Meda Rottapharm









Company Ownership History

Established 1998 by Rottapharm Group 1,200 employees

2007 Rottapharm acquire Madaus 2,000 employees

 2014 Rottapharm Madaus acquired by Meda 5,000 employees

• 2016 Meda acquired by Mylan 35,000 employees



Site Summary

- Located in Mulhuddart, Dublin
- Footprint 10,000 square metres
- 172 Employees on site
- Ship to 67 markets worldwide
- API, bulk manufacturing, primary & secondary packaging
- Sachet, capsules, tablets, liquids
- 4 manufacturing suites
- 10 packaging lines

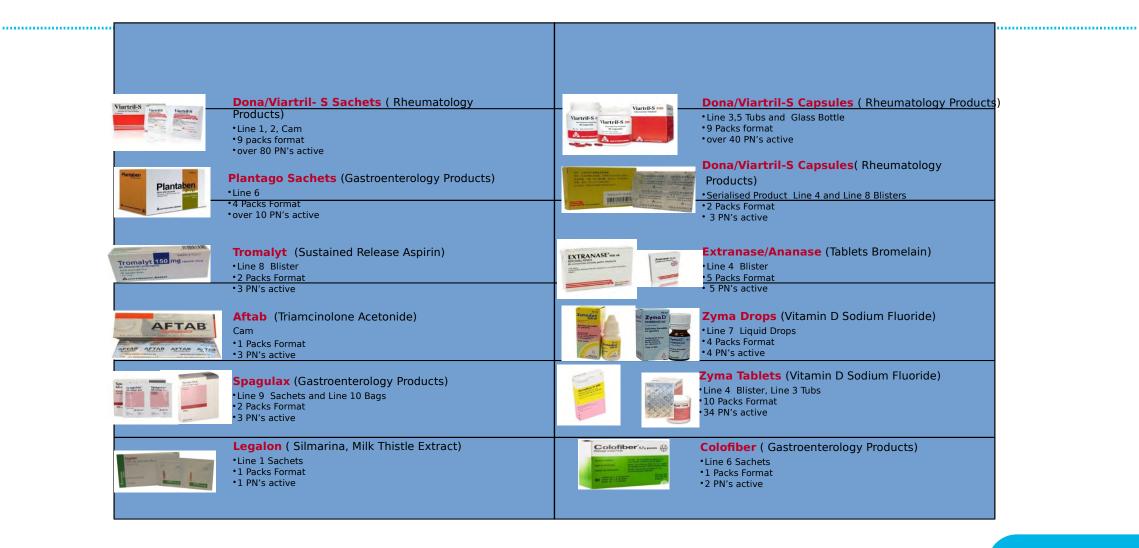


Products

Product	Form
Glucosamine Sulphate (VIARTRIL/DONA)	API, Sachets, Capsules
Bromelain (ANANASE/EXTRANASE)	Tablets
Plantago (PLANTABEN/SPAGULAX)	Sachets
Silymarin Extract (LEGALON)	Sachets
Sodium Fluoride / Vitamin D (ZYMA)	Tablets, Liquids
Aspirin (TROMALYT)	Capsules

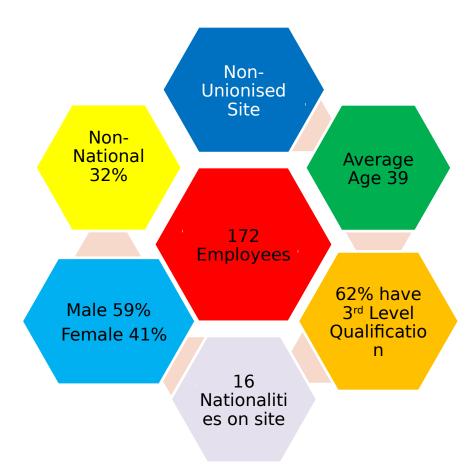


Products





HR Information





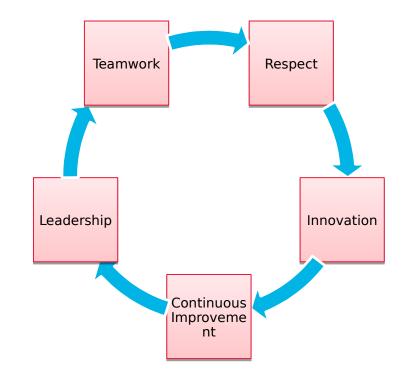
Our Core Purpose

To be the best for our customers, our people and the environment



Our Core Values

- Teamwork
- Respect
- Innovation
- ContinuousImprovement
- Leadership





2014 - 2024 Vision

To become recognised as one of the top 10 manufacturing sites in the world and triple our production output by 2024



OPERATIONAL EXCELLENCE

2006-2009



Improvement Initiatives 2006 - 2009

Superblender batch size increase 2006 √

Sachet line 1 OEE project 2007 x

Incremental batch file review 2009 √

Black belt six sigma sachet line 2006 √

Lean Labs Quality Control 2007

Lead by managers, extensive use of consultants, top down, some success



Superblender

- Manufacturing blend batch sizes increased from 800Kg to 2,400Kg
- 3-fold reduction in Area Clearances required in manufacturing and packaging leading
- Only 1 batch file needed for 3 times the quantity
- Number of batches for testing reduced by 67%





OPERATIONAL EXCELLENCE

2010-2016



External Environment 2010



- Generic copies of branded products increasing in market share
- Delisting of our products from reimbursement
- Reduction in reimbursement price by governments
- Parallel imports
- Threatening our future!
- We needed to increase cost competitiveness and attract new products



Town Hall Meeting 2010

Urgent and Important



Hard goal - major challenges in implementation

Urgent - no time to lose!!!

Required - must do

Ensure the best future for our customers, our company and ourselves



Word Class Manufacturing





What is meant by World Class Manufacturing?

- The relentless pursuit of excellence in all areas
- The utilisation of industry best practice
- The ability to compete effectively in a global market
- Development and utilisation of talents of all employees
- Continuous improvement and innovation of processes
- Relentless Quality and EHS compliance



Objectives 2010 - 2013

World Class Manufacturing Vision

Increase capacity by 20%

Reduce costs by 15%

Achieve 60% OEE across all lines

Achieve 100% employees involved in CI activities

To become a paperless pharmaceutical plant

To become a reference site for WCM within the Rottapharm|Madaus Group

Achieving the Vision will require striving for :





TPM

- Total Productive Maintenance (TPM)
- The responsibilities for improving the equipment performance lie not just with the maintenance department but with all the plant personnel
- TPM is a tool for helping to bring about change
- The culture of a plant evolves through the use of TPM
- Other tools such as Six Sigma, Lean, Kaizen, Root Cause Analysis, Reliability Centred Maintenance aid the overall change



The TPM Process

THE THE THE CONDITION PROBLEM PREVENTION MEASUREMENT CYCLE CYCLE CYCLE **Collect Process Develop Future** Develop History & **TPM Asset Care Best Practice Performance** Information **Plan the** Refurbishment, **Define OEE Spares & Manpower Measurement & Potential Review Progress Improve Carry Out a Condition Appraisal Assess Hidden** Low Losses/Waste. **Carry Out a Critical** Cost/No Technical Support **Set Improvement Solutions Solutions** Cost Assessment of the 3 **Priorities** Solutions **Equipment FEEDBACK**



