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Our vision: Ireland will be the globally recognised centre of excellence for innovation and development in the sustainable manufacture and supply of biopharmaceuticals, pharmaceuticals, and chemicals; and the location of choice for the launch of new products.

Foreword IDA Ireland CEO, Martin Shanahan

IDA Ireland reported a record breaking year for FDI employment with significantly higher levels of Foreign Direct Investment (FDI) in 2021 compared with 2020 and strong gains recorded in both gross and net employment. 249 investments were won for Ireland in 2021, 104 of which were from new name companies.

We recently announced our mid-year results which showed continued significant investment growth in the first half of 2022, returning FDI employment creation plans to above the pre-pandemic 2019 record levels, despite a continuing challenging global environment. 155 investments were won in the six month period with 73 of them new name companies.

Our success in growing FDI investment into Ireland has, in part, being due to our concentrated focus on those sectors which drive the modern global economy and Lifesciences is key among them.

The Biopharma industry has continued to grow and thrive in Ireland and IDA client companies in the sector now employ over 42,500 highly qualified people directly. In the last year alone there have been fifteen announcements of new investments or expansions in the sector. These new investments have been located throughout Ireland and they will ensure that the recent growth in employment will continue. These investments have been across both the small molecule and biologics manufacturing sectors and there has also been an increase in the number of Biopharma companies expanding their global business services activities in Ireland.

The life sciences industry globally excelled in its response to the COVID-19 pandemic. The development of effective vaccines and therapeutic medicines so quickly has saved countless lives and greatly reduced the impact of the virus on all our lives. The industry in Ireland has played its part and contributes to the global supply chain that has produced the vaccines and medicines that were so badly needed. Throughout the pandemic the biopharma manufacturing plants in Ireland demonstrated considerable agility, resilience and durability, continuing to operate successfully without any interruption in the supply of the essential innovative medicines that are produced here.

IDA Ireland is fully committed to the continued development of the sector in Ireland. The recently announced government funded Advanced Manufacturing Centre in Limerick has already started to work with companies in the sector and NIBRT has now begun construction of the additional capacity for the development of their Cell and Gene Therapy capabilities as these new advanced therapies continue to transform the ways in which we can help patients. IDA Ireland will also continue to work closely with Global Biopharma companies to ensure their activities in Ireland are successful.

"Throughout the pandemic the biopharma manufacturing plants in Ireland demonstrated considerable agility, resilience and durability, continuing to operate successfully without any interruption in the supply of the essential innovative medicines that are produced here."

IDA's new four-year organisational strategy 2021-2024 Driving Recovery and Sustainable Growth aims to consolidate and build on the positive impact of FDI as Ireland pursues a jobsled recovery that seizes on the opportunities of the green and digital transition. We have made significant progress implementing the strategy since its publication in January 2021, including the development of implementation plans by IDA's operating divisions to support the achievement of objectives across our strategic pillars of Growth, Transformation, Regions, Sustainability, and Impact.

I wish Biopharmachem Ireland every success with the implementation of its new strategy for the continued growth and development of this most important sector in Ireland. It is heartening to see the industry collaborating to solve the challenges it faces, including digitalisation and sustainability.

Ireland has a strong future in Biopharma and will continue to be a global leader in manufacturing and process development for many years to come. The advanced services activities that our client companies are increasingly establishing in Ireland will continue to grow and develop, contributing to that success.

Martin Shanahan CEO, IDA Ireland





Enterprise Ireland CEO, Leo Clancy

Irish enterprise has, over recent years, gone from strength to strength in every sector. In 2021 companies supported by Enterprise Ireland posted record gains in net job creation and in export value growth. This was complemented by a very strong growth in innovation expenditure by Irish owned companies to €1.35 billion euros.

All of these gains are particularly encouraging given that they occurred during a pandemic that inhibited travel and collaboration and forced new ways of working and collaborating. Many companies flourished and indeed contributed strongly to the advanced in Life Sciences that helped the world cope with and emerge from that devastating pandemic.

What is often overlooked is the companies across many industries in the supply chains of those on the front lines of drug discovery and production. This is true across services, equipment supply, facility construction and digital platforms among many more. Ireland has benefited greatly from the growth of biologics, pharmaceuticals and chemicals industries here and I believe that the best is yet to come. Irish small and medium companies and large Irish-owned enterprises, on the back of experience at the cutting edge of delivering for the best in the world, have huge potential to fuel this industry's growth here across every requirement the industry may have. I am also very optimistic that we will see innovative Irish companies at the core of the

industries continue to grow and that we will see new leaders emerge.

Enterprise Ireland's new strategy, Leading in a Changing World, anticipates Irish founded and scaled companies taking key positions in major global markets. We see a huge opportunity for Ireland to be at the heart of a new technological revolution, fuelled by excellent businesspeople and top talent leading through innovation and ambition.

This will only be achieved through collaboration between industry, academia, Government and strong industry bodies, working together on shared goals.

With that in mind I very much welcome the publication of this new strategy and look forward to continuing to work with BioPharmaChem Ireland on growing the scale and impact of this sector in Ireland.

Leo Clancy CEO, Enterprise Ireland "Irish small and medium companies and large Irishowned enterprises, on the back of experience at the cutting edge of delivering for the best in the world, have huge potential to fuel this industry's growth here across every requirement the industry may have."





Science Foundation Ireland Director General, Philip Nolan

Sustained government investment over the last two decades has delivered a thriving, world class, research and innovation ecosystem. Ireland is currently ranked 12th in global scientific rankings, excelling in areas such as immunology, pharmacology and materials science, and first in the world for knowledge diffusion and impact.

Furthermore, Ireland has evolved into a highly cohesive research and innovation ecosystem involving close collaboration between researchers in higher education institutions, private enterprise and government. Our highly connected and collaborative nature sets Ireland apart internationally, as well as being crucial in responding to major global challenges, delivering urgent solutions to the Covid 19 pandemic and underpinning our collective response to the climate crisis.

