Ireland – the Global BioPharmaChem Location of Choice

Our vision
Ireland will be the globally recognised centre of excellence for innovation and development in biopharmaceutical, pharmaceutical and chemical manufacture and supply; and the location of choice for the launch of new products.
Foreword from Martin Shanahan, CEO, IDA Ireland

Ireland is truly the home of advanced manufacturing with over 30% of value added to our GDP coming from manufacturing we are truly a leader in terms of future products and processes. Ireland has been very successful in attracting international investments in tech and digital allowing for a cross fertilisation of skills between the tech and life sciences sectors.
Ireland has seen major investments in both biopharmaceuticals and medical devices. 13 of the top 15 medical technologies companies have international operations in Ireland while all of the top 10 global drug companies have operations in Ireland. This has a huge impact on our economy with over 50% of goods exports by value coming from the life sciences sector. More important is the job creation potential which these companies bring to Ireland both in terms of the major capital investment in design, construction and validation allied to the long term highly-skilled jobs that a biopharma plant would create.

The Irish Government through the Department of Business, Enterprise & Innovation recently launched its Future Jobs Strategy with key funding earmarked over a five-year period. Ireland has won investments against significant international competition due to the skills of our workforce and our very strong regulatory culture across all parts of the industry. The Irish Government’s investment, through IDA Ireland, in NIBRT to support the development of skills and research in biologics is a key example of a Government initiative which has supported the sector in Ireland. IDA Ireland has already this year also announced the establishment of a new Advanced Manufacturing Centre to provide a development and collaboration space for our companies.

As we now look forward I am delighted to see our clients and the members of BioPharmaChem Ireland announcing a new strategy for the continued growth and development of the sector in Ireland. This culture which I see across our client base of collaboration between companies that at other times are competitors is always heartening. This collaboration is looking at the bigger picture of how certain initiatives will bring benefits to all and allow all companies in the biopharma sector to continue to grow in our country.

I would like to wish Biopharmachem and its members every success with the rollout and implementation of the strategy and assure you of IDA Ireland’s continued support for the future growth of the sector in Ireland.

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.

Martin Shanahan
CEO, IDA Ireland
BioPharmaChem Ireland (BPCI) published its first strategy in 2010 “Innovation and Excellence”, clearly recognising the many challenges the industry faced at the time. Many of those challenges were driven by the expiry of patents on blockbuster medicines – several of which were manufactured in Ireland – the so-called “Patent Cliff”.

Times have certainly changed, and many of the challenges identified at that time have been addressed. The sector has invested €10 billion euro in capital in the last decade – much of this in the manufacture and development of biotech products.

As a sector we now face a whole new set of challenges; each of these are addressed in this document:

- The need for a supportive and relevant industrial policy driven by Government;
- The ongoing talent challenges;
- The imperative to continue to stay innovative;
- A broader supportive infrastructure for the sector; and
- The importance of expanding and integrating the entire cluster

This document is intended to succinctly convey the strategy, and to invite comments from and debate amongst all our valued stakeholders including:

- Government and its agencies
- The research and educational community
- The public at large and community groups
- Other industry sectors
- Non-governmental organisations

We hope you find value in its contents, and we look forward to working with all to execute on its recommendations, helping to ensure this vibrant sector continues to bring health and prosperity to this country.

David Keenan
Chairman, BioPharmaChem Ireland
“The sector has invested €10bn euro in capital in the last decade – much of this in the manufacture and development of biotech products.”
Welcome to phase 5 of the BioPharmaChem Ireland (BPCI) strategy series. As an organisation we are in the 25th Year of existence; we hope that the growth of the sector here has mirrored our own growth. We have seen our membership diversify from one dominated by Active Pharmaceutical Ingredient (API) manufacturers to a much more diversified membership that includes biotech manufacturing, drug product formulation and specialist services, as well as chemical manufacturing. As an industry we have always worked hard to protect our competitiveness and also to try and make sure that the prevailing business environment is supportive. To a large extent we have been successful in achieving these aims - this evidenced by the continued growth of the industry which as seen one billion euro invested in capital every year over the last ten years.

However we cannot rest on our laurels or be complacent - the world continues to change and we need to keep pace with this change. Advanced Therapeutics are coming to the fore but manufacturing these in a cost effective and reliable way remains a challenge to be addressed. The role of data and digitisation of manufacturing and healthcare presents challenges and opportunities. How pharmaceuticals and chemicals are being manufactured continues to evolve and develop.