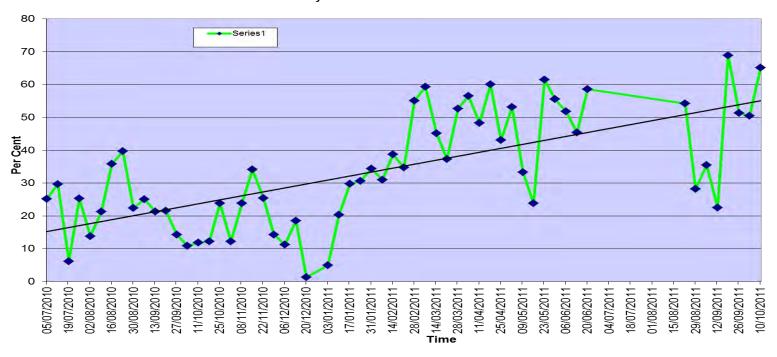
The Trial Period

- April 2010 four day training with TPM consultant on the TPM process – 19 people
- July 2010 two pilot projects launched 6 people per team
- Production stopped for 8 hours per week
- November 2010 pilot teams completed the 9 step process
- Improvements made, team structure developed
- Success operations/maintenance working together
- Roll out programme developed for the plant



Line 6: Pilot OEE rate

Line 6 OEE rate July 2010 to mid Oct 2011





Front Line Operator Asset Care (FLOAC) - Operator as the Technician



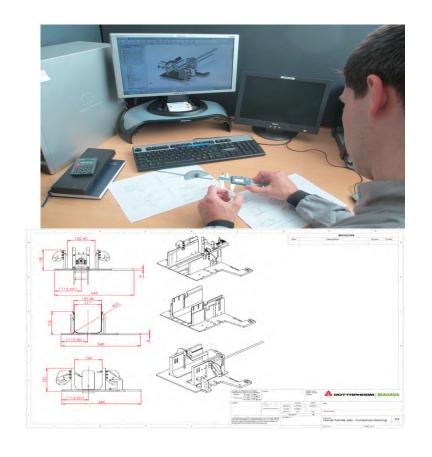


- The operator takes on the role of first line maintenance
- Checking the condition of the equipment during operation
- Carrying out maintenance during the weekly maintenance window
- Progressing to monthly maintenance and carrying out change overs on equipment

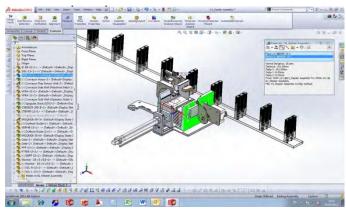




Technician as the Engineer



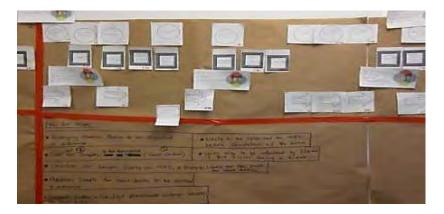
- Technicians spend more time on design and engineering out problems
- Less work is outsourced
- More knowledge and ability is developed inhouse
- · Technicians feel more motivated and more





Improvement Tools - PCO





- Introduction of Precision Change Over (PCO) using lean six sigma techniques
- Dramatic improvements Bulk API process increased output by 33%
- BIT Type 1 reduced by approximately 60% across most of the packaging lines



The People and the Teams



- TPM teams established across the plant
- Teams self managing, progress tracked via TPM audits level 1a 4b
- Culture of responsibility developed "how can I make a difference?"
- Cross Functional teams established for Six Sigma projects, A3 problem solving, Process Mapping
- Communications Cl newsletter, net presenter and improvement boards
- Celebration of success, reward & recognition



Total Productive Administration (TPA)

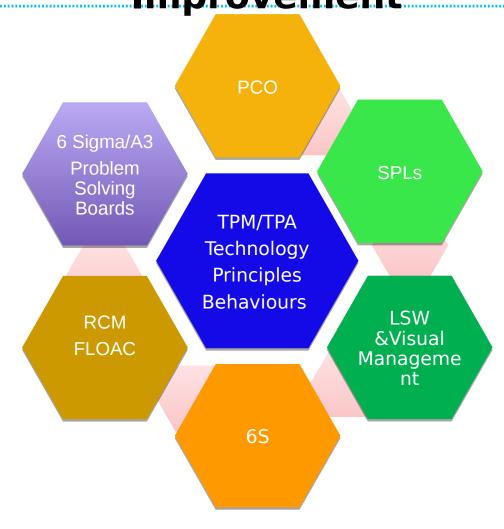




- Recognised the need to involve everyone in CI activities
- September 2012, teams from QC, QA, Finance and Logistics trained
- Process mapping to remove non-value adding activities in processes
- Continuous Improvement Structure developed for the administrative and support areas

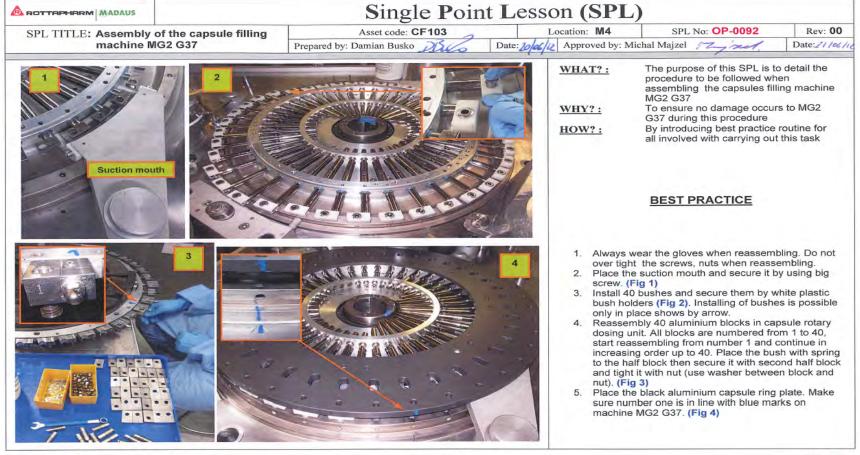


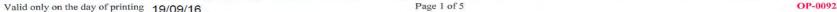
Helping to Generate a Culture of Improvement