SFI's strategy, Shaping Our Future, aims to further strengthen Ireland's research base through investment in excellent research and talent that delivers sustainable societal and economic benefits. A key objective of this strategy is to grow and evolve programmes that support collaboration between researchers in academia and industry, such as the SFI Research Centres. Centres including the SFI Research for Pharmaceuticals (SSPC), a key partner for biopharma companies

in Ireland, deliver the scientific breakthroughs and innovation that drive increased enterprise productivity and competitiveness, ensuring that enterprises stay at the cutting edge of scientific and technological developments. SFI will also grow the pipeline of high skilled researchers to meet the demands of industry with a goal that 65% of researchers will move to positions outside of academia by 2025. The biopharma sector is notable as a major destination for SFI funded researchers.

I welcome the ongoing commitment of the members of BioPharmaChem Ireland to research and innovation, which will future proof this important sector for Ireland, underpinning increased investment and high value jobs. Partnership with the higher education system will be critical to achieving the ambition of developing global leadership in the manufacture of next generation drug modalities and the development of Ireland as a test bed for ICT integration into the

"Ireland has evolved into a highly cohesive research and innovation ecosystem involving close collaboration between researchers in higher education institutions, private enterprise and government."

biopharma manufacturing. Additional opportunities for the sector include a move up the value chain toward drug discovery and development, leveraging Ireland's significant research capabilities in biotechnologies, microbiome science, advanced materials, drug delivery, data analytics and modelling; development of sustainable manufacturing processes; and development of all island research clusters.

I take this opportunity to congratulate BioPharmaChem Ireland on the launch of their new strategy and wish them every success with the implementation and rollout ahead.

Professor Philip Nolan Director General Science Foundation Ireland



Ireland ranks
11th strongest
innovator on the
European Innovation
Scoreboard, and 19th
overall on the Global
Innovation Index.



Welcome BioPharmaChem Ireland Chair, Paul McCabe

BioPharmaChem Ireland's (BPCI) strategy document 2019-2023 was titled "Ireland – the Global BioPharma-Chem Location of Choice" and was a clear recognition that Ireland had made significant strides in the previous decade to become a globally recognised centre of excellence for innovation and development in biopharmaceutical, pharmaceutical & chemical manufacture and supply.

The sector has continued to thrive and in 2021, the industry became worth ~ €100 billion to the economy in terms of exports, there are now more than 84,000 highly skilled people directly & indirectly employed in the sector and the expectation is that this will increase by up to 10,000 jobs over the next 5 years. The sector has also continued to be very successful in attracting international capital investments in the last decade – much of this in the manufacture and development of biotech products.

The sector still has many challenges in front of it. We have seen the impact of the COVID-19 pandemic, global conflicts, and changes to corporate tax rates. These have manifested in significant impact to Global Supply Chains and a renewed focus on our national competitiveness.

The challenges are addressed in this document:

- The need for a future focused industrial policy championed by Government,
- The importance of broadening our sectoral ecosystem beyond manufacturing & supply
- A supportive environment to enable indigenous SMEs to grow & flourish,
- The ongoing challenge to create a sustainable talent pipeline,
- The imperative to continue to stay competitive and innovative.

Ireland has an opportunity to broaden and deepen our ecosystem to ensure we have a sustainable sector into the future. As such, our strategy is pivoting towards themes such as Advanced "Ireland has evolved into a highly cohesive research and innovation ecosystem involving close collaboration between researchers in higher education institutions, private enterprise and government."

Therapeutics, Global Business Services, Indigenous Biotech sector, CDMO's and Digitisation.

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.

A quote which underpins our ambition is "The secret to change is to focus all of your energy not on fighting to keep the old, but instead on building the new"

Paul McCabe Chair, Biopharmachem Ireland



Ireland is
the world's third
largest exporter of
pharmaceuticals,
according to the
UN International
Trade Statistics
database.



Introduction BioPharmaChem Ireland Director, Matt Moran

Welcome to Phase 6 of the BioPharmaChem Ireland (BPCI) strategy series as we approach the exit of the COVID-19 pandemic. Notwithstanding the enormous economic turmoil that the globe has experienced in the past years, the Biopharmachem sector has continued to thrive and in 2021, the industry became worth over €100 billion to the economy in terms of exports, there are now more than 84000 highly skilled people directly & indirectly employed in the sector and the expectation is that this will increase by up to 10,000 jobs over the next five years.

The sector has also continued to be very successful in attracting international capital investments in the last decade – much of this in the manufacture and development of biotech products.

The sector still has many challenges in front of it. We have seen the impact of the COVID-19 pandemic, global conflicts, and changes to corporate tax rates. These have manifested in significant impact to Global Supply Chains and a renewed focus on our national competitiveness. The challenges include:

- The need for a future focused industrial policy championed by Government,
- The importance of broadening our sectoral ecosystem beyond manufacturing & supply
- A supportive environment to enable indigenous SMEs to grow & flourish
- The ongoing challenge to create a sustainable talent pipeline

The imperative to continue to stay competitive and innovative

The Irish Government need to publish a Life Sciences Plan setting out a 10-year strategy for the sector to build on Ireland's extensive life sciences expertise, demonstrated by the successes of the COVID-19 response over the past two years. The strategy should highlight what all life science stakeholders (regulators, industry, academia, NGO's, HSE etc.) need to do to create an environment in which the life sciences industry can continue to grow and flourish.

A central part of this strategy needs to be the establishment of an "Office for Life Sciences" to champion research, innovation and the use of technology to transform health and care services. The office should be led by the Department of Enterprise, Trade & Employment with support from other departments. With COVID-19 putting the spotlight on the life sciences sector, it is time for

"A central part of this strategy needs to be the establishment of an "Office for Life Sciences" to champion research, innovation and the use of technology to transform health and care services."

the Government to fully recognise the potential for Ireland to a global leader and establish an "Office for Life Sciences" to ensure that this becomes a reality.

Entering into the new era of advanced therapeutics/ cell and gene therapy, partnership between industry, the government and the HSE will be critical in ensuring that Ireland is a global hub for life sciences. Government need to recognise and centrally develop this partnership model, through the Office for Life Sciences.

Ireland has been very successful in attracting foreign direct investment in biopharma and chemical manufacturing, development and supply. It has been less successful in developing a strong indigenous biotech sector, such as APC and Avectas, to compliment this; hence the recent decision by Spear Street Capital to invest in a bioincubator at Cherrywood, South Dublin is welcome. The 30,000 square foot facility will be run by The Pioneer Group (TPG, formerly We Are Pioneer Group), a UK based operator in incubating and accelerating life sciences businesses. It is hoped that initiatives such as this will help to grow out a strong indigenous life sciences sector that can complement the already strong FDI sector.