We need to ensure that the pipeline of talent so critical for the ongoing development of our companies is strong and vibrant We have tried to address some of these issues within the body of this document. I would like to acknowledge the work of Nessa Fennelly and the BPCI strategy group for the work that they put in to pull this document together and I hope that you find it useful. I welcome any feedback that you might like to give us on it.

Matt Moran
Director, BPCI
Our mission
BioPharmaChem Ireland will support and represent the sector in realising its vision by bringing together all relevant stakeholders; industry, government, the research community and the public; to communicate the unique position of Ireland as the leading global location for the manufacture and supply of biopharmaceuticals, pharmaceuticals and chemicals.
A profile of Ireland’s BioPharmaChem Sector

The sector has invested €10bn in Irish facilities since 2009.

Biopharma exports from Ireland in 2018 totalled in excess of €73bn.

€1.8bn invested in manufacturing process development R&D in 2017.

The Global Top 10 Biopharmaceutical companies all have a manufacturing presence in Ireland.

75+ biopharmaceutical companies in Ireland.

30,000 people are directly employed with the same number indirectly employed.

Ireland is the Global BioPharmaChem Location of Choice.
Manufacturing excellence in both drug substance and drug product – covering small molecules and biotechnology.

The Biopharmaceutical Industry is in Ireland for the following reasons:

- Extraordinary compliance and regulatory track record
- Talent
- Track record
- Tax
- Regulatory stability
- Sub-supply capability
- Research and Training Collaboration

Ireland is the Global BioPharmaChem Location of Choice
Industrial Policy
+ 12.5% Corporation Tax
+ 25% R&D Tax Credit
+ Capital Allowance for Advanced Manufacturing

Clusters
+ Design a national framework for the “Cluster”
+ Alignment of academia with cluster industry needs
+ Encourage the development of support services

Infrastructure
+ Investment in Advanced Therapeutics Research Infrastructure
+ Allocation of funding for “Regulatory Science Ireland”
+ Support and development of “Clinical Research Development Ireland”
Innovation
+ Make Ireland a global leader in ATMP (cell and gene) characterisation, manufacturing and supply
+ Enhanced data analytics of manufacturing, supply chain and the patient
+ Biopharma 4.0

**Talent**
+ Attracting global talent
+ Industry-ready graduates
+ Apprenticeships
Ireland has a competitive rate of corporation tax, R&D tax credits and supports. The sector is high value add and a significant contributor to corporation tax receipts. It has a high growth rate of between 6.5% and 9.6%. Competition for Biopharma FDI is ramping up globally with several EU and ROW countries investing in “NIBRT-like” models. Ireland needs to replicate the vision and foresight that resulted in the creation of NIBRT and similarly position the country for the next wave of investment and innovation.

12.5% Corporation Tax
Ireland’s corporation tax rate and R&D tax credits policy, coupled with the tax treaty network and IP offering, presents a very competitive and compelling landscape for companies. The Irish statutory regime is agile with a choice of three financial reporting options – International Financial Reporting Standards (IFRS), Irish Generally Accepted Accounting Principles (GAAP) and US GAAP (in certain circumstances). The sector has invested €10bn in Irish facilities since 2009. Biopharma exports from Ireland in 2018 totalled in excess of €73bn. The sector is a high value-added sector and a large contributor to corporation tax receipts. International developments determine that Ireland needs to continually strengthen its competitive advantage for investment and remain the location of choice for manufacturing and innovation by retaining and maintaining a competitive taxation environment.

25% R&D Tax Credit
R&D is a critical component of our industry. Companies are increasing in-house R&D expenditure (in addition to staff numbers involved) and partnering with the Irish research system. The R&D tax credit plays a vital role in corporate decision making to undertake additional RD&I activity in Ireland. The sector invested €1.8 bn in manufacturing process development R&D in 2017. It is vital that it is retained.
Capital Allowance for Advanced Manufacturing

We are entering a new era of advanced biopharmaceutical manufacturing. In order to futureproof investment, accelerated capital allowances for several areas of advanced manufacturing (including computerised/computer aided machinery and robotic machines) should be introduced by Government.

Ireland is the second largest net exporter of medicinal and pharmaceutical products from the EU, accounting for almost 30% of Ireland’s total extra-EU trade, the highest amongst EU countries (source: Eurostat, 2017).

Pfizer

The medicines manufactured in Ireland are distributed to over 100 countries around the world in 36 different languages.

GE Healthcare

GE Healthcare Ireland (GEHC) is a secondary manufacturer of contrast media. We employ 590 staff and are a 24/7 operation exporting to 93 markets worldwide. Every second, of every day, 365 days a year a patient is diagnosed with the help of our products through procedures such as X-Ray and MRI. We improve lives in the moments that matter...

