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# **THE IMPORTANCE OF ENGAGEMENT: HOW AESICA CRAMLINGTON DELIVERED A STEP CHANGE IN SITE PERFORMANCE**

**1970s:** Green Field site acquired by Boots for Flurbiprofen facility

**1994:** Acquired by BASF

**2004:** Management Buyout forming Aesica Pharmaceuticals Limited

**2014:** Aesica Pharmaceuticals purchased by Consort Medical

- FTSE 350 Company
- Bespak / Aesica Operating Divisions
- 500m turnover
- 1500 people
- 9 Sites



## Cramlington

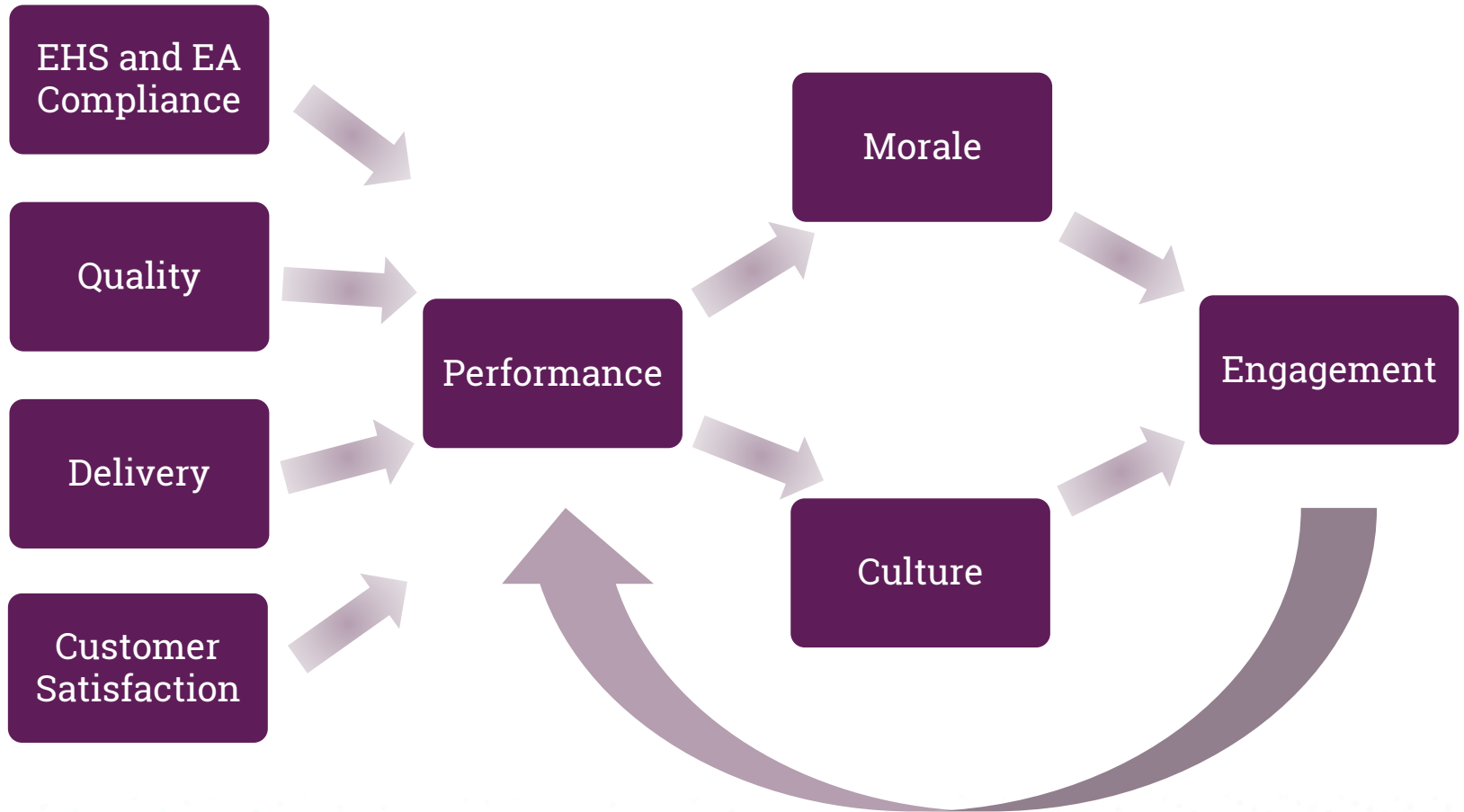
- Turnover ~ £22million
- 180 people
- Lower tier COMAH site
- Development, scale up and large scale production
- 40% Generic Manufacture
- 60% Contract Manufacture



