Delegates listen to the plenary session at Dublin Castle.
On the 21st and 22nd September 2016, the Irish Pharmaceutical Healthcare Association and BioPharmaChem Ireland, representing the research-based and manufacturing sides of the biopharmaceutical industry respectively, came together with the National Institute for Bioprocessing Research and Training (NIBRT) to host the inaugural BioPharma Ambition Conference in Dublin, Ireland.

This multi-platform event took place at four locations across Dublin, including NIBRT, Trinity Biomedical Sciences Institute, the Mansion House and The Printworks at Dublin Castle to inspire and showcase innovation. The weekend prior to the main events saw a Health Hackathon being run at the DCU Alpha Centre in conjunction with MIT’s Hacking Medicines programme.

Bringing together international policy leaders, renowned researchers and senior industry personnel, the event highlighted Ireland’s booming biopharma industry and its ambitions for the health and well-being of populations. It also inspired and showcased innovation in discovery, development, manufacturing and healthcare solutions.

Establishing Ireland as a biopharmaceutical centre of excellence was at the heart of this year’s event, providing a platform to call for specific investment in both Ireland and Northern Ireland. There was a large focus on sustaining talent, growing competitiveness, providing greater support for clinical trials, IT and key specialists and ultimately, ensuring that Ireland and Northern Ireland have the capability to drive innovation and bring medicines to patients quickly.

BioPharma Ambition provided a variety of case studies of various transformations taking place within the industry, including the introduction of new technologies, new research avenues, and new types of collaborations. The central themes featured at the conference were the future of manufacturing, pioneering discovery, and driving innovation. The agenda provided a platform for debate and discussion, and pointed to how Ireland will be central to the sector’s future.
Over the years, Ireland has established itself as a location of international significance for the biopharmaceutical industry and is particularly well positioned in manufacturing and development, with a strong research base, including high-calibre universities, scientific institutes and industry start-ups.

Since Ireland’s financial crisis in 2008, the biopharmaceutical industry has made a significant contribution to Ireland’s economic recovery and fiscal stabilisation through sustained employment, investment and reductions in the cost of medicines to the State. This dovetailed with support and commitment from the Government for research, notably, with Science Foundation Ireland playing a central role.

The new pricing and reimbursement framework agreement made with the Government this summer provides a stable platform for bringing new, innovative medicines to patients appropriate to Ireland’s economic status in Europe. As the fiscal crisis comes to an end, we now have an opportunity to focus on the value of medicines to patients and the community and the contribution that pharmaceutical innovation makes to economic and social development.

The biopharmaceutical industry is driven by innovation to deliver solutions for patients. This first BioPharma Ambition industry event emphasises that Ireland is well-placed to enable the biopharma industry to deliver therapeutic solutions for patients globally. We have excellent training and research for bioprocessing staff provided by the National Institute for Bioprocessing Research and Training (NIBRT), which allows biopharma to locate and grow here. We have high-quality regulatory science and oversight, with the well-respected Health Products Regulatory Agency. We have the human capacity and skills base and we are investing in education. The policy environment for business is good, including a transparent corporation tax regime that facilitates substantive business activity, as seen in bioprocessing. Furthermore, we continue to emphasise Ireland’s strategic, fully embedded membership of the European Union, including the Euro Zone and EU single market, while we continue to foster fantastic links internationally, in the US, North America and Asia.

Ireland has always been outward looking and, in today’s language, ‘networked’. We build on our social connectedness through the wider Irish family overseas. From a business perspective, to compete in the international pharmaceutical industry as in others, we have to be tuned into the world. We have to integrate internationally in markets, investments, science and education. It is particularly important to ensure our education and capacity to grow talent is of an international standard and that our economic policies attract people to work in the industry in Ireland. We have reached a high level but we are aware that what is competitive today might not be tomorrow. We are constantly adjusting to the new realities.

Biopharma Ambition is an all-island event and champions the island of Ireland as an attractive place for the biopharmaceutical industry, North and South. It showcases innovation and highlights the ambition of the industry in providing future health solutions. With the support of InterTrade Ireland, it also sets out the clear opportunities for closer co-operation between Ireland and Northern Ireland to make the island a true centre of international excellence.