BioMarin

BioMarin is a global biopharmaceutical company focused on developing first-in-class and best-in-class therapeutics that provide meaningful advances to patients who live with serious and life-threatening rare genetic diseases. Many of these conditions affect children and some are so uncommon that the entire patient population numbers as few as 1,000 people worldwide. On average, people with rare diseases wait more than five years to receive a proper diagnosis, and only 5% of rare disorders even have an approved therapy.¹ For more than 20 years, BioMarin has remained steadfast to our mission of bringing new treatments to market that will make a big impact on small patient populations. We are committed to improving the life and health outcomes of people with rare diseases by developing innovative therapeutics, advancing the standard of care, and providing personalized support and services.

Ireland has a highly skilled workforce. The sector employs 30,000 people directly, 60% of whom hold a third level qualification. Over 25% of all PhD graduates employed in Irish industry work in our sector.

**Attracting global talent**

Ireland ranks in 21st place in the IMD ‘World Talent Rankings’ of 63 countries in three main categories namely, appeal, readiness and investment & development. While Ireland comes in the top five for the prioritisation of attracting and retaining talent in addition to worker motivation in companies, it scores 38th place for cost of living as an incentive for professionals. Biologics manufacturing in Ireland will require many additional employees over the next five years. Government needs to prioritise the future attraction of talent to this sector.

**Industry-ready graduates**

A highly regulated sector such as biopharma depends on having the right level of employee in terms of qualification, aptitude and experience. Ireland continues to excel in this regard, however BPCI believes in the need to continually invest in our talent pool. We work closely with IDA, Skillnets and Nibrt to ensure the robustness of the talent pipeline. As the digitisation of the sector evolves, opportunities are emerging in entirely new skill sets such as information technology and software development. Advanced manufacturing technologies and data science are critical areas of focus therefore it is critical that industry work with academia to develop programmes to prepare students for these high-tech manufacturing jobs.
**Apprenticeships**

In order to diversify the talent pool and attract people from other sectors, BPCI member companies looked at developing a vocational route into the sector (echoing the German and Swiss models) which resulted in the launch of two laboratory apprenticeship programmes in 2018. We expect to see the development of further apprenticeships over the coming years in line with industry needs.

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**MSD Ireland**

MSD’s Irish sites manufacture approximately half of MSD’s top twenty products, saving and enhancing lives in over sixty countries around the world. Their site in Carlow opened in 2008 as MSD’s first vaccines facility outside of the US. Carlow is the filling site for the liquid form of our immuno-oncology treatment for the global market and is a state of the art vaccines and biologics facility. MSD Biotech, Dublin, will play a pivotal role in the manufacture of MSD’s biologics-based medicines, including in the area of immuno-oncology, and will expand MSD’s current internal network of biologics drug substance manufacturing plants when full manufacturing operations begin in 2021.

“Professor Luke O’Neill, Professor of Biochemistry at Trinity College Dublin, is one of the top 1% of immunologists in the world, based on citations per paper, according to Thomson Reuters/Clarivates.”

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"Invented for life"
Therapeutic modalities are becoming increasingly diverse, encompassing cell and gene therapies, antibody-drug conjugates, regenerative and genomic based precision medicines and RNA therapies. Data analytics is core to manufacturing excellence, quality and customisation. Irish manufacturing sites are globally recognised as manufacturing process/product development specialists. Ireland, with the correct supports is well positioned to be at the cutting edge of this multi-faceted ground breaking innovation.

Make Ireland a global leader in ATMP (cell and gene) characterisation, manufacturing and supply

BPCI is encouraged to see the commitment in the Governments “Future Jobs” initiative to embracing innovation and technological change. The industry has moved from the blockbuster into the speciality drugs era. We need to know and understand the disease and the patient. Drugs will be more expensive, however will potentially provide a cure thereby enabling people to return to work. Half of the top twenty drugs in 2018 were injectable and we are also seeing strong growth in the orphan drug space. Treatments are coming and patients are well informed, indeed CAR-T and other new technologies are not a treatment but a cure. However, there are new manufacturing challenges requiring scalable technology. Ireland, a globally recognised biopharmaceutical manufacturing centre of excellence, with the correct supports from government, is ideally positioned to take on this challenge and position itself for the next wave of biopharmaceutical innovation and investment in Ireland.

