

## Opportunity for Growth for Ireland's Pharma Sector

This March, the country posted its highest total exports in 13 years at just over €9 billion. Over 60% of this total came from the chemicals and allied products sector, that includes pharmaceuticals biopharmaceuticals and active pharmaceutical ingredients as well as chemicals - up 58% on 2014. This is clear evidence that the sector is entering a strong phase of a post-patent-cliff recovery, driven by over €3.5 billion worth of capital investment. The recent announcements by Alexion - €450 million and Mallinckrodt-€45 million both in the biologics space are the latest manifestation of this.

This positive environment presents huge opportunity for the industry and those who work in it, however there is seldom opportunity without challenge. The crystallising challenge for the sector is the emerging skills gaps - especially in the biological sector. PCI have met the government and IDA Ireland, who share PCI's concern, to discuss an appropriate response. A industry round-table meeting with key stakeholders will take place in July to develop PCI's future plans to address this deficit

PCI is currently engaged, in a programme of stakeholder engagement and has partnered with Pfizer in Newbridge, Cork and Grange Castle to meet with a range of elected representatives including members of the Dail, local authority representatives and MEPs to clearly explain to them the scope and scale of the sector in Ireland.

Coupled with site tours this has proved both interesting and illuminating for all - thanks to colleagues at Pfizer for their organisation and support. It is intended to roll-out this program at other sites around the country.

The Board has agreed to prepare and publish phase 4 of its industry strategy. This process commenced in 2010, to ensure that the sector in Ireland was capable of responding to its challenges and to staying strategically relevant on the global stage. PCI hold the view that the vision and foresight that its members showed back then, have contributed the recovery.

Before I sign-off can I thank all of you who attended and supported our AGM and annual dinner in May - especially the working group chairs who all delivered fantastic presentations. We were delighted to be able to welcome Health and Safety Authority CEO, Martin O'Halloran as our guest of honour at the dinner. He delivered an excellent and thought inspiring address to members The industry continues to take its commitment to health and safety very seriously.

Finally welcome to PCI's newly elected Chair, Seamus Fives of Pfizer. We all look forward to working with him and a deep vote of thanks to our outgoing Chair, John Nason now of Teva, formerly BMS. Through John's vision and leadership PCI has restructured and prepared itself for the next decade of success and growth for this great sector.



**Matt Moran**

Director PharmaChemical Ireland

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## Seveso III: Issues and Challenges for Operators



### The Seveso III Directive has now come into operation in Ireland (as of 1 June 2015), with significant consequences for the operators of Seveso establishments.

The new regulations will restrict operators from increasing the inventory of dangerous substances without prior approval of the Health and Safety Authority (HSA), possibly requiring operators to obtain planning permission if the HSA deem the change in inventory to be a “significant change”. They provide greater access by the public to information on establishments and their hazards, and may require operators to directly communicate more extensively with the public outside of the site due to the removal of the “specified area” from the legislation.

For upper-tier sites, the timelines specified in the 2015 COMAH Regulations may have significant implications for commencement of construction and operation of new establishments. The following illustrates how, for a new establishment, the safety report process could potentially impact the project timescale by over 12 months:

project managers need to factor Safety Report preparation and HSA approval into overall project timelines. In addition, modifications to existing sites (both upper and lower-tier) that constitute “significant changes” must also be approved by the HSA before they can commence. This may include an increase in inventory due to the installation of a new storage vessel. In some cases, modifications will require planning permission to be obtained for

developments that would otherwise be below the planning threshold. The timescales for this process are not specified and again could significantly impact project timescales. We eagerly await further clarification on what constitutes a “significant change”, and timescales for the HSA and planning authority review process. Another change for upper-tier sites is that the concept of the “specified area” is no longer included in the Regulations. This previously defined the area within which operators were required to inform members of the public of actions to take in the event of a major accident. It was based on the area within which the individual risk of fatality equated to 1E-07 per year (or 0.1 chances per million per year), and was derived as a result of quantitative risk assessment. As such, it was influenced by both the severity of the incident, and the likelihood that it would occur. Often the specified area remained within the site boundary due to the very low likelihood that conditions such as those necessary to carry toxic releases over long distances (low wind speeds and stable atmospheres) would coincide with an accidental release. The 2015 COMAH Regulations provide for the HSA to identify and notify the operator of the extent of the area within which persons are likely to be affected by a major accident. Whether this will be risk or consequence based remains to be seen. Ultimately, operators may be required to provide information to larger populations than previously required, a process which needs to be carefully managed. For the first time, operators of lower-tier establishments are required to provide public information about their