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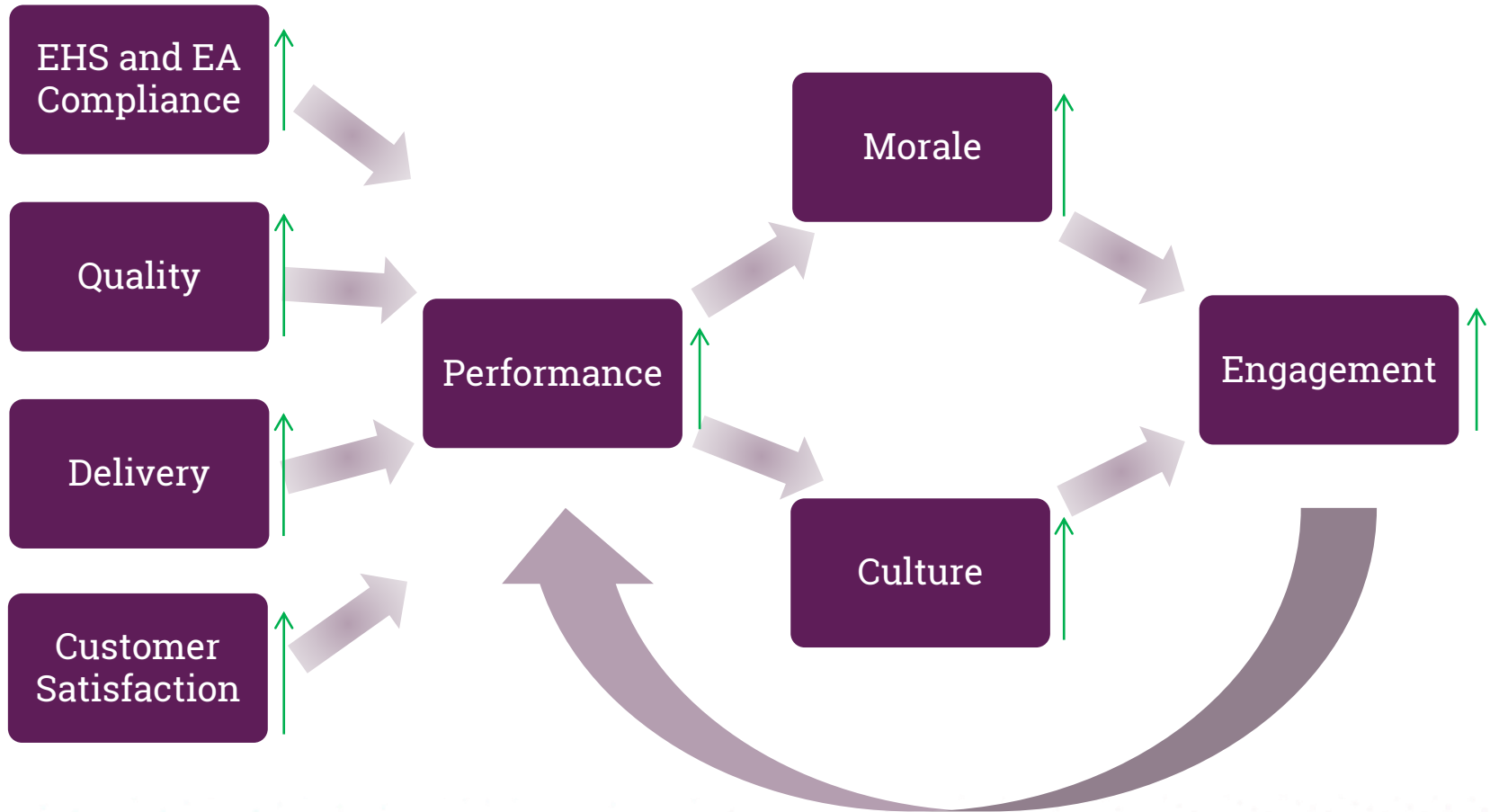
# THE NEED TO CHANGE