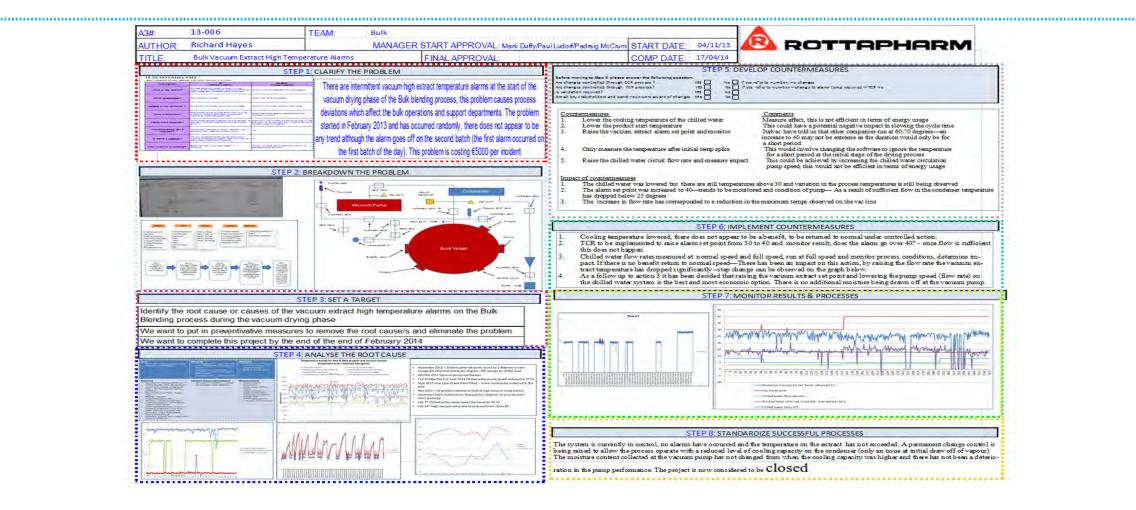
Single Point Lesson





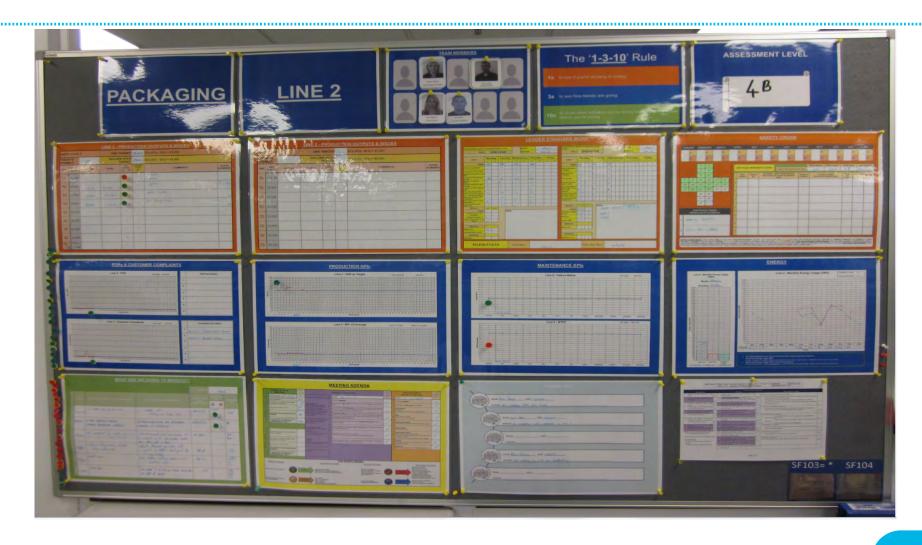


A3





Visual Management Board





Meeting Agenda

		Please Tick upon completion	WEEKLY CI MEETING		Please Tick upon		MANAGEMENT REVIEW MEETING	Please Tick upon completion	
	DATE: / /	~			DATE: / /	1		DATE: / /	1
	Do you have any safety concerns that you wish to highlight?			1	Check for attendance.		1	Check for attendance.	
E A R L Y	2 Are there any immediate machine issues that needs to be resolved?		Time Location: At the appropriate time to allow shift cross over and CI activities take place after the meeting. The meetings can take place in the local area or in a meeting room if a team based event follows after the meeting such as an A3 problem solving activity.	2	Check for any <u>safety items</u> (all safety issues are to be logged on the SOR system).		2	Check that the <u>Safety Cross</u> is up to date.	
	3 Do you have any BITs today?			3	Go through the <u>discussion items</u> on the SharePoint tracker site for the team. (New improvement or problem solving ideas can be discussed at this time but should be logged on the ideas register system).		3	OEE/Outputs. On target? Hourly targets, Golden Hours – any achieved?	
SHIFT	4 Do you have any issues that needs to be escalated?			4	Review new ideas that have been raised on the SharePoint tracker and assigned to the team for consideration (by relevant managers) or that have been raised by team members. If the ideas are not already on the register, ensure that the new ideas are logged.		4	BITs. BITs 1 and 2 vs. target BITs 3, 4, 5 status and trends?	
	Can you meet the daily plan with regard to: RESOURCES; MATERIALS; INTERMEDIATES: PO's?		The meeting should only last for 15—20 minutes, the focus should be on using the assigned time for improvement activity.	5	Review areas where we are losing and put <u>Improvement Actions</u> in place. Update the board.		5	Machine performance. Is the MTBF on target & Failure Rates below target?	
			Facilitation of meeting: Time keeping = 15-20 minutes per	6	Review progress on the <u>Goal Action Performance</u> (GAP) improvements for the month on SharePoint.		6	Energy Saving. Shift-end practices.	
L	Do you have any safety concerns that you wish to highlight?		meeting. Follow the agenda Ensure all members have appropri- ate tasks/actions assigned. Attendees. Weekly — Local team members and technician	7	Update the local team board as required. (Completed by the <u>board owner</u> and relevant <u>KPI update owner</u>)		7	Improvement Actions. What are the improvement actions? Who have they been assigned to & is there follow-up? Are they on Target? Do any items need extra support from Snr. Mngmt?	
A T E	Are there any immediate machine issues that needs to be resolved?			8	After the meeting - take on assigned individual or team based GAP improve- ments or problem solving activities as required.		8	Projects. Is there any A3 in progress? What is the 6S status? Is everyone involved?	
S H	3 Do you have any BITs today?		SME & designated facilitator Rotating through the various teams Local Production and Maintenance				9	Follow-up. Items to be pursued by Senior Management team?	
F	4 Do you have any issues that needs to be escalated?								
	5 Can you meet the daily plan with regard to: RESOURCES; MATERIALS; INTERMEDIATES; PO's?		Manager.						
					THE OUNCE MODEL				
	Guiding Principles		Supporting	C	THE SHINGO MODEL oncepts Guiding Principles			Supporting Cone	ents
Crea	ate Value for the Customer.	RESU	Measure what matters.	per	Focus on Process. Embrace Scientific Thinking. Flow & Pull Value.	Tomovewed,)	Stabilise processes. Rely on data and fact. Standardise processes. Insist on direct observation. FROCES: DIPEOVEMENT Reep it simple & visual. Identify and eliminate waste. No defects passed forward. Integrate improvement with	
	ate Constancy of Purpose. k Systemically,	ENTER		age	Lead with Humility. Respect Every Individual.	TI		Assure a safe environment. Develop people. Empower and involve everyor	



Leader Standard Work (LSW)

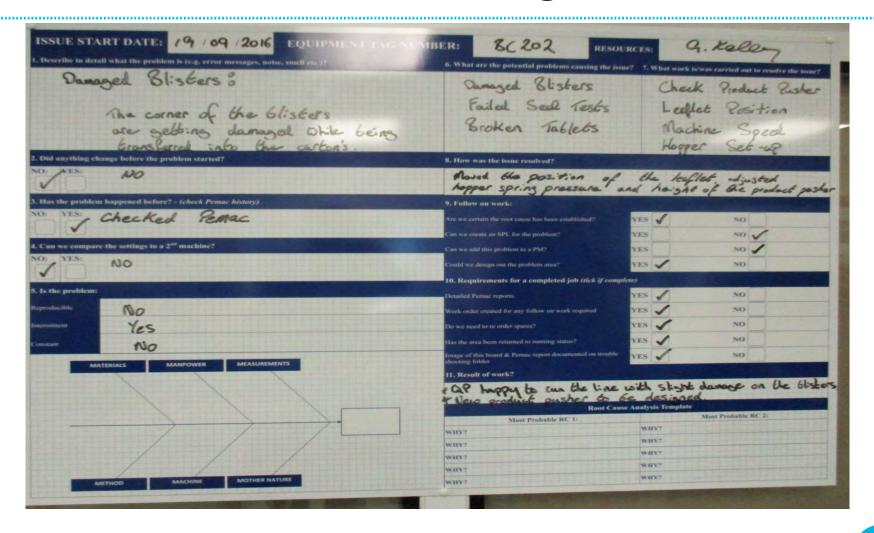




- Pulse walk at 07.00 on Production lines
- Escalated issues brought to 09:00 middle management meeting senior manager present
- Issues and schedules discussed. Items for escalation reviewed and addressed
- Escalated issues brought to senior management meeting at 10:00
- People at all levels taking ownership and responsibility for issues at their level