establishment and its hazards and to submit their Major Accident Prevention Policy to the HSA. Operators of both upper and lower-tier establishments will be required to make information permanently electronically available to the public. Information on inspections will also be publicly available.

Finally the 2015 COMAH Regulations provide that all information held by a competent authority is treated as environmental information and subject to the Access to Information on the Environment Regulations (2007 to 2014). Although these regulations include discretionary grounds for refusal (including commercial confidentiality and intellectual property rights), a request for environmental information shall not be refused where the request relates to information on emissions into the environment (such as a major accident?). The new regulations therefore may offer little protection to commercially confidential information included in safety reports (such as chemical names). This may yet be tested in the court system.

In conclusion, the 2015 COMAH Regulations introduce a new era with greater interaction between operators, regulators and the public. Project managers will need to consider Seveso implications from day one, putting control of major accidents at the centre of the project planning.

For more information on the COMAH Regulations 2015 see

Author: Maeve McKenna,  
Principal Risk Consultant



## Continuing the Innovation Journey throughout the Lifecycle-Driving the Industry Forward”

The 2015 PCI / ISPE / PDA conference entitled “Continuing the Innovation Journey throughout the Lifecycle – *Driving the Industry Forward*” will take place at the Radisson, Little Island, in Cork on 23/24 September 2015. Conference presenters will include regulators, policy makers and senior industry leaders.

The Plenary session on Day one will include presentations from the Health Products Regulatory Authority (HPRA) addressing “Patient health and product innovation – the role of the medicines regulator” in addition to the U.S perspective presented by Paraxel and GSK. Senior industry leaders will speak to the innovation being employed to ensure continued success of the industry going forward. The plenary session will also look at the cutting edge research taking place in Ireland. The social event on the evening of Day 1 will take place at Vertigo at Cork County Hall.

Day two of the conference will include the following five parallel sessions

### Session 1: Regulations & Inspections

Session 1 will address the latest development at home and globally. Speakers will include Senior representatives from the HPRA, European Medicines Agency (EMA) and Parenteral Drug Association (PDA).

### Session 2: External Manufacturing / CMO's

This session will focus on external manufacturing and CMO's. Presenters from the HPRA, AbbVie Ireland, BMS and Jazz Pharmaceuticals will participate in the Session.

### Session 3: Work-sharing

This workshop will examine the use of the work-sharing procedure for EU Variations. It will be led by Meg Mc Carthy – Pharma Q.A. Services Ltd.

### Session 4: Operational Excellence

Richard Keegan, Manager - Competitiveness Department - Enterprise Ireland (EI) will facilitate a Kaizen event for participants.

### Session 5: Lifecycle Management

The final session of the conference will look at Lifecycle Management. Industry representatives from Pfizer, Alexion and Hovione will present their case studies on cleaning lifecycle optimization and life cycle management.

#### Attending the conference will be

Industry site Leaders, Technical Leaders, OPEX leaders, Quality personnel, Technical Services, General Managers, CEO's & Managing Directors. From the Bio and drug development sector; R&D, Licensing, life-science professionals, Policy Makers, Regulators, Academia and Legal and Financial Advisors will be attending.

