TPM

A foundation of operational excellence

Case Studies | Mylan

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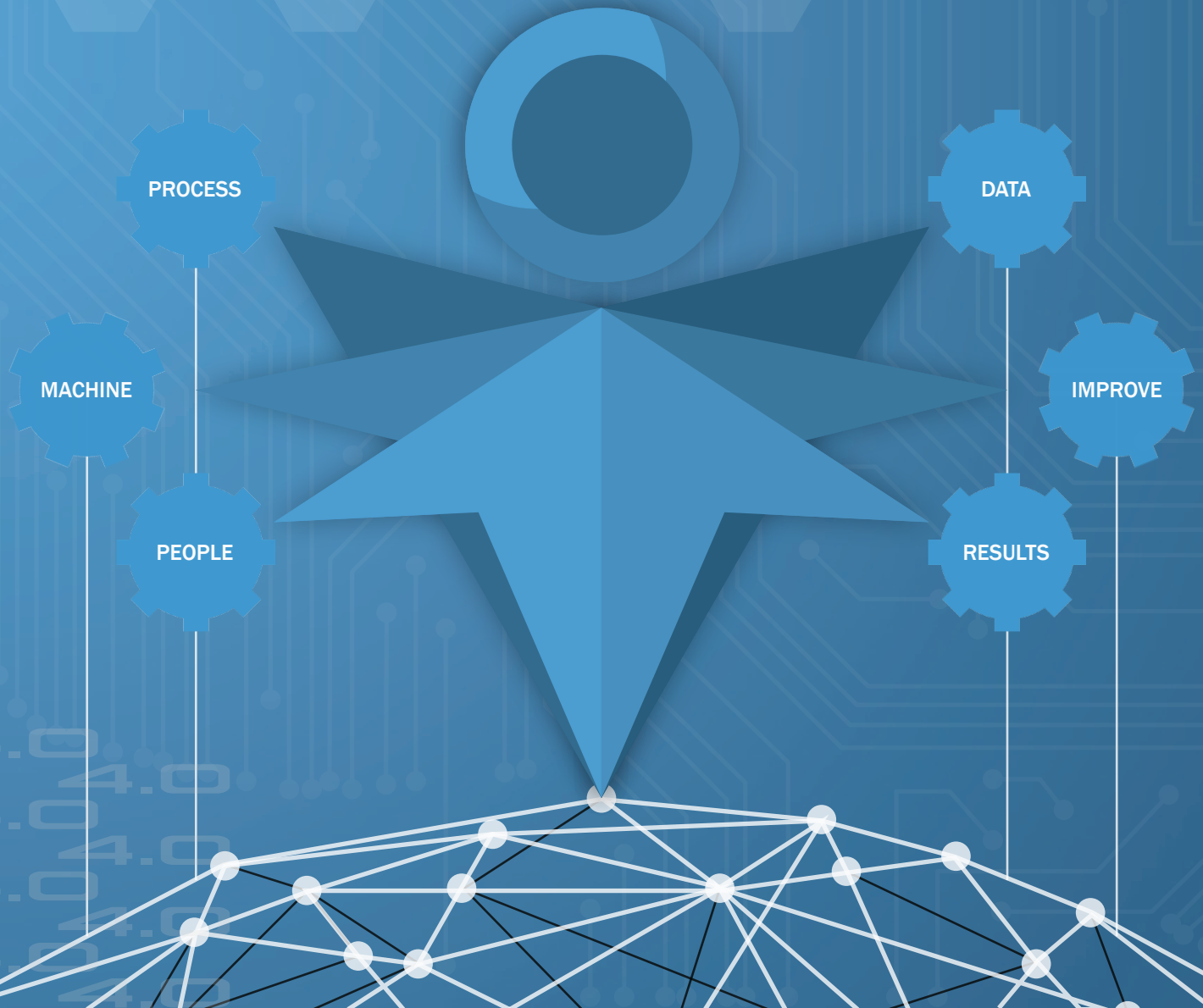

10.2 **Mylan Damastown (formerly known as Rottapharm Dublin)**

By Richard Hayes, Operational Excellence Director

Company background

The facility was established in 1999 and currently employs approximately 200 people. It became part of the Mylan group of companies, which has a workforce of 35,000 people worldwide, in August 2016. The Damastown site produces finished oral solid dosage pharmaceuticals in tablet, capsule and sachet formats. Liquid drop manufacturing and packing operations also commenced in early 2016, adding new technology and complexity to the site. The site took responsibility for new products involving the production of liquid drops, even though other sites within the group had the technology and capability to produce the new products. This was in recognition of the track record of cost competitiveness, ability to deliver projects and quality products on time and was also based on an outstanding record of operational excellence over the previous ten years.