Problem Solving Board



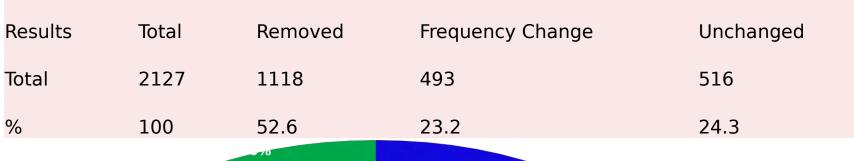


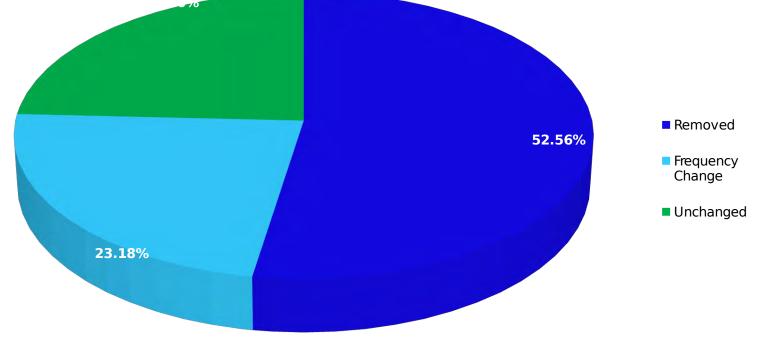
Reliability Centred Maintenance

- Eliminate non-value adding PM tasks
- Replace time based with condition based PM tasks wherever possible
- Avoid intrusive PM tasks wherever practical
- Ensure task frequencies are correct
- Identify where there are omissions
- to reduce PM workload and improve plant performance



RCM PM Review Results

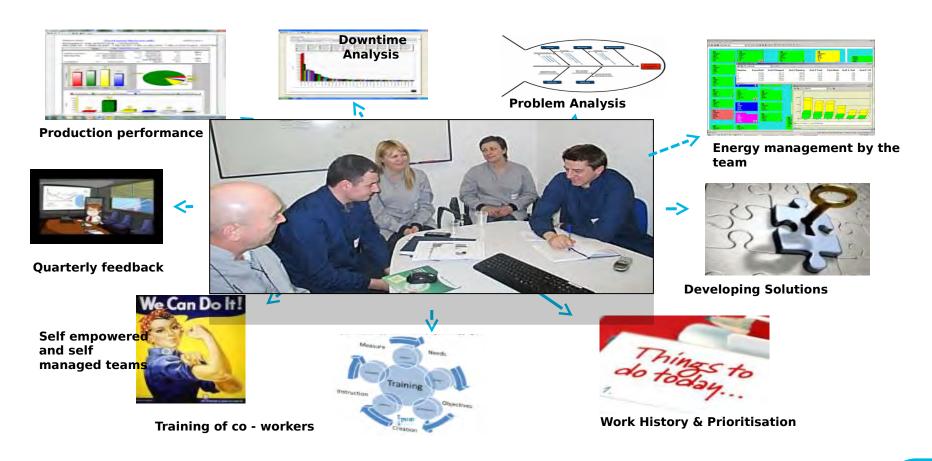






CI Team Focus

Dedicated CI Time in all departments





Objectives 2014 - 2015

Safety: 10% reduction in accidents each year

Environment: 5% reduction in energy used to produce each pack of product

Quality: 10% increase in right first time for finished product

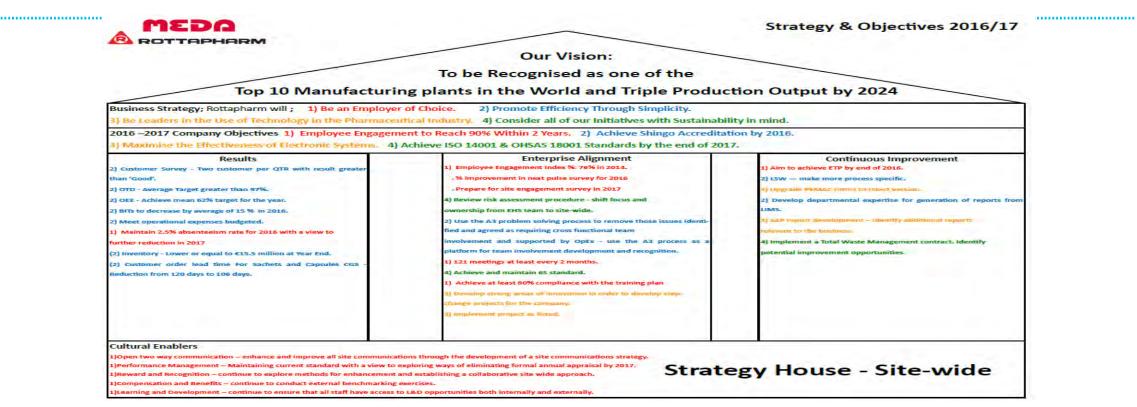
 People: 100% of employees to achieve CPD standard by December 2015

Customer: 10% reduction in order cycle time

Shingo: Challenge for Shingo prize by December 2015



Rottapharm - Strategy House - Site Wide



- Four key objectives established for the site
- Site wide consultations on the departmental objectives to support site objectives
- Individual objectives aligned to departmental objectives
- Site strategy and departmental strategy houses aligned



Technology & Innovation



The Paperless Plant

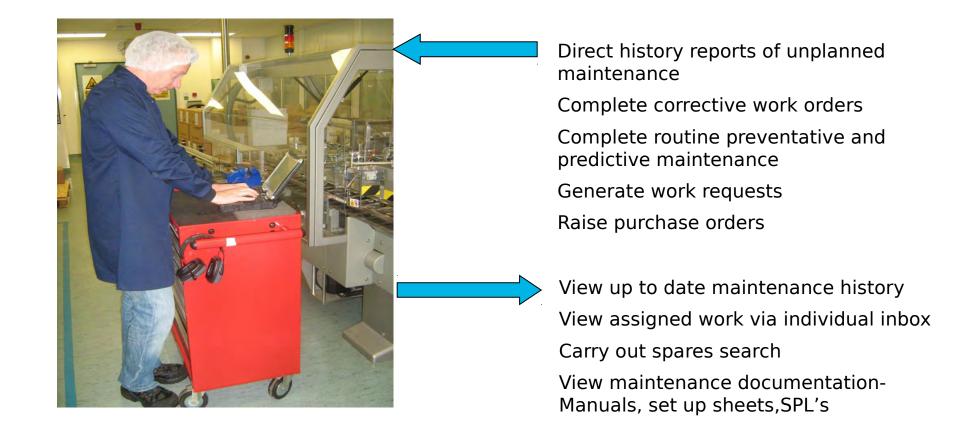




- Introduction of a Electronic Batch Records Manufacturing Execution System (MES)
- Introduction of a Laboratory Information Management System (LIMS)
- Introduction of Paperless Maintenance (CMMS)
- Introduction of an OEE system
- Introduction of Sharepoint
- Introduction of SAP
- Introduction of a Learning Management System
- Introduction of 3D Scanning and virtual spare parts library
- Over 1,000,000 wet signatures removed
- Operation and maintenance efficiency improved and errors eliminated
- Value of technology: elimination of waste & generation of information for CI

