Creating a Culture of Continuous Improvement and Sustainable Management Systems at Abbott Diagnostics Longford

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To improve the efficiency and quality of its operations, Abbott Diagnostics Longford, a healthcare manufacturing facility in Ireland, used its parent organization's well-established resources, created a customer-focused culture of system-wide empowerment in which employees at all levels would be comfortable with change, applied numerous lean Six Sigma techniques to enhance its processes, and linked its core competencies to the Shingo principles of operational excellence. As a result, the facility dramatically cut costs, lead times, nonconformance rates, inventory, energy costs, and waste while improving output and employee development and morale. In 2015, Longford earned the Shingo Prize for its accomplishments. Management expects to continue to use the site's lean management systems and culture of employee empowerment to continue to drive the behaviors and processes consistent with ensuring world-class performance. © *2016 Wiley Periodicals, Inc.*

Following the establishment of the Abbott Diagnostics manufacturing facility in Longford, Ireland, in 2004, the company's management and employees initially focused on the successful transfer of products from their sister site in Lake County, Illinois (outside Chicago), and the ramp-up of production volumes to meet the requirements of both customers and global regulatory bodies. In 2011, the fully operational manufacturing facility shifted its emphasis to becoming a process-focused organization that would deliver world-class results valued by its internal and external customers. The objective was to formulate a shared vision and create a sustainable continuous improvement culture centered on employee involvement.

This goal was realized through the successful application of Abbott systems and tools, deployment of lean Six Sigma strategies, and embedding of the Shingo principles of operational excellence (see **Exhibit 1** on page 10). As a result of enterprise-wide lean thinking and Six Sigma projects, cost improvement projects inspired by employee ideas, and focused continuous improvement programs and events, Abbott Diagnostics Longford has generated cost savings totaling more than $22 million across all areas of spend over eight years. Cost improvements have resulted from a reduction in raw material and energy usage, automation, batch size optimization, and multiple process improvement projects targeting the complete value chain. In addition, effective materials planning and control and manufacturing has resulted in a 69 percent reduction in material destruction orders, which measures the value of distressed inventory as a percentage of the total standard cost of production.

Among the facility's accomplishments:

- Nonconformance rate was reduced by 77 percent between 2007 and 2014.
- Lead times fell by 38 percent between 2011 and 2013.

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- Inventory holding decreased by 27 percent between 2006 and 2014.
- Test volume output increased by 576 percent between 2006 and 2014.
- Cost per unit manufactured was reduced by 60 percent between 2006 and 2014.
- Test output per direct labor hours increased by 807 percent between 2006 and 2014.
- Energy usage fell by 23 percent between 2012 and 2015, while production output increased by 68 percent over the same period.
- The site has maintained "zero landfill" status since 2010, when it began sending its general waste to be processed into solid recovered fuel (used as energy source for cement kilns) rather than to landfills.
- High morale is reflected in the site's excellent employee attendance record of at least 98 percent, compared to a national average of 96.2 percent.
- 419 employees were promoted internally between 2007 and 2014, attesting to the success of career mentoring and coaching programs.
- Employees volunteer more than 2,000 hours each year to the site's corporate social responsibility initiatives.

Abbott Diagnostics Longford has been certified in Environmental Management System ISO 14001, Energy Management System 50001, and Occupational Health and Safety Management Series 18001. For its numerous outstanding achievements, the facility has been recognized both internally and externally. For example, the site is a four-time winner (in 2009, 2011, 2013, 2014) of the Abbott Global Environment Health Safety & Energy Plant of the Year Award, a competition open to about 60 plants globally, and was runner-up three times (in 2007, 2008, and 2010).

In 2015, the Irish Medical Devices Association, Enterprise Ireland (a government organization responsible for the development and growth of Irish enterprises in world markets), and Industrial Development Agency Ireland (a government organization focused on attracting foreign direct investment) named Abbott Diagnostics Longford "Medtech Company of the Year" in Ireland for its innovative approach to product and service development. In the same year, the Irish Centre for Business Excellence honored Abbott Diagnostics Longford with the National Business Excellence Award. This award recognizes outstanding contributions for growing and transforming an organization while openly sharing that knowledge and best practices with member organizations of the Irish Centre Network. In addition, the Shingo Institute at the Jon M. Huntsman School of Business, Utah State University, recognized the site's initiatives in developing and maintaining continuous improvement to achieve operational excellence with the Shingo Prize in 2015. Furthermore, the Shingo Institute presented Abbott Diagnostics Longford with a special award for Behavioral Excellence for Safety at the Shingo Award ceremony in April 2016.

Laying the Groundwork for a Culture Comfortable With Change

A global, broad-based healthcare company devoted to discovering new medicines, technologies, and ways to manage health, Abbott is committed to helping people live the best possible life through good health. For more than 125 years, Abbott has introduced various products and technologies to the world—in nutrition, diagnostics, medical devices, and branded generic pharmaceuticals—that create more possibilities for more people at all stages of life. Today, 74,000 Abbott employees in more than 150 countries are working to help people live longer and better.

The Longford site is one of two Abbott Diagnostics manufacturing facilities in Ireland. It was established in 2004 on a 20-acre greenfield site on the outskirts of the town. The 135,000 square-foot building was specifically designed to allow the most efficient flow of product through the value stream—from raw material

receipt to finished goods shipment. More than 350 employees in the facility design, develop, and manufacture in vitro diagnostic products, also known as reagents, for distribution to laboratories and hospitals around the world. The product portfolio includes diagnostic reagents for the detection of thyroid, fertility/pregnancy, cardiology, renal, and metabolic markers. Manufacturing began in March 2005 and the first product was shipped in December 2005.

Initially focused on the transfer of the manufacture of all key diagnostic reagent products from its sister site in Lake County, Illinois, Abbott Diagnostics Longford participated in the Abbott Diagnostics ATLAS Program from 2003 to 2007, which created capacity in Europe to better align reagent manufacturing capacity with sales.

To better utilize the increased manufacturing capacity of the Diagnostics business, Abbott's Blueprint Operations Program was initiated in 2008 and remained active until 2011. This program streamlined the manufacturing network configuration and significantly reduced complexity to best meet long-range plan and capacity requirements. As part of the program, Abbott Diagnostics Longford was now required to export product to the United States; therefore, an important measure of success was establishing and maintaining compliance with U.S. Food & Drug Administration requirements. These programs fostered a culture focused on delivering quality, compliance, operational excellence, and supply chain results, as well as project execution and the development of employees focused on continuous improvement.

Tapping Into Existing Resources

From the start, the Longford site adopted many of the systems and tools used throughout Abbott and its Diagnostics Division to ensure consistent compliance with global standards in quality and other areas.

