supplied from a reliable vendor. WMI entered into a Quality agreement with the vendor thus further ensuring the reliability of the tooling.
- Although not discussed in detail in Chapter 4 the Training Dept. approved and implemented on-the-job training assessments for compression and coating operations. These assessments were designed to facilitate better operator understanding of the manufacturing processes.
- Flow rate measuring devices had been fitted to all OC presses resulting in greater control of dust extraction during compression and hence less process deviations for low assay results.
- The 69E/F high assay issue resulted in the implementation of an Overage Reduction Project. A reduction in the quantity of the two actives contained within these formulations (now 69G/H) introduced in 2008 resulted in a substantial reduction in MIRs for out of specification/high assay results. There were also sizable savings from this project as a number of batches had been rejected between 2005 and 2007.
- The new reduced viscosity 31A undercoat solution was validated and implemented.
- The Registration Dept. took a two pronged approach to the 31A weight and colour variation issue. They began submissions to harmonise all 31A filings to 31B thus eliminating future colour variation potential. They also made submissions to remove %CV for weight testing from all Market Authorisations (more than 30 in total). The expected completion date for this strategy is June 2009.

A number of key learnings were achieved through the actions and successes of the OC Recovery Project teams:

- The assignment of appropriate resources and the design and capability of the project teams, i.e. strong/weak matrix models utilised, was paramount to the workings and success of the project teams.
- Project governance was disciplined and involved communication and collaboration on a Team/Site/Corporate level.
- The support of senior management was critical to allowing the teams to focus on the task in hand.

- The Program Manager and PMs were experienced and capable.
- The co-location of the project teams (full time personnel) facilitated a natural sharing of knowledge, a concerted group focus and a holistic approach to issues encountered.
- Decisions were data driven, as evidenced by the metrics presented in this thesis, and not just "good ideas".
- The short timelines associated with the Tiger Teams engendered a sense of urgency.
- The sustainability plan developed by the Tiger Teams was an appropriate means to perpetuate the success achieved the Bulk Release Team.

Chapter 6: Future Work

Having re-established reliable product supply thus retaining market share, the OC PPU began a three year project (OC Strategy Project) to reformulate a number of tablet formulations in a bid to focus the business on the products and markets of greatest commercial and financial value.

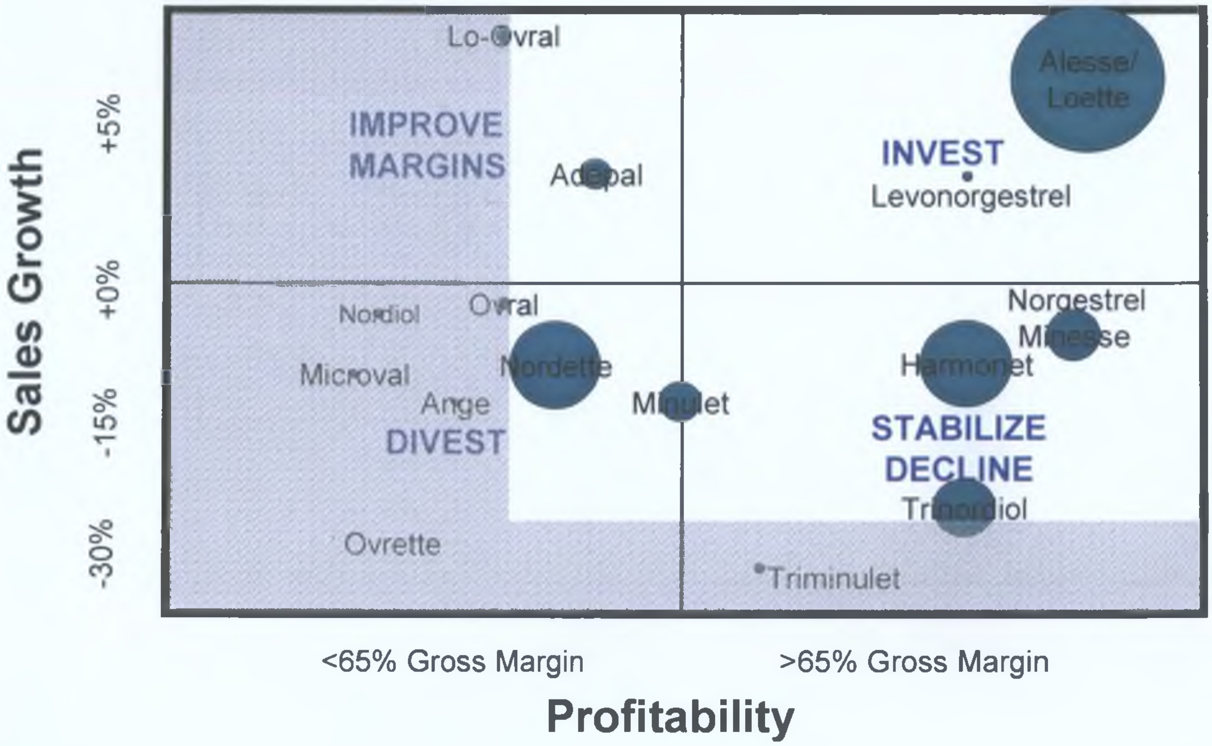

Figure 17: Boston Consulting Matrix.