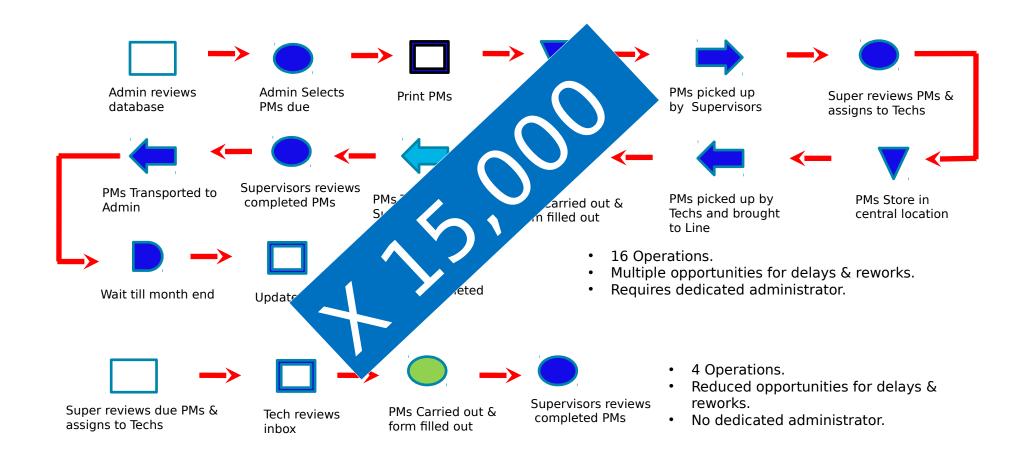


Paperless Maintenance





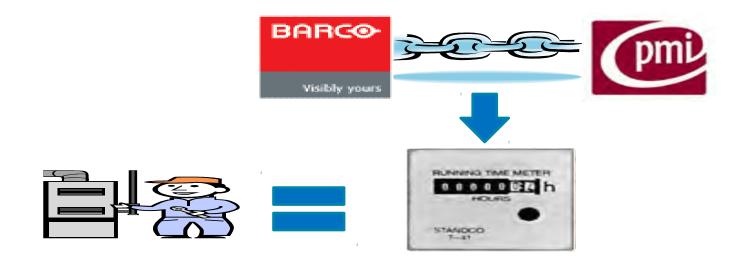
Minimising Waste





Meter Based Maintenance

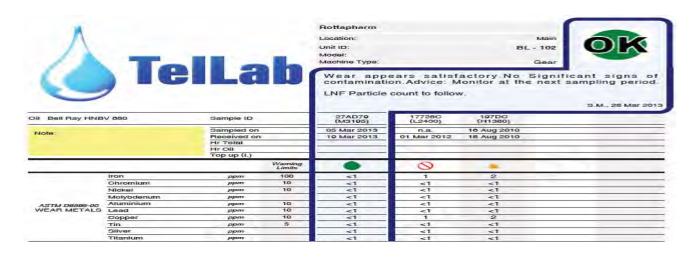
- Barco OEE system and CMMS (PMI) interface
- Allows actual running times determine routine maintenance schedule

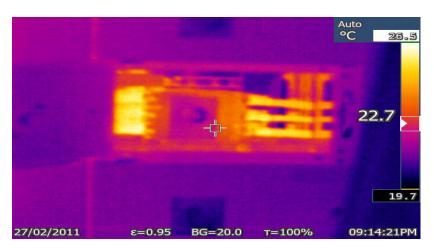




Condition Based Maintenance

Thermal Analysis, Oil Analysis, Vibration Testing

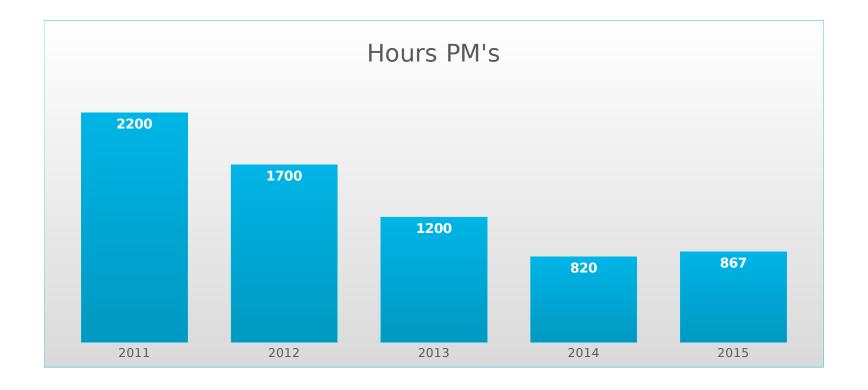






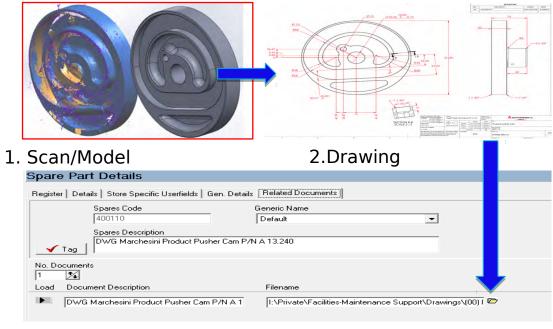


Results - Technician PM Time





3D Printing / 3D Scanning / Virtual Stores

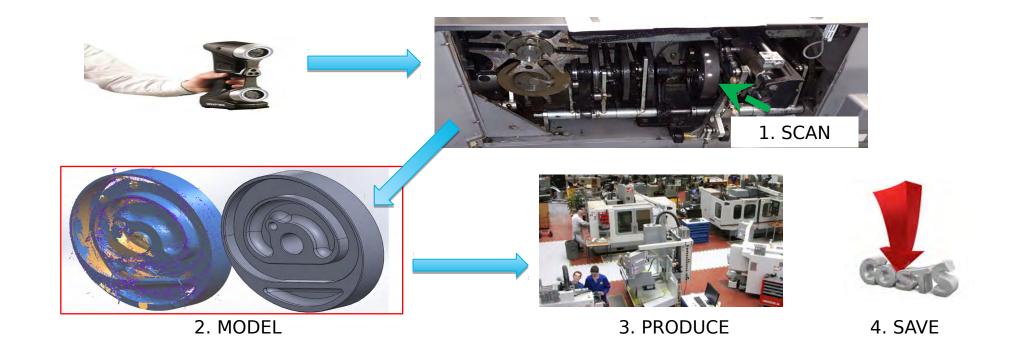


3. Link to CMMS

- Currently using 3D Printer to design and manufacture prototypes in plastic
- 3D Scanner and solid works software to develop a "Virtual Stores"
- 3D Scanner enables fast accurate development of models
- From the 3D model schematic drawings are developed and are attached to spares via the CMMS system
- Drawings can be provided to local vendors and the parts can be produced within hours.
- Results include reduced costs on spares, no long OEM Lead times, reduced inventory
- 121 Parts now created in the "Virtual Stores"



