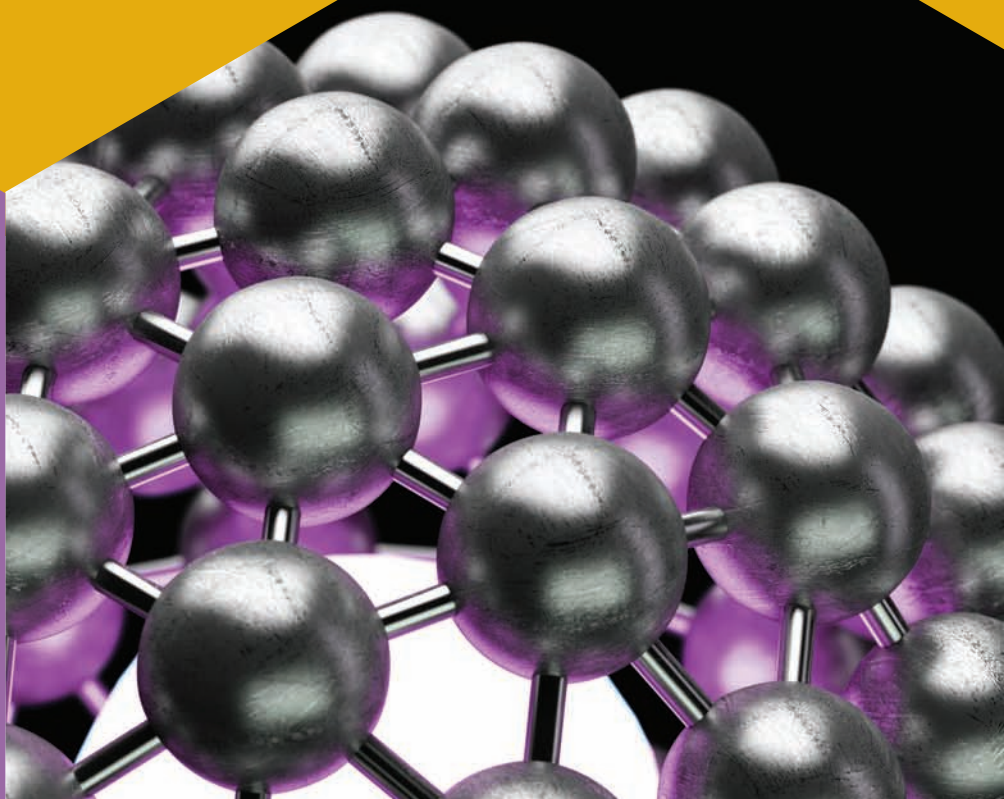


Molecules
make a difference

A Strategy for the
Biopharmaceutical
Industry in Ireland

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INTRODUCTION



Seamus Fives,
Chairman,
BioPharmaChem
Ireland

In March 2010 Pharmachemical Ireland launched the first phase of its strategy- “Innovation and Excellence” at the Drug, Chemical and Associated Technologies (DCAT) meeting in New York City. At that time the industry recognised real challenges to the future of the sector including how it would respond to the patent cliff.

Now as we launch phase four of this strategy we can reflect on how the industry has changed and indeed prospered during that period.

The evolution of a thriving biologics sector in the country has led the association to rename itself- “BioPharmaChem Ireland” – a more accurate description of the range of sectors operating in the country.

We have also seen the industry diversify during this period from pure manufacturing into manufacturing plus - plus development- plus process optimisation- plus shared services all supported by continued regulatory excellence.

Competitiveness remains a key focus area for the sector as it does for all sectors- BioPharmaChem Ireland continues to champion operational excellence which encompasses the principles of lean six sigma. We have many examples of how our Small molecule industry has responded to the need for cost competitiveness while successfully adapting scale and technology to support the launch and supply of a vibrant pipeline of new products.

I believe a key advantage of Ireland is the high level of collaboration between the industry, Government and the research community. We are delighted to include compelling cases presented by Government (through the IDA) and the research community (through the Synthesis and Solid State Pharmaceuticals Centre (SSPC)). These are all living examples of this collaboration. I am also delighted that Martin Shanahan, CEO of IDA Ireland, has lent his support to our Strategy.

I hope that you find the contents informative and useful and I welcome your feedback as we look forward to ensuring that Ireland remains one of the leading global locations for the launch, manufacture and supply of Pharmaceutical products and medicines.

EXECUTIVE SUMMARY



Matt Moran,
Director,
BioPharmaChem
Ireland

The recent wave of capital investments, amounting to over €3 billion are evidence of how the sector here has responded in a very positive way to the post patent cliff environment. We are witnessing the continued evolution of the sector in Ireland. With this evolution we see much more diversification within the sector; this is all positive news for Ireland as with diversity comes a more sustainable sector. Many of the new investments have been in the biologics sector with Alexion, Regeneron, Mallinckrodt and Bristol Myers Squibb all establishing significant facilities in Ireland. Ireland continues to develop into an important supply chain hub for the entire biopharma sector.

The case studies contained in this document clearly illustrate how this development has evolved- they also demonstrate how the entire infrastructure has developed in parallel to support the continued expansion of the sector in Ireland.

I see Ireland continuing to play an important role as a centre of manufacturing, supply and development for the entire pharma sector – from small through medium to large molecule. Molecules really do make a difference- to all parts of society, including the patient, through to the products that we make as well as making such a positive impact on the Irish economy.

FOREWORD



Martin Shanahan,
Chief Executive Officer,
IDA Ireland
(Irish Government
Development Agency)

Ireland remains an extremely attractive location for foreign direct investment. We have over many years been successful in attracting investment in a broad range of sectors. 2015 was one of the most successful year's to-date for Foreign Direct Investment. There are now 187,000 people employed in the IDA Ireland portfolio of companies and when one takes indirect employment into account approximately 1 in 5 people in Ireland are dependent on FDI for employment.

A key contributor to this success has been manufacturing and in particular the Life Sciences sector (Medical Technologies & Biopharmaceuticals). These companies are clustered in multiple locations around the country with strong infrastructural and academic supports. It is the largest exporter of products by value with manufacturing as a whole accounting for more than 20% of Irish GDP.

Ireland is the home of biopharma manufacturing with a strong and deep life sciences background for both drug substance and drug product. Ireland is currently seeing a steady stream of new international investments particularly in biopharmaceuticals. Nine of the top ten global biopharmaceutical companies have an international base in Ireland today. Over €10bn has been invested in the sector in the last decade.

In recent times the Irish sector has responded to global challenges faced by the biopharma industry (such as M&A's, patent cliffs and the global economic crisis) by focusing on increasing productivity and competitiveness through operational excellence, flexibility, process R&D and diversification into new technology areas. It is now vital that we retain the focus on competitiveness as the Irish economy and the sector returns to strong growth.

The Irish government sees the biopharma sector as key to the future success of our continued development as a knowledge-based economy where complex, high-value, right first time environments are key. In Ireland this stems out from deep skills in science, chemistry, engineering and business operations. There is a depth of management talent in Ireland with many years' experience in biopharmaceutical environments for multinational companies. The trend we are seeing now is the broadening of the footprint to include global supply chain teams, global QC and pharmacovigilance teams, next generation commercial marketing platforms and centralised finance and treasury operations.

IDA Ireland is also seeing a trend towards more collaboration in the Irish ecosystem. IDA Ireland works to supporting our clients to engage with academic research opportunities but also business to business through our population of innovative indigenous companies both for sub-supply and collaborative joint-development projects.

I believe that Ireland has a strong future in Life Sciences and will be a leading player in manufacturing excellence and process development work for many generations to come. To this end, I commend BioPharmaChem Ireland on their new strategy and in ensuring that we have all the building blocks in place for the continued success of both the current large group of companies and for future investments.

MEMBERS



BIOTECH PLATFORM

- 1 Alexion Pharmaceuticals
- 2 Allergan Pharmaceuticals Ireland
- 3 Amgen Technology (Ireland)
- 4 BioMarin International
- 5 Eli Lilly SA
- 6 Ethicon
- 7 Genzyme Ireland
- 8 Janssen Biologics Ireland
- 9 Jazz Pharma
- 10 Mallinckrodt Pharmaceuticals
- 11 MSD Brinny
- 12 MSD Carlow
- 13 Mylan
- 14 Pfizer Grange Castle
- 15 Regeneron Pharmaceuticals



SERVICES PLATFORM

- 34 Alexion Pharmaceuticals
- 35 Alkermes Pharma Ireland
- 36 Allergan Pharmaceuticals Ireland
- 37 BMS
- 38 Camida
- 39 Charles River Laboratories Preclinical Service
- 40 Eli Lilly SA
- 41 FMC International
- 42 Helsinn Birex Pharmaceuticals
- 43 Horizon Pharma
- 44 Hovione
- 45 Mallinckrodt Pharmaceuticals
- 46 Pfizer Ireland Pharmaceuticals
- 47 PPD Development Ireland
- 48 Recordati Ireland



API PLATFORM

- 49 Astellas Ireland
- 50 BMS
- 51 Cara Partners
- 52 Clarochem Ireland
- 53 Eli Lilly SA
- 54 GlaxoSmithKline
- 55 Hovione
- 56 Ipsen Manufacturing Ireland
- 57 Janssen Pharmaceutical
- 58 Mallinckrodt Pharmaceuticals
- 59 MSD Ireland (Ballydine)
- 60 Novartis Ringaskiddy
- 61 Pfizer Cork Limited
- 62 Recordati Ireland
- 63 Roche Ireland
- 64 Sigma Aldrich Ireland
- 65 Takeda Ireland
- 66 UCB Manufacturing Ireland



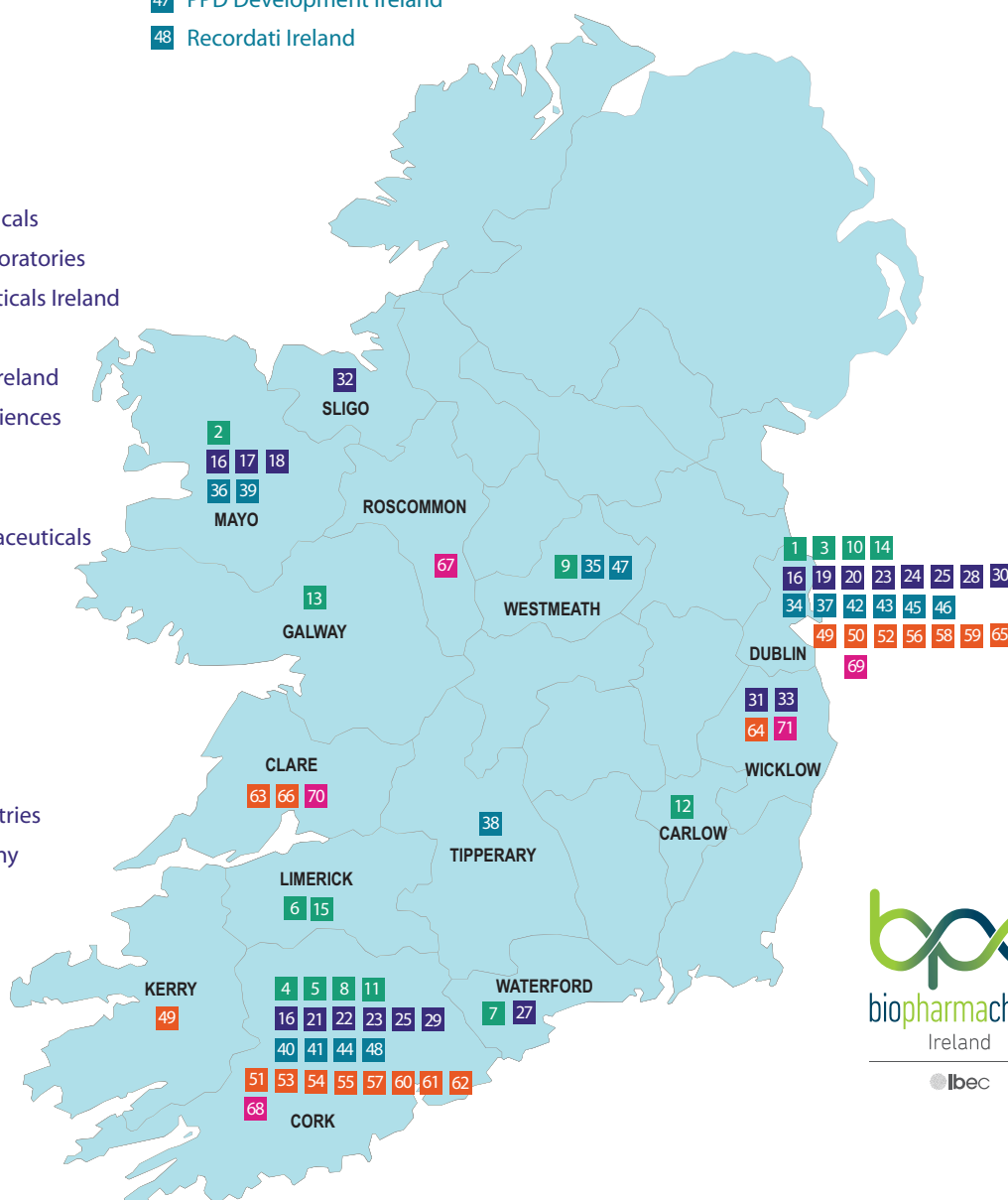
CHEMICAL PLATFORM

- 67 Arran Chemical Company
- 68 BASF Ireland
- 69 Henkel Ireland Operations and Research
- 70 Heraeus Metal Processing
- 71 Sigma Aldrich Ireland