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# CRAMLINGTON VISION STATEMENT

“Creating a continuous improvement environment in which individuals feel valued and empowered to drive the site to become a class leading API facility.”

## SITE RECOGNITION

Goal – Enter and be shortlisted for an industry award by 2020



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# GOALS

## Safety

- Exceeding the expectations of Competent Authority

## Quality

- Deviations – developing fit for purpose system

## Delivery

- Schedule Adherence including Turnarounds
- New product introduction
  - critical to site success
  - delivered to customer and internal expectations

## Cost

- Flurbiprofen Capacity Improvement

## People

- Engagement, development and belief
- Developing a culture of Operational Excellence

## Management Systems

- Performance Monitoring and Review
- Communication



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# BULK TANK INSPECTION PROGRAM

- Exceed expectations of the competent authority
  - Both in terms of our inspection plan
  - Our leadership / engagement
- >30 COMAH bulk tank inspections in 18 months
  - Cross functional improvement team empowered to deliver programme
  - Senior leadership monthly review of progress
  - Third party experts utilised to support inspection programme
  - Risk based programme of inspection
  - Completed programme in < 15 months
- Third Party Process Safety Management GAP analysis undertaken
  - Output formed part of long term COMAH improvement plan
- Engaged an ex E&I HSE Inspector to undertake GAP analysis
  - E&I improvement plan
  - Engaged third party to deliver ATEX rated inspection programme

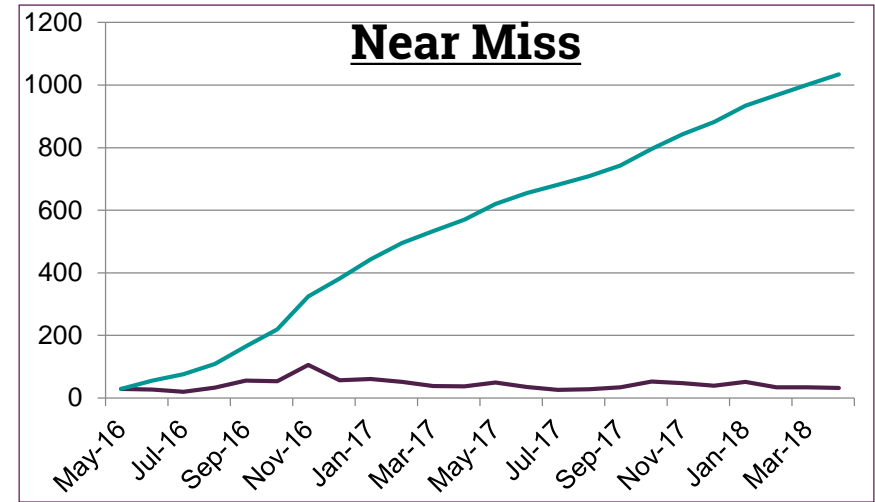


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# SAFETY MILESTONES

- Over 1300 days since last accident
- Over One million hours
- Thorough HAZOP process
- Identifies and addresses risk
- Completion of emission reduction project
- Near miss reporting used to engage staff
- Employee vigilance
- Safety at the heart of what we do
- First topic in performance review meetings and communications
- International Safety Award from the British Safety Council
- CEO award for the safety culture



Our EHS mission is to produce good quality products, safely and in an environmentally sustainable way.