For more than 50 years the biopharmaceutical industry has been a key investor in Ireland; we are working hard to ensure this position is maintained and grows as the science and business of researching, developing, manufacturing and reimbursing innovative medicines develops constantly.
Minister for Jobs, Enterprise & Innovation Mary Mitchell O’Connor, TD and Northern Ireland’s Minister for the Economy, Simon Hamilton, MLA pictured at the opening of BioPharma Ambition.
The biopharmaceutical industry is currently being challenged from multiple directions and faces unprecedented change. Such challenges include the burdens of chronic disease, the digitisation of health and rapid pace of technological change and scientific advancement, the introduction of biosimilars, the increasing demand for value, new pricing and reimbursement models, and the clear requirement to collaborate across stakeholders and institutional boundaries. These issues are set to have ramifications across every part of the sector.

In recent years companies have been looking beyond traditional boundaries and are renewing their commitment to innovation in all respects as the key to their future. Acceptance that the blockbuster model has shifted to a ‘niche-buster’ model has injected renewed energy into R&D alongside technological uptake across the value chain and a greater emphasis on collaboration.

BioPharma Ambition exemplified how the industry was prepared to take on new challenges across the spectrum. Speakers confirmed that it was an exciting, albeit challenging time for the biopharma industry, with plenty of opportunity. There is the potential to add 8,000 jobs over the next three years in Ireland, while Northern Ireland has the potential to double its biopharma footprint by generating revenues of £1.6 billion per annum by 2020.

In this environment of opportunity, the industry will evolve by turning to innovation and technology to address the main challenges. “There will still be blockbuster products, and as an industry we are obsessed with a product,” said Graham Symcox, Managing Director at Pharmacentaur AG, who spoke at the NIBRT session. “But what the patient wants is a solution. This is a move away from a product to a healthcare outcome – and that brings a whole new complexity to biopharma and manufacturing.”

Graham Symcox, Pharmacentaur AG
One significant challenge for the industry has been, and will continue to be, finding solutions around value and pricing with Government and payors. According to Sir Andrew Dillon, Chief Executive of the UK’s National Institute for Health and Care Excellence (NICE), one of the keynote speakers at the plenary session, the industry had a responsibility to consider the cost implications of the new drugs being developed. “The industry needs to recognise the stress it brings to health systems with its value proposition,” he said.

Moving forward, innovation would be required to address this issue, Sir Andrew said, with more flexibility by NICE on how to finance the value proposition, and more flexibility from industry on price, ensuring it is in the range of affordability. For example, more creative pricing options like managed access agreements should be considered, he said, but fundamentally the solutions would come from collaboration and mutual understanding. “Closer working is a really good way of making sure there is the best possible alignment between the industry’s ambition and the health system’s ambition of the adoption of new technology,” he said.

According to Elcin Ergun, Executive Vice President, Head of New Businesses Healthcare at Merck, the industry was faced with a “massive group of challenges”. “We’re used to working in a way that has been successful but it becomes harder to sustain,” she said. “For the industry going forward we have to manage this mindset otherwise we won’t be able to survive.”

The depth of innovation in the industry that would drive this new mind-set was highlighted throughout the event, as well as the importance of collaboration in achieving this, from manufacturing through to development, and training through to the adoption of new medicines in the healthcare system. The conference set the scene for all stakeholders to come together with the one purpose to bring innovation and new therapies to patients.
Ireland’s biopharma heritage has been built on the strength of its biopharma manufacturing expertise. The success of NIBRT in research and training for bioprocessing was considered a landmark example. The readiness to uptake new technologies, particularly in manufacturing, was an especially attractive asset and, according to a survey run by Pharmacentaur, this would be a significant reason for companies to consider further investment in the country.

However, much is changing in the global manufacturing environment, as conference delegates were told. Firstly, there are a number of technological developments, including continuous manufacturing; big data statistical analysis of bioprocesses; next-generation DNA-based approaches for contamination control; and mini-bioreactors.