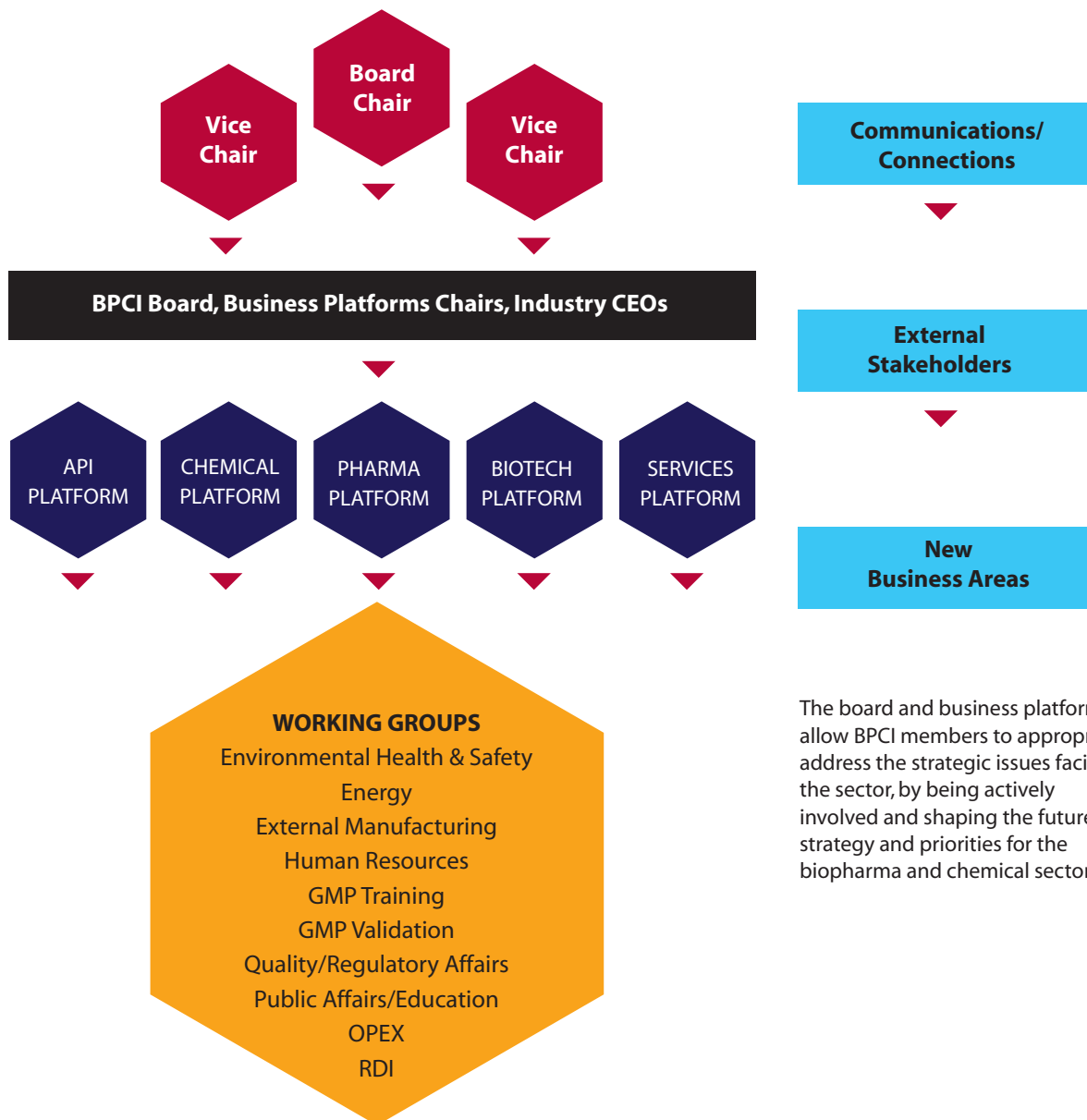


PHARMA PLATFORM

- 16 Abbott Pharmaceuticals
- 17 AbbVie Fournier Laboratories
- 18 Allergan Pharmaceuticals Ireland
- 19 Astellas Ireland
- 20 Forest Laboratories Ireland
- 21 GE Healthcare Bio Sciences
- 22 Gilead Sciences
- 23 GSK
- 24 Helsinn Birex Pharmaceuticals
- 25 LEO Pharma
- 26 Mylan
- 27 Teva Pharmaceutical
- 28 MSD
- 29 Pfizer Ireland
- 30 Rottapharm
- 31 Servier Ireland Industries
- 32 Stiefel a GSK Company
- 33 Takeda Ireland



ORGANISATION STRUCTURE



The board and business platforms allow BPCI members to appropriately address the strategic issues facing the sector, by being actively involved and shaping the future strategy and priorities for the biopharma and chemical sector.

BPCI BOARD

"BioPharmaChem Ireland is the biopharma, pharma and chemical sector association of Ibec. Representing our multinational and indigenous members, our strategy is ensuring Ireland is the global centre of excellence for innovation and development. In recognising the need to promote and support the establishment of a strong industry cluster in the country, the board of BioPharmaChem Ireland has outlined three key overarching recommendations to ensure the correct environment is created for the growth of this vibrant sector.

- Investing in education to build a future of highly skilled employees
- Ensuring Ireland creates a competitive environment to promote growth and innovation
- Creating the correct manufacturing environment

These are recurring themes that have always underpinned the success of the sector in Ireland"



John Nason,
Teva



Seamus Fives,
Pfizer



Gerry Collins,
Janssen
Pharmaceuticals



Paul Downing,
Hovione Limited



Gerard Gilligan,
Leo Pharma



Donal Johnson,
Eli Lilly SA



Kyran Johnson,
Janssen
Pharmaceuticals



Brendan Keane,
FMC International



Brian Keaveny,
Clarochem Limited



David Keenan,
Mallinckrodt
Pharmaceuticals



Geoff Mackey,
BASF International



Paschal McCarthy,
GE Healthcare Bio
Sciences



Julie O'Neill,
Alexion
Pharmaceuticals



Anthony Owens,
Arran Chemical
Company – An
Almac Company



Michael O'Donnell,
Biomarin
International



Padraig Somers,
Helsinn Birex
Limited



Ruth Beadle,
Genzyme

BPCI & IRISH INDUSTRY AT A GLANCE

BioPharmaChem Ireland is the biopharma, pharma and chemical sector association of Ibec. Representing our multinational and indigenous members, our strategy is to ensure that Ireland is the global centre of excellence for innovation and development.

55,000 people are employed directly and indirectly in the biopharma, pharma and the chemical sector in Ireland.



Recent investments of over €3 billion from global leading biotech companies have embedded Ireland as a leading location for the development and manufacturing of biologics. Employment in the biopharma sector stands at approx. 6000 people. Forecast figures show that employment in biotech companies will reach over 11,000 people by 2018. 50% of the total country exports are generated by the biopharma, pharmaceutical and chemical industry. The replacement value of the sector is estimated to be €40 billion. In 2015 the sector exported products to the value of €64 billion.

Ireland's pharmaceutical sector has an extraordinarily good track record in terms of compliance with statutory and quality regulations. The US Food and Drug Administration (FDA), Health Products Regulatory Authority (HPRA) and consumer audits consistently rate Irish manufacturers' good manufacturing practice (GMP) compliance as world class. Companies' competence in this area gives them a key competitive advantage over industries in other regions around the world.

RECOMMENDATIONS

"Ireland has a very well-educated, hardworking, flexible workforce with a 'can-do' attitude and a pride that often results in the Irish operations excelling in a corporate environment. The workforce, together with low taxation, financial incentives and grants, and access to profitable key markets, makes it the number one choice for doing business."



Competitiveness

Ensure that Ireland creates a competitive environment to promote growth, innovation and operational excellence. Enhancements to the corporate tax regime will deliver more and better jobs and increased tax revenue. 50% of the total country exports are generated by the biopharma, pharmaceutical and chemical industry. The replacement value of the sector is estimated to be €40 billion.



Talent

Ireland's talent pool remains a key global competitive advantage for the sector. We need to ensure that Ireland is an attractive location for highly-skilled employees. They in turn will then promote Ireland as a location for future investment and attract more similarly skilled people. The quality and capability of the people working in the sector is vital as companies invest and move up the value chain of innovation.



Innovation & Manufacturing Excellence

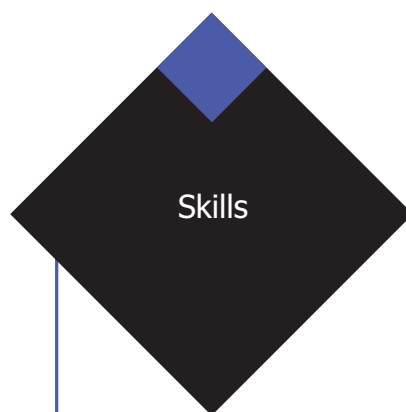
Ireland has a global size cluster with a proven track record in operational excellence, compliance and supply security in addition to a green image. The correct manufacturing environment is critical therefore it is vital to keep up to date with manufacturing technology – moving from batch to continuous, utilising skid technology, prioritising innovation in both process development and manufacturing technology.

"We are a mature, largely exporting, business established in 1978 in Cork- consistently growing with our global customers in Pharmaceutical and food applications. While wage and salary restraint have contributed to retaining our competitive edge, having good people focused on operating excellence and also continuing to invest in automation and productivity have been critical. We had just expanded the production capacity coming into the recession, and our focus on safe operation, productivity and value adding activity has led to the very recent creation of significant additional employment in financial services and customer support. Access to and retention of good people and successfully driving unit costs lower has been and remains critical to our success."

Brendan Keane General Manager, FMC International, Cork



A key advantage of the Irish business environment is the productive collaboration between industry, academia and government agencies. All stakeholders work together to consolidate Ireland's position as a knowledge based economy and as a primary location for research and development. Industry links and networks should continue to be developed and enhanced.



Demand for skills in Ireland remains very strong therefore continuity of investment in education is critical to building a future stream of highly skilled employees. It is important to nurture talent through the promotion and investment of science technology at the earliest stages in the academic lifecycle. An increase in spending on science, technology and innovation to 2.5% of GDP by 2020 would be an important step.



Ireland's pharmaceutical sector has an extraordinarily good track record in terms of compliance with statutory and quality regulations. The US Food and Drug Administration (FDA), Health Products Regulatory Authority (HPRA) and consumer audits consistently rate Irish manufacturers' good manufacturing practice (GMP) compliance as world class. Companies' competence in this area gives them a key competitive advantage over industries in other regions around the world. Typically, inspections by the FDA rate Irish facilities extremely highly.

COMPETITIVENESS

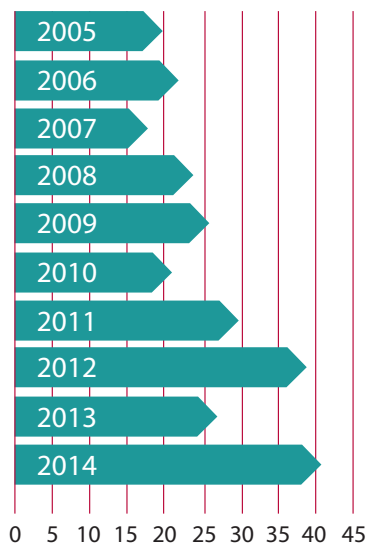
FEEDING THE FDI PIPELINE

The last three years has seen strong resurgence in the Irish Life sciences sector and 2015 has been another banner year. Major projects have been announced from companies such as Alexion, Amneal and Regeneron. This new wave of announced investments since January 2012 has now totalled to over \$4bn in capital committed and over 3,000 new high value direct jobs with a large number of additional indirect jobs in construction and other services. A striking feature of this investment has also been the strong regional dispersal, with locations such as Westport, Galway, Limerick, Cashel, Waterford and Athlone all benefitting.

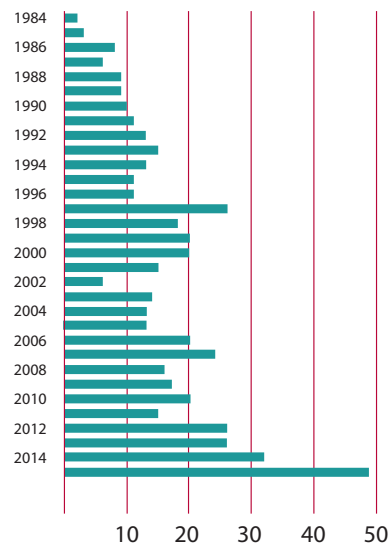
What are the trends that IDA is watching?

New drug approvals are up and a number of areas have seen very high potential drugs being approved.

New Molecular Entities Approved



Number of Approved Orphan Products by Year

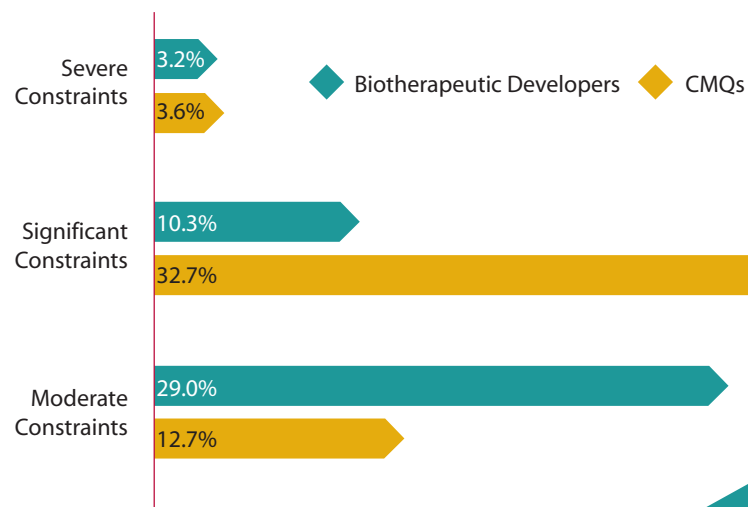




In infectious disease the Hepatitis C drugs from Gilead and Abbvie have been huge successes and led to investment in Ireland. In cardiovascular disease the PCSK9 antibodies have captured the markets' imagination and Regeneron and Amgen have invested in their supply chains in Ireland. The last few years have been a golden age for oncology research and Ireland has benefitted in the form of major investments to produce the new Pd1 antibodies Opdivo and Keytruda from BMS and MSD. Finally we see continued growth in drug approvals in the orphan and ultra-orphan spaces as evidenced by additional investment from companies such as Alexion and Biomarin.