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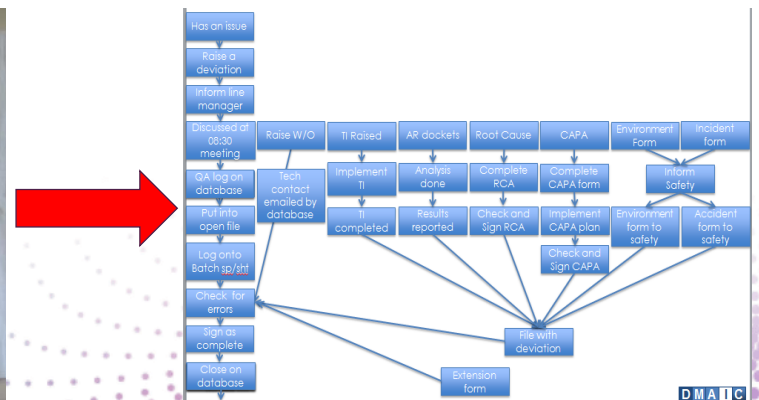
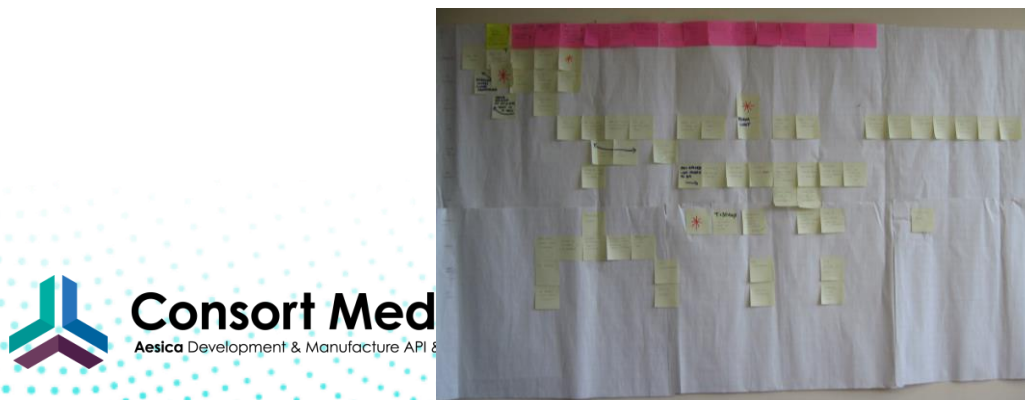
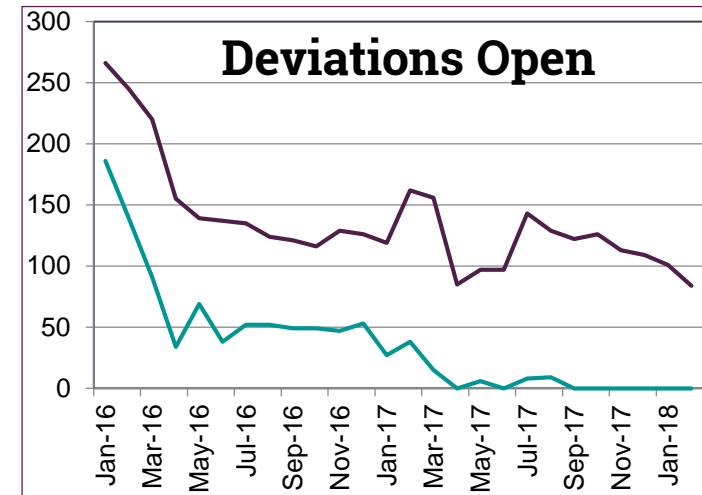
# QUALITY PROCESSES

## January 2016

- ~ 260 – open deviations
- ~ 180 – deviations open beyond review
- lack of control in the addressing the deviation

## End of April 2017

- No open deviations beyond review date.
- Reduction in number of deviations open by 50%.
- A new process flow was defined in order to address some of the issues which had been identified.
  - A full site roll out of the new process was carried out
  - Raise awareness, ownership and accountability
  - Improved simplified system.
  - Step change in the closure of deviations before review date.