BPCI has identified six strategic themes, which we believe will underpin the future success of the sector here. BPCI will ensure that this builds on the huge success of the existing biotech and vaccines sector previously identified as a priority by BPCI; a sector that will and must remain a priority for the country.

BPCI looks forward to working with all its stakeholders, through its members to ensure that this important sector continues to grow and flourish well into this century.

Matt Moran Director, Biopharmachem Ireland



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

Biopharmaceutical and chemical sector had an export value of

€106bn

in 2020 – the first time a sector has exceeded the €100 billion mark in a single year.

67% of the total goods exported from Ireland



11.2bn

Covid-19 vaccine doses produced in a single year



85+
companies



in capital investment

of the topselling medicines manufactured Over 80,000 employed directly and indirectly by the sector



50FDAapproved pharma and biopharma plants



of the top 20 global pharma and biopharma companies based in Ireland 25% of all PhD researchers in the Irish industry are employed in the sector.





of the top 10 world's Biopharma companies



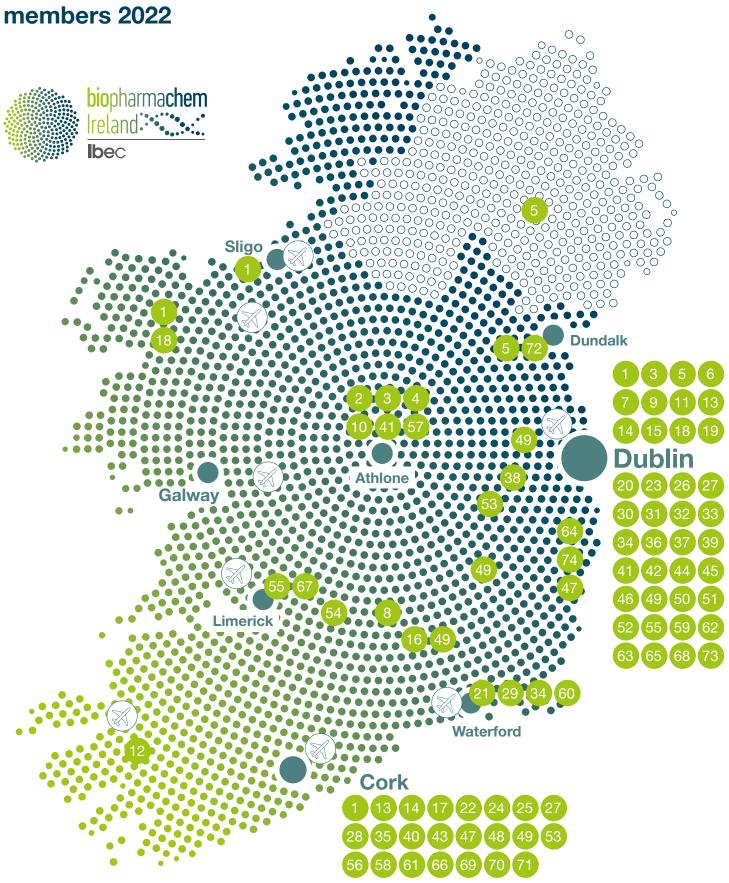
Ireland has an exemplary compliance record with regulatory agencies

like the Food and Drink Administration (FDA) and European Medicines Agency (EMA), who collaborate and work closely with our Health Products Regulatory Authority (HPRA) to achieve trouble-free compliance.

Ireland has one of the largest shares of tertiary education with 47% of 25-64 year-olds having third level degrees, with 85% of tertiary educated adults employed and enjoying greater earnings according to the OECD



BioPharmaChem Ireland



Member companies

- Abbvie Ireland N.B.V
- 2. Aerie Pharmaceuticals Ireland Ltd
- 3. Alexion Pharma International Operations UC
- 4. Alkermes Pharma Ireland Ltd
- 5. Almac
- 6. Amarin
- 7. Amgen Technology (Ireland) UC
- 8. Amneal Ireland Limited
- 9. APC & VLE Therapeutics
- 10. Arran Chemical Company Ltd
- 11. Astellas Ireland Co Limited
- 12. Astellas Ireland Co Ltd
- 13. BASF Ireland Limited
- 14. BioMarin International Ltd
- 15. Bristol Myers Squibb Cruiserath
- 16. Camida
- 17. Cara Partners & Wallingstown Co Ltd
- 18. Charles River Laboratories Ireland Limited
- 19. Clarochem Ireland Limited
- 20. DHL Supply Chain Ireland Limited
- 21. Eirgen Pharma Ltd
- 22. Eli Lilly Kinsale Limited
- 23. EyeOn Ireland Limited
- 24. Fournier Laboratories Ireland Ltd
- 25. GE Healthcare Ireland
- 26. GH Research
- 27. Gilead Sciences Ireland UC
- 28. GlaxoSmithKline Cork
- 29. GSK Haleon
- 30. Grifols Worldwide Operations Ltd
- 31. Guerbet Ireland ULC
- 32. Helsinn Birex Pharmaceuticals Ltd
- 33. Henkel Ireland Operations and Research Ltd
- 34. Horizon Pharma
- 35. Hovione Ltd
- 36. Indaver Ireland Limited
- 37. Innopharma
- 38. Intel Ireland Limited
- 39. Ipsen Manufacturing Ireland Ltd
- 40. Janssen Pharmaceutical Sciences Unlimited Company
- 41. Jazz Pharmaceuticals Ireland Ltd
- 42. LEO Pharma
- 43. Life Science Consultants Limited
- 44. Mallinckrodt Pharmaceuticals Ireland Ltd
- 45. McArdle Transport Ltd
- 46. McDermott Laboratories
- 47. Merck
- 48. Micro Bio Ireland Limited
- 49. MSD Ireland
- 50. NIBRT
- 51. Novartis
- 52. Pfizer Ireland (Grange Castle) Pharmaceuticals
- 53. Pfizer Ireland Ltd
- 54. Pinewood Healthcare
- 55. PMTC
- 56. Portfolio Concentrate Solutions
- 57. PPD Development Ireland Ltd
- 58. Recordati Ireland Ltd
- 59. Rottapharm Ltd
- 60. Sanofi