Secondly, there are a number of unique challenges affecting biopharma manufacturing, including globalisation and the cost associated with multiple manufacturing sites; the need to reduce drug substance costs; supply versus cost issues; the convergence of modalities and technologies; the integration and regulation of new technology; the continued need to train people in bioprocessing; new manufacturing infrastructure, especially in emerging markets; and the complexity associated with strategic manufacturing decisions.

In addition, attention increasingly focuses on streamlining manufacturing and improving efficiency, and ensuring that complex biologic pipelines can be delivered, particularly in regards to the major advances around biosimilars, precision medicine and advanced manufacturing. Consensus at the conference was that the uptake of technology in manufacturing can help this, although there were concerns around regulation.

In the USA, regulators were directly addressing this issue through the Office of Pharmaceutical Quality (OPQ), which was established to help drive and foster innovation and quality in the industry. According to Dr Michael Kopcha, Director of the OPQ at the US Food and Drug Administration (FDA), two thirds of drug shortages were a result of quality issues. The OPQ aimed to prevent drug shortages by focusing on more efficient and emerging manufacturing technologies, he said, which would lead to more robust manufacturing, less failures and more consistent clinical performance.

“We need to understand the advances in technology to help us in regulation and help forward innovation. We want to be seen as encouraging emerging technology,” Kopcha said. There were numerous examples where the OPQ was spearheading success, such as the approval of cystic fibrosis drug Orkambi, which marked the first New Drug Application approval by the FDA for a continuous drug product manufacturing process.
A number of speakers at the conference also presented case studies, with continuous manufacturing a particularly strong theme, including Dr Humphrey Moynihan, Research Advisor at Eli Lilly and Co, and Professor Kieran Hodnett, from the Solid State Pharmaceutical Centre (SSPC), funded by Science Foundation Ireland (SFI), who discussed the impact of collaboration between the small molecule industry and academia, with a particular area of opportunity on continuous manufacturing.

The presence of biosimilars, meanwhile, promised to present a unique challenge for companies from a manufacturing, regulatory and uptake point of view. According to Nigel Darby, Advisor at GE Healthcare Life Sciences, one of the event sponsors, biosimilars would fragment the marketplace. In psoriasis, for example, there are currently as many as six antibodies approved to treat the disease but there are around 10 biosimilars in development plus new antibodies in the pipeline. Thus, by 2020 there could be 20 different antibodies on the market as treatment options for psoriasis, Darby said, adding that in the coming years, each originator product could expect five to 10 biosimilar competitors.

With such interest in biosimilars, it makes sense that Ireland take advantage of the opportunity this provides. Already, the Irish Government has explored this, with the Department of Health currently assessing the area with a plan to develop a policy that supports biosimilar use in Ireland. Meanwhile, the Health Service Executive’s Medicines Management Programme has already supported the development of biosimilars and “the Government is looking to create the right market conditions that will enable the biosimilar industry to grow”, Minister of Health Simon Harris TD, told conference delegates.

According to Graham Symcox, Ireland was winning as a manufacturer compared with Switzerland and Singapore. “In Ireland, we have the ecosystem plus tax, plus track record, plus capability. Manufacturing sites in Ireland are strategic.” He believed Ireland would feature highly as a future go-to destination for biopharma manufacturing.

“"The Government is looking to create the right market conditions that will enable the biosimilar industry to grow."
Simon Harris, TD, Minister of Health
Today’s research landscape has changed dramatically as new scientific advances and technologies transform the space. Notably, this includes: synthetic biology and developments in genomics, gene editing, proteomics, metabolomics; nanotechnology; automation and robotics; novel drug delivery strategies; and advanced diagnostics, analytics and sensors. In addition, alternative therapeutic modalities are on the cusp of emerging; notably cell therapy, gene therapy, regenerative medicine, and electroceuticals. Meanwhile, bioinformatics, big data and developments in the digital world are further transforming research and the healthcare space.