Abbott's proactive environment, health, safety, and energy (EHS&E) management system has been successfully applied at Abbott Diagnostics Longford: The site is a four-time winner and three-time runner-up of the Abbott Global EHS&E Plant of the Year Award. As of July 2016, the facility has accumulated 3,649 lost time accident-free days. In addition, it has significantly lowered its carbon footprint by reducing energy consumption, eliminated waste going to landfill, and created an on-site biodiversity garden. Furthermore, various programs, such as Active@Work, Live Life Well, and Exercise Across Abbott, create awareness of the benefits of physical activity, encourage all employees to become more active, and provide a supportive workplace environment for doing so.

The approach to ensuring the quality of Longford's products reflects the Diagnostics Division's overall quality policy—"To improve healthcare by providing high quality, safe and effective diagnostic products"—and its quality system, which integrates seven major subsystems: management, design and development, purchasing controls, product documentation, documentation and records, production and process controls, and corrective and preventative actions.

The Drive Toward Operational Excellence: Embracing the Shingo Model

Since 2009, middle-level managers at Abbott Diagnostics Longford have participated in Abbott Ireland's annual multidivisional Leadership Excellence Program (LEP). The objective is to develop managers for higher level leadership roles within the organization.

As a prerequisite for LEP certification, Longford attendees are challenged to choose projects that focus on culture and strategy rather than just cost improvement. This not only takes middle leaders out of their comfort zone and gives them real development opportunities but also yields valuable outputs that can shape the future of the Longford site. Examples of LEP projects that have helped the facility achieve operational excellence included:

- The creation of site-specific behavioral standards that were developed by the employees and rest on the guiding principle of "Treat others as you would like to be treated."
- The establishment of an APPREC8 employee-centric reward and recognition scheme. Under this program, any employee can write a thank you note to acknowledge another employee whose behavior exemplifies the site's behavioral standards. The thank you note is posted on an APPREC8 board outside the company cafeteria. Each quarter, the cards are removed and some of the employees commended are invited to an award event. Furthermore, the site director chooses one of the nominees as the winner of the annual Site Director's Award. The recipient is recognized at an all-employee meeting and receives a trophy and gift vouchers. This scheme places a greater emphasis on recognition rather than reward and complements Abbott's other reward and recognition initiatives.
- The development of the Longford site's vision of "world-class performance in everything we do."
- The development of the Longford site's strategy map and balanced scorecard (Kaplan & Norton, 2000), which includes stretch goals addressing financial, customer service, internal process, and people and learning efforts. The site's strategy supports its vision and identifies customer loyalty and business performance as value propositions. To support these value propositions, internal processes are required to be customer-focused and operationally excellent, which, in turn, requires engaged and highly skilled employees. For all strategic goals, cross-functional site projects or programs were selected to ensure the appropriate level of support and structure to deliver on the strategic commitments.

Two new departments were created at Longford to nurture operational excellence and customer focus throughout the site.

- A Business Excellence Department to support the operational excellence strategy: Consisting of a business excellence manager (a senior manager reporting directly to the site director), a Lean Six Sigma Black Belt, and/or a Black Belt candidate, the team is responsible for facilitating cultural change. It is supported by a cross-functional Operational Excellence Focus team composed of strong advocates for operational excellence within their own functional areas.
- A Customer Systems Technical Support Department to provide specialized customer support: This function has since evolved into a Global Support team consisting of a global manager and five managers/scientists located around the world. Through proactive engagement, the team seeks to understand and deliver what the customer wants. It also provides technical support to Abbott sales and marketing staff during tendering processes and supports customer events. The global team interacts with and supports customers in their own laboratories and hosts multiple on-site visits and customer forums.

This scheme places a greater emphasis on recognition rather than reward and complements Abbott's other reward and recognition initiatives.

From 2009 to 2011, the Project Management Department at Longford was responsible for ensuring business excellence. This team included several Lean Six Sigma Black Belts whose time was fully consumed implementing various improvement projects throughout the facility. Creating a culture in which all employees would be responsible for continuous improvement and sustainable management systems was not their priority. The site director, however, had the foresight to realize that a small, autonomous, and culturally focused Business Excellence Department would better serve the facility's long-term objectives.

Given the site's stated vision of "world-class performance in everything we do," the new Business Excellence team had to develop its own vision and strategy, which would establish a roadmap to achieving world-class operational excellence. First, however, the team had to define "operational excellence" and decide what it meant by "world-class." After much research, the team decided that the Shingo Model for Operational Excellence (see Exhibit 1) addressed both concepts.

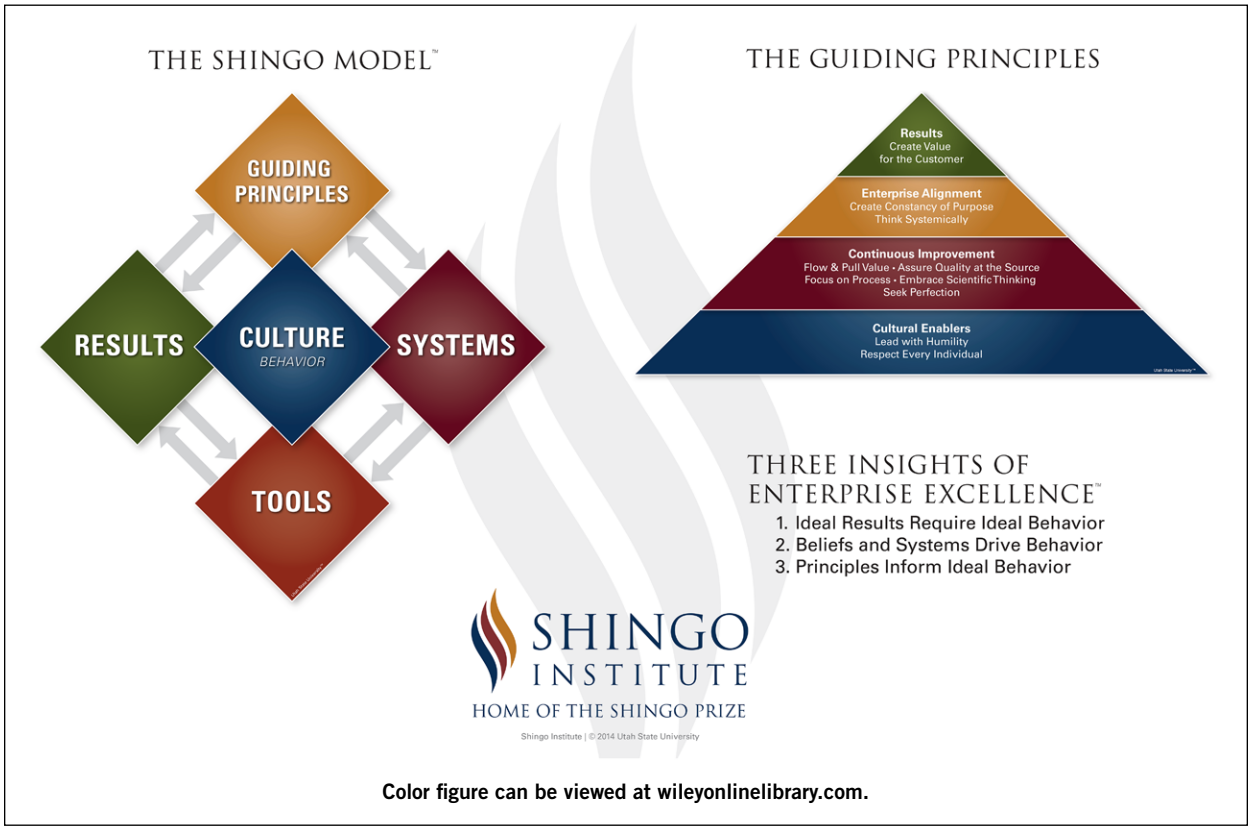
To learn more about the model, the Business Excellence manager and site director attended a Shingo Principles of Operational Excellence Workshop in May 2012 at the Jaguar Land Rover Halewood manufacturing site in Liverpool, England. This experience confirmed their view that the Shingo Model was fit for guiding cultural transformation at Abbott Diagnostics Longford.