Drivers behind Damastown's operational excellence aspirations

Figure 10.1: Pat Gerrahy, Managing Director of Rottapharm, receives the Shingo Silver Medallion at the Shingo Conference April 2017

The Dublin facility has an established history of running lean operations and using tools such as Six Sigma since 2006 and Total Productive Maintenance (TPM) since 2010. A positive culture and many desired behaviours developed from the use of these tools, but the emphasis was initially on the tools and the results they provided, rather than on the culture that was being created using these tools and systems of work. In a search for a benchmark as to how the company was performing, Damastown identified the Shingo Model™ to help shape how lean tools and thinking were deployed and to develop the culture within the organisation.

In 2013 the company introduced a strategy of cultural change within the Dublin plant aimed at providing excellent sustainable results through a principle-based model. This case study provides some examples of how the site has achieved excellence through behaviours based on the guiding principles of the Shingo Model, especially over recent times. As a result, the company received the Shingo Silver Medallion for operational excellence at the Shingo International Conference in Atlanta Georgia in April 2017.

The strategy and associated activities pursued by the Damastown site over recent years and particularly over the last two to three years have been aimed at securing the long-term future for the plant. The objectives of the company are to provide the best products for customers (patients) and develop employees for the future by working in a sustainable manner for the benefit of the environment. The Shingo Model™ with its guiding principles has been used to develop the culture within the plant that allows people to thrive in their normal job and push the boundaries, enabling people to realise their full potential.

The role of TPM as an enabling tool to deliver efficiency and results

Over the past number of years, the site has focused on efficiency throughout the plant production and support functions. The introduction of Total Productive Maintenance (TPM) and development of a continuous improvement (CI) system with a focus on removal of waste have resulted in substantial improvement in terms of business results.

Against the backdrop of the business need to absorb products and equipment from Europe by unlocking their existing capacity and retaining the same overhead and employment base, Damastown is very proud of its success in using TPM as its main foundation 'enabling tool'. In 2010 the company initiated a TPM programme, which

they called Total Productive Manufacturing to emphasise the implied and necessary teamwork between **production** and **maintenance**. Following an initial and thorough planning and scoping phase, the TPM journey comprised a chronological focus and sequence as highlighted here:

- Initial diagnostic/scoping study to establish the business case
- Site leadership team 'buy-in' to the TPM process to help deliver the business imperatives
- Initial four-day TPM practitioner's 'hands-on' training workshops – Go see & do, 'learning by doing'
- TPM pilot projects, roll-out planning and programme governance
- Progressive middle and senior management TPM 'pillar champion' coaching and mentoring
- Focused improvement activities such as VS mapping, 5S workplace organisation, area clearances/precision changeovers (SMED)
- Early equipment management/TPM for design
- Total Productive Administration in the manufacturing support functions
- Regular evidence-based top-down and bottom-up TPM audit and review processes
- An annual 50-point maintenance strategy review
- Integrating safety, environment and energy conservation opportunities into the day-to-day good manufacturing practice (GMP) tasks.

This step-by-step sequence and focus has helped the site to not only avoid some of the common pitfalls, but to continually remind and suggest how the business could best improve its competitiveness. This approach also ensured that other improvement activities, such as safety, environment and energy conservation opportunities, were integrated into the day-to-day GMP tasks within the plant. The business has also made significant savings by applying total productive administration (TPA) in the support departments.

A key part of the initial diagnostic/scoping study phase was to describe the manufacturing and packaging logic, sequence and interdependencies of the facility (Figure 10.2).

In parallel with, and based on the early successes of the initial TPM pilot projects, the site then set about defining the TPM roll-out plans for the ensuing four years (Figure 10.3).

A great deal of effort was also put into defining the TPM programme infrastructure and governance processes (Figure 10.4) linked to regular evidence-based top-down and bottom-up TPM audit and review processes.