Biotech manufacturing capacity remains constrained

Industry feedback continues to point to potential for capacity shortages in biotech manufacturing in the coming years as exciting new drugs are launched and many others approach approval. A number of uncertainties remain including how successful the launch of new first in class drugs will be (e.g. PCSK9 and PD1 antibodies), what impact biosimilars will have, how contract manufacturing organisations can work in partnership with innovator companies and where is the industry going with respect to adoption of new manufacturing technology (stainless steel, single use, process intensification and continuous manufacturing). IDA and Ireland must remain strongly engaged with all major companies as developments in this sector are moving extremely fast.



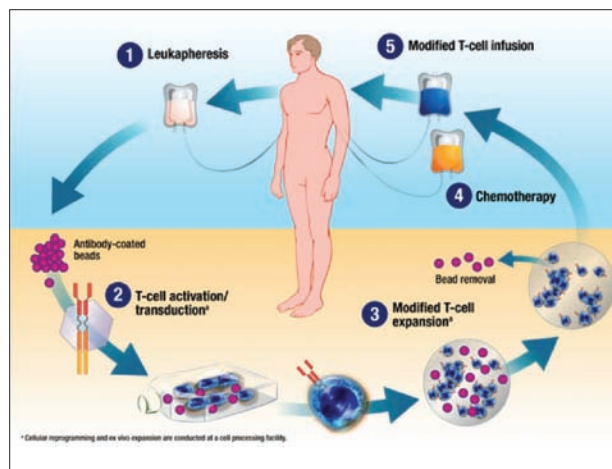
Drug Delivery Devices are delivering

A number of major investments seen in Ireland in recent years have centred around drug delivery devices. Generics companies such as Teva, Mylan and Amneal have invested in development and manufacturing of respiratory drug delivery devices and Irish company Aerogen are developing world-leading technology in drug nebulization. For parenteral drug delivery, the growth in biologics and biosimilars means that the delivery devices (pen injector, auto injector, pump, patch pump) are becoming more important to companies. Sanofi-Genzyme has invested in Waterford in this area for their long acting insulin drugs and Abbvie has made their Sligo site a global centre of excellence in drug delivery devices. Device companies Nypro, Becton Dickinson and Tech group/West Pharma have made significant investments in Ireland to expand their presence in the cluster.



Highly potent compounds manufacturing capacity is in demand

Small Molecule business's focus on competitiveness and Highly potent compounds manufacturing capacity is in demand. With the success in anti-cancer drugs, and a wider trend towards medicinal chemistry that results in more highly targeted and potent drugs, there continues to be a trend towards requirement for containment manufacturing, typically in a low volume (reflecting the change in product portfolio from large volume blockbuster products to smaller volume), highly flexible manufacturing context. It also creates opportunities for sites to invest in new manufacturing technology and process R&D in the small molecule space. These companies efforts in responding to the patent cliff have made them competitive and they are not only surviving but thriving in the post LOE world. The Pfizer Cork sites have been successful in making this jump in recent years and the Irish company Eirgen made this area their sole focus and reaped the reward, with the purchase of the company by US pharma company Opko in 2015. Small molecule sites have through focusing on excellent/best chemistry, operational excellence and lean manufacturing succeeded in retaining post patent business.



Next Generation therapeutics have gained momentum

IDA sees a number of fast emerging technologies which are progressing through clinical development and attracting significant research investment. Examples include CAR-T cells in cancer, bispecific antibodies, oligonucleotides and gene therapy. All of these are relatively novel platforms with challenges in development and manufacturing with complexity in supply chain. Ireland must remain engaged with

companies active in these areas in order to avoid missing out on a new wave of investment. In recent years the UK Government has placed a strong focus on manufacturing R&D and their life sciences Catapult centre has particular focus on manufacturing research in the areas of gene and cell therapy.

Shared Services

IDA continues to target shared services investments to ensure that Ireland can develop a healthy and diversified mix of manufacturing and service-based investment. Traditional shared services investments in areas such as finance continue to grow while supply chain management is an area of particular strength, especially with the emerging subsector of speciality pharma companies such as Alkermes, Jazz, Horizon, Alexion etc. IDA is also targeting potential for investment in shared services supporting wider commercial operations in Europe. We have seen “innovation centres” emerging in Medtech from companies like Cook, Medtronic and Stryker which support their EU commercial operations and opportunities exist in the pharma space in this regard. An early mover has been Novartis and their operation in Dublin continues to grow apace. Finally in the area of clinical trial management and data analysis, the growing cluster of contract research organisations in Ireland, such as Icon, Quintiles, and Parexel etc. creates opportunities for biopharma companies to use Ireland as a hub for management, control and data analysis for EU trial activity. Mid-sized biotech companies like Biomarin and Regeneron are increasingly considering Ireland as a location for management of clinical trial and commercial launch of pipeline products.

How is IDA responding to these opportunities?

Research, Development and Innovation is a common theme running through all of the opportunities outlined above. For this reason, IDA has an ever-increasing level of engagement with the R&D side of our client companies. We work with local site heads and their technical leads and also engage at the most senior level at corporate (Chief Medical/Scientific/Technical officer) to try to win new R&D-based investments for their Irish site.

Process research is hugely important in all areas of manufacturing. Bioprocess research is required to increase process yields in upstream and downstream, adopt new technology (such as single use systems/continuous perfusion) and ensure the product remains consistent through high-end analytics). In small molecule manufacturing, companies are adopting new technology such as biocatalysis, continuous manufacturing and handling of more complex chemistry and highly potent compounds. Research on next generation medical devices can enable new opportunities in drug delivery, including inclusion of microelectronics to monitor patient compliance and outcomes. A huge opportunity exists in Ireland to build better linkages between the biopharma, Medtech and ICT sectors and IDA is committed to driving this agenda. In next generation therapeutic development significant research will be required to optimise manufacturing processes as these products get closer to commercialisation. In CAR-T therapy, the ability to handle cell production and logistics will be a huge challenge while many new biologic drugs (such as oligonucleotides and antibody-drug conjugates) require both synthetic chemistry and bioprocess expertise. In the services area, ICT-based R&D in areas such as data analytics, cyber-security, digital content development & localisation and cloud computing will be key to the process of business transformation and investment in R&D in these areas will be vital.

IDA supports companies to invest in specific R&D projects through our RD&I grant program. R&D grants now make up a large majority of IDA's total grant funding budget and the life sciences sector is particularly active in accessing this grant program. Under the Government's new science strategy, we will seek to grow the supports available to companies to invest in in-house R&D. IDA also works with colleagues in Government to ensure continuous development of Ireland's tax proposition with regard to R&D, including the R&D tax credit and the newly introduced knowledge development box. IDA is also placing an increased focus on trying to foster opportunities for business-to-business collaboration and significant opportunities exist to explore this in life sciences in areas such as advanced manufacturing/factory 4.0 (with engineering companies and equipment vendors) drug delivery devices (with Medtech) connected health (Medtech and ICT) and next generation shared services (with ICT).



Minister for Jobs, Enterprise and Innovation, Richard Bruton, TD speaking at Alexion.

Opportunities exist for companies to further engage with academic research groups and IDA collaborates with sister agencies such as Enterprise Ireland, SFI and HEA to develop and promote academic research capability. The SFI funded centre SSPC continues to grow from strength to strength with the work they do with the small molecule manufacturing sector here. NIBRT is also seeing extremely strong growth in activity and engagement with industry and it is developing a growing reputation with the biotech sector in Ireland and internationally. IDA has committed additional funding to NIBRT to expand its process research activity, including recruitment of additional principle investigators and to win competitive grants from EI, SFI and Europe (H2020). The PMTC centre works on applied research with a variety of companies in the industry and collaborates closely with SSPC and NIBRT, seeking to maximise potential for synergies. IDA, EI and SFI are now working to develop the case for investment in an advanced manufacturing centre. This will likely focus heavily on “discrete manufacturing” and hence be of strong relevance to the medical device industry but could have strong relevance to innovation in advanced drug product and packaging lines, especially where drug delivery devices are involved. We hope to see progress on this initiative in 2016.

Beyond the manufacturing R&D area, we are seeing some very nice initiatives in areas such as preclinical and healthcare research, with Ireland remaining strong in areas such as immunology and companies like Pfizer and Abbvie investing in research collaborations in these areas with support from the SFI partnership program. This work can also open up opportunity for research support on next generation therapies through initiatives such as the EU H2020 program.

IDA is particularly interested in supporting more activity in the area of clinical research, not only trials conducted in Ireland but the management and analysis of trials conducted across Europe. As the industry starts to explore connected health technology, the “connected clinical trial” is an area of interest to IDA. Given the concentration of CROs in Ireland and the presence of some of the world’s leading tech companies, who have new technology to collect, connect and transform data, this could be an area ripe for development. It is IDA’s view that this area will develop faster in specific therapeutic areas and we will work closely with the Health Research Board and Clinical Research Coordination Ireland to build a case for more investment in areas which are ripe with opportunity.



Human capital Development

The ability of locations to win and retain high value FDI is heavily dependent on the ability of the location to supply the human capital in the context of a global “war for talent”. This is especially true in the pharma sector where companies have so much at stake as they supply global markets with life-saving drugs. IDA must engage with senior leadership in global pharma companies and reassure their HR experts that Ireland can supply the highly educated and flexible people required for their investments.

Much emphasis has been placed on the supply of talent for new investments in areas such as biotech drug substance manufacturing and advanced formulation (e.g. aseptic processing). With the global capacity constraints in biotech manufacturing outlined above, the location that has the most compelling talent value proposition will be in a strong position. IDA has invested heavily in NIBRT to address exactly this opportunity by providing a “flight simulator” environment for training and education in biotech manufacturing. NIBRT is on target to train almost 4,000 people in 2015. Many of these people are post-hire trainees, employed on sites which are in start-up or expansion mode (such as Lilly, Biomarin, Regeneron) where the company sends them for immersive, hands on training in NIBRT. Others are pre-hire trainees, undergraduates or unemployed candidates whose training is funded by the HEA or Department of Social Protection through programs such as Springboard or Skillnets. The NIBRT facility and training initiatives are unique world-wide and have been cited as a key factor in major recent investments by Alexion and BMS. We look forward to working with BPCI, the industry and the relevant agencies to drive further investment in human capital development for biotech. As new emerging therapeutics gain traction (such as gene therapy and cell therapy) NIBRT must continuously develop its training offering and collaborate with related organisations with expertise in these areas such as NUIG.



CEO of IDA Ireland, Martin Shanahan, VP and Site Head Regeneron Pharmaceuticals, Niall O'Leary and Minister for Jobs, Enterprise and Innovation, Richard Bruton, TD.

Of equal importance is supporting ongoing competitiveness and flexibility in well-established sites such as small molecule API and OSD sites. IDA's training grant program has been utilised extensively by a large number of existing facilities to upskill their workforce and support greater flexibility in the adaptation to new technology platforms. Much can be learned from the medical device sector in this regard as they have used IDA and other supports (e.g. Skillnets and Springboard) to drive operational excellence initiatives and to adapt to new technology. While a number of older manufacturing sites have suffered closure/divestment announcements in recent years, a number of other sites have seen turnarounds in competitiveness and reversal of closure decisions. IDA knows how hard-won each new investment is and hence we are equally committed to working with management on building a case for retaining and expanding existing sites where possible.

Summary

Overall the FDI pipeline remains strong in life sciences for 2016 and beyond. While we can never become complacent on topics such as R&D supports, competitiveness and skills, the opportunities are significant and exciting. In particular there are opportunities at the convergence points between small and large molecule, drug and device, pharma and ICT. If Ireland can continue to develop a joined up ecosystem of players in these areas, with companies and agencies working together, IDA will have a compelling value proposition to take to senior decision makers in industry.





COMPETITIVENESS

COMPETITIVENESS AT PFIZER

Pfizer is one of the world's largest pharmaceutical companies. Its global healthcare portfolio is centred on medicines and vaccines. The company operates in 175 markets worldwide with over 97,000 colleagues and has 65 manufacturing sites across the world. Pfizer is a research based pharmaceutical company focused on innovating to bring therapies to patients that significantly improve their lives and specializes in making medicines and vaccines that help people when they are sick and prevent them from getting sick in the first place.

As one of the first pharmaceutical companies to locate in Ireland (1969), Pfizer has a rich heritage of innovation and expansion over a forty year period. Pfizer has over 3,300 colleagues across 7 locations in Ireland.

Pfizer is one of Ireland's leading employers and the largest pharmaceutical sector investor with a total capital investment by the company in Ireland exceeding \$7billion.

Pfizer's business interests in Ireland are diverse which include manufacturing, shared services, R&D, treasury and commercial operations.

Ireland is a leading manufacturing base for Pfizer globally, exporting to global markets. There is a manufacturing presence in Active Pharmaceutical Ingredients, Solid Dose Pharmaceuticals, Sterile Injectables, Vaccines and Biopharmaceuticals.

- Pfizer has two Active Pharmaceutical Ingredient (API) sites located next to Cork harbor and a short distance from Cork City. They are the Ringaskiddy API site (approx. 480 colleagues) and the Little Island API site (approx. 140 colleagues).