> Through proactive engagement, the team seeks to understand and deliver what the customer wants. It also provides technical support to Abbott sales and marketing staff during tendering processes and supports customer events.

Training on the Shingo Model and External Benchmarking

All senior leaders at Abbott Diagnostics Longford attended off-site Shingo Principles of Operational Excellence workshops. They were not only trained

Exhibit 1. Shingo Model and Principles of Operational Excellence



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on the model but also got to benchmark best practices in companies that had several years of experience in working toward operational excellence. In addition, the Business Excellence team organized an in-house Shingo Principles of Operational Excellence workshop for Longford's middle managers.

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All employees were encouraged to benchmark best practices, build networks, share learnings, and implement observed best practices in the Longford site. Abbott Longford employees attended Shingo Principles of Operational Excellence workshops at Newsprinters (Shingo Prize winner), Lake Region Medical (Shingo Bronze Medallion), Vale (Shingo Silver Medallion), Jaguar Land Rover, Aero Engine Controls, The Royal Mint, and PZ Cussons. Employees also participated in benchmarking visits to DePuy Synthes (Shingo Prize winner), Abbott Vascular (Shingo Prize winner), Toyota, Cogent Power, Allergan, Alkermes, Pepsi, Coca-Cola, Boston Scientific, Merck Sharp & Dohme, Abbott Nutrition, Vistakon, Lufthansa, Abbott Diabetes Care, Abbott Point of Care, Bombardier, and Emerson Copeland.

In 2011, Abbott Diagnostics Longford became an active member company of the Irish Centre for Business Excellence. Two years later, Longford became a host site for the Centre's Operational Excellence Best Practise Visits. In addition, the site has hosted three public Shingo Principle of Operational Excellence workshops, as well as workshops for participants in Toyota Motors/University of Kentucky (UK) Lean Certificate programs and a Mike Martyn "Building a Team-Based Daily Kaizen Culture" public workshop (Martyn & Crowell, 2012).

The site director at Longford is a board member of the Irish Medical Device Association and the operations manager has chaired the Irish Medical Device Association Operational Excellence Group. These wide-ranging networking and benchmarking activities clarified what good looked like. The employees at Abbott Diagnostics Longford have embraced all the constructive feedback they have received from visitors and assessors and used it to further improve the behaviors, systems, and tools that drive the facility's culture of operational excellence.

Empowering and Involving Employees at Every Level

At Abbott Diagnostic Longford, respect for every individual in the organization is paramount, and efforts are made to harness the power of all employees by involving them in daily kaizen (continuous improvement) activities. The goal is a continuous cycle of generating, prioritizing, and implementing ideas that will yield improvement. To date, the ideas that employees have generated have enabled the company to make and sustain multimillion-dollar cost improvements and maintain an excellent compliance and safety record.

For instance, one of the site's Kit-pack team members (who pack reagent bottles into their final packaging) recently determined that having to manually count and verify package inserts into bundles of 25 as part of the material accountability process was the main cause of long Kit-pack process set-up time. She researched available resources and found and evaluated a thickness compensator feeder counting system capable of accurately counting all package insert types. The new system is expected to decrease set-up times by 67 percent and save 739 work hours per year.

In another instance, two employees responsible for filling and labeling the diagnostic reagents identified the need for a small filler system that would be capable of filling and capping small batches

of bottles (fewer than 2,000 bottles). This system would be operated independently from the highly utilized dedicated filling areas and would require minimal set-up and close-down time. One of the employees was mechanically minded and the other was capable of coding software. They combined their skillsets to design and construct a small batch filler that was subsequently validated for use. The system, which is 100 percent more efficient than standard fill lines when filling batches of fewer than 350 bottles, increased filling capacity by 20 percent, saving 900 work hours per year and reducing material prime volume by 80 percent.

The company has also continually refined its employee suggestion schemes over the years. Established in 2011, an electronic Excel-based idea generation system proved successful in capturing employee ideas, but did not allow for interpretation, prioritization, and ownership for implementation. The transition to a daily kaizen card-based process addressed the disadvantages of the electronic system (Graban & Swartz, 2012). Each team now has its own daily kaizen board where employees can post a card describing a concern (typically about one of their local processes) and a proposed countermeasure on the "Idea" section of the board. The teams review new ideas daily, and the proposed countermeasures are either accepted, refined through brainstorming, or rejected. If an idea is rejected, an explanation is included. Ideas selected for progression are moved to the "To Do" section of the daily kaizen board until the team can determine when the idea can be implemented and who will be responsible for doing so. Then the card describing the idea is moved to the "Doing" section of the board until the improvement has been implemented.

The visual and interactive nature of this process enables employees and managers to see all the ideas being generated and to track their status in terms of both progress and barriers to implementation. It also enhances local engagement and ensures recognition for individuals and teams who have successfully implemented ideas. "Daily Kaizen Idea of the Month" lunch vouchers are awarded for the best ideas implemented locally and a gift voucher is presented to the employee with the best idea implemented in the site during the month.

The use of daily kaizen supports the development of Longford's continuous improvement culture by empowering employees to have complete autonomy over improvements and problem-solving related to their own work areas. Most identified concerns are readily solved and countermeasures implemented by those working in the affected area. If the countermeasure is not obvious, then teams use weekly time slots dedicated to continuous improvement activity (CI huddles) to determine the root cause of a particular issue and to implement countermeasures.