- Industry partnering with Research





Irish Universities and Technological Universities



Research Centres

- 61. Schering Plough (Ireland) Company
- 62. Sebela Ireland Ltd
- 63. Seroba Life Sciences Management Limited
- 64. Servier Ireland Industries Ltd
- 65. SK biotek Ireland Limited
- 66. Sterling
- 67. Synthesis & Solid State Pharmaceutical Centre
- 68. Takeda Ireland Ltd
- 69. Thermo Fisher Scientific Cork Limited
- 70. Viatris
- 71. Westbourne IT Global Services
- 72. WuXi Biologics Ireland Ltd
- 73. Zifo Scientific Informatics Services
- 74. Zoetis Belgium SA Irish Branch



A sample of investments in the sector in 2022



MRCK

€440m

invested in Cork





AMGEN
€100m
invested in Dublin





€27m invested in Dublin



Office for Life Sciences

We are calling on the government to develop a national industrial life sciences strategy that reflects international best practice in industrial policy by embracing clustering. This should be led by the Department of Enterprise Trade and Employment, like Ireland's Industry 4.0 Strategy 2020-2025, and appoint appropriate resources at the Department to oversee and implement same.

The life sciences sectors of biopharma, medtech, and digital health, have demonstrated their value in improving lives, and stimulating sustained economic growth even in the face of global challenges. Nevertheless, to achieve these industries potential and solidify our position as global leaders we need a coordinated, and focused industrial policy to surmount rising obstacles, broadening our base from manufacturing and supply chain, creating an environment where homegrown startups and SMEs flourish, access to worldclass talent, along with maintaining our hardwon competitiveness, while moving up the value by developing and commercialising next generation innovation.

Recommendations

- The Government develop a national industrial life sciences strategy led by the Department of Enterprise Trade and Employment, with the support from other relevant Departments within Government.
- Establish an "Office for Life Sciences" to champion research, innovation, and the use of technology to transform health and care services globally.
- Review global best practice in ecosystem development as a mechanism for strategy/ ecosystem development such as the MIT REAP Regional Entrepreneurship Acceleration Program (MIT REAP) which provides opportunities for communities around the world to engage with MIT in an evidencebased, practical approach to strengthening innovation-driven entrepreneurial (IDE) ecosystems. A typical MIT REAP region has a population of 1-10 million people.



How Ireland will benefit

Active coordination of business policies and industry leadership has made Ireland a location of choice for business with the world's top life sciences companies selecting here as a gateway to Europe and the world.

Our reputation for manufacturing is of an indisputably high calibre with Ireland being the only country in Europe to see exports rise with growth of 5.4% largely supported by the crucial role of the life sciences industry in tackling Covid-19.

To keep pace with the international business trends, and the increasing complexity of the health innovation ecosystem we need to adapt. To continue on the road to success we need to forge a new path, or get left behind.

While manufacturing sites in Ireland continue to win projects and deliver in a challenging environment with more companies embracing smart factories to develop products, and more resilient supply chains to deliver on customer expectations, this is not enough to stand out.

However, we cannot compete as a low-cost manufacturing economy, but we have the potential to rise in the ranks to be at the vanguard of life sciences innovation thanks to our well established ecosystem that has a culture of collaboration with worldclass talent and leadership. By adopt industrial polices that promote clustering we can create the means to achieve more strategic methods of cooperation across sectors both vertically and horizontally with key stakeholders represented.

This view is reinforced by the OECD 'Empowering the health workforce: Strategies to make the most of the digital revolutions' which advises that a successful digital transformation requires system wide reorganisation underscored by an overarching strategy, with leadership that establishes a framework for coordination among decision making actors.

Given this trend, national and/or cluster ecosystem strategies are becoming common place in countries known for life sciences and innovation. These regions have recognised the opportunity to develop a national collaborative approach for future competitive advantage.

Strategic themes 2023-2027



Global Business Services (GBS)

- National strategy to identify future GBS talent needs
- Branding of GBS as Global Location of Choice
- Establishment of an "Office for Life Sciences

Contract Development and Manufacturing Organisation (CDMO)

- Focus on development of project management and CRM skills
- Ensure that labour intensive assets are kept in Ireland
- Map the full-service provider ecosystem



Cell and Gene Therapies (CGT)/ Advanced Theraputics

- Adoption of an integrated approach to CGT by State Agencies
- Realising Ireland's potential in next generation biologics, including the development of a thriving indigenous and start-up ecosystem
- Identify a funding strategy for CGT

Industry (Pharma) 5.0

- Sponsor and promote Ireland as the location of choice for the sustainable manufacture of medicines
- Focus on digital skills
- Bring new products to Ireland and grow the ecosystem

Skills

- Ensure the recommendations of the Expert Group on Future Skills Needs (EGFSN) are implemented involving all relevant stakeholders
- Ensure Ireland's Higher Education Institutions are aligned and sufficiently resourced to meet the future skills needs of the Biopharma sector.

Active Pharmaceutical Ingredients

- Sustainability grants for renewable energy
- Development of a major supply chain hub in Ireland
- Develop a footprint of API in Ireland



Strategic theme 1 Industry (Pharma) 5.0

The two most significant challenges facing Europe over the next decade are the transition towards a climate neutral society and the retention of our industrial competitiveness. Industry 5.0 can help drive this twin transition and involves the interpretation of Industry 4.0 Technologies through a human-centric lens.

It broadens the focus from solely shareholder value to value for all stakeholders in society and indeed greater resilience – particularly of supply chains and the manufacture of strategically important goods. Recent disruptions have shown the importance for Europe to be more self-reliant and or flexible in manufacturing and supply to adapt to changing conditions.

The European Commission's Industry 5.0 Policy Brief emphasizes the powerful role industry can play in achieving societal goals through green and sustainable production. Industry 5.0 provides an opportunity to reframe digitalisation and the techno- economic vision of the Industry 4.0 revolution through a human- centric lens, moving the focus from solely shareholder value to value for all stakeholders. Across Europe we have over 10M citizens working in high- tech manufacturing. Not only do the industries within this sector save lives by developing much-needed medicines, medical

technologies and food products, they change lives by providing rewarding and exciting careers across regions and within Member States. To sustain and grow those 10M careers, we must successfully digitalise these operations.