Pfizer Ringaskiddy



Pfizer Little Island

- Both sites are key manufacturing facilities in the Pfizer Global Supply Network specializing in new product introduction and bulk manufacturing of a wide range of Pfizer's patented and non-patented products.
- Products made across the two sites include treatments for cholesterol, lung cancer, diabetes, Oncology and a breakthrough therapy for the potential treatment of patients with breast cancer. Some of Pfizer's newest most innovative medicines targeted at oncology and pain are also manufactured at the Cork Pfizer plants. Pfizer Cork is also the default location for all Pfizer Small molecule new products.
- Consistent with peer Pharmaceutical companies Pfizer has seen a significant shift in its product portfolio over the last decade. The large volume blockbuster products have gone off patent and the research portfolio consists of smaller volume niche medicines. For the Cork API Sites this has had a dramatic effect on the business model.
- The sites were built and designed to make large volume products which are now off patent. To secure ongoing manufacturing of these off patent large volume products the sites had to become much more flexible and competitive. Plus to ensure Pfizer in Cork continue to launch and commercialise all small molecule new products the sites also needed to secure investment to fundamentally redesign one of the production buildings, removing all the large reactors and equipment replacing with unique scale and capability.
- The Cork sites have achieved much better competitiveness. Colleagues and the unions have played a big part in this by becoming more flexible resulting in competitive costs versus benchmark. The technical excellence of Pfizer colleagues combined with operational performance consistently delivering technically complex products.

Pfizer's business interests in Ireland are diverse which include manufacturing, shared services, R&D, treasury and commercial operations.





Pfizer Grange Castle

The Cork Sites approach to competitiveness is based on 3 focus areas. This is a continuous journey and while significant progress has been made Pfizer believe there are many opportunities to further improve competitiveness and enhance our role in the Post LOE world.

The 3 areas focused on to achieve competitiveness:

Best Chemistry Focus

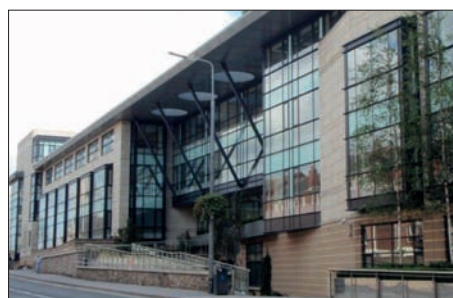
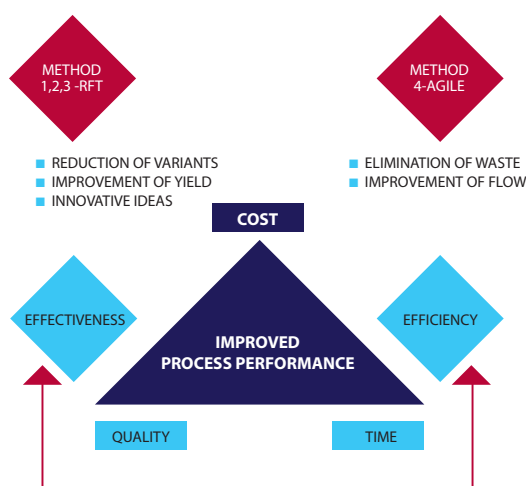
- Ensuring the best and most competitive Chemistry process

Site Optimisation (Efficiency)

- Using lean operational tools and managed by the Hoshin process the sites have focused on ensuring the operating process and environment is efficient and lean
- Lean tools are applied to ensure the operating environment is most effective

Site Performance and reputation for delivery (Effectiveness)

- Operational Excellence and a focus on eliminating variation and consistency of flow/standard work



Pfizer GFSS



Pfizer Citywest

Best Chemistry

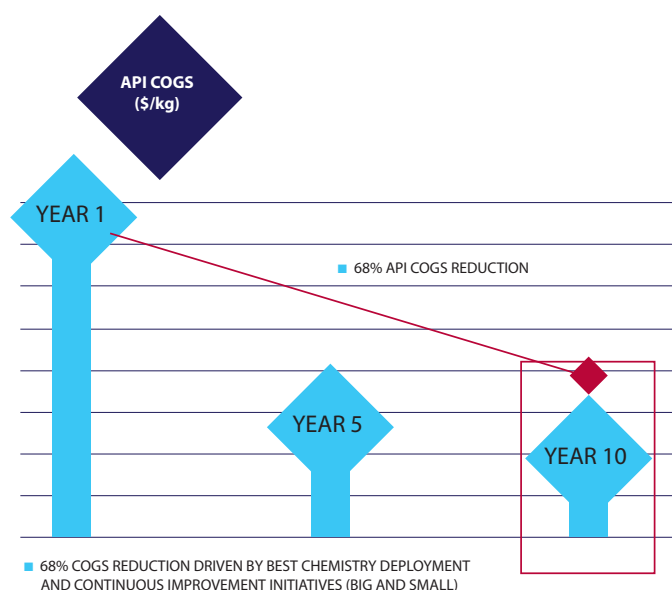
As part of the competitiveness journey Pfizer believe that optimal technology leads to optimal competitiveness and Process redesign is at the core of Pfizer manufacturing competitiveness strategy. To support this strategy there is a dedicated Blue skies chemistry team (the Process development centre) based at the Cork sites. This team focus on route optimisation for many of the small molecule products globally.

Over the last decade this group have had a Transformational impact on Pfizer manufacturing. Some examples of this teams achievements:

- 6 Worldwide refilling's complete on priority blockbuster products
- Average cost reduction >50%
- Average footprint reduction 40%
- New technology focused on:
 - biocatalysis
 - continuous processing
 - advanced process output control
 - modeling
 - new chemistry
- From an Ireland perspective this work has been very well supported with the appropriate systems like SSPC/PMTC/NIBRT etc to support Industry attaining optimal technology.
- In summary the relentless drive for competitiveness across all products continues. Combination of Best chemistry and second generation processes plus the focus on reduction of variation throughout all area of sites combined with Lean and the elimination of waste has given us:
 - Award winning performance in the fundamentals
 - Competitive Cost of goods for our post LOE products



Pfizer Newbridge





COMPETITIVENESS

MANAGING A GLOBAL SUPPLY CHAIN FROM IRELAND

Mallinckrodt Pharmaceuticals is a global business that develops, manufactures, markets and distributes specialty pharmaceutical and biopharmaceutical products and therapies, as well as nuclear imaging products. Areas of focus include autoimmune and rare diseases in specialty areas like neurology, rheumatology, nephrology and pulmonology; immunotherapy and neonatal critical care respiratory therapies; analgesics and hemostasis products; and central nervous system drugs. The company's core strengths include the acquisition and management of highly regulated raw materials; and specialised chemistry, formulation and manufacturing capabilities.

Mallinckrodt's Irish Presence

Operating today as Mallinckrodt Pharmaceuticals Ireland Ltd., the company has had a presence in Ireland for over 20 years, and in May of 2015 the company announced a multi-million Euro investment to expand its Dublin-based operations. A new state-of-the-art manufacturing facility and office building will be built at College Business and Technology Park, Blanchardstown, Dublin 15 to house existing global external manufacturing operations management, international payroll, various finance operations and produce a key product for the company. This significant capital outlay brings Mallinckrodt's cumulative investment in Ireland to more than €200 million over the past 22 years.

A significant operational activity performed in Ireland is the management and oversight of Contract Manufacturing Organisations (CMOs) by Mallinckrodt's Global External Supply (GES) group. The GES function was chartered in 2009 in the U.S. and later reorganised in 2014 to be headquartered in Dublin with additional personnel in the U.S. and other European countries. This group is responsible for all Mallinckrodt products manufactured by external companies and for internal manufacturing sites that are contracted to produce non-Mallinckrodt products for external customers. GES also leads the integration of new Mallinckrodt products – whether developed through the company's R&D pipeline or acquired through business development activities - where the products are manufactured by external parties.

The company's Irish-based GES organisation, as noted, is a global team with employees based in five different locations across five different time zones. The products managed by this group are diverse and complex, ranging from biologically derived drugs to controlled substance products; transdermal patches, and medical device-drug combination products. This international team is composed primarily of scientists and engineers working in quality assurance, operations, and performance excellence with support from supply chain, finance and procurement personnel. With qualifications ranging from bachelor's degrees to masters and doctorates, all members of the GES team have multiple years' experience working in an internal manufacturing environment and/or external manufacturing organisations.

Supply Chain Collaboration

External, or “collaborative” manufacturing, whereby manufacturers contract with other companies to provide products and services, is becoming increasingly important in the pharmaceutical industry. Many companies choose external manufacturing partners for efficiency, and for access to experience and specialised capabilities. Mallinckrodt, like other pharmaceutical companies, is using an increasing number of CMOs to manufacture key products for its markets. In fact, a number of companies that Mallinckrodt acquired over the past two years relied entirely on a network of external manufacturers in their supply chain, utilising no internal manufacturing operations.

The challenges of managing an externally manufactured product are very similar to an internally managed one; the team must ensure that the right product at the right quality and cost is delivered to the customer at the right time. The main difference, however, is that the company providing the product is an external manufacturer typically supplying multiple products to multiple companies, and the CMO owns the direct control over the manufacturing process. Mallinckrodt’s management of such diversity and complexity in a virtual world requires skillful handling, and the establishment and development of long-term relationships with these key suppliers is critical to the success of managing a collaborative network.

Benefits to Locating in Ireland

More and more companies are locating the management of external manufacturing operations in Ireland, primarily driven by the availability of experienced technical, operational and back-office talent. The country has had a significant pharmaceutical and medical device industry for over 30 years, providing a wealth of experience managing complex healthcare products in a global regulated industry, and substantial talent resources for companies looking to operate a virtual network from Ireland. While historically the manufacturing industry here has been internally focused, those skills are complementary to ones required for managing an externally manufactured product. Numerous Irish support services such as regulatory, legal, engineering and finance expertise are also key factors in successfully establishing a GES organisation.

In 2015, Pharmachemical Ireland (PCI), recognising the increasing number of companies managing virtual product manufacturing from Ireland, established a services platform group. Under the auspices of PCI, companies like Mallinckrodt can come together to discuss common challenges and best practices, including recent meetings held with Irish regulatory agencies which were very well attended.

In short, just as Ireland has been a prime location for manufacturing operations of all kinds, it is equally beneficial to those companies looking to expand or establish their global supply operation in the country as well.



Photo montage of planned new administrative office and manufacturing building currently under construction at College Park Dublin 15.

LILLY'S BIOTECH PIPELINE

Lilly has invested over one billion EUR in its Kinsale site to date—including 630 million EUR in new facilities since 2006 that positions Ireland as a key location for Lilly's biotech pipeline.

Eli Lilly first invested in Ireland in 1980. The company initially developed a classical, small-molecule, organic synthesis business that supplied intermediate products for the Lilly network. This mission evolved early on to supply final bulk product to our global markets and ultimately Kinsale became a key launch site for new Lilly products entering the market.

Through ongoing investment in our people and facilities, we have become a center of excellence for chemical synthesis and the commercialisation of new molecules. Several new medicines are currently undergoing development work in Kinsale and new manufacturing technologies such as process analytics and continuous processing are being deployed in Kinsale in collaboration with our colleagues in Process Development in the United States.

In 2006, Lilly announced that Kinsale would become the main center for the manufacture and commercialisation of active ingredients for its new biopharmaceutical medicines.



Eli Lilly's Biotech manufacturing facilities at its campus located outside Kinsale in Cork, Ireland.

To support this changing mission, a significant investment of over €300 million in biopharmaceutical manufacturing and commercialisation facilities was made and operations began in 2011. This investment allowed the site to diversify into technologies to produce monoclonal antibodies (mAb's) and provides the capability to further enhance the company's ability to bring treatments for illnesses such as cancer and diabetes to patients worldwide in partnership with our colleagues in the US.

In recent years a further €330 million investment in a new manufacturing facility was made to add to the existing biopharmaceutical commercialisation and manufacturing operations. This new facility will commence the manufacture of medicines for the treatment of a number of disease states in 2017.

The Biotech operation has a staffing of over 350 highly qualified engineers, scientists and operations personnel and now accounts for over two thirds of the site population.

These investments in the Kinsale site represent the culmination of Lilly's strategy to ensure sufficient manufacturing capacity for potential biotech medicines advancing through the clinical and development pipeline. Lilly now has 65 assets in development; about 50 percent of which are biotech compounds. Many of these investigational therapies require similar production technologies, and will be manufactured in Kinsale.

The successful diversification of the Kinsale site is a reflection of its excellent performance record, the talent of the workforce, and the support from Governmental agencies such as IDA Ireland in over 35 years of manufacturing medicine in Ireland.





COMPETITIVENESS

CREATING A NEW BIOLOGICS MANUFACTURING FACILITY IN IRELAND

Bristol-Myers Squibb is an evolving company and we now stand on the frontier of new possibilities regarding patient care. With us, the work you do can be powerful and life-changing, uncover new stories, and discover life-changing opportunities.

In an effort to significantly expand our biologics manufacturing capacity, continue to innovate and strengthen our biologics, immuno-oncology and cancer treatment drug development, we are building a state-of-the-art facility in Dublin, Ireland.

The cutting-edge, 30,000 square metre project will house six 15,000 litre bioreactors and a purification area, as well as contemporary office and laboratory spaces. Currently under construction, the plant is built on the grounds of the company's previous bulk pharmaceutical manufacturing plant, and is the fastest built plant of this size and specification in history.

Immuno-oncology is a rapidly evolving field that focuses on the immune system in the fight against cancer. Global mortality remains high for many patients with advanced tumors. The goal of immuno-oncology research is to fulfill the unmet need for improving clinical outcomes in several advanced cancers.

We are dedicated to finding new ways to stop cancer from evading the immune system, thereby restoring the body's natural ability to recognize and eliminate cancer. As well as providing a place to develop and focus on our immuno-oncology drugs, the facility will have the capability to work across therapeutic areas and enable us to produce transformational medicines with enormous efficiency.



The new high-tech facility will have modern laboratory amenities. Our employees will work and collaborate with other teams and their work will truly make a difference to patient's lives.

Throughout the last few years, we have continued to pursue our community-based activities across the globe and across therapeutic areas to help underserved populations and to benefit the places in which we live and work. The new Dublin facility at Cruiseraeth represents a significant investment in the local area building on our established presence in Ireland for more than 50 years. This investment provides opportunities to potential and existing employees, as well as offering careers in a place that supports best-in-class systems and processes that is always striving for continuous improvement. Local management has developed a strategy endorsed at the corporate level to ensure our continued growth and success. Opportunities include enhanced operational excellence skills with a value stream approach to increase efficiency across the product supply chain and competitive commercial processes at launch.

