Pfizer
Process Development Centre (PDC)

Liam Tully
31 October 2008
7 active ingredient manufacturing plants globally (3 in Ireland)

Technically strong teams at each site
- Manufacturing support
- Valuable short term incremental improvement
- Less frequent major process change

Belief that untapped value existed in manufacturing processes to make the key commercial products

Decision
- Recruit and ringfence a single team to find hidden value for all sites through Research & Development work
  - High risk activity for a manufacturing division!!

Tendering Process
- Ireland successful
  - 3 Irish sites track record
  - Culture of innovation
  - Business focus
  - Laboratory area available
PDC budget put in place in 2002

UCC supported PDC for first 6 months allowing use of the undergraduate laboratory
  - Facilitated recruiting and chemistry to start
  - Sent important signal globally in Pfizer that we were “open for business”
  - Demonstrated valuable support coming from outside Pfizer locally to help make this a success
Transformational Change

MANDATE
Working on commercial pharmaceuticals….. discover, develop, scale – up and support worldwide regulatory approval……. delivering:-

◆ Best Process Chemistry
  • Lowest cost
  • Most capacity efficient
  • Quality, safe and green chemistry

◆ Best Analytical Technology
  • Rapid chromatography

◆ Application of New Technology
  • Biotransformation
  • Continuous processing
Transformational Change

Team Size and Skills

- PDC now three times the size budgeted in 2002
- Chemists and Analysts joined by Chemical Engineers and Kilo Technologists
  - 75% Ph.D

Facilities

- $2 million laboratory put in place in 2002
- $13 million Kilo Technology Laboratory currently being commissioned at Ringaskiddy
Transformational Change

Value Delivered

- 4 refiled & approved processes to commercial API’s with 2 more refilelings Q1 09.
  - Transformational change (incl total new routes on Pfizer’s biggest selling pharmaceuticals)

- Included above new continuous processing technology – chemistry in a pipe with continuous separation & evaporation with supporting Process Analytical Technology

- Significant $ savings - over $1 billion accumulated saving projected over 10 years

- Major capital avoidance

- Processes that can compete post loss of exclusivity….. in-house manufacturing retention options with $ savings and other benefits…beneficial to Ireland

- Green Chemistry including biotransformation

- New Intellectual Property – 8 US / worldwide patents
PDC Awards

2007 Internal Pfizer global Green Chemistry Award – (Neurontin®)
- $5000 donated to UNICEF

The 2006 international IChemE award for Excellence in Green Chemistry and Engineering – (Lyrica®)
Key to Success

People

◆ Quality 4th level graduates, post-doc’s and experienced industrial chemists

◆ Training – work placement

- PDC ↔ UCC, IT’s and other Universities

  • Typically 3 months, half way through 4th level
  • Chemists already skilled in their discipline and receptive to additional learnings (working in teams, industrial EHS, Project Management, Scale-Up, manufacturing equipment etc)
  • PDC have 16 places for 2009
  • 32 students have come through the PDC in 5 years

◆ Pfizer support of Ph.D’s through scholarship – IRCSET

◆ Ongoing communication of ever changing skillset needs through discussions, IBEC / University forums, workshops
Key to Success - People

PDC Team today at recent Creativity & Innovation workshop
Key to Success

Facilities

◆ New route R&D requires the best available analytical equipment
  • The 400 MHz NMR is key to new synthetic route work in PDC
  • LCMS and GCMS in Prof. Glennons laboratory
  • LCMS in the Waters ABCRF Mass Spectroscopy laboratory
  • Microanalysis Laboratory
  • Microbiology

◆ Solid State Pharmaceutical analysis
  • Industry/University collaboration in pharmaceutical cluster

◆ PDC capability supported by above ensures no obstacle to effective efficient R&D in Ireland
Finally

Thanks to all in UCC for your great support of the PDC 😊

Any Questions?