The European Commission has published a policy brief on Factory 5.0 – in their view Industry 5.0 can help to drive this twin transition and involves the interpretation of Industry 4.0 Technologies through a human centric lens. This brief emphasises the powerful role that industry can play in achieving societal goals through green and sustainable production.

There lies an opportunity for the sector in Ireland to defend its competitiveness while at the same time meeting its sustainability targets reducing its carbon footprint. By embracing the principles of Factory 5.0 Ireland can ensure the long-term future of the sector here.

Case Study Lighthouse 5.0 Partnership

The Lighthouse 5.0 Partnership is a cluster of Irish based high-tech Manufacturers, Service Providers and Government agencies formed with the goal of leveraging sectoral competencies and best practice experience to accelerate the transition of current operations towards Industry 5.0. The cluster involves benchmarking current state, identifying best practise exemplars and areas of opportunity through a digital maturity and sustainability assessment exercise that will enable the development of a data rich strategy that considers the unique technological and organisational direction, roadmap and destination. The cluster has exploited benchmarking methodologies developed by Innopharma.

Following engagement with EU industry groups, there is a broad agreement with respect to the benefits of accelerating the digital transformation of Europe's high-tech manufacturing sector and considering this initiative an essential investment in collaboration with sectoral investment, Member State, Horizon Europe and EU Recovery and Resilience funds. It is only through this approach that we will identify a research and Innovation strategy and accelerate the adoption of Industry 5.0 in a European setting and indeed demonstrate leadership at global level.

The Cluster is a champion of change around the Industry 5.0 principles of human-centric, sustainable and resilient manufacturing. Initial focus is on small molecule chemical manufacturing which is well positioned to benefit from 'Factory of the Future' advancements with the intent to broaden scope to other sectors within the ecosystem such as biologics, chemicals, medtech, engineering and agri/foodtech. Lighthouse 5.0 members include Life Science leaders like Lilly, MSD, SK Biotek, J&J, Merit Medical, Thermo Fisher Scientific, Pfizer, GE Healthcare, Merck. The cluster is supported by IDA Ireland and Enterprise Ireland.

Key benefits of such an approach are:

- Provides all leaders and experts with a comprehensive awareness of Industry 5.0 in the context of their own organisation's self-assessment
- Effective supply chain resilience from increased visibility, improved vendor management, and better understanding of all aspects of the end-to-end value stream
- Improved sustainability resulting in less carbon footprint and climate impact
- Provides a granular benchmark score against other life science companies
- Provides a unique insight into people and culture and their critical role on your transformation journey
- Provides recommendations of areas where initial transformation projects (both site specific and cross-site projects) should focus
- Provides the foundational inputs into developing a digital transformation roadmap (both technological and skills) to improve competitiveness and sustainability
- Builds an ecosystem aligned with National, European and global goals and objectives
- Provides a national fingerprint of digital maturity and sustainability readiness



Strategic theme 2 Skills

As the sector continues to invest and expand its operations in Ireland, the demand for the right kind of talent becomes acute. BPCI is very happy that Government recognises this and has tasked the Expert Group on Future Skills Needs (EGFSN) with the job of preparing a report on the current skills scenario within the sector in the country.

The attraction and retention of talent are the top priorities identified by Ibec member HR professionals for prioritisation in 2022. Attracting the right employees is a top priority for over a quarter of respondent organisations (29%), with three out of five respondents rating it within their top five priorities. Retaining existing employees as a top priority in 13%, with almost half (48.9%) listing retention among their top five priorities for the next year.

In response to global demand for top talent, life sciences leaders are transforming their talent acquisition strategies, selecting partners, piloting technologies and customising new recruitment and retention strategies. There is strong business case for diversity, equity, and inclusion (DE&I) – including its profound and very real power to attract the best talent and build high-performing teams

The areas of product and technology transfer, downstream processing and quality professionals are under increased pressure to locate talent. The rise of automation and artificial intelligence (AI) has brought new opportunities and with that, new skills are required. Companies are challenged with finding these skills within the current workforce and are now battling with every other industry sector in the world for ultra-high demand talent.

The availability of skills and talent is seen by the industry as a key prerequisite for future competitiveness, investment, and employment. The need for a collaborative approach to ensure the adequacy of the supply of Biopharma skills and talent has been raised by the industry in discussions with the Department of Jobs, Enterprise and Innovation and State agencies.

The measures listed below will help the sector to advance its Skills agenda:

- Continue to provide adequate funding for competitive funding such as Springboard, Apprenticeships and Skillnets allowing the Biopharma industry to be talent developers – not just consumers.
- Ensure the recommendations of the Expert Group on Future Skills Needs (EGFSN) are implemented involving all relevant stakeholders.
- Ensure Ireland's Higher Education Institutions are aligned and sufficiently resourced to meet the future skills needs of the Biopharma sector.





Case Study BioPharmaChem Skillnet / Laboratory Apprenticeship

BioPharmaChem Skillnet

The BioPharmaChem Skillnet works in alliance with Ibec industry association BioPharmaChem Ireland to help companies across the broad life sciences sector to identify current and evolving skills needs. It meets those needs through the provision of a range of specially designed education and training programmes ranging from short rapid learning sessions to virtual reality programmes on highly technical aspects of the manufacturing process, and fully accredited diploma level courses. BioPharmaChem Skillnet also meets the specific needs of individual companies through the delivery of customised programmes which can then be reworked for rollout to other companies in the sector.

Companies are investing heavily in training and education and the number of programmes being delivered to industry on an annual basis through the BioPharmaChem Skillnet has risen by over 40% over the last three years. The number of businesses availing of the BioPharmaChem Skillnet programmes has increased by 55% with the numbers being trained increasing by 110%. Talent shortages and talent retention are key factors in this investment.

Changes in manufacturing, digitalisation and sustainability are all key areas that the BioPharmaChem Skillnet are working closely with their industry partners to address. BioPharmaChem Skillnet has moved beyond the use of communications technology to deliver programmes online which formerly took place in person. In a highly innovative use of the latest technology two new virtual reality (VR) training programmes have been created with a third in development. The first, launched in 2021, addressed Aseptic Techniques for Biomanufacturing, and the second on Powder Handling for Active Pharmaceutical Ingredients was launched in mid-2022.