Process - Reverse Engineering



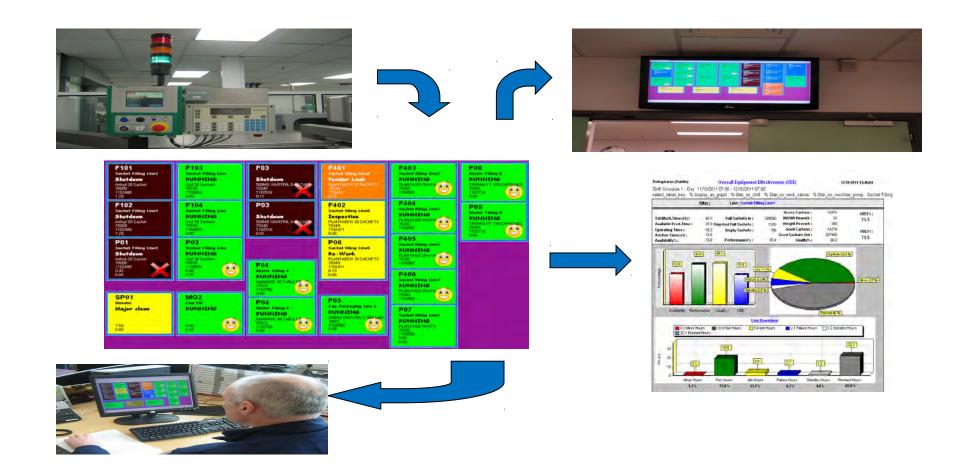


Example of Savings

Part Description	<u>Local Cost</u>	Vendor Cost	Saving
DWG Dosator Sieve Bearing	€10.50	€153.36	93.15%
DWG Dosator Bearing 30mm x 20mm P/N 271.01.512	€11.00	€97.07	88.67%
DWG Sealing Jaw Drive Shaft P/N 235.21.228	€70.00	€390.00	82.05%
DWG Funnel Mounting Support Block P/N 07910103	€24.00	€125.76	80.92%
DWG Sealing Plate Isolator P/N 235.21.256	€22.20	€201.23	88.97%
DWG Code Block Drive Ring P/N 235.45.231	€30.00	€153.40	80.44%
DWG Pusher Pull Back Guide Track P/N RM092.048	€360.00	€1,350.00	73.33%
DWG Sealing Jaw White Plastic Wire Cover Left P/N 235.21.257	€66.00	€614.87	89.27%
DWG Sealing Jaw White Plastic Wire Cover Right P/N 235.21.357			
	€66.00	€614.87	89.27%
DWG Vertical Cutting Blade P/N 235.20.351	€40.00	€572.14	93.01%
DWG Chain Tensioner Assembly	€235.00	€885.50	73.46%
DWG Product Pusher Cam P/N A 13.240	€830.00	€3,512.16	76.37%

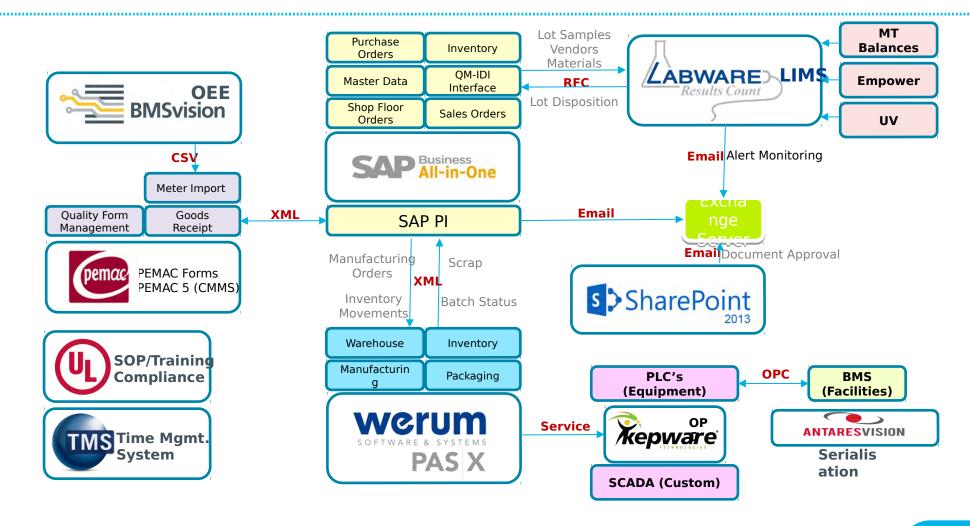


OEE - Real Time Equipment Monitoring



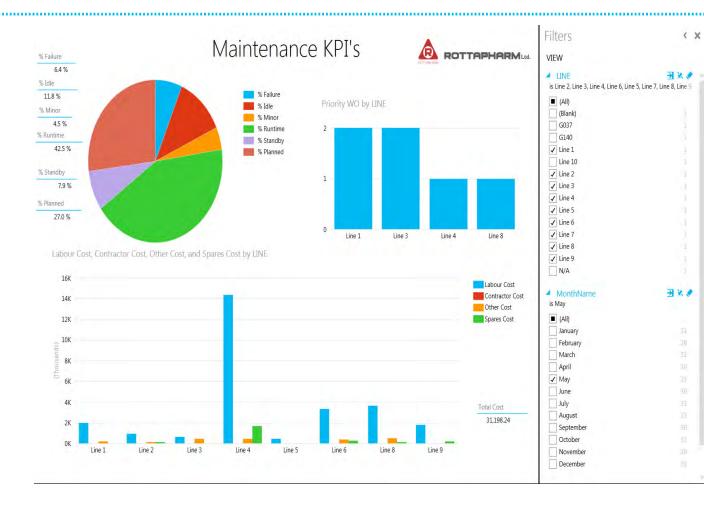


IT Systems Network





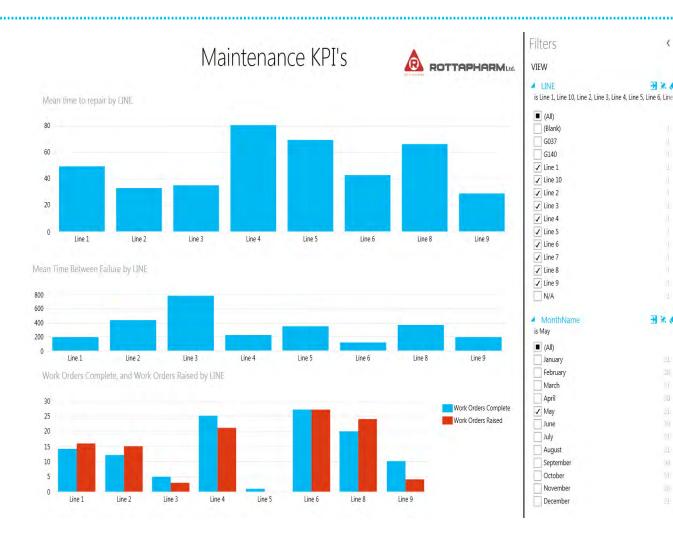
Business Intelligence in Maintenance



- Data from multiple systems stored in Data warehouse
- Customised reporting based on user requirements



Business Intelligence in Maintenance



Reports used for more accurate analysis

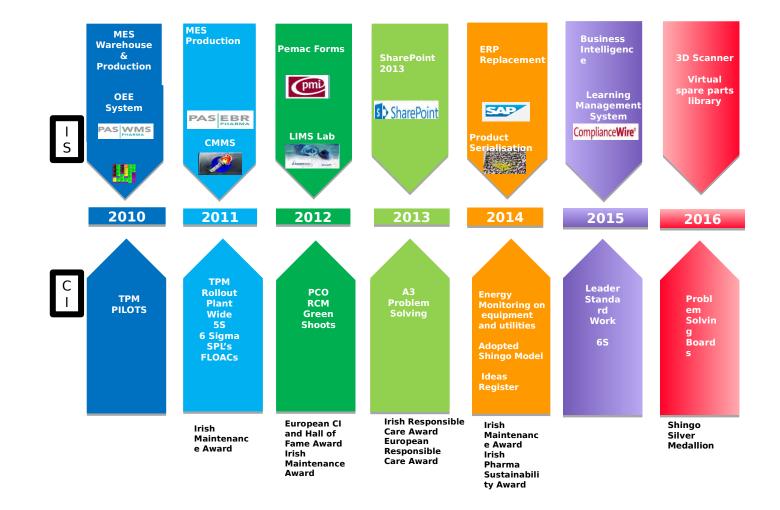
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- Automatic KPI's
- Hosted on Engineering SharePoint site