During CI huddles, employees use lean problem-solving tools to assist in root cause analysis. If significant cross-functional resources are required for implementation, employees are also given the option of presenting proposed solutions to the site's senior managers during their weekly project portfolio management meeting. Here, project proposals submitted by the teams that are advocating the employee suggestion are reviewed from a financial and resource perspective (benefit/effort). If the project is selected for implementation, a project manager is assigned to form a team and oversee their efforts. Progress against project milestones is also reviewed at project portfolio management meetings and, if required, interim reviews are scheduled to communicate risks, contingencies, and potential reassessments. A monthly review of all products and projects in the pipeline is also held as part of the integrated business planning cycle for the site and its division. This monthly meeting also alerts managers to resources that will be needed over the long term to support the site's project portfolio. Projects that are not selected because of resource constraints are added to a project hopper for consideration at a later date, and the person who initiated the idea is notified.

To support employee empowerment and education throughout the facility, in 2012 Abbott Diagnostics Longford's Lean Six Sigma Program was changed to focus on training as many employees as practical to a basic (Yellow Belt) or intermediate (Green Belt) level of Lean Six Sigma competency, rather than training only a few site experts (Black Belts) who would be primarily responsible for delivering improvements. The site developed its own one-day Yellow Belt course to teach the fundamentals of lean thinking and the Six Sigma DMAIC (define-measure-analyze-improve-, and control) problem-solving methodology. Following their training, the students complete a project and make a presentation on the improvements and lessons learned during poster sessions that are open to all employees. A Lean Six Sigma awareness training program was also developed for all employees, and many managers have been formally trained in advanced coaching. This has led to the introduction of a coaching program whereby employees are assigned a coach to enable them figure out how to help themselves when they encounter problems.

> A monthly review of all products and projects in the pipeline is also held as part of the integrated business planning cycle for the site and its division. This monthly meeting also alerts managers to resources that will be needed over the long term to support the site's project portfolio.

Linking Core Competencies to Operational Excellence

Abbott has five long-established corporate core competencies that can be readily aligned to the four Shingo dimensions of operational excellence, each supported by expected leader and individual contributor behaviors. They are:

1. Build (develop yourself, your team, and the organization)
2. Innovate
3. Anticipate
4. Set vision and strategy
5. Deliver results

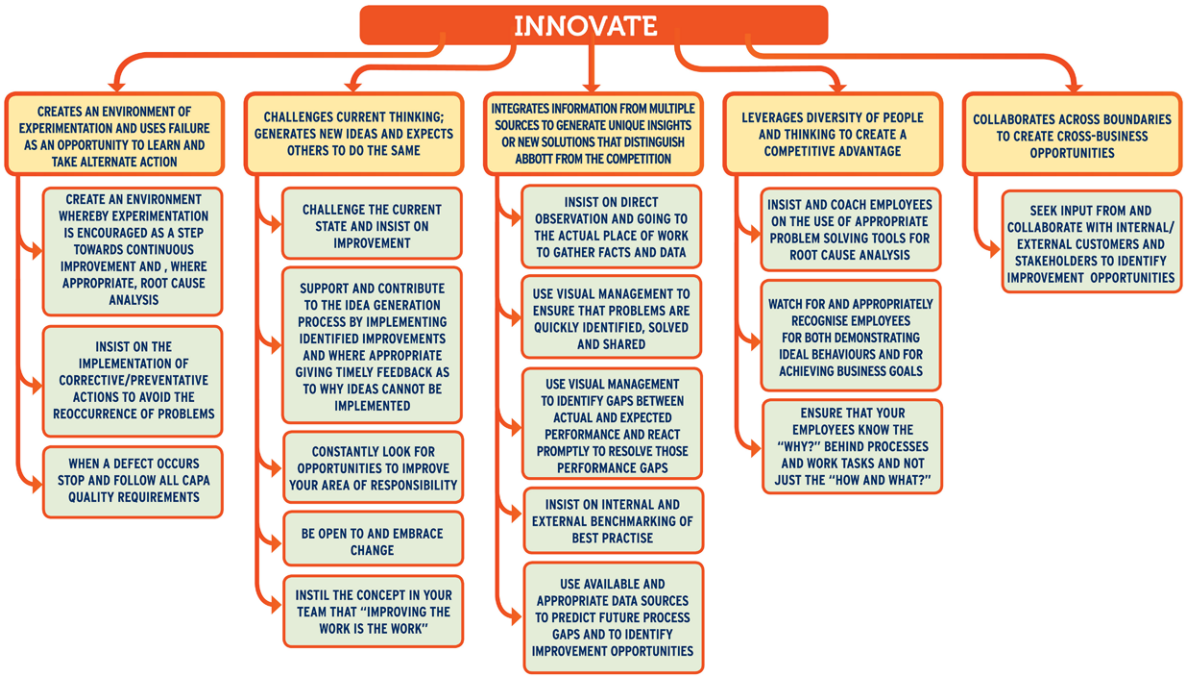
Abbott Diagnostics Longford managers refer to these core competencies to help ensure that new recruits are a good organizational fit. Interview questions are designed to determine whether candidates have an aptitude for and experience in these competencies. Employee behaviors are formally assessed against these competencies, with constructive feedback provided through the annual performance management process. Furthermore, Abbott Diagnostics Longford has translated the corporate leader behaviors for each core competency into Longford-specific leader behaviors. An example is given in **Exhibit 2** (page 14), which lists the "innovate" behaviors expected of leaders at the Longford facility.

A Multipronged Approach to Strategy Deployment

Abbott Diagnostics Longford's functional departments develop their own strategy maps and balanced scorecards by aligning their goals to the site strategy. Departmental goals are then agreed on and cascaded through the organization. For example, to ensure that the site meets its order fulfillment goals, teams in Operations will set schedule adherence goals to help ensure that they meet the demands of the production schedule.

All departments contribute to site initiatives and develop their own department-level initiatives that support the attainment of their goals. The departmental strategy maps and balanced scorecards give employees a clear line of sight into how their jobs are linked to both site and departmental strategy, enabling them to work in a coordinated and collaborative fashion. The strategy maps and balanced scorecards also provide a cause-and-effect visual representation of the critical objectives and initiatives that drive performance and will enable the site's long-range plan.

Exhibit 2. Abbott and Longford-Specific Leader Behaviors: The Innovate Competency



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Through enterprise alignment workshops, employees have been educated on the site's vision and strategy, and on the part that various communication tools play in the organization's success. The site director personally delivered the workshops to all the managers of the facility, who then passed on the content to their teams. The workshops explained how the site strategy was aligned to the divisional strategy and how it offers a roadmap to achieving the site's vision of world-class performance. They also showed managers and other leaders how they can contribute to strategy deployment by creating departmental goals that focus on people development, the continuous improvement of their processes, and the needs of their internal and external customers.

Company-wide visual management and daily management systems, which display local daily or weekly performance measures and how a particular team is performing against them, give employees a clear idea of the results of their efforts toward operational excellence. Individual performance with respect to goals and expected behaviors is formally reviewed through the performance management process.