These novel VR programmes have a variety of advantages over traditional in-person courses and address the unique challenges associated with providing training for people who deal with extremely high value and sometimes hazardous substances.

Laboratory Apprenticeship

The Laboratory apprenticeship offers an unrivalled opportunity for employers to build a valuable talent pipeline. Launched in 2018, the programmes were developed by industry for industry and are aimed at addressing skills gaps and attracting and retaining talent. The apprentice will gain practical, handson experience while working towards a level 6 or 7 qualification. The apprenticeship is delivered in Dublin, Waterford and Cork and ensures work ready candidates, with the skills required to work in a regulated laboratory, graduate from the program. With more than thirty companies employing lab apprentices across Ireland, the program has seen fantastic growth and feedback from companies in the life science and food sectors has been incredibly positive.

Strategic theme 3 Active Pharmaceutical Ingredients (API)

API's have formed the traditional core of the sector when many of the large multinationals first established in Ireland. These companies still represent a very valuable component of the industry. As global networks come under increasing cost pressure, it is vital that Irelands API sector stays competitive and continues to grow.

A Lighthouse Project on Factory 5.0 has been established with the aim of digitising the sector, as well as driving sustainability in the industry. Advancements in automation, artificial intelligence (AI) and machine learning in recent years have improved the success rate in the structural design of small molecules. API companies are adding more sustainable manufacturing processes in line with stated aims to achieve zero carbon emissions from global global operations by the mid-2020s onwards.

The Lighthouse Project – a consortium of companies supported BPCI & IDA Ireland – is developing a roadmap to support an ecosystem to bring the small molecule API sector towards the principles that underpin Factory 5.0. The consortium is focused on addressing the digital and sustainable transformation of Irish small molecule manufacturing and the associated supply chain to achieve digital capabilities and green sustainability targets aligned to the Industry 5.0 strategy.

Ireland has a wealth of skills associated with API manufacturing and the announcement by AstraZeneca in 2021 of the construction of a \$360m API manufacturing facility in Dublin demonstrates this point. New small molecule products account for 50% of global new medicines therefore it is vital that existing sites continue to transform through upskilling staff, investing in new technology platforms, and manufacturing processes, in order to be flexible, agile and at the cutting edge of API production.

Measures to help the API industry continue to flourish include the following:

- · Sustainability grants for renewable energy
- Development of a major supply chain hub in Ireland
- Mapping a footprint of API in Ireland



Case Study Eli Lilly Kinsale – Dunderrow Solar Farm Project

The Dunderrow Solar Farm location is in a remote area immediately adjacent to the Lilly site. It is over 500m from any residence and because all surrounding hedgerows and trees have been maintained during the farm development, it is virtually invisible to the surrounding community with no impact from reflective glare from the system. Planning permission was granted for the development in early October 2020 with no submissions or objections by the local community. Observations related to the potential impact on aircraft approaching Cork Airport were addressed to the satisfaction of the DAA.

A particular focus in the planning of the farm was the protection of archaeological anomalies in the fields to be developed that were identified during initial site surveys. While the anomalies were not deemed to be historically significant a special ballast based solar panel support design was used in their vicinity to protect them for the future.

Both phases of the solar farm required in excess of a €7m investment by Lilly and Enerpower and were also supported by SEAI under the Better Energy Communities scheme. They include the installation of over 20,000 solar panels across four fields. At maximum output these panels can provide close to 8.0 MWp DC (or approx. 80% at peak output) of the site's imported power. The annual power generated exceeds the power consumption of Kinsale Town. It is a

significant contributor to Lilly's sustainability objectives by reducing the site's carbon footprint by over 3500T/ Yr. The development is also currently the largest private 'behind the meter' solar development in the country.

After successfully managing through COVID construction constraints the system went live on July 19th 2021. It is expected that the completed system (after the addition of Phase 2 in late July) will supply almost 8GWh per year representing just under 15% of the annual electricity imported by the site.

- In the future opportunities for battery and thermal storage of solar energy and an associated potential for additional generation partnerships with adjacent landowners will be investigated.
- The plant's annual output of over GWh is projected to reduce carbon dioxide emissions by over 3500 Tonnes/ year and this equates to the annual carbon sequestration of approximately 6,700 acres of forestry.
- Lilly is committed to its 2030 sustainable goals
 which include sourcing 100% of its electricity
 from renewable sources. Additional sustainability
 initiatives were also incorporated into the
 Project, including introducing sheep to keep the
 development naturally grazed and by planning
 the introduction of beehives on the solar site
 later in 2022 to promote local bio-diversity.



Strategic theme 4 Cell and Gene Therapies/Advanced Theraputics

Advanced therapeutics represent a significant opportunity for the Irish biopharma sector. The recent opening of the cell therapy production unit by Takeda at Grangecastle represents another important milestone. This will be Ireland's first stem cell therapy production facility and heralds a further step in the journey of innovation that the sector has been on since its establishment back in the 1960s.

This journey has seen the sector evolve from the chemical synthesis of active pharmaceutical ingredients (APIs), through final dosage forms, biotech manufacture right into the exciting new world of advanced therapeutics. The product being made at Grangecastle is designed to treat a side effect of irritable bowel syndrome and is an example of a family of products we know as cell and gene therapies.

Cell and gene therapies comprise a major part of advanced therapeutics with technologies such as chimeric antigen receptor – T cell or CAR-T able to provide a route to the permanent cure of diseases such as cancer. Recently, Ireland's first CAR-T therapy was administered out of Trinity St James's Cancer Institute. The patient was given the treatment for lymphoma. This is a very positive development for the evolution of therapeutics in this country.

Over the last five years there has been a steady rise in the number of approvals in the broad category of advanced therapeutics and vaccines; a category of innovative medicines that includes cell-based and gene-based therapies and is often termed as simply Cell and Gene Therapy (CGT). It is widely predicted that advanced therapeutics and vaccines will be the next big wave of biopharma growth, with analysts now predicting that CGT revenues will reach \$10 billion-\$60 billion globally by 2025/26.