# FLURBIPROFEN CAPACITY

- Increase capacity of our generic product – Flurbiprofen
  - 35 year old process
  - Long standing issues not resolved
    - **“How many of these will we fix?” “None!”**
- Engage workforce in driving performance improvement
  - We needed a successful pilot!
- Stage 1: U4500 (bottleneck) operation OEE study
  - Investigate reasons why control system went into hold
  - Eliminated root cause
  - Reduced cycle time by approximately 5hrs (>20% improvement)
  - Identified plant operations – which caused significant delays
  - Introduced Visual Controls – with maximum times associated with them
- On-going process improvement to drive performance



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# CAMPAIGN PRODUCTION

- On average 50 days late at campaign start
- Customer performance directly related to our ability to turnaround between products
  - Lack of focus / drive of process turnaround activities
- Appointed Turnaround Manager to manage end to end turnaround activities
  - Introduced detailed turnaround plans (reviewed as part of SQDCP daily review process)
  - Undertook SMED activity to reduce overall turnaround time
- Stability
  - FY17 – 86% of turnarounds delivered on time (remaining 2 delivered within 7 days of plan)
  - Turnaround activities incorporated into maintenance engineering plan
- Improved
  - FY18 - Reduced standard turnaround times by 25% (7 day reduction on standard 28 day turnaround)

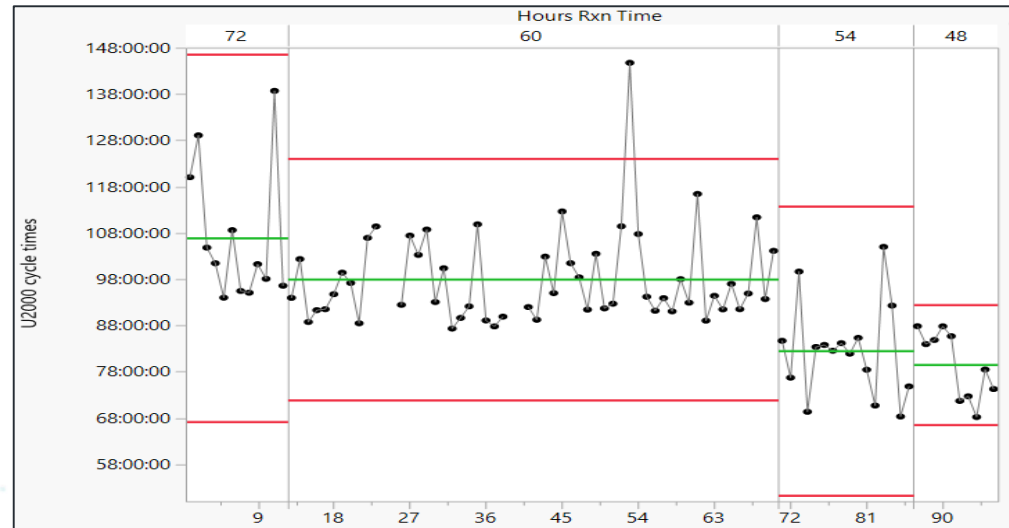


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# CAMPAIGN CYCLE TIME REDUCTIONS

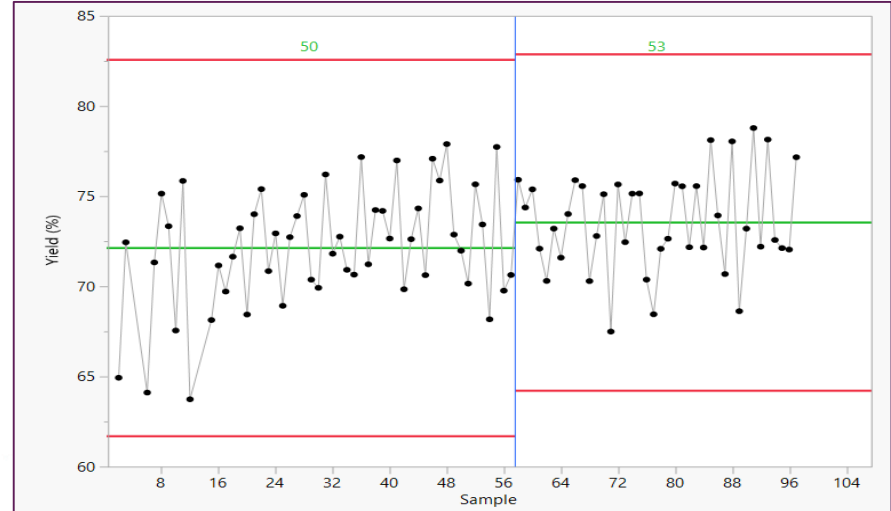
- New product introduction
  - Four year contract
  - ~ £1million pound investment
  - Three Production Stages
- Cross functional improvement team set up to drive performance
  - Generated 130 improvement ideas
- Bottleneck cycle time reduction of 25%



