

An Industry perspective on the Biopharma sector in Ireland

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The Global Biopharma Market

- The Global biopharmaceutical market was valued at \$106bn in 2009 and by 2012 its value had risen to in excess of \$140 bn and is growing at 15-18 percent annually. By 2016 it is expected that 7 of the top 10 blockbuster drugs will be biopharmaceuticals. The biopharma sector is a relatively new area of the pharmaceutical industry, with the first biopharmaceutical drugs being approved in the 1980's and 1990's
- Biopharma manufacturing is challenging due to the extreme complexity and variability of the process and the product and the highly regulated nature of the industry.
- Bioprocessing is regarded by the EU as a KET in that it has applications in multiple fields of manufacturing (medicine production, energy, waste treatment, food, industrial processes etc) but requires very significant CapEx and risk.
- Hence research on bioprocessing has been identified as a KET for priority investment by the EU due to the high potential for economic impact (through lowering COGS or enabling production of breakthrough new products) but the parallel risk of underinvestment/market failure due to the high CapEx requirements, regulatory challenges and attendant risks.

Biopharma Cluster in Ireland

- More than 5,000 people employed in Biotech development and manufacturing in 2014
- NIBRT provided training in biopharma manufacturing to 2,000 people in 2013
- NIBRT Centre of excellence supports companies spread across Ireland



\$2bn Investment Wins in Ireland

ETHICON™
Biosurgery

April. 2014
Manufacturing
of biologic
device
combination
product.
270 jobs \$100M

ALEXION

April. 2014
Global supply
chain, quality
fill finish &
packaging.
250 jobs \$100M

REGENERON

Aug. 2013
\$300M investment
in 400,000ft²
biotech drug
substance facility

GRIFOLS

July. 2013
Establishing
packaging, quality
and supply chain
function in Dublin

Employs > 100

genzyme

Feb. 2013
\$44m investment
in Biotech campus

Employs > 500

AMGEN

Apr. 2012
\$200m
investment

Employs > 300

Lilly

Apr. 2012
New Biotech
facility in Cork

\$420m/200 jobs

 **Mylan**

Apr. 2012
\$500m investment in
two strategic sites
Respiratory and
sterile fill finish
Employs > 700

 **ALLERGAN**

Jan. 2012
\$350m
investment
Manufacturing &
development
200 new jobs

BIOMARIN

June. 2011
Manufacturing
plant

\$50m/100 jobs

In the past 10 years, Ireland has seen 15 major investments in biopharma manufacturing, with an average investment of \$400M and average initial employment creation of 230 high-value manufacturing related jobs per investment. Many of these facilities have significantly expanded their workforce in recent years bring the total for direct employment in high value biopharma manufacturing to over 5,000. Ignoring the very significant construction employment associated with these highly technical, large capex investments and assuming a modest FDI multiplier effect of 0.7, this equates to almost 8,500 high value jobs created

Why companies invest in Ireland

- Knowledge based economy
- Flexible workforce
- Research collaboration
- Corporation tax
- Best practices/seamless transitions
- Formulation R&D and manufacturing facility
- Process development and commercialisation
- Innovative indigenous companies
- Significant life science cluster
- Political stability
- Strong local management
- Cost effectiveness
- Full compliance





- Biotech manufacturing
 - Complex product & process
 - Variable product and process
 - Highly regulated
- NIBRT Vision
 - Biotech is growing – skills shortage globally
 - Biotech is complex and variable – needs research
 - Biotech is regulated – need a “flight simulator” for training and for testing new ideas/tech
- 6500m² GMP-like facility
 - Pilot scale Training and Research Facility
 - Research on **Process and product** characterisation
- 2,000 people received practical training in NIBRT in 2013



An Irish based industry achieving it's goals

- Ireland to be the hub of excellence in development and manufacturing for pharmachem/Biopharma
- Ireland- the location of choice for the global Sector
- Irish Site-strategically relevant –centre stage for the global supply chain
- Ireland, part of the solution for evolving and emerging delivery of healthcare and therapeutics