Enhanced data analytics of manufacturing, supply chain and the patient

We need to harness the potential of data – gathering and analysing it for outcomes-based measurement and personalised healthcare. The sector needs to deal effectively with the level of data it generates. Machine learning and artificial intelligence can be deployed to improve healthcare delivery and patient outcomes. With the large concentration of life science and technology companies in Ireland, there is a unique opportunity to collaborate on new technological approaches to drug development and patient care. This should be an area of focus for the 2020 Future Jobs review.
Biopharma 4.0

Biopharma 4.0 (echoing Industry 4.0) heralds the onset of digitisation and emergence of disruptive technologies. Companies need to understand and implement concepts and technologies around AI, continuous manufacturing, data analytics and 3D printing. With this will come the need for requisite skills in addition to regulation that is more science and risk based. The Biopharma Ambition 2018 Conference report stated “Industry 4.0 and the changing global healthcare landscape brings a raft of new challenges for the biopharmaceutical industry; integration of emerging technologies, digitisation, regulatory hurdles, access, pricing and reimbursement and R&D productivity and costs. What this will mean in the short, medium and long-term for the sector is already the subject of intense discussion. The industry is taking care to diversify and collaborate”

Takeda Ireland Ltd – Grange Castle

Takeda has invested almost €200m in its Grange Castle site since it started manufacturing in 2002. Alofisel is a ground-breaking stem-cell therapy for the treatment of complex perianal fistulas in adult patients with Crohn’s disease. It will be manufactured at Takeda Grange Castle site in Dublin. Alofisel is the first allogeneic stem cell therapy to be approved in Europe.

Henkel

Henkel has invested heavily in its Dublin facility to develop and showcase new to the world polymer materials for 3D printing. Under the LOCTITE brand, a portfolio of new 3D resins, post-processing materials and equipment has been introduced. These allow customers to create truly functional parts, across a wider range of applications. A new dedicated Innovation and Interaction Centre has been built to promote Henkel’s 3D printing capability.

Lilly

Lilly’s unique manufacturing campus at Kinsale uses both biologic and chemical synthesis platforms to make drug substance to support the commercialisation and supply of many medicines in Lilly’s portfolio. The site has a long history of innovation, evidenced most recently with the addition of process analytical technology, continuous manufacturing and digital plant technology to its capabilities in Kinsale.
BPCI has identified three areas, which will position Ireland for the next wave of biopharma investment. We urgently need government funding for “ATMPs” – Advanced Therapy Medicinal Products. Governments globally are making significant investments in this space and Ireland similarly needs to invest in order to compete and stay ahead of the game. Regulatory Science Ireland will enable Ireland to operate at the forefront of global regulatory development, which is hugely challenging and presents an exciting opportunity for us. Clinical Research Development Ireland is unique opportunity to create an innovative force for the development of clinical and translational research in Ireland.

Investment in Advanced Therapeutics Research Infrastructure

Ireland is lacking in infrastructure to support the development of cell and gene therapy manufacture, which is needed to meet future challenges and opportunities. The “Disruptive Technologies Innovation Fund” administered by the Department of Business Enterprise and Innovation is the appropriate funding mechanism to address this deficit. The €10bn investment in Ireland by the sector over the past decade, in addition to its €1.8 bn investment in manufacturing process development R&D in 2017, more than demonstrates its commitment to Ireland. In-house R&D expenditure and the number of employees involved in R&D has been steadily rising. Companies are partnering with the research system on biopharma projects. We need a commitment from Government to fund infrastructure, which will serve to place Ireland at the forefront of advanced therapeutics manufacturing development.

Allocation of funding for “Regulatory Science Ireland”

The sector is highly regulated and Ireland has a strong global reputation for excellence in manufacturing and regulatory compliance. Regulatory Science Ireland is committed to the development of an integrated Irish response to the global Regulatory Science effort by establishing an environment through which relevant research, training and communication creates a cohort of Irish based Regulatory Science experts and further strengthens the value proposition of Ireland as an attractive location for Health Care products. Regulators need to be on board with what the industry want to do. It is important to make GMP risk based as the old GMP is killing innovation. Regulation is getting in the way. “Approvals are coming faster and faster. FDA want clinical trials to be faster. They want an automated aseptic filling process” (Gert Moelgaard –
Regulations must be modernised to become more science and risk based. Global regulators need to support novel manufacturing processes. The regulatory process drives the cost of development and time to market. Increased global regulatory stringency may affect innovation activity.

Support and development of “Clinical Research Development Ireland”

Clinical Research Development Ireland is unique opportunity to create an innovative force for the development of clinical and translational research in Ireland, which would be recognised, both nationally and internationally, as a model of organisational excellence focused on advancing evidence based patient care and network coordination. We need to set an ambition target for clinical trials. The number of trails being carried out in Ireland in declining (from 114 in 2007 to 96 in 2017). Clinical trials enhance Ireland’s innovation value proposition and in turn its attractiveness for future investment in manufacturing.
A Cluster is when the business model is characterised by a dynamic ecosystem involving multinationals in different sectors generating local SMEs and partnering with the indigenous sector along with higher education, health and research institutions” - Ibec. Achieving the full potential of the Biopharma cluster will create an ecosystem to sustain and evolve the sector.