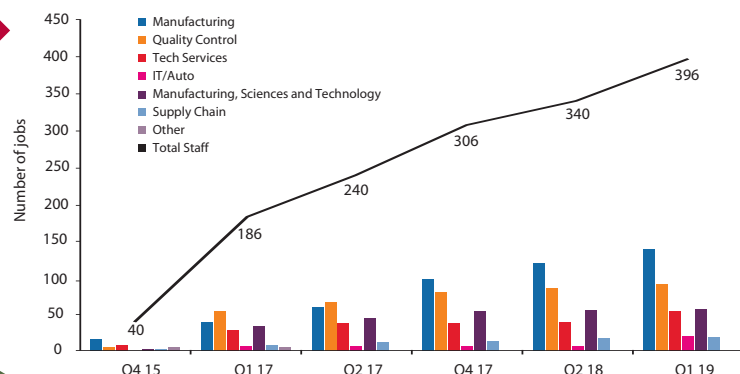
We are hiring now with staff increasing to a targeted 400 roles by 2019 across many business functions in operational and lab-based roles including manufacturing, engineering, quality, manufacturing science and technology (MS&T) and operational excellence professionals.

Bristol-Myers Squibb has a healthy pipeline of products and is dedicated to providing excellent opportunities for growth and career development. A company with a strong commitment to top quality people management, we are looking for individuals who have passion, a sense of urgency, are accountable and innovative.

Our Company

Bristol-Myers Squibb is a global specialty BioPharma company firmly focused on its mission: to discover, develop and deliver innovative medicines that help patients prevail over serious diseases.

RECRUITMENT TARGETS TO 2019



LEGAL SUPPORT IN IRELAND – ENGINEERED TO MAKE A DIFFERENCE

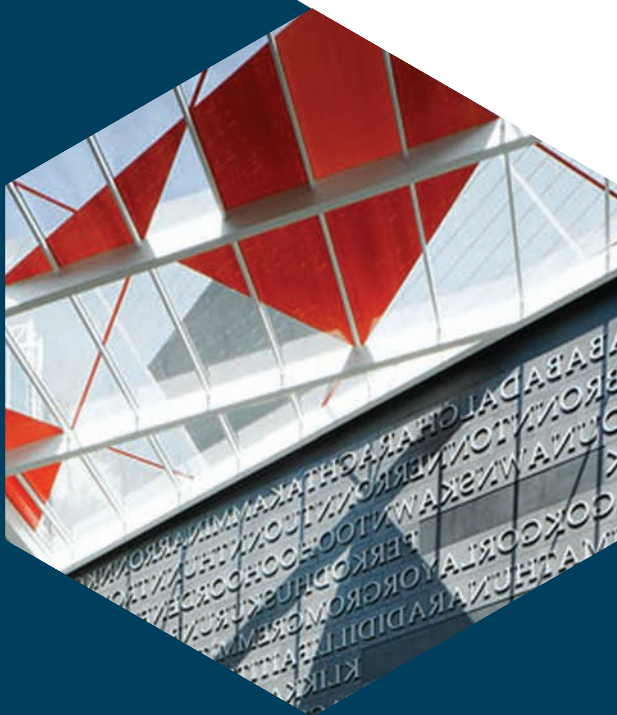
The importance of the pharmaceutical/biotechnology industry to Ireland and Ireland's commitment to its continued growth cannot be overestimated. From its beginnings as a traditional manufacturing base nearly 50 years ago, Ireland has matured and developed into an internationally recognised global supply chain hub and centre of excellence for innovation in advanced process manufacturing. With this has also come the development of related 'spin-out' areas such as clinical trial activities alongside an increased focus and investment in other areas such as pre-clinical research and development and connected health technology.

The key ingredients for Ireland's continued attractiveness to the sector are clearly led by the appetite for growth and innovation amongst the industry itself, the development of expertise in academic and research institutions and government driven support in the form of competitive tax incentives and funding initiatives. Other elements of the value proposition are the wide range of related and specialised support services to the industry that have grown with it and this includes market leading legal services.

Specialists within Ireland's legal professions have had the benefit of 'growing up' with the industry in Ireland over its development in the past 50 years and have built up an exceptional knowledge base and a thorough understanding of the issues facing and driving the industry. This symbiotic relationship has resulted in a highly specialised legal offering being available to both the existing industry within Ireland and to new entrants to the market that further enhances Ireland's value proposition as a leading location for the supply and development of pharmaceutical/biotech products. Not only do these legal specialists help overcome the legal challenges faced by their individual clients and help to drive their business forward, but there is a high level of engagement between legal professionals and industry bodies such as BioPharmaChem Ireland and the Irish Pharmaceutical Healthcare Association (IPHA) and government bodies such as the Irish Development Authority (IDA) in their shared desire to attract continued investment in the sector in Ireland and to drive any necessary changes to support it.

There is a hive of day-to-day activity in the sector in Ireland with investments at all levels of growth, start-up and university spin out activity, research and development projects, and strategic collaborations and alliances both between industry players and with research and academic institutions. William Fry has the privilege to work with an extensive range of players within the industry. The trends we have observed in recent years reflect those already identified by other commentators in this document, in particular the rise of importance of biopharmaceuticals (both originator and biosimilar), orphan/speciality drugs and drug delivery technologies, collaborations and convergence with other sectors, particularly ICT, the increase in regulatory compliance requirements (such as the Falsified Medicines Directive) and at the commercial and clinical side of the industry, the importance of new technology and legal issues in the fields of ehealth and connected technology, particularly in respect of data mining/analysis and cyber security.

In addition, and inevitably for a country which operates as a global manufacturing and supply chain hub, freedom to operate issues continue to arise and patent litigation (both enforcement and defence) continues to represent a large and core part of the work William Fry does in the pharmaceutical/biotech sector. Indeed, having regard to the size of the country, the Irish Courts see more than their fair share of patent disputes and this is testament to the activity levels in the sector in Ireland. The increasing familiarity of the Irish Courts with these highly specialised disputes and the fast-track and close case management procedures of the Commercial Division of the Irish High Court and the new Court of Appeal can offer comfort to those pharmaceutical/biotech companies operating in Ireland, for whom patent litigation is an inevitable and necessary part of their business. Further, whilst the law often tends to follow somewhat behind the pace of business, we think it is true to say that Ireland is committed to ensuring that the legal landscape for the sector is shaped to be best in class, taking into full account the interests of all stakeholders. The introduction early last year of changes to the Irish 'bolar exemption' provisions to bring it more into line with other European member states is an example.



IRISH TALENT AT THE TOP

TALENT



Paul Duffy,
Pfizer

Dr Paul Duffy is Vice President, Biopharmaceutical Operations & External Supply for Pfizer. In his current role Paul has responsibility for 26 manufacturing sites globally with over 8,000 colleagues that manufacture many of Pfizer's leading medicines, his team also manages a network of over 200 external supply partners. Paul joined the Company in 1991 and has held various roles over the years with increasing responsibilities. He began his career as a development chemist with SmithKline Beecham.

Paul holds a B.S. in Chemistry, a Ph.D. in Synthetic Organic Chemistry from the University College Galway and an M.B.A. from the Open University, U.K.

Paul was recently selected as Chair of the newly established Workplace Relations Commission following a Ministerial appointment. He is also Chair of Pfizer's all Ireland working group, the Country Coordinating Committee. He is a former President of the American Chamber of Commerce and has served on the board of the Irish Development Authority.



Julie O'Neill,
Alexion

Julie is Executive Vice President, Global Operations for Alexion Pharmaceuticals. Prior to that, she served as the Vice President for Operations for Gilead 1997 to 2014.

A graduate of Trinity College Dublin with a BSc in pharmacy, Julie has also attained an MBA from University College Dublin and is a Chartered Director.

Julie is currently Chairperson of the National Standards Authority of Ireland, a member of the Board of the American Chamber of Commerce in Ireland, and the National Institute for Bioprocessing Research & Training. Julie is the former Chairperson of Pharmaceutical Ireland and former President of the Irish Business Employers' Confederation (IBEC).



Liam Murphy,
Henkel

Liam Murphy is President of Henkel UK and Ireland and Global Vice President of Safety, Health and Environment for Henkel Adhesive Technologies. Having worked at Henkel for over 36 years, he has a wealth of experience in various roles and holds a Master of Industrial Engineering and a Diploma in Chemical Engineering from University College Dublin and a Bachelor in Natural Science - Chemistry from University of Dublin, Trinity College.

Henkel is a global leader in brands and technologies and part of Liam's role is to ensure that Health, Safety and Environmental performance is continuously improved globally. He is also responsible for chairing the UK board, acquisitions and managing risk while supporting the various businesses and functions.



Greg Timmons,
Takeda Pharmaceuticals

Greg Timmons is Vice President and Head of Business Process Redesign for Takeda Pharmaceuticals. Reporting to the CFO, Greg leads a global team responsible for evaluating and redesigning all of the companies end-to-end business processes and systems. Having been active in acquisitions over the past 10 years, the role of business process redesign is a key enabler to establish One Global Takeda. Consolidating and harmonizing diverse processes and platforms will enhance Takeda's agility to adapt to changing business environments.

Greg has brought 30 year of international and operational experience to his role. Having lived and worked in Japan for 10 years with roles in IT, investment and pharmaceuticals, he returned to his native Ireland to spend 20 years with Takeda, establishing and growing their operations and worldwide supply-bases both in finished pharmaceuticals and active pharmaceutical ingredients.

Greg received a Bachelor of Science in Mechanical Engineering from Dublin Institute of Technology.



David Keenan,
Mallinckrodt
Pharmaceuticals

Dr. David Keenan is Vice President of Global External Supply and Managing Director of Mallinckrodt Pharmaceuticals Ireland Ltd. since 2014. He is a member of the Mallinckrodt Global Operations Team. David joined Mallinckrodt in 2006 as Plant Director of the Dublin Bulk API site and then served as Senior Director of Manufacturing for Mallinckrodt's Contrast Imaging and Delivery Business from 2011 to 2014. He is also a director of a number of Mallinckrodt companies in Ireland.

A graduate of Maynooth University with a BSc and PhD in Chemistry, David also attained an MBA from Dublin City University.

David is currently Vice Chairman of BioPharmaChem Ireland and Chair of the Services Platform within BioPharmaChem Ireland.

INNOVATION

SUSTAINABILITY FOR THE FUTURE

Janssen Biologics (Ireland), based in Ringaskiddy, Co. Cork, is part of the Johnson & Johnson family of companies. The 100-acre greenfield site was purchased in 2004 when Janssen needed additional capacity to manufacture monoclonal antibody products. Construction commenced in 2005 and the plant began operations in 2009. Originally built to manufacture two block-buster products, this state of the art facility now accommodates multi-product and clinical manufacture. Cleanroom space was retrofitted to include two small scale manufacturing suites which enabled early clinical phase product manufacturing.

Janssen Biologics (Ireland) is committed to sustainability and is aligned with the Johnson and Johnson credo value to 'maintain in good order the property we are privileged to use, protecting the environment and natural resources.'





Wind Energy:

In April 2014, Janssen Biologics (Ireland) marked an exciting milestone in its push to go greener when the electrical load for the site was transferred to a newly operational 3MW (megawatt) wind turbine. Not only is the site now powered entirely by wind, but any excess electricity can be sold and exported to the national power grid. This sustainable energy project will allow for the generation of renewable electrical energy, reducing the site's electrical energy costs and CO₂ emissions and improving its competitiveness well into the future.



Janssen Biologics (Ireland)
has reduced its annual
Carbon (CO₂) emissions
by an average of 24%
since the wind turbine
began operation in 2014.

Collaboration:

The wind energy project is an excellent example of collaboration with other pharmaceutical companies. The Cork Lower Harbour Energy Group (CLHEG) comprises of DePuy Synthes, GSK, Janssen Biologics and Novartis. In 2011, supported by the IDA, the CLHEG began to look at wind energy opportunities in Cork Harbour. Following the granting of planning permission, the construction of three 3MW wind turbines at DePuy Synthes, GSK and Janssen Biologics got underway in 2013. An important part of the project was the use of a community outreach team to assist with grant funding for sustainable initiatives. Through sharing resources, lessons learned and best practice, this collaborative effort has increased competitiveness, increased energy efficiency, and benefitted the local environment and local communities.

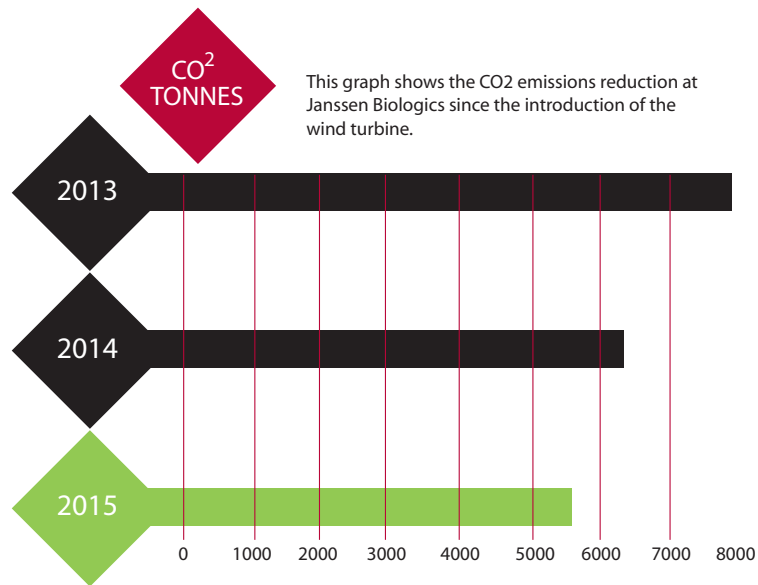
“Bringing the wind turbine online was a significant achievement, and many people across the site spent a great deal of time and effort to reach this milestone,” said Liam O’Leary, Project Lead, Janssen Biologics (Ireland). “The project was implemented safely, within budget, and even ahead of schedule despite poor weather conditions.”