Leader Standard Work Bolsters a Lean Management System

Longford's lean management system drives effective behaviors through various tools that monitor, measure, and sustain the employees' endeavors throughout the site (Mann, 2005). Leader standard work (LSW) outlines the key activities required, such as:

- Daily Management—daily review of performance metrics and problem solving

- Visual Management—visual tracking of performance versus strategic targets
- Gemba Walks—observing work and/or processes while coaching improvement
- Daily Kaizen—continuous cycle of improvement idea generation, prioritization, and implementation
- 6S/5S (Japanese methodology for workplace organization)—sort, set in order, shine, standardize, and sustain, plus safety
- Employee Development—for example, one-on-one with reports and career mentoring
- Performance Review Management Walks—regular cross-functional management gemba walks to operations and back-office visual boards, where performance and problem-solving outcomes are reviewed and where help is given when obstacles to improvement are identified

LSW helps to ensure that all managers spend an appropriate amount of time during gemba walks to review and address area performance, coaching employees, and encouraging active participation in problem-solving. LSW not only details the task frequency and a timetable for action but also outlines *how* the task should be completed and *why* it is required. For instance, this would be the "how" and "why" for conducting performance review management walks:

- **How?** Adhere to leader standard work with respect to time and place of the walk. Participate in the walk, observe, and ask questions with respect to area performance, continuous improvement, and obstacles that are hindering work in the area.
- **Why?** Opportunity to observe the interactions between people and process. Establishes relationships and trust between leadership and staff. Learn to see your operations through "lean eyes." Shows lean leaders' commitment to lean initiatives. Motivates employees and drives accountability within the organization. Creates an opportunity to teach and mentor.

Each functional area maintains standardized visual management boards that facilitate work transparency and real-time communication to ensure that problems are promptly exposed and addressed (see **Exhibit 3** on page 16). Compliance with LSW ensures that the boards are regularly updated and reviewed. At a glance, the boards communicate who is on the team and what it means to "win" in keeping with the local vision and strategy, the team's daily and weekly schedule and tasks, and their performance. Furthermore, root cause analysis outcomes, which are recorded on the boards, reveal what the team is doing to improve. According to the 1-, 3-, 10-second rule, someone viewing the site's visual boards should be able to tell in one second whether the team is winning or losing, note in three seconds the team's performance trends, and see in ten seconds what the team is doing to improve. Since high performance is synonymous with teamwork, another very important element of the board is local employee recognition. This acknowledgement comes in the form of thank you notes or recent employee achievements posted on the Recognition section of the board.

The boards are reviewed at daily team huddles and at weekly middle and senior management gemba performance review walks. During the walks, the entire value stream is reviewed with all functional areas represented. Area and value stream performance is discussed with a focus on expected future performance and planned activities. The walks are also an opportunity for functional areas or process owners to request support from other functional areas when obstacles need cross-functional input for resolution. When performance does not meet expected targets, managers also look for evidence of root causes.

The Longford facility also maintains a metrics hall, where the site's key performance indicators are visually represented on a historical annual basis and on a monthly current year basis. Grouped under the headings of service, cost, quality, people, and

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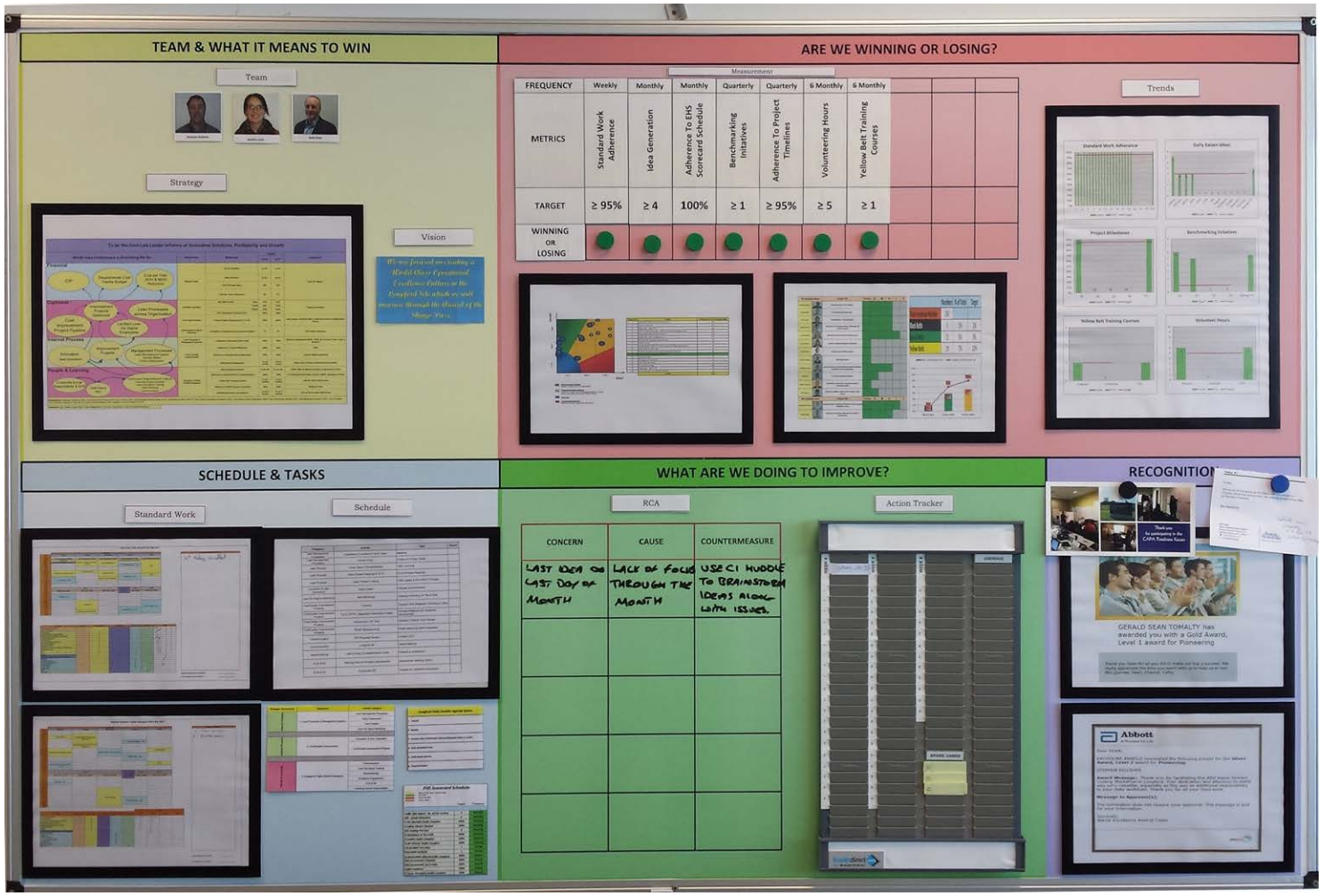
Exhibit 3. Example of a Visual Management Board



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projects, the metrics are reviewed monthly as part of the management walk. The site's metrics hall also contains an action tracker (actions are recorded on T-cards and published on the T-card board by due date) so that actions discussed during management walks are made visible and accountability for these actions is established. When a gap between actual and expected performance is identified, immediate action is taken. Each work area owns the gap and initiates problem-solving activities to determine the root cause and implement effective corrective actions (see **Exhibit 4** on page 18).