To select the products to be retained and reformulated the Strategy Development Team focused on a number of factors including gross margin, product robustness, product lifecycle, market growth and contractual obligations across the product family network, see Figure 27 for profitability matrix.

In June 2008 authorisation was approved to implement the OC Strategy Project. This authorisation included reducing the number of products, Stock Keeping Units (SKUs) and countries engaged in commercialising OC products. As part of the authorisation granted, it was also approved to transfer OC production from the existing OC manufacturing suite to a new state-of-the-art OC suite also at WMI. In this suite, the old sugar coated formulations will be reformulated as new dry blend film-coated tablets.

Migrating OC production to the new suite at WMI will bring significant benefits, it will:

- Improve OC supply reliability and afford increased flexibility to respond to variations in volume.
- Lower the Cost of Goods (COGs).
- Enhance capability to apply future product improvements, including formula harmonisation and shelf life extensions.

The OC Strategy Project is due for completion in 2010. It is intended that the new dry blend tabletting process will bring with it reliability, robustness and repeatability. The efforts of the OC Recovery Project teams have enabled the transition from "old" to "new" thus ensuring the future manufacture of OC products at WMI.

APPENDIX 1

Typical OC Bulk Release Team weekly priority list from December 2007

Item	Description	Bulk	QC Target	QC Actual	Out of Stock		Comments
B6313	MICROVAL (30/-)	C49105	17 December 2007	07-Dec			
B6313	MICROVAL (30/-)	C49106	20 December 2007	05-Dec			
B6313	MICROVAL (30/-)	C49107	20 December 2007	05-Dec			
B6311B	TRINORDIOL 75/40	C49111	30 November 2007	05-Dec		QA	
B6311B	TRINORDIOL 75/40	C47748	30 November 2007	03-Dec		QA	
B6314	STEDIRIL 30 / NORDETTE	C48762	13 November 2007	29-Nov		LIR MIR	LAB FAILURE LIR TO BE RAISED FAILED WEIGHT mir 16557
B6374	HARMONET/MICROLET (75/20)	C49080	04 December 2007	06-Dec	OOS	MIR CLOSED	Mir lod out of spec16510
B6374	HARMONET/MICROLET (75/20)	C49081	04 December 2007	07-Dec	OOS	PROCESSING	Batch File Required from Processing
B6349	STEDIRIL (500/50)	C47750	04 December 2007	06-Dec		PROCESSING	Batch File Required from Processing
B6311C	TRINORDIOL 125/30	C47765	12 December 2007	30-Nov		MIR CLOSED	MIR 16467 INCORRECT COATING STRAGEDY & LIR 16536
B6394	EVANOR TABLETS	C40491	30 November 2007	30-Nov		QP	
B6316	PREM PAK C (NORGESTREL 150)	C49194	10 December 2007	29-Nov		MIR	Technology mir micro issue 16614
B6593	PLACEBO Minesse	C52252	22 November 2007	26-Nov		MIR CLOSED	COATING DEFECTS
B6314	STEDIRIL 30 / NORDETTE	C52676	27 November 2007	06-Dec		QA	to be reviewed
B6314	STEDIRIL 30 / NORDETTE	C52675	28 November 2007	05-Dec	OOS	MIR CLOSED	mir on halb sab issue
B6394	EVANOR TABLETS	C45537	06 November 2007	06-Dec		QA	REVIEWED
			BATCHES WITH MIR/LIR TO BE CLOSED				
B6374	HARMONET/MICROLET (75/20)	**C48226**	23 November 2007		OOS	LIR	Broken PUNCH MIR 16464 CLOSED LIR DEGS PART A RAISED
B6311A	TRINORDIOL 125/30	C45842	07 July 2007	09-Nov		MIR 16673	mir to be raised for missing checks
B6394	EVANOR TABLETS	C12392	25 September 2007	OVERDUE		PRE QP'D	**may require stats to close out and memo to mir**
B6314	STEDIRIL 30 / NORDETTE	C48765	Wednesday	possible reject		LIR	halb not down from the lab c47819 has lir
B6311	TRINORDIOL 125/30	**C16688A**	15-Oct	23-Oct	OOS	APPROVED FOR France	MIR TO BE RAISED TO ALLLOW SHIPMENT TO BRAZIL
B6314	STERDRIL (halb C01227 Approved)	C00385AB C00385A C00385	03 November 2007	late	INSPECT	MIR	RESORT BATCH ALLOCATION PLAN TO SHIP 14/6 FAILED FOR HEIGHT CAN ONLY GO TO BRAZIL TCCR 07-0706

Key:

REJECTED	MIR	WITH QP	APPROVED		Date due from QC	Schedule Attainment

APPENDIX 2

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