These advances provide new and exciting research avenues, which Ireland is embracing, positioning the country as a hotbed of innovation. This was showcased at the BioPharma Ambition Conference during the event at the Trinity Biomedical Sciences Institute at Trinity College Dublin. Here, examples of leading-edge research in Ireland were presented by speakers from several Irish universities and institutes, including the National University of Ireland Galway, University College Cork, Dublin City University, University College Dublin, UCD Conway Institute, and Trinity College Dublin.

At the National University of Ireland Galway’s Regenerative Medicine Institute, for instance, human stem cells were being transplanted to injured organs to stimulate tissue repair. Significant early phase trial results had led to a Phase II trial that was about to begin, which would look at stem cell impact on mild to moderate osteoarthritis. Professor Frank Barry, Professor of Cellular Therapy at the Institute, said that if the trial was successful this could be the first disease-modifying agent developed for osteoarthritis, and could pave the way for treating other joints and discovering new drugs.

At the University College Cork’s APC Microbiome Institute, researchers were mining data from gut bacteria to develop pharmabiotics to promote health and treat disease. A range of projects were being explored, from faecal transplants and antibiotic discovery to the brain-gut link and the possible role of probiotics. Meanwhile, Systems Biology Ireland, based at University College Dublin, was using omic technologies and computational biology to model cancer networks to describe and analyse biological processes and develop new therapeutic approaches to cancer. Conference delegates were also introduced to the pioneering cell-based research at Dublin City University, presented with examples of the various research groups at the Conway Institute, and shown how connected health technology was being used in research at Trinity College.
Professor Orla Hardiman, Professor of Neurology and Academic Director at the Trinity Biomedical Sciences Institute (TBSI), who chaired the conference event, said Ireland was open for business and was ready to collaborate. She cited the depth of research innovation at the TBSI, which had received €83 million in research funding, produced 1,598 publications and 71,059 citations, had 85 partnerships with the industry, and had further created seven spinout companies.

During the plenary session at The Printworks, Professor Luke O’Neill, Chair of Biochemistry at Trinity College Dublin, spoke of the advances in immune system research, which had been boosted by the success of several immuno-oncology drugs. According to O’Neill, $12 billion had been invested in the area between 1999 and 2015, as researchers asked whether the immune system could be harnessed to cure all diseases. The interest had led O’Neill to setup the university spinout Opsona Therapeutics to focus on innate immunity research and to specifically explore toll-like receptors and inflammasome signalling earlier in the immune pathway.

The pioneering research taking place in Ireland would contribute to the new and innovative drugs that would move into the biopharma industry’s pipeline. These advances would not only change the way diseases were treated in the future but would also forward precision medicine and address unmet patient medical needs.
Importantly, innovations in technology and research avenues create new opportunities and, ultimately, the development of new types of drugs. Innovation in medicine is also seen with the convergence of different technologies and sectors, which would have an impact on the pharmaceutical industry, healthcare and society. It was this theme that dominated the plenary sessions during BioPharma Ambition at The Printworks.

According to Dr Mike Thien, SVP, Global Technology and Commercialisation at MSD: “It’s clear that the types of products we make in the future won’t be the types of products we make now.” Although he believed small molecule and monoclonal antibody drugs would still be manufactured, he said more emphasis would be on personalised medicines and providing more value to patients and healthcare systems. “We will have to think about what we’re making and how we deliver it, and make sure the patient will derive the full benefit from the therapy.”

In this sense, the industry was moving into a new era with clear signs of progress in pharmaceutical innovation, according to Dr Garret Fitzgerald, Director at the Institute for Translational Medicine and Therapeutics, University of Pennsylvania. He said there was, for instance, an increasing use of big data, in the form of electronic health records and biobanks, to help uncover unexpected disease associations and to inform individual health requirements.

This was echoed by Professor Patrick Johnston, President and Vice-Chancellor at Queen’s University Belfast, who noted numerous examples of UK initiatives to forward research and drive innovation, including the UK Biobank and 100,000 genome project, and said collaborative working was critical for future innovation. Likewise, according to Dr Gerard Fox, Senior Director and Head, Calico Collaboration at Abbvie, some of the best ideas resulted from the totally unexpected interactions between different technologies. He gave the example of Calico, the Google setup that is researching the biology of ageing and which Abbvie has also invested.