In addition, Abbott Diagnostics Longford has developed a rapid gemba 3Cs (concern, cause, and countermeasure) problem-solving tool that encourages a structured, scientific approach to root cause analysis. When a particular concern is identified, its cause is determined through the use of such tools as cause-and-effect diagrams and "5 whys" analysis, whereby asking "Why?" multiple times helps uncover the root cause of a problem. Finally, countermeasures are determined and accountability for implementation assigned. Knowledge sharing during management walks and value stream meetings ensures that lessons learned are effectively communicated throughout the organization.

For example, if a team could not manufacture a particular item listed on the day's production schedule, this would appear in red as a metric miss on the team's visual board. Then team members would investigate the fundamental failure in internal process that caused the miss—for example, a lack of alignment between customer demand for the part and the ordering of a specific type of filter consumable needed to make it, resulting in insufficient stock levels. A suitable corrective action might involve putting all consumables on the bill of materials—the list containing the quantities of raw materials required for the manufacture of a part but not the consumables required—so that increased customer demand would signal the requirement for increased stocks of consumables.

More complex problems are solved using the DMAIC Six Sigma methodology or kaizen events, which are continuous improvement workshops with subject matter experts who can focus on solving complex problems efficiently. In the case of projects completed as part of Lean Six Sigma Yellow Belt Certification, the DMAIC process outputs are summarized in a poster that shares information to promote a culture of continuous improvement.

Abbott's Quality System decrees that when a requirement is not fulfilled, an exception report must be entered into the electronic Corrective Action/Preventative Action system. This highly structured system ensures that problems are defined, affected items are identified and restricted for use, an investigation is initiated to determine root cause, resolution plans are developed and implemented, and the effectiveness of the solution evaluated. Furthermore, once a root cause is identified, its global impact is assessed. Quality managers or delegates from all global manufacturing sites meet each week to review their investigation outcomes and to determine whether the same issue could occur at another site. If there is the possibility of impact to other sites, then the corrective action must be implemented there as well.

> Daily kaizen promotes a culture in which improving the work *is* the work.

The daily kaizen process is also used to drive full employee involvement in identifying and resolving issues hindering work flow and in eliminating process waste. Daily kaizen promotes a culture in which improving the work *is* the work. This process may sometimes require the use of gemba 3C problem-solving tools and, where necessary, DMAIC. It also provides the input to local teams' continuous improvement huddles.

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Exhibit 4. Longford Problem-Solving Processes

Longford Problem-Solving Processes

System	Inputs	Root Cause & Countermeasure Identification	Countermeasure Implementation	Knowledge Sharing
Global Quality Management System (GQMS) electronic Corrective Action & Preventative Action System (CAPA)	Quality System non-conformances or potential non-conformances such as: -Non-fulfillment of quality requirements -Customer complaints -Audit/inspection outcomes -Supplier corrective actions -Process analysis outcomes (tracking & trending) -Management Review outcomes	Cross-functional team using such tools as: -Brainstorming -6Ms -5 Whys -Contradictory Matrix	Cross-functional team and tracked through GQMS with effectivity checks	Weekly Global CAPA Steering Committee elevation process
Lean Management System	Metric misses	Team or cross-functional team using gemba 3C's problem-solving tool if required	Team or cross-functional team and tracked through visual management	Management walks and planning and control meetings
Daily Kaizen	Employee improvement ideas and waste (TIMWOODS) identification	1. Employee with team endorsement 2. Weekly team continuous improvement huddles using gemba 3C's problem-solving tool if required 3. DMAIC projects, e.g., yellow belt	1. Team or cross-functional team and tracked through daily kaizen boards 2. Project management-project core team and tracked through product and project management (PPM) review 3. DMAIC project core team and tracked through PPM review	1. Management walks 2. PPM weekly review 3. Divisional project review meetings 4. Yellow belt poster days 5. DMAIC tollgate review 6. BEx integrated business planning monthly meetings 7. Abbott Ireland BEx forum

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Each functional area has generated service agreements that document its commitments to their internal and external customers. These agreements are supported by departmental metrics that ensure that commitments are measured and monitored. Functional areas are held accountable through the lean management system and are expected to continuously improve through problem-solving. Furthermore, several support function transactional processes have been standardized and responsible-accountable-consulted-informed charts are used to assign roles and responsibilities. The site has also standardized its meeting calendar to ensure attendance at critical cross-functional meetings.

This [process] ensures collective accountability for area performance and the prompt resolution of issues, which can arise on a daily basis. Then the team reviews the work ahead for the day (agenda item four) and makes sure that everyone understands their daily responsibilities and tasks—their specific contribution to daily team performance.

An essential component of Longford's Lean Management System, the daily huddles that every team conducts in front of its visual management board promote enterprise alignment. **Exhibit 5** depicts the site's standardized agenda for these daily gatherings. The first two items address environmental health and safety and quality, which take priority over any other issues. Only then does the team move on to the third item, a review of the previous day's work area performance. This ensures collective accountability for area performance and the prompt resolution of issues, which can arise on a daily basis. Then the team reviews the work ahead for the day (agenda item four) and makes sure that everyone understands their daily responsibilities and tasks—their specific contribution to daily team performance. During the daily kaizen review (agenda item five), continuous improvement ideas that have been posted the previous day are acknowledged. New ideas can be assigned for immediate implementation or placed on the agenda for the weekly continuous improvement huddle. Finally, open communication is actively encouraged during the huddles so that any pertinent information can be discussed.

Exhibit 5. Longford Daily Huddle Agenda Items

Longford Daily Huddle Agenda Items
1. EHS/6S
2. Quality
3. Previous Day Performance Review/Obstacles (Won or Lost?)
4. Daily Schedule/Tasks
5. Daily Kaizen Review
6. Communication

The huddles typically last no more than ten minutes. The Good start, Improvement, Focus, Team, Status methodology is used to ensure that they are efficiently run and effective (Yip, 2011). A *good start* means that the meeting begins on time, is held standing up to avoid lengthy deliberations, and follows an established routine, taking place at the same time and same place to discuss what happened yesterday and what needs to be achieved today. By exposing problems and identifying obstacles, the meeting should lead to *improvement* activity. It should also, however, maintain *focus* by identifying the appropriate people to solve identified problems after the meeting and discouraging side-bar conversations. To encourage teamwork, collective accountability, and active participation, the *team* rather than the leader should run the meeting while ensuring that the facilitator role is rotated among team members. The meeting should end with a *status* update, such as any relevant information that needs to be shared.