Design a national framework for the “Cluster”

Ireland has an impressive mix of large multinationals, high growth SMEs and start-ups. Enterprise Ireland support over 100 Irish owned companies specialising in drug discovery, development and delivery in addition to API, veterinary and human finished products manufacturing. Also pharma service, regulation, engineering, construction and clinical trial management. The Irish life sciences manufacturing sector has grown exponentially in recent years with major investments from large multinationals. In parallel, indigenous Irish companies have developed to support the cluster of multinationals.

Alignment of academia with cluster industry needs

“As for the Irish pharma cluster, it is in an enviable position as a world leader in pharma manufacturing. Strategic Government investments (such as the Science Foundation Ireland pharmaceutical research centre SSPC and the IDA Ireland-funded National Institute for Bioprocessing Research and Training) and successful indigenous companies (such as ESP and APC) bode well for the sector here. Ireland is well positioned to be a leader in the industry 4.0 space in life sciences”. Barry Heavey Life Sciences Practice lead at Accenture Ireland.
Encourage the development of support services

A national framework to identify the strengths of the existing organically developed clusters and replicate them on a co-ordinated country wide basis would greatly enhance the evolution of the sector. We have seen great success in the development of innovative Irish companies to support the ever changing multinational environment in addition to the alignment of academia with industry needs. A focus on this very important and productive area is timely.
About Ibec

Ibec is Ireland’s largest lobby group representing Irish business both domestically and internationally. Its membership is home grown, multinational, big and small, spanning every sector of the economy. Together they employ over 70% of the private sector workforce in Ireland. Ibec and its trade associations lobby government, policy makers and other key stakeholders nationally and internationally to shape business conditions and drive economic growth. It has over 230 professional services staff in seven locations including Brussels and has 38 different trade associations in the group.

Ibec and its sectors groups lobby government, policy makers and other key stakeholders nationally and internationally to shape business conditions and drive economic growth. The Ibec team includes experts across all of the major policy areas key to business:

- Economics and taxation
- Education and skills
- Energy and environment
- Transport innovation
- Digital economy
- Labour market
- Diversity
- Public services
- All island investment
- Trade
- EU and international affairs

Ibec is a market leader in forecasts and surveys. Ibec’s role as public commentator on the economy has been significant, having correctly identified the turnaround during the economic crisis. More recently, Ibec has accurately forecast economic growth rates and identified the opportunities that these, along with low interest rates, provide for national infrastructure investment.

Through its press office, Ibec sets out the views of business on key issues, regularly leading the national print and broadcast media. Ibec executives regularly speak at major national and international conferences and debates, and are members of key government expert groups and committees.

Ibec provides a wide range of professional direct services to members including employer advice and representation on HR and industrial relations issues. The on-the-ground aspect of this service places Ibec in a unique position of being close to the challenges and concerns of employers. This enables the team to better capture and articulate issues affecting competitiveness and business development to government and policy makers.
About BioPharmaChem Ireland

Biopharmachem Ireland (BPCI) is a business association within Ibec representing the biopharma and chemical sectors.

BPCI can help your organisation to be more competitive, productive and to develop your business:

+ BPCI consists of a board and five business platforms in addition to 15 working groups. This structure allows members to appropriately address the strategic issues facing the sector, by being actively involved and shaping the future strategy and priorities for the sector including the development of new business models. Participation in the association and working groups enables members to network and build relationships and discuss issues of common concern in the industry

+ Biopharmachem Ireland provides a rapid, confidential response to member queries on any subject being faced by senior management

+ The Annual Salary Survey Report, includes detailed information on rates of pay and conditions of employment. This impressive survey is only made available to participating members and contains vital sector specific information including forecasts on rates of pay for the coming year

+ The Biopharmachem Skillnet encourages companies with shared training needs to collaborate and achieve their training goals in a cost effective manner

+ Biopharmachem Ireland has had an extremely active “Discussion Forum”, where members can circulate questions & queries on a broad range of topics, for a rapid response from industry peers

+ Membership gives you access to Ibec’s comprehensive information resources. Accessing this high-quality and timely information saves time and expense, as you can make informed business decisions and avoid pitfalls

+ Ibec services include the most comprehensive HR database in Ireland in addition to industry specific surveys and reports
Notes