Recognition:

Janssen Biologics (Ireland) received the ISO 50001 Energy Management standard in 2014. The Cork Lower Harbour Energy Group (CLHEG) received the Collaboration Award at the SEAI 2014 Sustainability Energy Awards from Minister for Energy, Alex White.

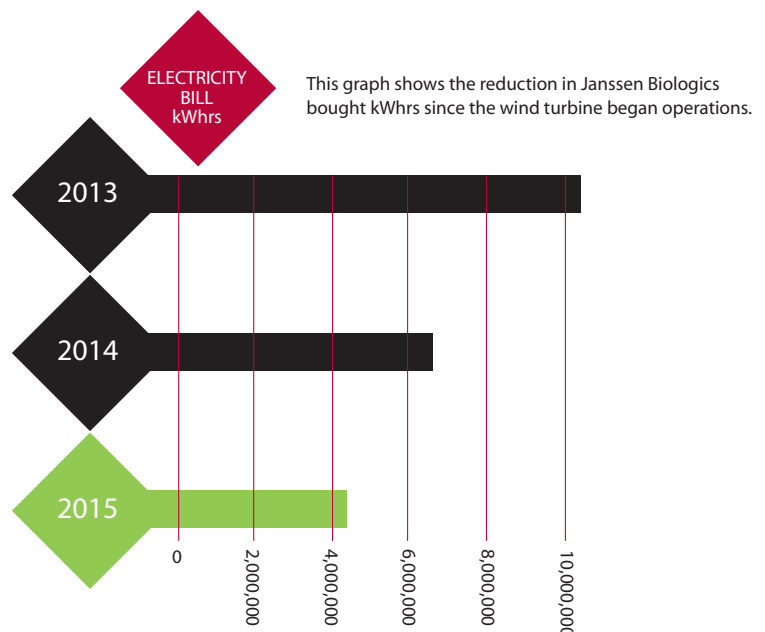
CLHEG demonstrated how a collaborative venture between four companies in the pharmaceutical/medical devices sector can have widespread benefits.





Conclusion:

As a member of the Johnson & Johnson family of companies in Ireland, the Janssen Biologics (Ireland) wind energy project is aligned with the J&J Campus Ireland Energy Team's vision to be recognised globally as the benchmark for Energy Management and to be a leader in energy cost reduction, efficiency, sustainability, research and CO₂ reduction. Thanks to this green initiative, Janssen Biologics (Ireland) is achieving a win-win reducing environmental impacts, reducing energy costs and helping to make the site more competitive for future investment opportunities.



"Bringing the wind turbine online was a significant achievement, and many people across the site spent a great deal of time and effort to reach this milestone."

Liam O'Leary, Project Lead



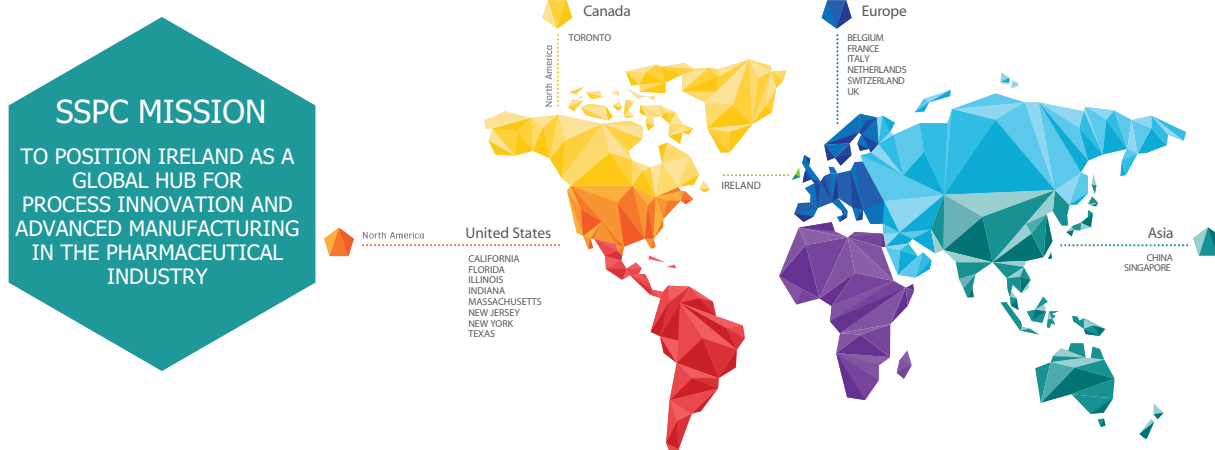
ACADEMIC COLLABORATION

FROM THE MOLECULE TO THE MEDICINE

At the heart of Ireland's success as a global leader in the pharma sector is its commitment to innovation. One need not be an insider of industry or a seasoned scientist to realise the value that pharma and biopharma hold for a nation whose ties to the sector span just over half a century—the numbers speak for themselves. Pharma has created nearly 25,000 Irish jobs and continues to attract foreign and domestic investment for many reasons; a highly educated and informed skilled work force a national strategy in support of impactful research and a desirable corporate taxation policies to name but a few.

Beyond the numbers, which tell their own story of what pharma has meant to Ireland, is another equally important story. Through innovation and collaboration, Ireland is poised to be a global hub not only for advanced manufacturing of pharmaceuticals, but also as a new frontier for process innovation at the development stages—from the molecule to the medicine. At the fore in this new century of Irish pharma is the Synthesis and Solid State Pharmaceutical Centre (SSPC) eager to lead, to collaborate, to innovate.

The SSPC began as a research cluster focussing on the crystallisation stage of the active pharmaceutical ingredient (API) in the manufacturing process. The cluster, active from 2007-2013, grew out of a successful collaboration between researchers at the University of Limerick and Aughinish Alumina (2004-2007). The crucial cooperation between academia and industry created an opportunity to overcome challenges faced by the sector. Forming the cluster in 2007 magnified the potential of similar collaborations in engaging the expertise of five academic institutions and nine industry partners, and supported by €9 million from Science Foundation Ireland and industry.



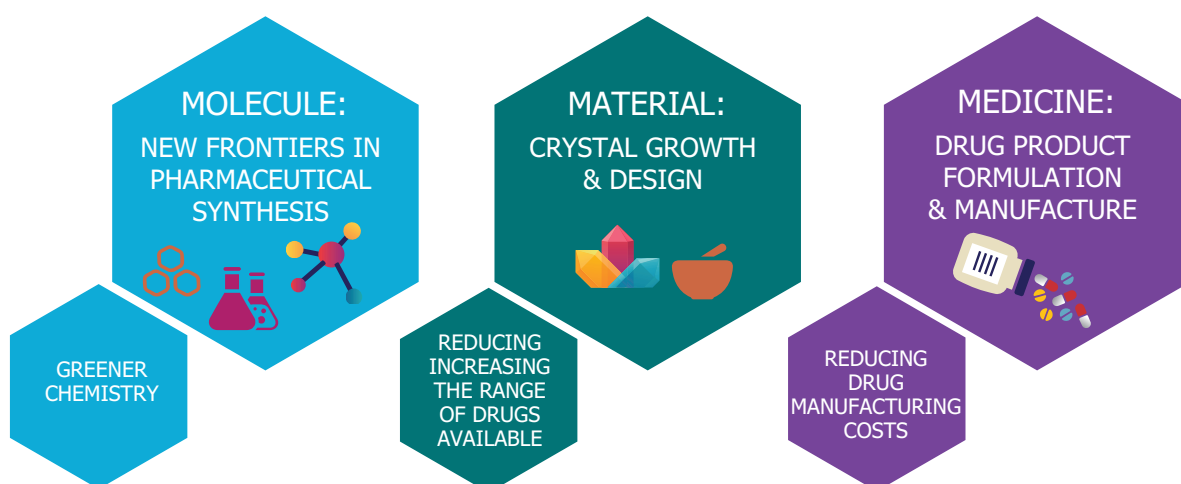
Now a research centre comprising twenty-two industry partners, nine research performing organisations, twelve international academic collaborators, nineteen research projects, thirty-eight investigators, sixty PhD candidates and twenty-eight post-doctoral research associates, the SSPC is honoured to be working alongside the country's most talented researchers and industry experts to broaden the knowledge-sharing base in Ireland and globally and to meet the challenges of the pharmaceutical sector.

As the centre has expanded, so has its focus. Drawing from the expertise of its diverse membership, SSPC is dedicated to developing medicines that are cleaner, more widely available and more affordable. To this end, the centre's projects focus on three primary strands:

- New Frontiers in Pharmaceutical Synthesis to develop cleaner methods of developing APIs
- Crystal Growth and Design to harness the knowledge of the mechanisms that control the crystal properties of the material through novel approaches of production such as nano-processing and continuous manufacturing
- Drug Product Formulation and Manufacturing to bring scientific and process engineering expertise to bear on the development of new and more effective medicines

The ethos of the SSPC continues to promote collaboration and innovation equally among all members, and has even successfully fostered cooperation between potentially competitive industry leaders. This culture of knowledge-sharing in the pre-competitive space is equally apparent in its other related projects including linker projects and its recently formed biopharmaceuticals spoke in partnership with NIBRT. The unique ties that bind the SSPC members together are strengthened by dedication to communication both among its many members and to the larger, global pharma community. Communication outreach platforms include the centre's lead role in the development of Therapeutics.ie, a researcher repository encompassing all capability in Irish academia relevant to the (bio)Pharma, and the Best Practice Crystallisation (BPX) portal, with more than 16,000 web users globally.

To date, the centre has attracted €65 million in investment from the Irish government, Science Foundation Ireland, industry partners and additional State and European funding bodies. This support, coupled with SSPC's investment in human capital—its people—make SSPC's role in the story of Irish pharma an exciting one.



CONTINUOUS MANUFACTURING PLATFORM - THE NEXT GENERATION OF MANUFACTURING MEDICINE

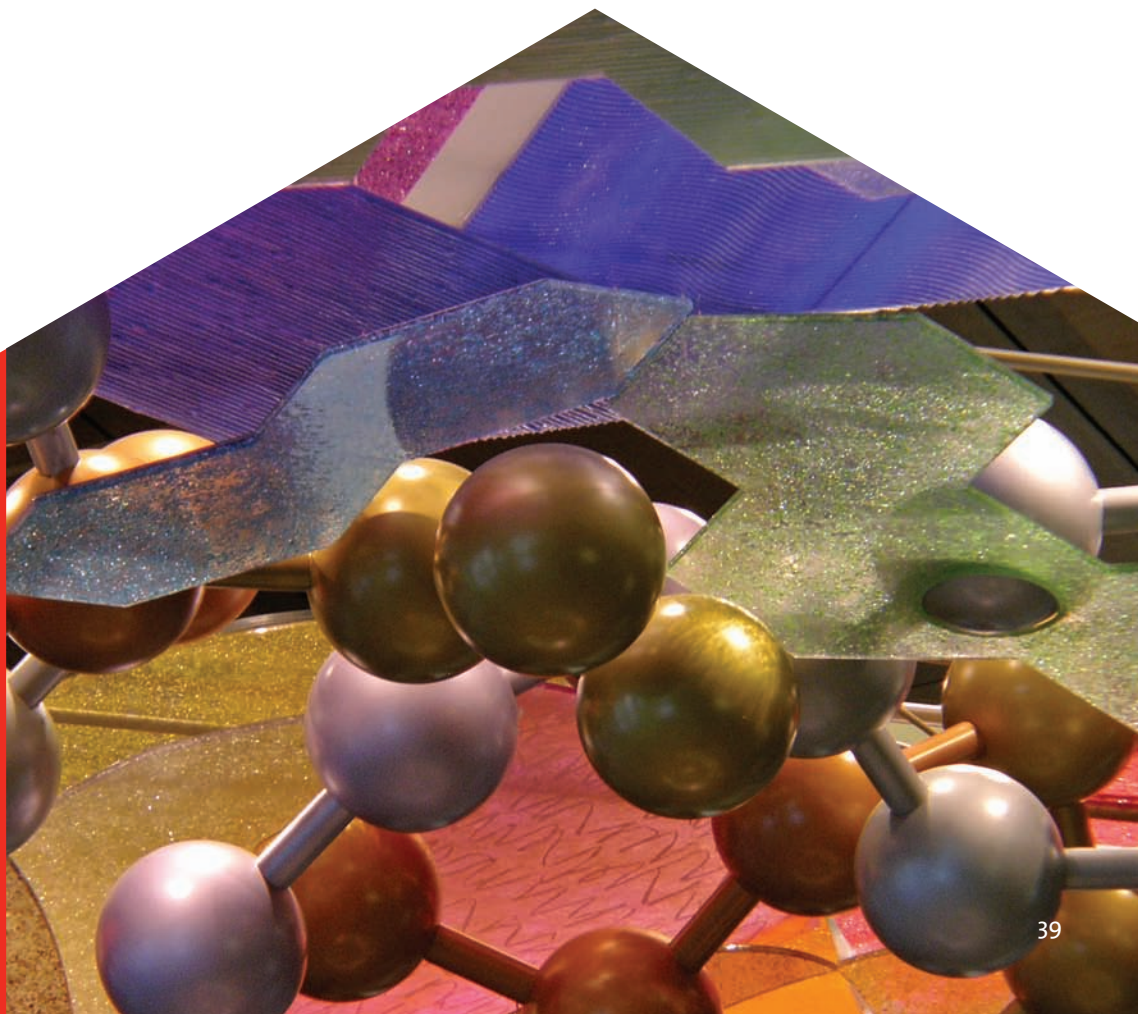
Eli Lilly and Company is a leading, innovation-driven corporation committed to developing a growing portfolio of pharmaceutical products that help people live longer, healthier and more active lives.