Establishing an Effective 360° Communication Process

Longford managers understand that without providing open and honest two-way communication systems, they cannot reflect the Shingo principles of

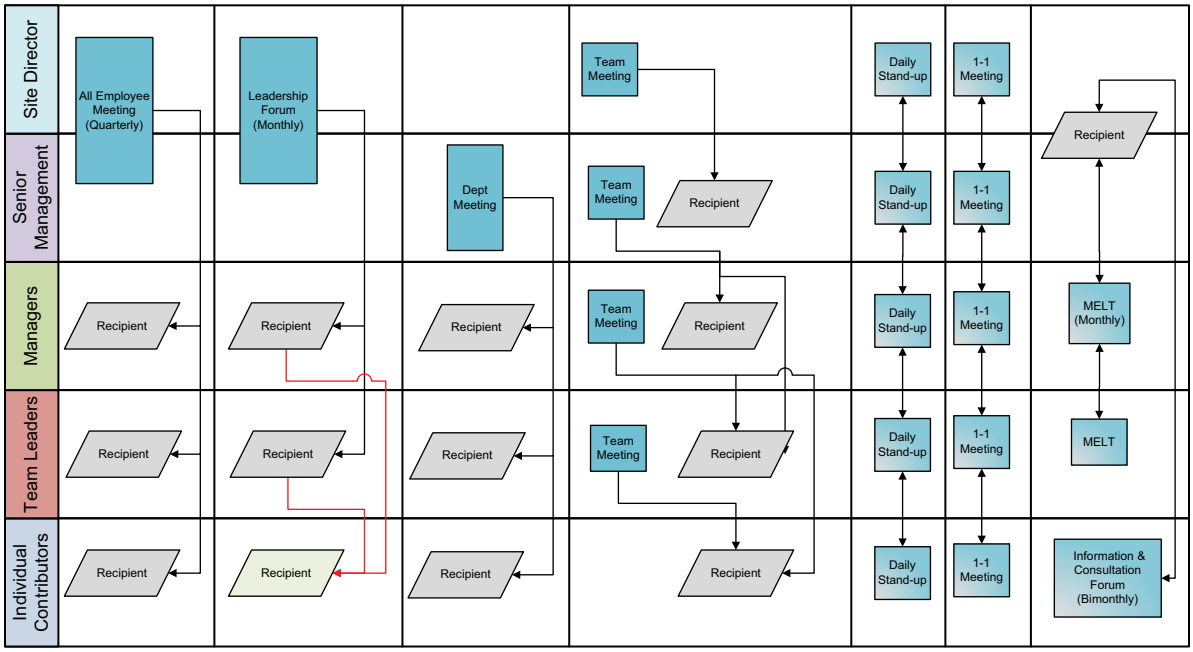
leading with humility and respecting every individual. The site has introduced a variety of communication mechanisms to keep all employees informed at all times (see **Exhibit 6**). The facility's open plan office design and open door policy also are conducive to effective communication.

An Operational Excellence Focus Team with representatives from all functional areas serve as advocates for operational excellence initiatives within their own department and communicate the "Why?" and the "How?" behind every new effort. For example, they promoted the new daily kaizen process and explained why the change from the electronic idea generation process was a significant improvement in terms of capturing helpful feedback on the status and implementation of ideas. They also explained how the process worked, thereby ensuring consistency throughout the site. Furthermore, they solicited feedback on the process and suggested improvements, such as the introduction of a reward and recognition system to acknowledge the best ideas that were implemented.

Composed of middle management representatives, a Management Excellence Leadership Team meets with the senior management team each month to highlight and address any concerns. Furthermore, an information and consultation forum is regularly held between representatives from nonmanagement employees and senior managers. The site director hosts quarterly all-employee meetings and monthly leadership forums, as well as a quarterly informal lunch with a cohort of employees.

As already detailed, every team conducts a daily huddle to review performance and rapidly disseminate information. As required, these communication huddles are supported by departmental and team meetings. Held on a regular basis (as

Exhibit 6. Communication Processes at Abbott Diagnostics Longford



Color figure can be viewed at wileyonlinelibrary.com.

deemed appropriate by the team), one-on-one meetings between employees and their manager can be supplemented by a one-over-one meeting with the next-level manager. Site, divisional, and corporate intranet sites, as well as a quarterly newsletter, *Business Excellence News*, are additional vehicles for communication. *SNIPS*, a monthly magazine focusing on social news, information, and personal stories, contains information on other topics of interest.

Finally, to get direct feedback from employees on communications and the degree of success of operational excellence initiatives affecting culture, continuous improvement, and enterprise alignment, an operational excellence pulse assessment using gemba walks is performed periodically. Here, employees selected at random during gemba walks are asked specific questions designed to determine local levels of operational excellence. As a follow-up to the results of one of these assessments, the site developed the strategy alignment workshops discussed above, which were designed to improve employees' understanding of how their everyday tasks contribute to the site's vision and strategy.

Ensuring a Focus on the Customer

Abbott Diagnostic Longford employees respect their customers and promote meaningful interactions so that they can fulfill customer needs. Customers include the internal International Distribution Centre, laboratory managers, clinicians, and, most important, the end-user patient. Site management makes every effort to keep the facility's customers, particularly patients, uppermost in employees' minds. For instance, the site hosted a "Healthy Heart" event featuring an employee presentation on heart attacks led by invited physicians. It included a moving speech made by the father of an employee who described suffering a heart attack and how he benefited from Abbott's products, including a life-saving Abbott stent.

The site also regularly holds voice-of-the-customer forums to listen to their concerns. Issues that are raised subsequently are addressed through a customer assay and system enhancements program that emphasizes customer needs over cost improvements. Furthermore, the site has provided several operational excellence workshops for the staff of hospitals that use Abbott Diagnostic products and who are trying to introduce or reinforce lean principles. Critical to the Abbott Diagnostics value proposition of customer loyalty, these workshops have generated excellent customer feedback. In addition, employees regularly visit customer laboratories to learn about customer needs first-hand, and site-sponsored employee programs, such as one on the value of in vitro diagnostics, are held to demonstrate how the diagnostic products they create improve people's lives.