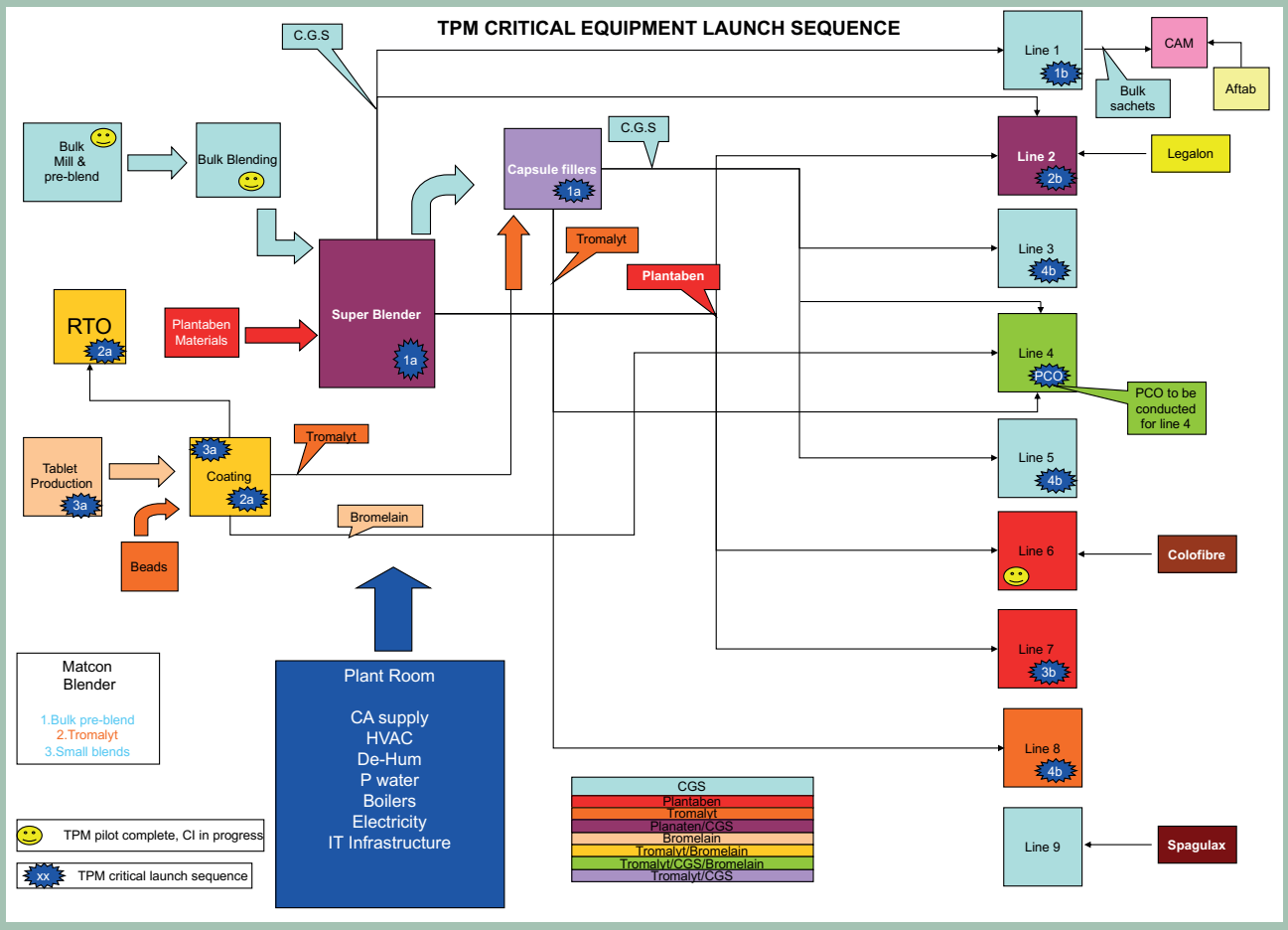

Figure 10.2: Site manufacturing and packaging process flows

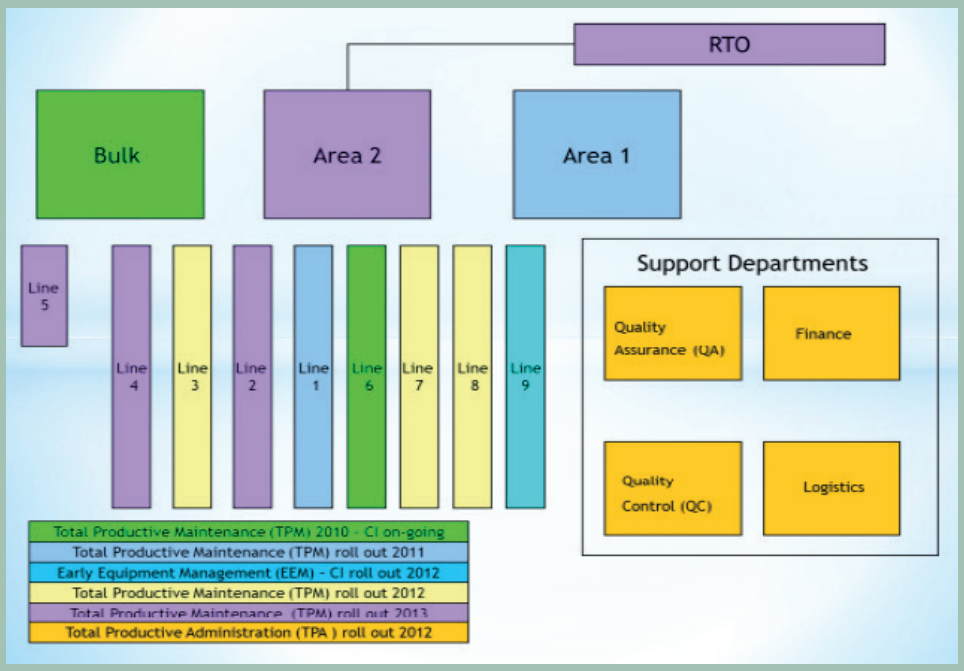

Figure 10.3: Four-year TPM roll-out plan sequence

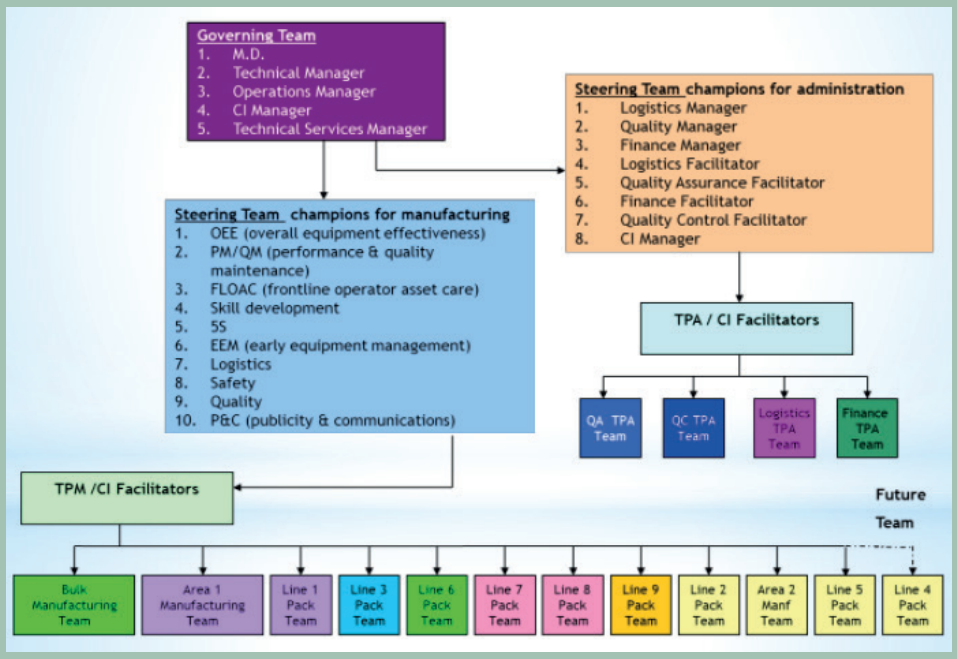

Figure 10.4: Site TPM governance and infrastructure

As an illustration of the level of improvements made possible using the TPM system, Figure 10.5 shows the results for one of the packaging lines over a nine-month period to Milestone 2 audit criteria achievement.

12 Months Average 2010		Improvement	4 wks Average by 30 Sept 2011
OEE	20.7%	x 2.5 increase	49.5%
Eq Failures	25.7%	Down by x 6	4.0%
Idle Time	38.0%	Halved	21.5%
No Data	2.1%	Eliminated	0%
Line Restraint	5.9%	Eliminated	0%
Minor Stops	7.8%	Down by 65%	2.7%
Actual v. Target (Prod Plan)	73.0%	100% OTIF	100 %

Figure 10.5: Initial TPM pilot project packing line 6 results to Milestone 2 achievement

As illustrated in Figure 10.5, TPM is designed to enhance OEE by increasing equipment availability, decreasing rework and rejects, and hence increasing productivity. It involves the integration of engineering maintenance, project engineers, production process operations personnel and the wider workforce, thereby encouraging teamwork and asset care practices. By using the 11-step model shown in Figure 10.6 TPM seeks to involve workers at all levels and departments. The resultant improvements are felt in time, money and other resources in dealing with reliability, availability, maintainability and performance issues. In many process-based industries, maintenance costs, together with energy costs, can represent the largest part of operational budgets.