Indeed, there were plentiful examples presented at the conference where companies were thinking outside the box in regards to innovation, and finding non-traditional solutions to address challenges and drive improved patient outcomes.

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One case study discussed by Dr Bernadette Doyle, Vice President, Global Technical and NPI, Global Manufacturing and Supply at GlaxoSmithKline, was the firm’s IIM Digitisation Lab as an approach to new technology. This virtual environment, essentially a digital factory, rapidly tested and trialled new systems and technologies including augmented reality, RFID, and virtual reality. The company had also collaborated with Formula 1 car racing brand McLaren to tap into its data analysis expertise. “We created an ecosystem for cross collaboration and to develop a system where it was okay to take risks,” she said.

Merck, meanwhile, had created a new entity, which worked as a biotech unit and would maximise several promising R&D assets that could benefit from a risk-sharing, externalisation approach. The unit reported to the CEO but worked at arms length and was empowered to be agile and make fast decisions unlike the traditional model.

There was also innovation in the types of new partnerships that were developing. MSD, for instance, had a number of collaborations with non-traditional biopharma partners. In one case study, presented by Dr Mike Thien, the company wanted to explore access to vaccinations and low vaccination rates. MSD found that when there was no vaccine storage options at the doctor’s clinic, less than a quarter of the patients requiring a vaccine would be vaccinated because of the hassle in obtaining the vaccine. To find a solution, MSD partnered with a vending machine company to develop a smart refrigerator that automatically recorded the use of stock and fed information back to the distributor to ensure timely refilling. Use of the refrigerator resulted in increased rates of vaccine uptake and was now being expanded to another market.

These case studies were examples where disruptive technologies had been applied to healthcare, highlighting the convergence of life sciences, physical sciences and engineering. According to Professor Charles Cooney, FT Haslam Professor of Chemical Engineering at Massachusetts Institute of Technology, the introduction of such technologies would present challenges and would require forethought on how these technologies would be integrated and used in the future. He added that the industry had to embrace risk.

The direction that most innovation was pointing to was towards personalised or precision medicine, where information from our genetic code, proteome, lifestyle, environment and other health data would be used to tailor more effective drugs for sub populations, and ultimately the individual. Conference speakers confirmed this area was set to expand over the coming years. “The more we understand diseases, the more we follow the science, the more we see the need for personalised medicines,” said Dr Damian Page, Group Scientific Director for Personalised Healthcare and Molecular Information at Roche, who spoke at The Printworks. He believed the more comprehensive the genomic information, the more likely the move to a one patient, one tumour profile.

Currently, one of the most prominent research areas in precision medicine was the identification of biomarkers to predict disease, divide patients into subgroups and determine drug response. Advances in this area are seen, for example, where, in 2015, more than half of all non-small cell lung cancer cases were known to be driven by genomic alterations, whereas, in 2004, genomic alterations were known to contribute to only a third.
According to Dr Damian O’Connell, Senior Vice President, Drug Discovery, Global Head of Clinical Sciences at Bayer Pharma, biomarkers were becoming of “fundamental importance”, particularly when drugs without a biomarker were found to have a third less chance of success, he said. Advanced diagnostics would be a major theme over the next five plus years, he added.

Alongside precision medicine was the increasingly broader focus on health solutions that go beyond just medicine, said Dr Leisha Daly, Country Director at Janssen and President of the Irish Pharmaceutical Healthcare Association (IPHA). This could mean that non-medicine treatments such as smartphone apps would be prescribed and technology would increasingly be used to compliment medicines through patient support programmes, such as homecare services and real-world data collection via remote monitoring. Daly believed this was the future.