Towards World Class Manufacturing Information Systems and Continuous Improvement





Operations Performance in the Pharma Industry

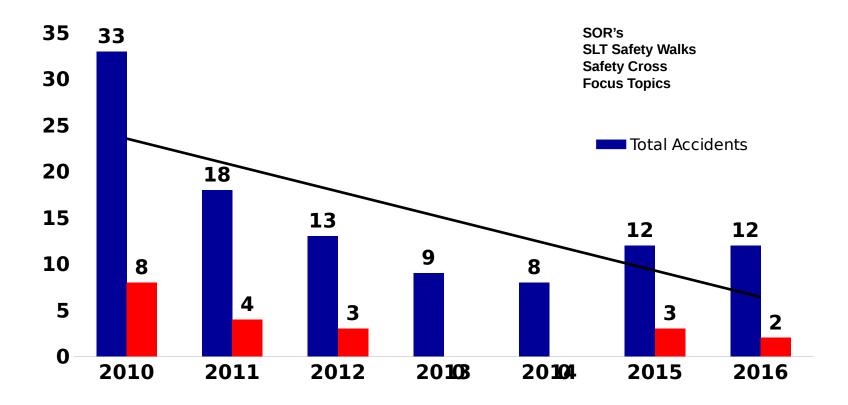
Measure	Pharma	Meda Rottapharm
Percent OEE	10-60	63
Percent Right First Time	60-80	94
Lead time in days	120-180	108
Inventory of finished goods in days	60-90	30



KPI Trends

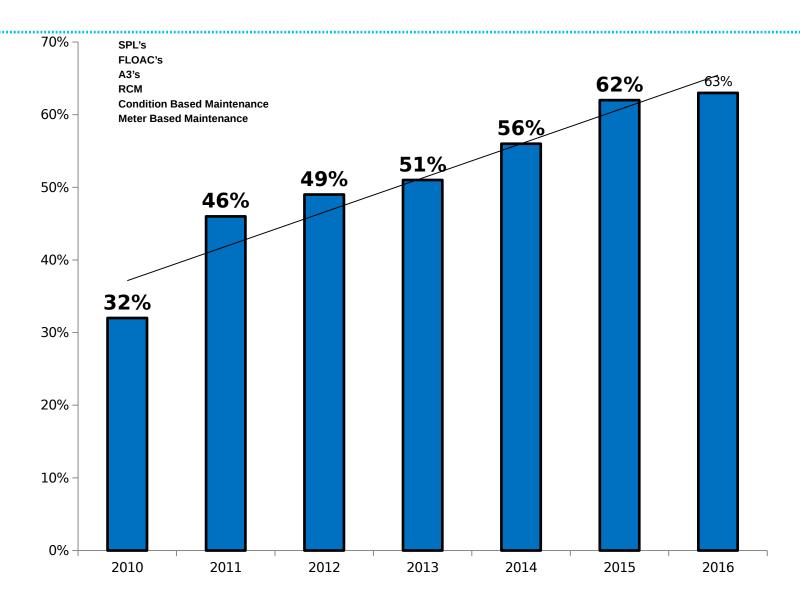


Accidents



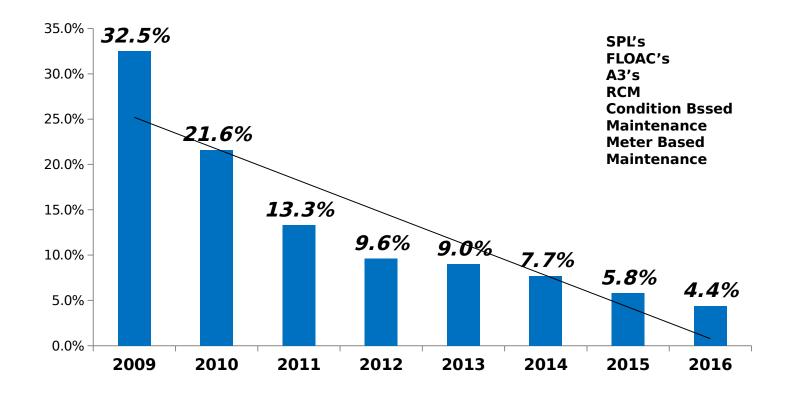


Plant OEE Average





Equipment Average Failure Rate



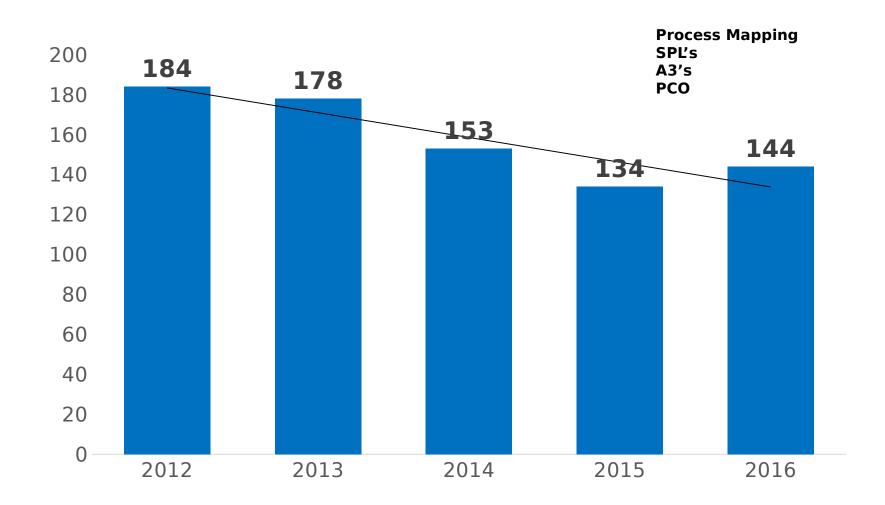


Mean Time Between Failure (minutes)

SPL's FLOAC's **A3's RCM Condition Based Maintenance**

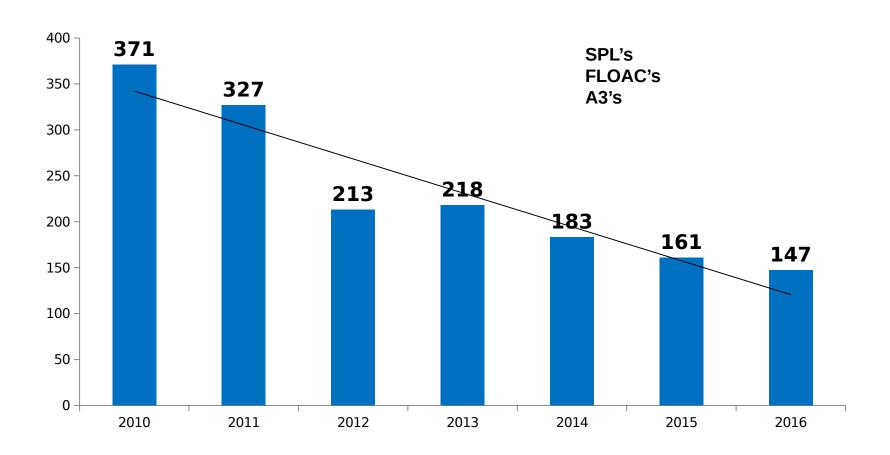


Batch Interval Times (BITs in minutes)