The company utilises a range of advanced chemical and biological processes to produce active pharmaceutical ingredients across a number of therapeutic categories, including oncology, diabetes, neuroscience and autoimmune disorders. These products are formulated at various facilities to supply medicines to patients worldwide.

The Kinsale manufacturing facility has evolved and transformed its mission and business focus over its thirty years in Ireland. Today the site not only continues to be a worldwide manufacturer and supplier of the company's newest Small Molecule medicines, but has expanded its role to become the company's primary location for manufacture of the company's biopharmaceuticals portfolio. In addition, it has now also become a strategic location for the commercialisation and scale up of Lilly's small molecule and biopharmaceutical pipeline of medicines.

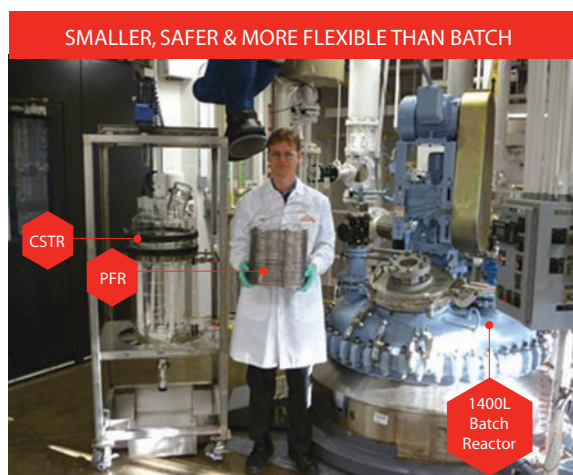
**Eli Lilly Small Molecule continuous manufacturing –
a new technology breakthrough for Pharma manufacturing**

The Lilly Kinsale site has gained over 30 years of Small Molecule manufacturing expertise in the commercial production of active pharmaceutical ingredients. During the past decade, the Kinsale site has developed a low volume manufacturing facility which has positioned the company as a commercialisation hub for new chemical entities. As part of our continuous evolution and the transformation of our facility, Scientists and Engineers from Kinsale have combined with colleagues in Research and Development (R&D) in Indianapolis, US, to pioneer continuous processing technology which will revolutionise how medicines are manufactured into the future and which, in addition, has the capability to yield several Productivity, Quality, Environmental and Safety benefits.



Continuous Processing versus Batch Processing

Continuous processing is a mode where a reaction is run in a flowing stream and material is continuously produced in kgs per hour, rather than in batch mode over a number of hours. In continuous processing, the manufacturing train is always full, and because of this, the output rate is better than batch processing for similar sized equipment.



30L Continuous Stirred Tank Reactor (CSTR)
or
0.8L Plug Flow Reactor (PFR)

≡ 1400L Batch Reactor

Continuous processing has now been identified as a key capability for Lilly, and over recent years the technology has been proven through the successful manufacture of a number of new chemical entities.

Small Volume Continuous processing utilises a flexible platform at a smaller scale than traditional batch processing, to manufacture commercial quantities of the medicine. Traditional large scale facilities would typically utilise 10,000L batch vessels. However this new technology utilises small (30 -50L), plug flow, or continuous stirred tank reactors located in fume hoods, equivalent in throughput to 1400L batch reactors. The small size of the equipment involved means the manufacturing footprint is greatly reduced in comparison to the existing, large, batch facilities. Throughput comparisons show significant advantages for Small Volume Continuous processing over batch by achieving the same total output in approximately one-third of the time. Additional benefits include improved safe operating conditions, improved quality profile and reduced environmental footprint.

Lilly's Small Molecule Development Portfolio

Lilly's Small Molecule portfolio is now moving towards lower volume products, typically less than 5 MTPA. To support this portfolio, Lilly in Kinsale is now investing €20M to build a dedicated Small Volume Continuous manufacturing plant with a planned manufacture start-up date in 2017.

The new facility will consist of 11 walk-in fume hoods and the equipment will be skid-mounted and mobile, allowing the flexibility to align with future processing requirements.

As a consequence of this development the Kinsale site is now well positioned to help fulfil the commercialisation of the newest portfolio of Lilly's newest Small molecule medicines and in doing so will ensure we will be at the forefront of transforming how the company develops and manufactures our medicines into the future.



Layout and visualisation of Lilly's Small Volume Continuous manufacturing facility



SKILLS

10 YEARS BOOSTING SKILLS IN THE PHARMA SECTOR

The PharmaChem SkillNet has been developing and providing training programmes to the pharmaceutical, bio-pharmaceutical, chemical and medical device sectors for ten years. Established in 2006, the network facilitates subsidised training and networking under the Skillnets training programme. The network operates as a business resource for organisations nationally and has been formed in response to a real need in the workplace for “best in class” training and development at a realistic and very affordable price. Since 2006 the network has successfully trained 7,500+ employees trained over 27,000+ training days and had over 70 network members.

TESTIMONIAL

1

“We have been using Pharmachem Skillnet back as far as 2008, for us, this is the best way to source the right type of course for our type of industry.

The courses are always of high standard. The learning gained from our employee's is always well used and related to the work place. It is a very efficient way to network with all the other pharmaceutical companies.

One of the benefits of the Skillnet group is benchmarking and agreeing best practice on problematic topics.

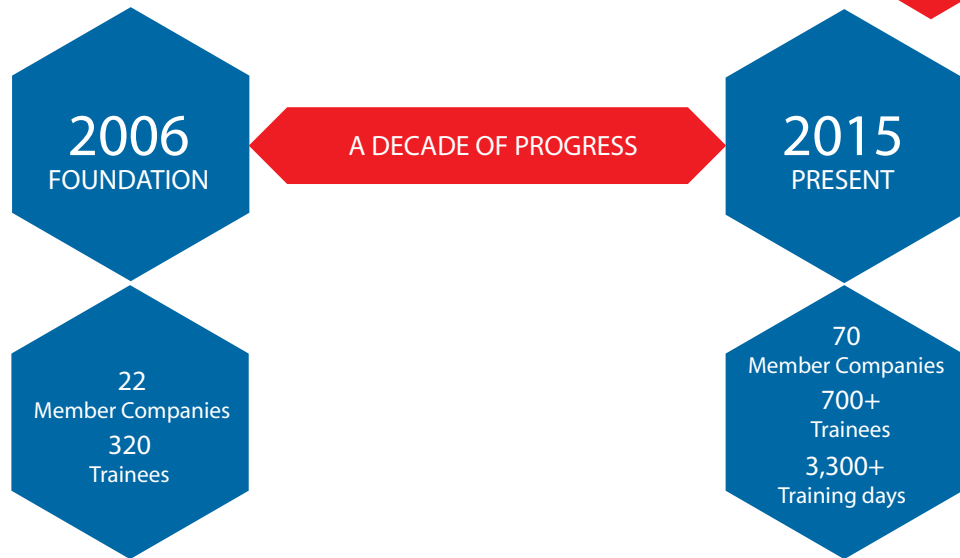
In recent years some of the topics we have engaged in are:

- ◆ The 7 habits of Highly effective People
- ◆ Influencing Skills
- ◆ Project Management

We are delighted to let Skillnet source the best trainers to deliver excellence to our colleagues on the topics we want to upskill them on.

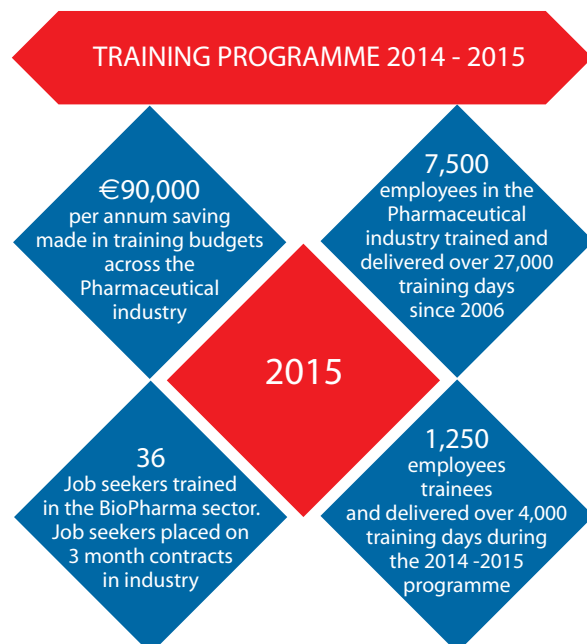
We find that it is beneficial from a budget perspective to share in some courses with other pharmaceutical companies; this works well and is executed by the diligent managers of the network.”

Michael Calnan, Quality Excellence Leader, Pfizer Ringaskiddy, Cork



“There are two main benefits to Janssen Pharmaceutical as a member of the Pharmachem Skillnet group, the first is being part of a steering group that meets on a monthly basis, we can share our experiences with the other Pharma companies. Through the many meetings and workshops organised through Pharmachem Skillnet we are in a position to discuss the best training practices in Good Manufacturing, Environment, Health and Safety and Continuous people development. Discovering new ways of training our Employee’s, helps us to set new standards within the industry. The second area is being able to tap into a one stop shop for scheduling training courses, a reliable service where we know Vendors have been endorsed by our peer companies and approved by the Network, resulting in a high quality of training delivery.”

Tom Nyhan, Training Manager, Janssen Pharmaceutical, Little Island, Cork



UNIVERSITIES, INSTITUTES OF TECHNOLOGY & RESEARCH CENTRES BY LOCATION

DUBLIN

Trinity College Dublin
Dublin City University
University College Dublin
Blanchardstown IT
Dublin IT
IT Tallaght

SPECIALITY RESEARCH CENTRES

National Institute for
Bioprocessing Research and
Training (NIBRT)

Biomedical Diagnostic
Institute (BDI), DCU

Clarity, UCD
Molecular Therapeutics for
Cancer, Ireland

AMBER

REST OF IRELAND

UU Coleraine
Letterkenny IT
Queens University
UU Jordanstown
Dundalk IT
Athlone IT
Carlow IT
Sligo IT
Waterford IT
Institute of Technology Tralee

CORK

Institute of Technology
University College Cork

SPECIALITY RESEARCH CENTRES

Alimentary Pharmabiotic
Centre, UCC

Tyndall

LIMERICK

University of Limerick
Limerick IT

SPECIALITY RESEARCH CENTRES

Biomedical & Environmental
Sensor Technology Centre

Biomedical Electronics Centre

Synthesis & Solid State
Pharmaceuticals Cluster

Pharmaceutical Manufacturing
Technology Centre

GALWAY

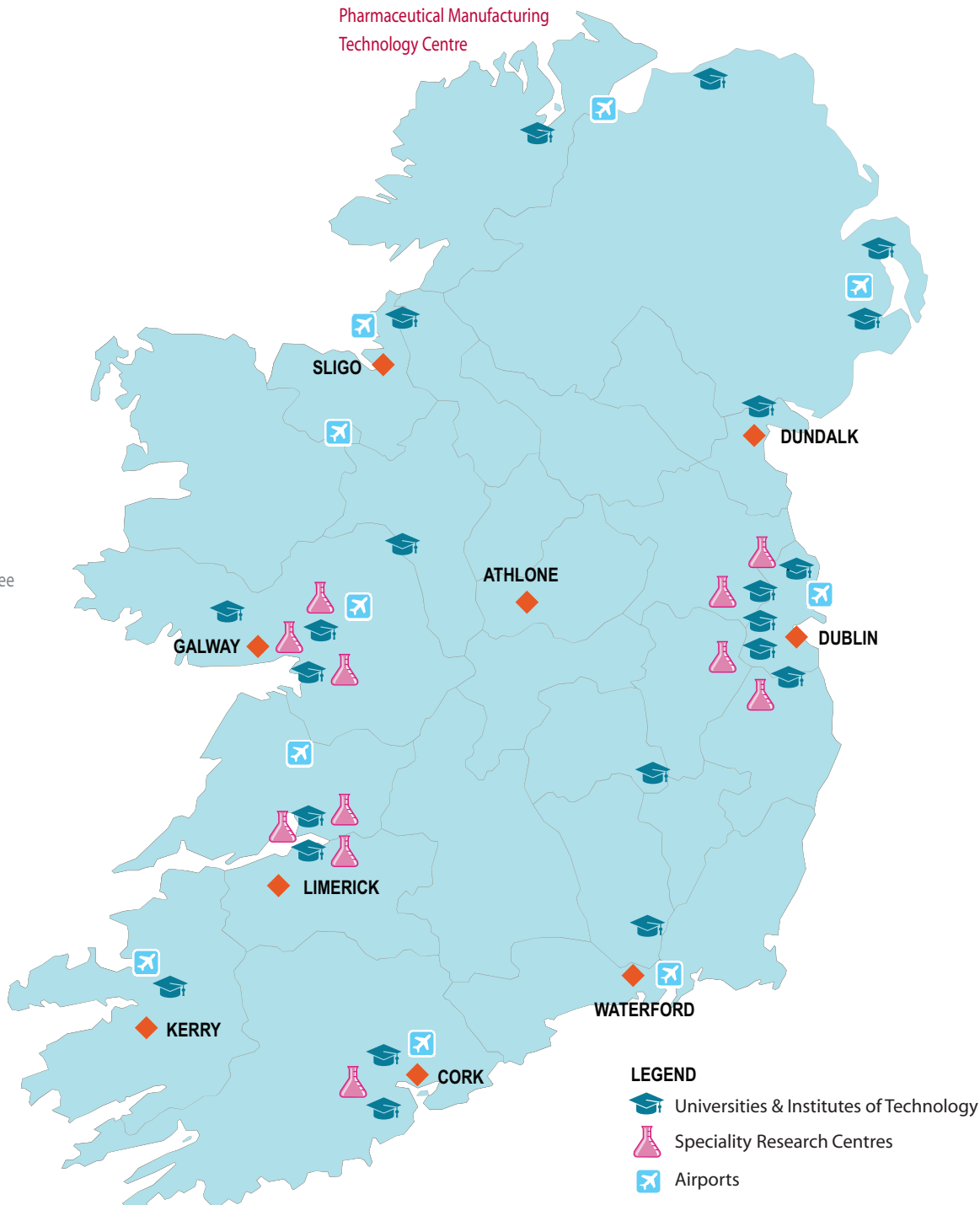
National University of Ireland
Galway Mayo IT