Case Study The Cell & Gene Therapy (CGT) Forum

Over the last two decades, Ireland has established itself as a global leader in biopharmaceutical manufacturing and has had considerable success in attracting multinational companies to establish their manufacturing operations across the country. Biopharma foreign direct investment (FDI) in Ireland has exceeded €10bn over the last decade, with over 40,000 people now directly employed in a sector that contributes more than €100 billion in national exports annually.

Ireland, building on its successful track-record, its existing infrastructure, its experienced workforce and supportive business environment, has a major opportunity to attract CGT investment both from MNCs and the wider biopharma investor community in the coming years. Ireland can become a global location of choice for the development of and optimisation of CGT manufacturing, however, there is considerable international competition from countries that are also well-placed to attract investment.

Within this context, NIBRT and a group of other likeminded stakeholders with interests in the advanced therapeutics area came together in 2018 under the banner of the Cell & Gene Therapy (CGT) Forum. The strategic vision of the CGT Forum is to help make Ireland a Global leader for the development, manufacture, supply and adoption of advanced therapies, including cell and gene therapies and novel vaccines, through strong investment in world-class training, an innovative research base, a supportive entrepreneurial environment and excellent clinical trials infrastructure.

The CGT Forum now includes over one hundred members representing large multinational biopharma companies, biotech companies, biopharma technology vendors and service providers, engineering firms, recruitment agencies, venture capitalists, consultancies, academic researchers, clinicians, representative bodies, like BPCI and IPHA, and government agencies, including IDA Ireland, Science Foundation Ireland (SFI), Enterprise Ireland (EI), Health Research Board (HRB) and Health Products Regulatory Agency (HPRA).

The Forum now operates around seven working groups, with five of the groups oriented mainly CGT manufacturing and the other two working groups having a broader remit; one exploring what Ireland needs to do to develop and grow more indigenous CGT companies and one exploring Ireland's required capabilities to drive CGT clinical trial activity.

ATMP in Ireland

ATMP in Ireland is a national network of industry, academia, and government agency representatives. The goal is to promote, support and facilitate research and education in the area of Cell and Gene Therapies with a view to making Ireland a world-leading location for the production of these revolutionary new medicines. www.nibrt.ie/atmp-in-ireland/



Strategic theme 5 Global Business Services (GBS)

A growing number of biopharma companies operate Global Business Service (GBS) centres in Ireland. While originally set up to manage finance for corporate networks, they have laterally diversified into other areas, including HR, management of medical information, connected health to name but a few. Such centres are becoming more aligned with the manufacturing part of the industry and could look to establish control towers to manage supply chain in CGT products for example.

The Irish based GBS operations have earned a reputation for managing complexity and uncertainty, through their high knowledge base. A strong compliance focus has led to a solid reputation for managing risk activities. A robust capability in transfer pricing has also been applied to supply chain management. Ireland is seen as a 'safe pair of hands. Crucially, the Irish GBS sites host a Global Scope and network and have strong relationships with Global stakeholders

We need to ensure that Ireland is the location of choice for pharma GBS against other very competitive locations through our talent pool and raising the sectors profile in the labour market. The key to this is managing knowledge-based activity in, as transactional activity moves to lower cost locations. GBS can diversify into other areas such as Cell and Gene Therapy, Clinical Trials, and Supply chain. Ireland is ideally placed to host CGT "Control Towers" and leverage co-location with manufacturing sites in addition to leveraging data to provide new insights/opportunities into the business.

To sustain and grow pharma GBS in Ireland, we need to identify what is needed in terms of employees, skills, competencies, and tech skills. A National strategy to identify future GBS talent needs in partnership with Government, agencies and Third level institutions is required to ensure the availability of a talent pipeline and to identify future gaps and determine alternative sources of supply. The branding and marketing of Ireland in pharma GBS as the" Global Location of Choice" with a focus on the "Power of the Cluster" in addition to the establishment of an "Office for Life Sciences" within Government with an acknowledged position for Pharma GBS, would greatly enhance our objective of making Ireland a global centre of excellence in Pharma GBS.

- National strategy to identify future GBS talent needs
- Branding of GBS as Global Location of Choice
- Establishment of an "Office for Life Sciences"

Case Study GBS Skills pathway program

Ireland successfully began its "shared services" journey in the late 1990's competing as a cost-effective location for lower skilled transactional activities, centralised into hubs and benefitting from wage arbitrage and efficiencies of scale.

However, success was short lived as other more cost efficient locations emerged and Irish organisations recognised the need to provide more technically proficient colleagues which would facilitate moving up the "knowledge value chain" where skills and abilities, rather than costs, became the priority. In this environment, the next generation of shared services – "Global Business Services" (GBS) evolved.

Where the traditional shared-services organizations focused on supporting tasks associated with a single function, GBS specialises across multiple functional areas – e.g. IT, finance, human resources etc. creating alignment amongst business units, serving as a single enterprise organization or network that can drive collaboration and efficiency while improving service delivery.

Over the last couple of decades, Ireland has become one of the locations of choice for the more sophisticated, complex, and technical areas within GBS, based on its ability to continuously deliver a world class talent pipeline.

The Pharma industry quickly recognised the value of combining the inherent strength of manufacturing and support services to the developing talent and expertise in GBS to offer a World Class opportunity for investment in Life Sciences in the Irish Economy

In a sector like GBS, our ability to continually provide a world leading talent pipeline, expert in GBS, is the difference between long term sustainable success or ultimate failure. As the industry has evolved and more diverse activities have come within the scope of GBS, the industry recognised the need to establish a more formal education program that supported the future needs of the industry, enhance the reputation of Ireland

as the location of choice for Life Sciences FDI and offer colleagues within the industry a formal qualification in their chosen field with a defined career progression as a "GBS" professional. This has resulted in the development of the "GBS Skills pathway program".

The programme is a structured learning and development initiative that spans entry level to leadership development. It is highly specialised in a GBS context with practice-based pedagogy and assessment strategies to reinforce an applied and work-based focus. Currently the pathway programme consists of two accredited qualifications – a CPD Diploma in GBS and a MSc in GBS.