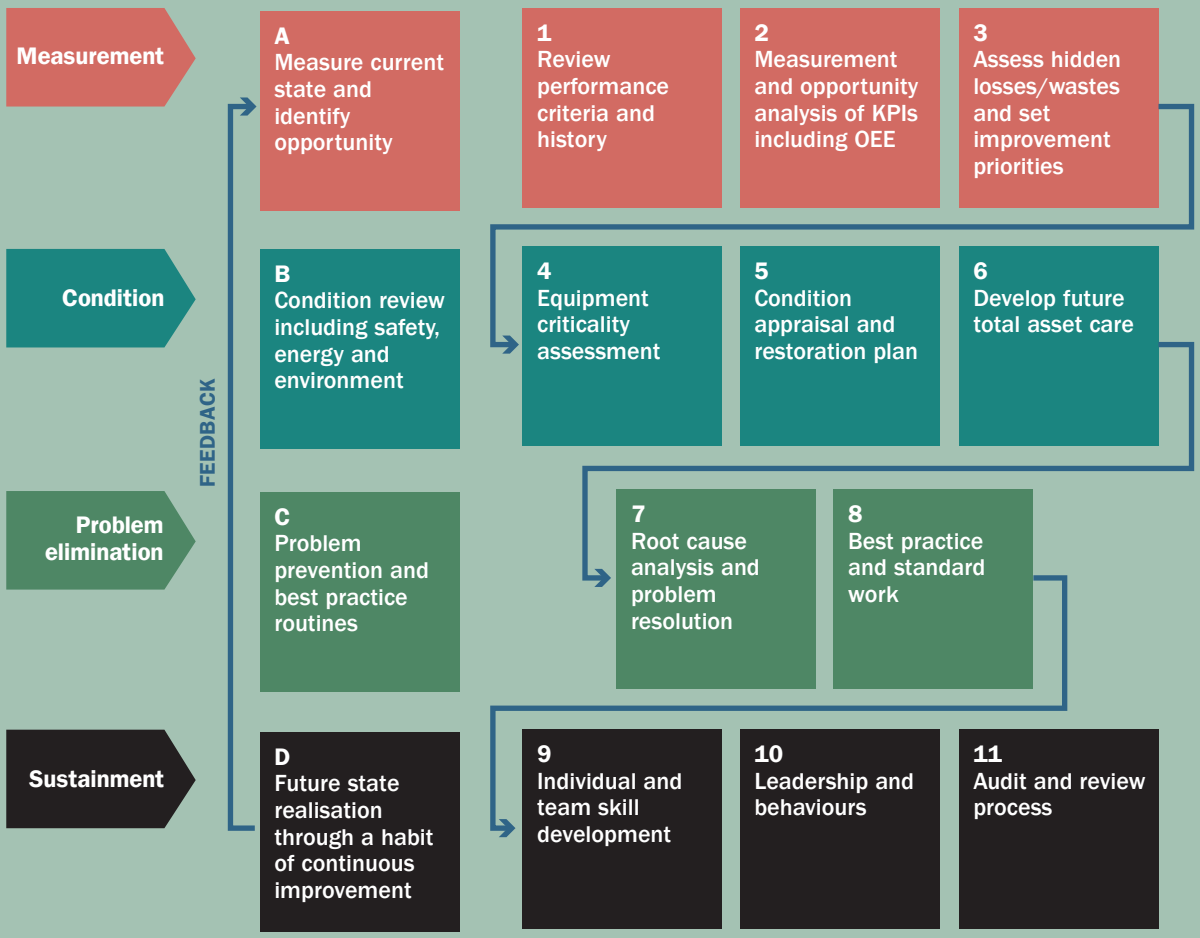

Figure 10.6: The TPM four-cycle process

Operational performance is measured using metrics commonly employed across a variety of industries. The McKinsey study of 2011 published a comparison between the pharmaceutical industry and other industries. While the report indicates that the pharmaceutical industry lags behind other industries, Damastown stands out as best in class within pharma. Through a sustained focus on OEE, the company has created value for the customer by generating year-on-year improvements and continues to show world-class levels of OEE (typically between 10% and 60% for the pharmaceutical sector, according to McKinsey). As Figure 10.7 illustrates, the OEE for Damastown, at 63% for 2016, continues in a steady upward trend as a result of the culture of operational excellence within all the teams in the company.

Batch completion time is a measure of the length of time taken to approve each batch record once a batch has been completed in production.