These new innovations would see the industry change in many ways. One way, according to several of the conference speakers, would be more collaborations with patients to improve insights and thus outcomes. It was only through working with patient groups that the industry would be best placed to understand diseases and the disease experience, said Dr Anthony Coyle, SVP/CSO Centres for Therapeutic Innovation at Pfizer. Furthermore, he believed the basic days of discovery in pharma were over. “If we’re to be competitive we need to look externally because we don’t have the skills to adapt to the changing biological space,” he said.

Other changes would come from moves to improve efficiency of the drug development pathway to reduce costs, as well as a different approach to IP and rewarding innovation, according to Professor Garret Fitzgerald. Meanwhile O’Connell said real-world evidence and use of big data analytics would become increasingly crucial in the new biopharma world. “Accelerating innovation will require us to rethink the evidence base to reduce uncertainty of reimbursement.” He added: “To drive innovation, the industry will need to continue to create partnerships with multiple stakeholders focused on solving difficult scientific, clinical and business challenges. We can’t do it alone, it’s all about partnerships.”

“We will have to think about what we’re making and how we deliver it, and make sure the patient will derive the full benefit from the therapy.”

Dr Mike Thien, SVP, Global Technology and Commercialisation, MSD
The 3R group winners of the Health Hackathon, L to R: Dr. Adrian Rutledge; Myeda Kamel; Thomas McCartin; John Gorman with Matt Moran, Director of BPCI

Prof. Brian MacCraith, President, Dublin City University

Richard Bergstrom, Director General, EFPIA
Consensus among many conference speakers was that Ireland was ideally placed to host the future biopharma industry because of its established biopharma ecosystem and infrastructure. This came down to the strength of its various institutions, such as the NIBRT, SFI, the NovaUCD start-up incubator, the Conway Institute and the Belfast Biobank. There were numerous reasons Ireland was seen as a good place to invest, according to Seamus Fives, Site Leader at Pfizer Pharmaceuticals and Chairman of BioPharmaChem Ireland. He cited regulatory compliance, manufacturing performance, talent, skills training, can-do attitude, tax advantages and the climate of collaboration between government, academia, agencies and companies themselves, among the reasons for Ireland’s attractiveness as a biopharma destination.

Indeed, it was for these reasons that the country had seen growing interest and investment over the years, with nine of the 10 largest pharmaceutical companies running their operations in Ireland. Just prior to the BioPharma Ambition conference, GE Healthcare announced a €150 million investment in a biomanufacturing campus in Cork, which was expected to create up to 500 new jobs. The company was also establishing an advanced manufacturing training centre at the NIBRT. The news was viewed by conference speakers as testament to the attractiveness of Ireland’s biopharmaceutical environment.

It came as no surprise then that the three Government Ministers from Ireland and Northern Ireland who spoke at the BioPharma Ambition Conference emphasised the unique contribution the biopharmaceutical industry made to the economy. In Ireland, it employs more than 26,000 people and accounts for more than 27% (more than €30 billion) of total Irish goods exports in 2015 – the largest net exporter of medicines in the European Union.

According to Mary Mitchell O’Connor TD, Minister of Jobs, Enterprise and Innovation, the level of biopharma investment in Ireland “recognises Ireland’s stellar reputation for high value, quality products and is a testament to the quality of the workforce”. The Government was not taking this reputation for granted and it planned to continue to invest in the industry and support its continued growth, she said, adding: “We’re interested in working with the industry to make sure Ireland is world leading in innovation investment and to make sure the right conditions are in place to ensure continued investment and employment.”
Simon Hamilton MLA, Minister for the Economy in the Northern Ireland Executive, echoed this saying the biopharma industry was a “priority sector” for Northern Ireland and the 20% growth in turnover and employment over the past three years served to “underline the importance of the industry to our future economic growth”. “We recognise the significant potential to develop the economy and public health benefits. It’s important that we in Government are focused on supporting research and innovation.”

Minister Hamilton also stressed the need to promote a climate of partnerships between Government, academia, clinical and private sectors. Moving forward, the success of the industry would rely on capturing the “spirit of collaboration” to help develop new and innovative processes and promote growth, he said. Minister Mitchell O’Connor said the BioPharma Ambition Conference was a medium to encourage future collaborations within the industry.