The critical strength of this initiative, that marks it out in a global setting, is that it is built on a triple helix partnership of (i) the State, through ICT Skillnet, providing the organisation and funding for the skills pathway programme, (ii) the engagement of the industry, with key players such as Pfizer providing critical input to the programme design and piloting as they incorporate the programmes into their professional development frameworks, and (iii) the higher education sector, through TU Dublin who in partnership with the Hackett Institute have designed, accredited and deliver this specialised sectoral suite of programmes.

The program has already delivered significant and meaningful results laying the foundation for continued development of the GBS sector within the Bio Pharma Industry in Ireland. Amongst the many innovative expansion of scope opportunities for GBS has been the emergence of an expertise in Cell and Gene Therapy (CGT) support through the development of initiatives like the GBS CGT Control Tower, where GBS are providing an E2E oversight and coordination facility for the CGT Industry – a first of it's kind, and demonstrating the partnership between GBS and the rest of the Industry that promotes Ireland as the continuing location of choice for FDI.

Strategic theme 6 Contract Development and Manufacturing Organisation (CDMO)

The CDMO sector is expanding and evolving globally; this is being driven by existing operators but also the transfer of some existing API operations. There is further potential to expand this sector, building on Ireland's excellent reputation for quality and strong regulatory compliance. Ireland is ideally placed also, sitting at the bridgehead between the US & Eurasia.

Project management is key for CDMO's and is a skillset that could be supported through skills development such as Skillnet funding for project management and CRM skills. Agility is key when sites are moving from a single to a multiproduct environment. Irish sites have proven to have a consistently high standard globally particularly in relation to products with higher levels of complexity. An extensive ecosystem of suppliers is in place in Ireland.

CDMO is a labour-intensive enterprise, and an extensive ecosystem of suppliers is in place in Ireland (a mapping exercise of the full-service provider ecosystem will demonstrate this) and should therefore be supported and promoted. There are enormous employment benefits associated with growing a service offering in CDMO.

Government agencies need to focus more on the CDMO opportunity for Ireland and support growth for a service offering not only in small molecule but

also in biologics CDMO's. Specialist CDMOs with a dedicated biologics capacity will be best placed to support companies in getting their innovations to market.

The pharmaceutical CDMO market has been valued at ~\$90B, growing at ~7% CAGR.¹ Traditionally, investment has been directed at small molecule therapeutics. In recent years, the market share of small molecule treatments has declined while the volume of large molecule and biologic treatments has grown rapidly.

Measures which will encourage the growth of CDMO's in Ireland include:

- Focus on development of project management & CRM skills
- Ensure that labour intensive assets are kept in Ireland
- Map the full-service provider Eco system

Pharmaceutical Outsourcing Market: Current and Future Strategic Trends. Pharma Tech Outlook: 12/31/2021. (Marwood Group 2022 Global Pharmaceutical CDMO Outlook)



Case Study Hovione

Hovione is a global company with over 60 years of experience as a Contract Development and Manufacturing Organization with a fully integrated offer of services for drug substance, drug product intermediate and drug product, always based on a culture of innovation, quality and delivery.

We, at Hovione, are dedicated to helping customers bring new and off-patent drugs to market and offer innovative particle engineering technologies, at all scales, to address challenges in drug delivery. "In it for Life" is our motto: we exist because patients need us and serving patients is a privilege.

Fast-paced, dynamic, empowering, diverse, and inclusive: we are proud of the exciting work environment we have built at our Cork site. More than ten years after acquiring the site from Pfizer, Hovione has been the longest site owner, demonstrating its commitment to the Cork pharma hub.

Currently employing more than 230 team members, the Hovione Cork site offers Contract Manufacturing for both drug substance and particle engineering. The plant is regularly inspected by the FDA and by the Health Products Regulatory Authority. With extensive facilities for drug substance manufacturing with approximately 430 cubic meters of state-of-the-art cGMP capacity and the potential for 12 discrete chemical process trains, the site also houses one of the largest commercial pharmaceutical spray dryers available on the market, that is particularly suited for large volume products.

In Ireland, Hovione has been independently certified by B-Corp, Business in the Community Ireland, Ecovadis, Responsible Care, excellence in energy efficiency design (EXEED) and most recently achieved the ISO 50001 Energy management certification. This demonstrates the commitment of the Company to be a responsible and sustainability focused organization.

As one of the growth drivers of our business strategy, innovation is fundamental to our company. Over 200 of our team members, representing approximately 10% of our global workforce work in R&D and most possess an advanced degree and leading knowledge in areas such as Chemistry, Analytical Chemistry, Process Engineering, Particle Design, Inhalation, and Drug Product Development. Our strategy also relies on partnerships and collaborations with leading R&D institutions and start-ups.

Hovione in Cork is one of the strategic growth engines of the company. It combines hard-to-find skilled professionals, unique capabilities, and an outstanding compliance track record.

We believe in Ireland's strong future in life sciences – thanks to its track record, regulatory stability, and talent pool – in the next years we will continue to invest to enable the production of Highly Potent Active Pharmaceutical Ingredients (HPAPI) and to facilitate onboarding of Drug Substance Manufacturing projects of all sizes. This means Hovione will create more than one hundred local jobs over a three-year period,

This investment in talent and capacity will contribute to the strengthening of this great ecosystem in which large customer projects with unique technologies can find a home by connecting to the existing infrastructure and equipment.

About BioPharmaChem Ireland

BioPharmaChem Ireland represents the biopharma and chemical sectors. We 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. Our Laboratory apprenticeship programmes allow companies an unrivalled opportunity to grow and develop their talent pipeline and drive business growth into the future. In addition, our Pharamchem Skillnet encourages companies with shared training needs to collaborate and achieve their training goals in a cost effective manner.

www.biopharmachemireland.ie



About Ibec

Ibec is Ireland's largest lobby and business representative group. Our purpose is to help build a better, sustainable future by influencing, supporting and delivering for business success. With over 250 employees, Ibec engages with key stakeholders in Ireland and internationally through our six regional offices and our Brussels office, along with an extensive international network in the UK and US.

Ibec positions are shaped by our diverse membership, which range from small to large, domestic to multinational and our 40 trade associations cover a wide range of industry sectors. Ibec members employ over 70% of the private sector workforce in Ireland.

As well as lobbying, Ibec provides a wide range of professional services and management training to members on all aspects of human resource management, occupational health and safety, employee relations and employment law.

www.ibec.ie



To find out more visit www.ibec.ie

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