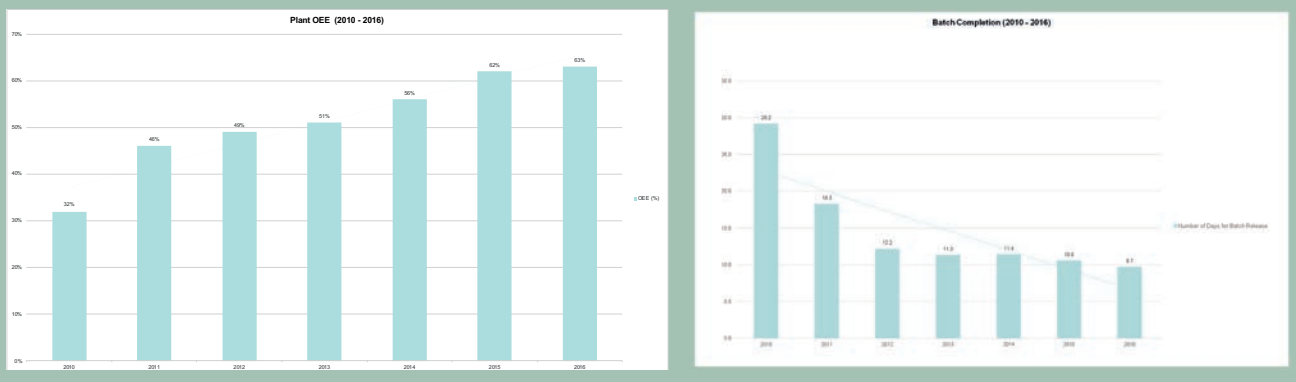

Figure 10.7: Rising OEE and falling batch completion times, 2010–2016

Figure 10.7 shows a decreasing trend in batch completion times from 2010. Over recent times this trend has continued downwards, with the current average number of days standing at 8.5 days.

Damastown has embraced scientific thinking and deployed many tools to conduct investigations into problems and eliminate recurring deviations. Solutions ranging from quick fixes on equipment to full-scale six sigma projects have been used to resolve difficult process issues. The trend on this metric has continued to decrease, with the current number of deviations reduced by 20% on the 2016 figure. The on-time delivery metric has improved over the past number of years (Figure 10.8). In June 2016 the metric was changed to Release On Time In Full delivery (OTIF). During 2017 this metric, which is harder to achieve than the previous one, had an average figure of 99% with eight of those months hitting 100%.

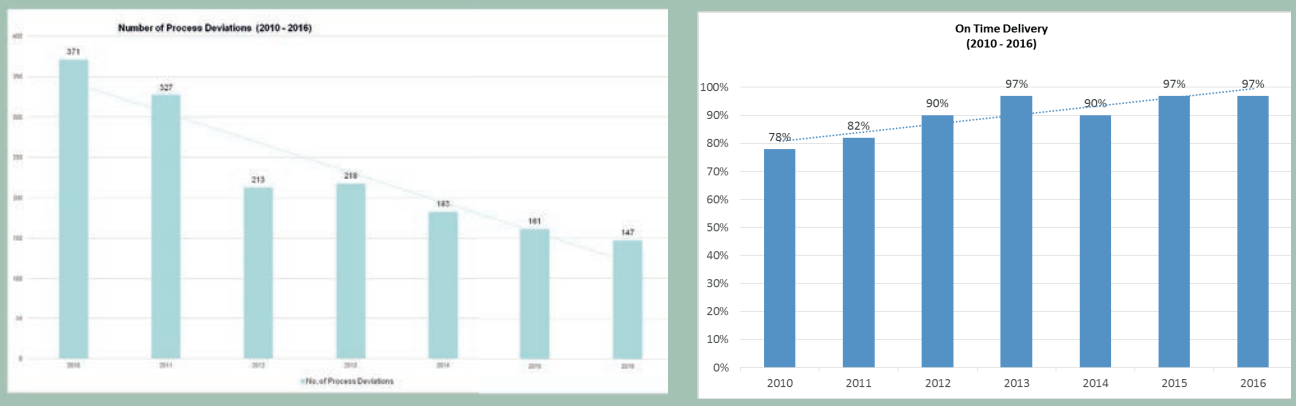

Figure 10.8: Reduction of process deviations an improvement in on-time delivery

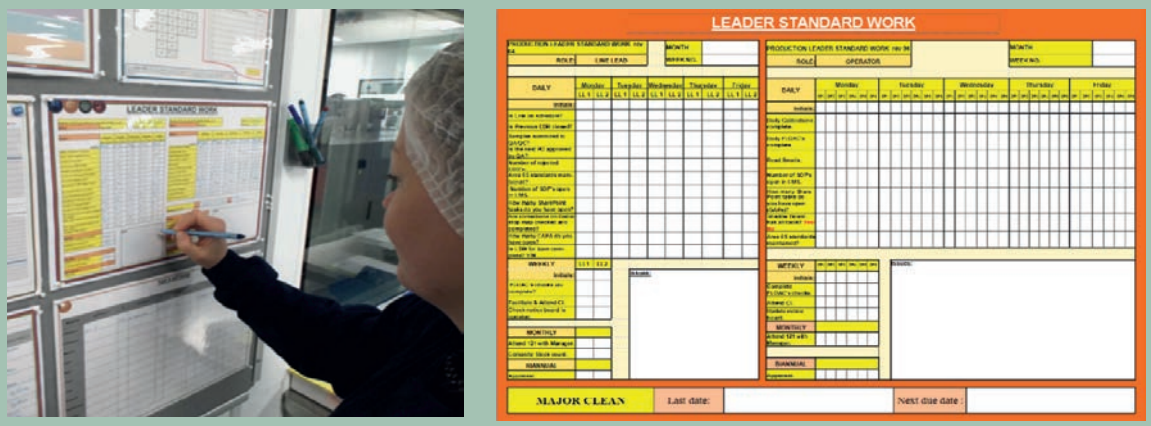

Figure 10.9: Leader Standard Work (LSW) task sheet for the packaging line lead operator