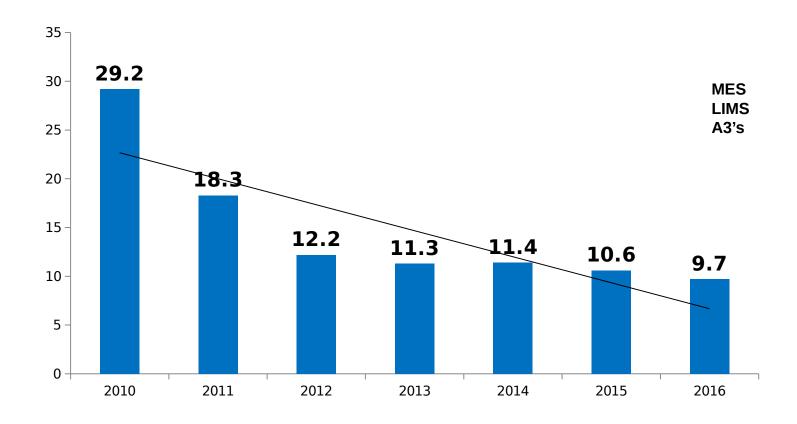


Number of Process Deviations



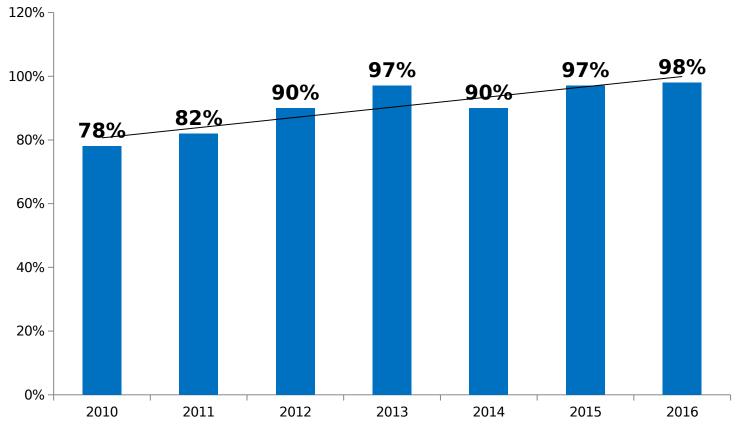


Batch CompletionNumber of days for batch release





On Time Delivery



Process Mapping
SPL
FLOAC'S
A3'S
Condition
Maintenance
RCM
Meter Based
Maintenance



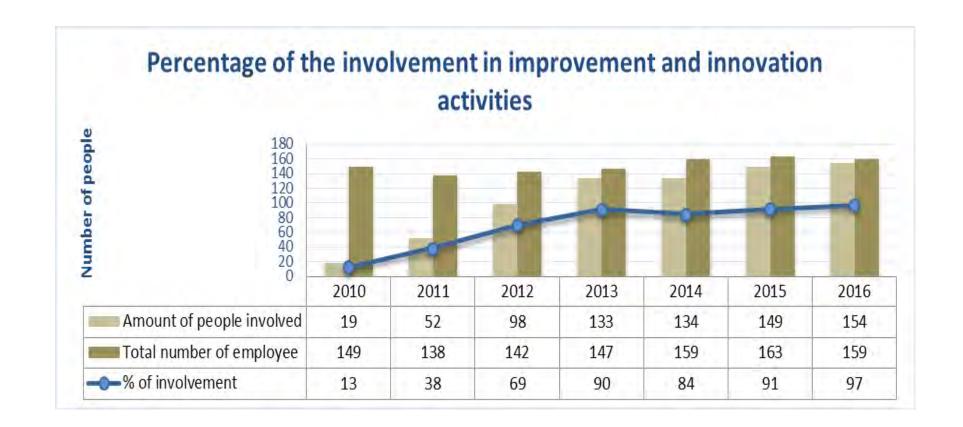
Energy Consumption per Pack

ws --- kWhrs of energy used per pack produced

Energy consumption reduced by projects on AHU's, boilers, compressors, lighting and behavioural change. Energy meters on all packaging lines.

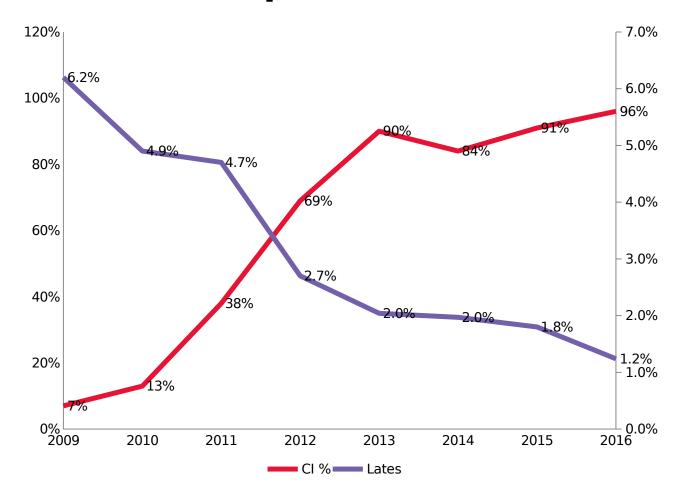


CI Participation Results





Culture Change - Lates and Continuous Improvement





Employee Engagement 2014 -v- 2016

Engagement with	2014 Engagement %	2016 Engagement %
Manager	74.6%	80.0%
Team	79.6%	85.0%
Organisation	72.6%	72.6%
Work	79.7%	82.5%
Company Total	76.2%	80.1%

- On-line survey conducted by independent consultant
- Response rate 90%.



Company Values and Key Behaviours

- Focus on behaviour required to sustain changes and maintain our CI journey
- Company Values embedded through recognising and celebrating the correct behaviours
- Behaviours form part of 6 monthly appraisals and monthly 1: 2:1 's
- Rottapharm All Stars monthly award was borne allowing peers to nominate colleagues who have excelled in the display of behaviours





Values and Behaviours

Our Values and Behaviours



Constancy of Purpose

- 2010 Volume Decrease
- 2011 Redundancies
- 2012 Rottapharm for sale
- 2014 Rottapharm acquired by Meda adopted
 Shingo Model
- 2015 Meda consider divestment of manufacturing
- 2016 Meda acquired by Mylan



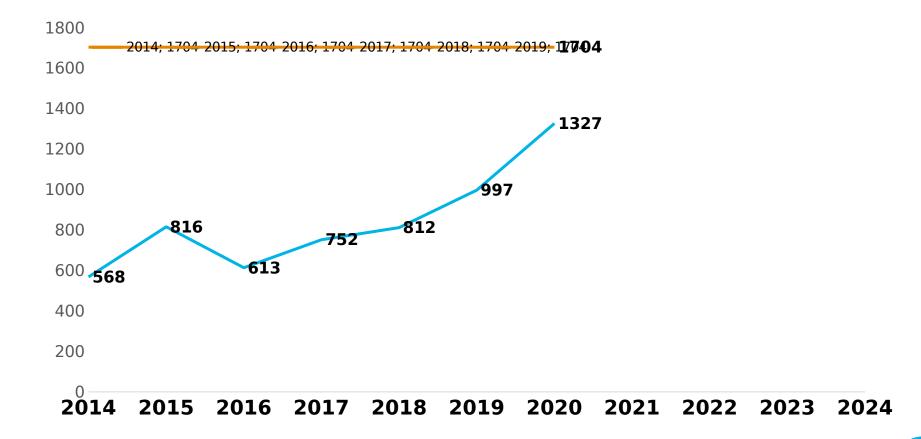
Period of Change Constancy of Purpose





2014 - 2024 Vision

Number of Doses





Volume and Cost Trend 2006 - 2015

Volumes

+196%

Factory Running Cost

+34%



Employee Output Summary 2006- 2015

2006 2015

Number of packs 9.8m 29m

Headcount 120 152

Packs per employee 81,000 191,000

Increase in packs produced per employee 135%



Learnings

- Reach out and involve everyone in improvement initiatives
- Allow people the freedom to create their own templates
- Front line manager is the conduit for engagement
- Make the job of the Production Operator as easy as you can
- Communicate early and often
- Have the right people in the right seats
- Developing people is central to a successful continuous improvement journey
- Step changes are easier to accomplish with a culture of continuous improvement



Management Responsibility

Employees commit a big part of their lives to employers
We should not waste their time