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# YIELD CAMPAIGN PROJECTS

- Low conversion across 3 stages
- The benefit of higher conversion would be to sell additional Flurbiprofen (potential 6 figure amount)
- The initial focus area Stage 2
- JMP data analysis software used
- Look at many variables
- Post reheat temperature was increased
- 11 kg increase in batch yield



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# ENGINEERING DELIVERY MODEL

## Need for Change

- <20% of Engineering Technicians on Site at any given time
- Low level maturity around planning and scheduling
- Many people scheduling – No owner accountable for bringing the schedule together
- Backlog of work that has grown over a number of years
- Limited long term plan based on asset health and forecasting of future costs
- Limited knowledge of asset management system (SAP)
- Completion for engineering resources for Maintenance, Engineering Projects, Turnarounds

## Changes Implemented

- Change to Engineering structure resulting in 80% of Eng. Techs on Site Monday - Friday
- Recruitment of Engineering Planner
- Recruitment of Reliability Improvement Engineer (Newly created role)
- Introduction of Mechanical and Electrical Lead Technicians (Monday – Friday)



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# ENGINEERING DELIVERY MODEL

## Results to Date

- Improved planning process with weekly long term and short term planning meeting
- Significant Reduction in backlog of work
- Sustained zero overdue EHS and Quality Inspections for >4 months (as a result of improved focus on high priority tasks)



- Dedicated resources on dayshift to focus on preventative maintenance
- Review of CMMS Master Data



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# EMPLOYEE ENGAGEMENT

- Make the Cramlington facility a great place to work and be part of
- Improve employee relationships
- Improve communication
  
- Leadership
- Culture
- Communication
- Personal Development
  
- Set up a bottom up cross functional engagement group
- Helped develop the site vision (listed earlier)
- Developed a communication strategy (listed earlier)
- Leadership training for all front line managers
- Family Fun Day – first one
- Lunch And Learn – Sharing knowledge and best practice



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# SUMMARY OF SUCCESS

- **Step Change in performance**
- **Engagement of people**
- **Target improvement to address key business challenges**
- **Cross Functional Team Working**
- COMAH inspection 3 months ahead of schedule
- >1300 days since last accident
- Open deviations reduced by 50%
- FBP cycle time >20% reduction
- Turnover improvement 25%
- Campaign cycle time reduction of 25%
- 2% yield improvement
- Transformation of engineering delivery model
- Engagement activities
- First family fun day in 10 years
- **Winner NEPIC Manufacturer of the Year**
- **Shortlisted for CIA Company of the Year**



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# MOVING FORWARD

## Safety

- Retain current safety compliance and record

## Quality

- Retain Quality compliance and audit readiness by application of 5S to key areas
- Focus on RFT for production and documentation

## Delivery

- Campaign product cycle time reductions
- Consistently achieve 21 day turnaround per campaign

## Cost

- Target utility reduction of key contributing equipment
- Product yield and material usage improvements


## People

- Increased number of ideas implemented

## Vision

- Strive towards both company and site visions

OUR  
VISION  TO BE RECOGNISED AS THE #1  
CDMO FOR CUSTOMER SERVICE.

SITE  
VISION  Creating a continuous improvement environment  
in which individuals feel valued and empowered to  
drive the site to become a class leading API facility.