Operational efficiency using LSW

The parallel improvement of the use of leader standard work (LSW) and visual management has resulted in everyone within the plant having a clear understanding of what the daily expectations are in terms of process adherence and process performance (see Figures 10.9 and 10.10). The focus on process performance and adherence has led to plant-wide improvements in performance. People are more focused on getting things done on time and in recognising when process trends require action. Every team has a visual management board with laminated sheets that are updated daily. A number of meetings take place at these boards. The first meeting is held when work starts at 07:00 in the production areas and at 08:00 in the support areas. These are known as the pulse meetings and are carried out with the team and immediate supervisor or middle manager. At 09:00 the middle managers from operations, engineering, quality assurance and control, the

warehouse and logistics meet at the plant operations board and review any issues that have been raised and that required escalation by the various teams. A member of the senior leadership team (SLT) also attends this meeting on a weekly rotational basis. Appropriate actions are discussed and decided at the meeting. If an issue cannot be resolved and requires support from the SLT, it will be escalated to the senior team meeting at 10:00 with appropriate actions decided and communicated back to the middle management team.

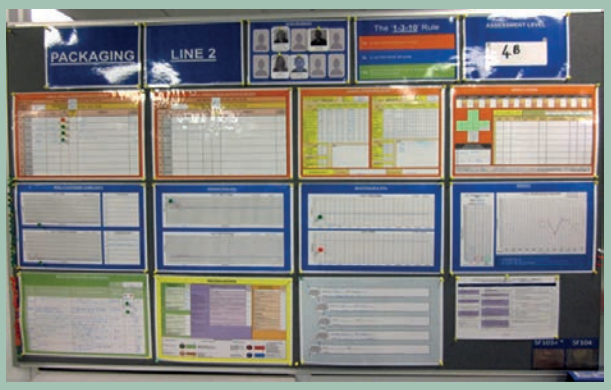

Figure 10.10: Standard visual management board to sustain focus and operational efficiency

The visual management boards have a standard layout that follows a 1-3-10-second rule. In 1 second you can tell if a team is winning or losing (orange laminate in the photo example); hourly outputs are recorded and marked with a red or green indicator to show whether or not they are on target for that hour. In 3 seconds you can tell how the KPI charts are trending (blue laminate). In 10 seconds you can tell what the team is doing about those areas where they are losing or trending below their target (green laminate). The board also includes pictures of the team members, LSW, a safety cross for each day of the month with a tracker for appropriate safety actions and a thank-you sheet to enable people to thank whom they wish for help during their work activities. The SLT meet with a production and a support team once a week and review the team's visual management board. Performance metrics and areas where the teams need support are discussed. Each team meets with the SLT at least once a quarter. Both the SLT and middle managers also meet with the people in the company during gemba walks. The SLT and middle managers split into small teams and go out and ask people how they are getting on, from both a work and general perspective, to engage with the people in the organisation. These gemba walks have proven successful in allowing opportunities for improvement to be identified and in some cases explaining why certain policies or procedures are in place. This has helped to create an open and honest culture with people who are also engaged and focused on operational efficiency.

Innovation: 3D hand scanner and printer for local spares provisioning

The emergence of Industry 4.0, combined with improvement in operational efficiency using TPM, precision changeovers and lean tools has accelerated the introduction of technology and removal of the use of paper records from the plant, which in turn has resulted in the creation of additional time for improvement activity. See Figure 10.11.

An example of this is the time provided to technicians to work on innovative and value-adding activity. Technicians and engineers have been trained on advanced design software packages such as Solid Works and applications to aid design, such as failure analysis software. The investment in both equipment and training in Solid Works and a 3D printer and scanner has empowered technicians and engineers to use the new technologies in their normal day-to-day activities.

It has resulted in users developing their ideas, designing prototypes and printing out their models for testing. If the prototypes are not suitable for the designed

application, the designer can modify the design and print another test piece. This brings cost savings by not having to manufacture actual parts that may not be suitable for their intended use, before producing the actual finished working piece. Technicians have also saved on the costs of purchasing spare parts from vendors by producing spare-part designs and having them manufactured by local tooling companies, with typical savings of between 70% and 90%.