An Array of Programs Devoted to Continuous Improvement

Abbott Diagnostics Longford has several problem-solving systems in place that require root cause analysis, countermeasure implementation with effectivity checks, and knowledge sharing. Many improvement initiatives can be implemented by local teams or by cross-functional teams. Other efforts require project activities that are chartered and led by project managers, Six Sigma Belts, or Belt candidates. The site holds a weekly project portfolio management meeting to review progress versus chartered milestones and to discuss project prioritization and resource requirements. Other inputs that drive continuous improvement activity include product and process monitoring, customer complaints or improvement suggestions, management review, audit outcomes, supplier notifications, and divisional improvement initiatives.

The Longford site relentlessly focuses on reducing all waste, including that which is hidden in financial standards. These are among the various systems and tools used to help identify and eliminate waste:

- Waste Visualization—visually exposing the TIMWOODS eight wastes: transport, inventory, motion, waiting, overproduction, overprocessing, defects, and skills of employees. These are linked to daily kaizen efforts.
- Process and Value Stream Mapping—visually mapping a process or a product's production path from supply to ship, while including information flow and highlighting nonvalue-added steps.
- Day in the Life of Studies—monitoring employee activities when performing tasks while recording times for each step and identifying nonvalue-added process activities.
- Gemba Walks—observing work and/or processes while coaching improvement.
- Distress Inventory Reduction Process—visualizing all distressed inventory and conducting root cause analysis when waste is identified.
- Material Usage Variance Reduction Process—visualizing all positive and negative variance from the predefined quantities of materials required per process order and root cause analysis when significant variance is observed.

Through automation and the upgrading of workforce skills, Longford has improved production flow via more robust processes, increased throughput, and reduced set-up times and nonconformances. For example, the use of an automated kit assembly system for the packing of filled bottles into their kit cartons increased throughput threefold, with half the nominal operations resource and quick changeover times (less than five minutes). The skills and experience of the existing Kit-pack employees were then readily utilized in other areas of the business. As a result of outcomes likes this, the site has significantly reduced the costs associated with the direct manufacture of its products. For instance, a reduction in the amount of a critical raw material used in one particular diagnostic reagent significantly improved assay performance and yielded annualized savings of $450,000.

Over the years, the indirect activity required to support Abbott Diagnostics Longford's products has increased substantially because of ever-increasing regulatory requirements. In response, the management initiated a "Building Our Future" program to stabilize indirect activity drivers. It called for key strategic projects utilizing lean and Six Sigma methodologies to streamline support processes and reduce process and product variability, which drives nonvalue-added indirect support activity. This was supported by a Business Excellence Team focused on site-wide cultural change. Back-office processes, such as supplier change notification, warehouse receiving, incoming raw material testing, corrective action/preventative action, change and design control, financial approvals, and quality assurance processes, were redesigned so that roles and responsibilities were clearly defined, work practices were standardized, nonvalue activity was removed, and demand/capacity models and metrics were developed to drive desirable behaviors and complete transparency and accountability in every process. The new processes were designed so that information is obtained and decisions are made promptly, and escalation mechanisms to management were developed to sustain timeliness.

Furthermore, the Technical Operations Team has embraced operational excellence and introduced a new customer-centric team structure to improve response times and facilitate proactive product support. The team has standardized its training process, introduced group mailboxes, begun developing product information cards to house product specific knowledge, and created standard templates for protocols, technical rationales, and electronic laboratory notebooks. Meaningful customer-centric metrics have dramatically reduced technical support response times, and the time-consuming documentation of investigations has been streamlined through the use of the standard templates. Furthermore, the on-boarding of new technical operations employees now follows a very structured process. As a result, new employees are better trained and

start adding value to the business much more quickly than before.

With more than 100 active participants contributing from across all site functions, Abbott Diagnostics Longford's Accelerate Program has further improved internal processes, developed workers' skills, and reduced costs. Through focused work stream Lean Six Sigma project activities, the program reduced manufacturing lead times by 40 percent, eliminated customer backorders, decreased inventory holdings by 10 percent, realized $2.4 million in annualized financial benefits, and increased transparency and flexibility.

The Longford site also embarked on a Class A planning and control program to improve its planning and control processes. Based on the site-wide continuous improvement culture, it standardized planning and control processes so that employees became better at doing routine tasks routinely. By making processes more predictable, it allowed employees to focus more on preventing problems and less on having to solve them. It also fostered ownership and accountability, and enabled the creation of realistic plans using accurate system data.

A division-wide quality program was initiated to simplify the quality system processes and reduce the likelihood of human error by improving and standardizing manufacturing processes. Global process communities have been established to sustain the standardization and further drive process improvements. Goal-oriented learning, learning units, and process picture maps also were introduced to improve learning outcomes and reduce human errors.

Since multiple process adjustments can have a significant impact on production scheduling, cycle time, cost, and capacity, Longford has collaborated with the University of Limerick in Ireland to utilize the Lean Six Sigma methodology to reduce the need for adjustments in the manufacture of critical assay components. Through input and output process mapping, the project identified areas for design of experiment and measurement systems analysis. This enabled the facility to identify the sources of variation, establish a root cause, and devise an effective solution. Furthermore, Day in the Life of studies and value stream mapping led to the elimination or significant reduction of non-value activities. Executed through an innovation partnership program, the project was co-funded by Enterprise Ireland and the European Union through the European Regional Development Fund 2014–2020.

Looking to the Future

The efforts of all employees to establish a culture of continuous improvement and sustainable management systems led the senior managers at Longford to apply for Shingo recognition. The assessment they had to conduct as part of the application process provided them with a world-class benchmark for gauging their facility's level of operational excellence. They continue to use the valuable feedback they obtained from the Shingo assessors to ensure that all Shingo principles of operational excellence remain deeply embedded across the organization and continue to be reflected in the everyday behaviors of employees.

To sustain success over the long term, Longford's management team continually explores opportunities to attract new business from the parent Diagnostics Division. Recently, the Longford site successfully launched several new products in collaboration with Abbott's research and development facility in Lake County, Illinois. Furthermore, a centralized incoming quality assurance and mass spectrometry laboratory, which supports test method development, validation, and release testing of chemicals and commodities for all diagnostic reagent manufacturing sites, has been established in the Longford site.

Abbott Diagnostics recently developed the Alinity™ instruments, a harmonized suite of next-generation systems across immunoassay, clinical chemistry, point-of-care, hematology, blood and plasma screening, and molecular diagnostics. Pending appropriate regulatory approvals, these transformational platforms will help customers address key challenges and opportunities while driving growth. Thanks to its proven track record of efficient production over the last ten years, Abbott Diagnostics Longford has been selected to play a key role in the supply of the immunodiagnostic reagents required for the verification, validation, and commercialization of one of these new products.

As of 2016, Abbott Diagnostics Longford has been awarded significant new business, which will substantially increase both the size of the facility and the number of its employees. Sustaining the site's well-established lean management systems and culture of employee empowerment will become even more important to drive the ideal behavior and robust processes consistent with its vision of "world-class performance in everything we do."

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