SPECIALITY RESEARCH CENTRES

National Centre for Biomedical
Engineering Science

National Centre for Laser
Applications

Regenerative Medicine Institute
(REMEDI)



MEMBER CONTACT DETAILS

A Strategy
for the Biopharmaceutical
Industry in Ireland

Abbott Pharmaceuticals - http://www.abbott.ie	Hovione - http://www.hovione.com/locations/hovione-cork
Abbvie Fournier Laboratories - http://www.abbvie.ie	Ipsen Manufacturing Ireland - http://www.ipsen.com
Allergan Pharmaceuticals Ireland - http://www.allergan.ie	Janssen Biologics Ireland - http://www.janssen.ie
Alexion Pharma International - http://alexionpharma.ie	Jazz Pharma - http://www.jazzpharma.com
Alkermes Pharma Ireland - http://www.alkermes.com	Leo Pharma - http://www.leo-pharma.ie
Amgen Technology Ireland - http://www.amgen.co.uk	Mallinckrodt Pharmaceuticals - http://www.mallinckrodt.com
Arran Chemicals – An Almac Company - http://www.arranchemical.ie	MSD Brinny - http://www.msd-ireland.com
Astellas Ireland - http://www.astellas.ie	MSD Carlow - http://msd-ireland.com/about-us/51/carlow
BASF Ireland - https://www.basf.com/ie	MSD Ireland - http://www.msd-ireland.com
Biomarin International - http://www.biomarin.com	Mylan - http://www.mylan.ie
Bristol-Myers Squibb - http://www.bmsireland.ie	Novartis Ringaskiddy - https://www.novartis.ie
Camida - http://www.camida.com	Pfizer Cork Limited - http://www.pfizer.ie
Cara Partners - http://www.carapartners.ie	Pfizer Grangecastle - http://www.pfizer.ie
Clarochem Ireland - http://www.cfm-group.it/production-plants/clarochem-ireland-ltd/	Pfizer Ireland Pharmaceuticals - http://www.pfizer.ie
Charles River Laboratories - http://www.criver.com	PPD Development Ireland - http://www.ppd.com
Eli Lilly SA - http://www.lilly.ie	Recordati Ireland http://www.recordati.com/en/pharmaceutical_operations/products/ireland
Ethicon - http://www.ethicon.com	Regeneron Pharmaceuticals - http://www.regeneron.com
FMC International - http://www.fmc.com	Roche Ireland - http://www.roche.ie
Forest Laboratories Ireland - http://www.frx.com	Rottapharm - http://www.rotta.com
GE Healthcare Bio Sciences - http://www.gelifesciences.com	Servier Ireland Industries - http://www.servier.ie
Genzyme Ireland - http://www.genzyme.ie	Sigma Aldrich Ireland - https://www.sigmaaldrich.com/ireland
Gilead Sciences - http://www.gilead.com	Stiefel – A GSK Company - https://www.stiefel.com
GlaxoSmithKline - http://ie.gsk.com	Takeda Ireland - http://www.takeda.ie
Helsinn Birex Pharmaceuticals - http://www.helsinn.com	Teva Pharmaceutical - http://www.teva.ie
Henkel Ireland - http://www.henkel.co.uk	UCB Manufacturing Ireland - http://www.ucb.com/worldwide/ireland
Heraeus Metal Processing - https://www.heraeus.com	
Horizon Pharma - http://www.horizonpharma.com	

KEY CONTACTS



Enterprise Ireland - <https://www.enterprise-ireland.com>

Enterprise Ireland's priority is the achievement of export sales growth from Irish-owned companies. Export sales growth leads to an increase in demand for Irish goods and services, and increases the flow of income into the Irish economy. This is fundamental to job creation and maintenance in Ireland.



The Health Research Board - <http://www.hrb.ie>

The Health Research Board (HRB) is a statutory agency under the aegis of the Department of Health. As the lead agency in Ireland responsible for supporting and funding health research, information and evidence, we are motivated and inspired by our vision "Healthy People through excellent research and applied knowledge."



IDA Ireland - <http://www.idaireland.com>

There are many reasons why companies locate themselves in Ireland, but it all starts with positive leadership and policies. Successive governments have developed an open economy and invested heavily to develop Ireland's infrastructure. This has allowed the IDA (Industrial Development Authority), a semi-state body, to continue to attract high-performing industries to our shores, even through challenging times.



Institutes of Technology Ireland - <http://www.ioti.ie/>

IOTI is the representative body for 13 of Ireland's Institutes of Technology, which are recognised as a major success story in Irish education. The Institutes of Technology operate a unique system in that they allow students to progress from two year (associate degree programmes) through primary degree to Masters and PhD. Institutes of Technology awards are integrated with the highest award levels of the Irish National Qualification Framework which in turn is aligned to the Bologna Framework. They are to the forefront in ensuring that Ireland's modern economy continues to have the requisite array of leading-edge skills demanded by our knowledge-based industries. The Institutes provide programmes that reflect current and emerging knowledge and practices and promote self-management, critical analysis, decision making and entrepreneurship. They foster graduates ready to undertake roles, responsibilities and challenges in business, industry, the professions, public services and society.



Irish Universities Association - <http://www.iua.ie/>

We are the representative body for Ireland's seven universities. Through consultation and collaborative projects we develop strategy and policy to advance third and fourth level education and research. Our shared aim is to ensure that we maximise the universities' contribution to Ireland's social, cultural and economic well-being.



Knowledge Transfer Ireland - <http://www.knowledgetransferireland.com/>

Knowledge Transfer Ireland takes a national perspective on the knowledge transfer (KT) system in Ireland. KTI works with business, investors, universities, Institutes of Technology, State research organisations, research funders and government agencies to maximise State funded technology, ideas and expertise getting into the hands of business to drive innovation.



National Institute for Bioprocessing Research & Training - <http://www.nibrt.ie>

NIBRT is a world-class institute that provides training and research solutions for the bioprocessing industry. Our mission is to support the bioprocessing industry by providing a unique learning experience for trainees in an environment that replicates the most modern industrial bioprocessing facility. In parallel, we also undertake leading edge research in key areas of bioprocessing in collaboration with industry.



Pharmaceutical Manufacturing Technology Centre - <http://www.pmtc.ie/>

The Pharmaceutical Manufacturing Technology Centre (PMTc) is hosted by the University of Limerick with core funding of €1M per annum from the Irish government (Enterprise Ireland and the IDA Ireland). Income is supplemented with co-funding from industry and other public sources. PMTC, established in December 2013, is led by an industry steering board with an active research program driven by its industry members. Companies access PMTC to create projects and execute world-beating industry-relevant research in advanced technology solutions to address contemporary manufacturing issues.



Regulatory Science Ireland - <http://www.regulatoryscienceireland.com>

The ever-increasing complexity of health care products requires a data driven, evidence based approach to their regulation. Regulatory Science Ireland (RSI), a national response to these developments, is a network of interested parties from; Academia | Regulatory Body (HPRA) | Pharmaceutical Industry | Medical Devices Industry | Government Agencies.



Science Foundation Ireland - <http://www.sfi.ie/>

Science Foundation Ireland (SFI) is the national foundation for investment in scientific and engineering research. SFI invests in academic researchers and research teams who are most likely to generate new knowledge, leading edge technologies and competitive enterprises in the fields of science, technology, engineering and maths (STEM). The Foundation also promotes and supports the study of, education in, and engagement with STEM and promotes an awareness and understanding of the value of STEM to society and, in particular, to the growth of the economy. SFI makes grants based upon the merit review of distinguished scientists. SFI also advances co-operative efforts among education, government, and industry that support its fields of emphasis and promotes Ireland's ensuing achievements around the world.



The Synthesis and Solid State Pharmaceutical Centre - <http://www.sspc.ie/>

The Synthesis and Solid State Pharmaceutical Centre (SSPC), a Global Hub of Pharmaceutical Process Innovation and Advanced Manufacturing, funded by Science Foundation Ireland and industry, is a unique collaboration between 22 industry partners, 9 research performing organisations and 12 international academic collaborators. The SSPC transcends company and academic boundaries and is the largest research collaboration in Ireland, and one of the largest globally, within the pharmaceutical area. The role of the SSPC is to link experienced scientists and engineers in academia and the pharmaceutical industry, to address critical research challenges. The SSPC leads the way for next generation drug manufacture and spans the entire pharmaceutical production chain from synthesis of the molecule, to the isolation of the material, and the formulation of the medicine. The aim of the SSPC is to deliver industry relevant solutions, which result in job growth and retention within the pharmaceutical industry in Ireland.

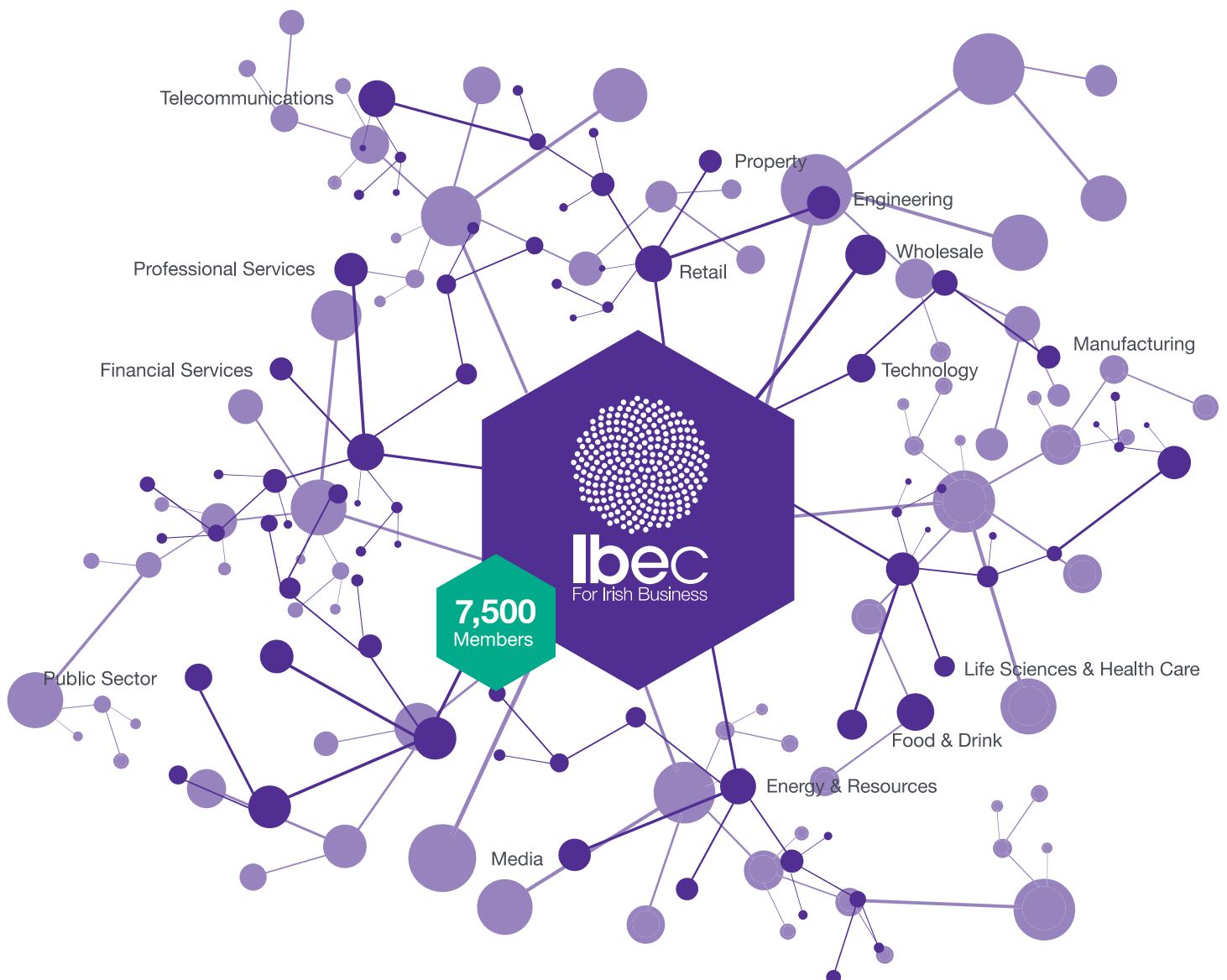
ABOUT IBEC

Ibec is the national voice of business in Ireland. The organisation and its sector associations, work with government and policy makers nationally and internationally, to shape business conditions and drive economic growth.

From the dynamic, modern manufacturing of the high-tech, life sciences and food sectors to the vanguard of quality services provision, including financial, software, retail and tourism; from companies operating in small

villages to those serving a global customer base, and those doing both at the same time; from those managing 5 employees, to those managing 50,000. Ibec's strength lies in our diversity.

We offer our members a range of professional services and training on human resource management, occupational health and safety, employee relations and employment law.



The background of the entire page is a deep purple color. Overlaid on this background is a complex, interconnected network of white lines and circles, resembling a molecular structure or a network diagram. The circles vary in size, and the lines connect them in a non-linear, branching fashion, creating a sense of depth and complexity. This graphic is positioned behind the two main text boxes.

VISION

Ireland will enhance its reputation as a recognised centre of excellence for innovation and development in pharmaceutical, biopharmaceutical and chemical supply, thereby becoming the location of choice for the launch of new products.

MISSION

BioPharmaChem Ireland will influence, support and represent the sector in realising its ambition by bringing together all relevant stakeholders in the State, namely: industry, the government, the research community and the public at large to effectively communicate the unique attractiveness of Ireland as a leading location for the supply and development of pharmaceutical products.