Indeed, a number of collaborations were highlighted during the conference, such as Trinity College’s partnership with tech firm Shimmer on a smart inhaler to improve compliance, and GSK’s collaboration with the University of Limerick to digitise patient information leaflets. Meanwhile, Abbvie was tapping into Ireland’s scientific expertise and Pfizer, which has already invested in excess of $7 billion into Ireland, was partnering with the SFI and five Irish institutions, and was looking to partner with more Irish academics.

Meanwhile, the Irish Government planed to build further on Ireland’s biopharma positioning, with Simon Harris TD, Minister for Health, saying he planned to address the Brexit scenario by submitting a bid to bring the European Medicines Agency (EMA) to Ireland. “As well as having a proactive and committed national medicines agency in the shape of the Health Products Regulatory Authority (HPRA), Dublin offers many other advantages as a location for the EMA, including a thriving pharmaceutical sector, excellent air connectivity with other EU capitals, and a highly educated, English-speaking workforce,” he said.

Besides the bid for the EMA, Brexit also offered new opportunities for expanding direct investment in Ireland. It gave the Government a reason to invest in universities, education and research with the aim to get peers in the UK to develop satellite sites in Ireland.

There were, however, areas that required investment to further bolster Ireland’s attractiveness. A number of speakers, for instance, emphasised the importance in maintaining high levels of training for the future workforce. NBRT as a training centre was seen as a real jewel for Ireland but ensuring education was relevant to what the industry required, for instance in bioinformatics, would be critical for the country’s future, as would be ensuring people were encouraged to pursue STEM studies, many speakers concluded.
Leisha Daly, President of the Irish Pharmaceutical Healthcare Association (IPHA), Minister for Jobs, Enterprise & Innovation Mary Mitchell O'Connor and Seamus Fives, Chairman of BioPharmaChem Ireland

Delegates at the manufacturing session in NIBRT

Oliver O’Connor, CEO, IPHA
For Ireland, moving forward, there was also much interest in establishing a stronger clinical trials landscape, which has already been identified as an area for growth. Improvements in clinical trial activity were seen with the HPRA approving the commencement of 108 clinical trials in 2015 compared with 80 in 2014, while a number of clinical trial hubs had been set up, for example Mercy Hospital and University College Cork.

There had also been the recent announcement of the Wellcome-Health Research Board Irish Clinical Academic Training Programme to advance clinical research capability among doctors in Ireland. The development of electronic health records would be another step to furthering this ambition, said Tom Lillie, Vice President and Head of European Clinical Development at MSD. The expectation was the clinical trial landscape would evolve as real-world evidence and patient identification also became increasingly important. Seamus Fives said opinions were changing and predicted more trials would be done in Ireland in the future, which would further bolster the country’s attractiveness.
A new era is underway in biopharma, replete with challenges and opportunities. Some of the challenges include: the introduction of biosimilars from a manufacturing and regulatory point of view; the development of personalised medicine and diagnostics; continued research funding; the integration and regulation of big data and new technology; and, more broadly, the strategic challenge around emerging markets.

There are also clear opportunities. For Ireland specifically – with its infrastructure, researchers, collaboration and continued investment – there is no reason why the country cannot be at the forefront of the industry’s rapid evolution. Indeed, according to the conference speakers, Ireland was very well placed to grasp the opportunities provided by scientific, healthcare and manufacturing innovation across the industry and outside the industry’s traditional boundaries.

BioPharma Ambition showcased the ambition of the industry, heralding Ireland as a leader in innovation, manufacturing and partnerships. According to the IPHA’s Dr Leisha Daly, who closed the conference, the presence of three Government Ministers who spoke at the event “shows the value and importance of biopharma companies and their contribution to the economy”.

The conference provided a platform to highlight Ireland’s competitiveness, support for innovation and collaboration. It demonstrated the central role patients played in the new healthcare environment and the dedication of the industry to deliver innovation for patients. Said Daly: “BioPharma Ambition is the beginning not the end. It reaffirms our commitment to providing innovation from bench to bedside.”