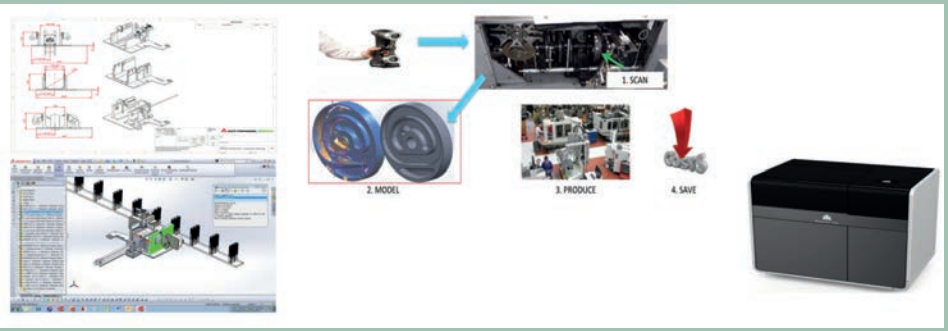

Figure 10.11: Capturing parts shapes from CAD systems or physical scanning, then outputting a replacement part on a local 3D printer

During 2016 technicians scanned and generated over 300 parts for inclusion in a virtual store. These designs can be then sent to the local supplier when needed and made available for use within 24 hours, substantially reducing typical lead times from the equipment vendors of up to three to four weeks. The aim for the engineering department is to reduce spares inventory by up to 50% over the next two to three years.

The development of the technicians in the use of these innovative tools is also particularly evident in their ability to scan worn parts in place and produce a drawing for a replacement part based on the scan, and in the use of CAD and Solid Works to reverse engineer and reproduce the required part. The associated costs for the scanner, Solid Works software and 3D printers (the original has now been replaced by a more advanced model) and training for the technicians has paid itself back multiple times over.

Raising quality standards

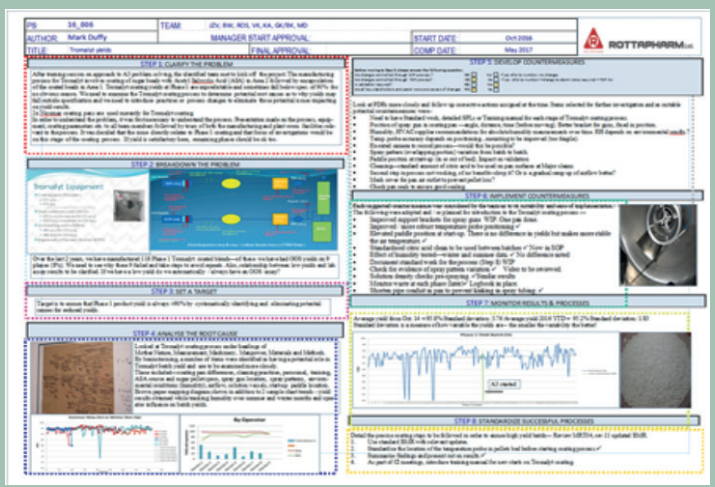

Figure 10.12: 8-step A3 methods used to solve problems

A focus on standardisation and training according to best practice for how tasks are completed has helped increase the quality of products and the operation of processes within the Damastown facility. These steps are well aligned with the Shingo principle of seeking perfection and supporting concepts of standardising processes, keeping it simple and visual, identifying and eliminating waste, and

integrating improvement with work. For example, production and maintenance personnel have developed single point lessons (SPLs) that cover routine equipment operation and operator and technician maintenance tasks. The team members capture and agree the best practices and then illustrate those practices in a simple and visual way – see Figure 10.12. SPLs can be accessed from any PC in the company via the internal SharePoint site. SharePoint is also used for managing the versioning system to ensure that only up-to-date SPLs are available. In addition to the use of SPLs, training videos are also used to demonstrate the operation of computerised systems and safety systems for trainees. By allowing the users to create the standards and continually improve those standards, the level of product quality and the processes creating those products have improved. The focus on problem solving and removing root cause issues has also helped improve quality throughout the company. Problem-solving projects and continuous improvement activities have been completed in all areas of the organisation. The use of 8-Step A3 methodology and problem-solving boards, designed by the technicians and production operatives, are located throughout all the production areas and have helped reduce deviations by 20% over the last 12 months.

Summary

This case study contains a sample of activities deployed at the Mylan Damastown plant in the area of operational excellence, using TPM principles as our start point and the foundation to drive our wider but focused improvement endeavours. Key performance indicators covering cost, quality, service, safety and the environment are all extremely positive. In the period 2010 to 2017

- the number of accidents decreased by 63%
- on-time delivery increased by 24%
- the incidence of complaints decreased by 68%
- energy consumption per pack decreased by 36%
- the time for batch release post production decreased by 64%.

The site now has an international reputation for world-class operational excellence practices and regularly hosts best practice visits for companies from within Ireland and abroad. Mylan Damastown are also recognised within the Mylan group as a best practice site and this has been reinforced through the recent awarding of additional products, which will support the 2014–2024 vision of tripling production output. The future and outlook are bright for the Damastown site as a result of building a high-performance culture that provides excellent sustainable business results.