**Register [NOW](#)**

**An early bird price €800 + VAT available till 26 June**

[www.pharmaceuticalireland.ie/conference](http://www.pharmaceuticalireland.ie/conference)

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## PCI Annual Rates of Pay Survey

On an annual basis PharmaChemical Ireland commissions the Ibec research unit to carry out a survey on salaries for managerial and executive grades. In 2014, a total of 28 companies employing 7,381 employees, responded to the survey. Summary statistics are provided for basic and total remuneration (i.e. basic salary + fixed bonus + variable bonus payments + profit sharing). Details of pay rates are also provided for some 80 positions on a company-by-company coded basis, with data sorted in descending order based on total remuneration. Detailed information is only provided where the number of cases is greater than six. Information for each job title is also provided by region, company size and main activity. Details of average employee turnover and absenteeism rates are provided. Also the average payments made to employees for overtime and call-out and stand-by are provided. The objective of the survey is to provide companies operating in the pharmaceutical and chemical manufacturing area with a comprehensive guide to market rates for managerial and executive grades salaries and benefits. PCI would encourage as many members as possible to complete the survey when it is issued in June.

For further information, please contact Nessa @ [nessa.fennelly@ibec.ie](mailto:nessa.fennelly@ibec.ie)

## Thank You

The time has arrived for Fiona Horrigan, Alkermes to hang up her PCI validation chair hat. Fiona has been chair of this group since 2012. PCI cannot thank Fiona enough for the consistent time, effort and expertise that she has brought to the group. It has been appreciated by everyone who has worked with Fiona.



We welcome Philip Jarvis, BioMarin as the incoming Chair and look forward to an exciting year ahead.

## Process Validation Lifecycle



On 15 June fifty delegates attended the PCI process validation workshop in Ibec, Dublin. The workshop consisted of five presentations:

### **Application of QbD and CPV Approach**

*Aidan Collins, Eli Lilly*

### **NPI Transfer and Capability Assessment**

*Stephanie Devlin, Janssen Biologics*

### **Novartis Strategy for CPV Implementation**

*Fionnuala Langford, Novartis*

### **Tailoring PV to the Regulatory Submission**

*Stephen Galvin, Eli Lilly*

### **ISPE 2015 Statistician's Forum on PV**

*Fiona Horrigan, Alkermes*

Following on from these presentations the afternoon hosted a highly interactive break-out sessions in which the following hot topics were discussed

Process design

PPQ

Continued process development

Knowledge management over product lifecycle

Decision making over product lifecycle

Process validation challenges

With 28 member sites represented at this workshop, both the quantity and quality of knowledge sharing was exceptional.

For further information, please contact Jenny@ [Jenny.loughney@ibec.ie](mailto:Jenny.loughney@ibec.ie)

### Key dates for RDI WG

TBC October Joint workshop with SFI  
TBC November in Takeda Grange Castle

### Key dates for HR WG

28 Oct in Servier

### Key dates for EHS WG

16 Sept in GSK, Cork  
TBC Dec in BMS Cruiserath, Dublin





## Industry Strategy Review

PCI will shortly commence work on its fourth industry strategy document. The inaugural strategy document entitled “Innovation and Excellence” was launched at the global DCAT meeting in New York in March 2010. It was followed in June 2011 by a second strategy document “Ireland, a location of choice for scientific investment” with a subsequent report “Strategy in Action” published in 2013. A detailed project outline will be issued to members in the coming weeks, and a strategy task force will be established. The strategy will be rolled out in early 2016.

For further information, please contact Nessa @ [nessa.fennelly@ibec.ie](mailto:nessa.fennelly@ibec.ie)



## Skills Shortage in the Sector

In light of the recent investments and growth of the biopharma and pharma sector some key skills shortages are emerging in the sector especially in the biologics sector and if not addressed, could constrain future economic growth of the sector. Responding to needs in the sector and to establish a national skills strategy, Pharmaceutical Ireland in conjunction with the IDA will host a industry round table meeting Monday 6 July @ 11 am to 13.00 pm in the Ibec offices Dublin. The aim of this discussion is to formulate a industry strategy to response to the skills gap.

For further information, please contact Siobhan @ [Siobhan.dean@ibec.ie](mailto:Siobhan.dean@ibec.ie)

## Regulation of Lobbying Act 2015

The Regulation of Lobbying Act 2015 has now been signed into law and will require companies and organisations that lobby to record their activity on a web-based register. Key dates for the lobbying register are:

1 May, the Lobbying Register went live.

1 September, the act will come into effect.

21 January 2016, businesses and other organisations must provide the first set of returns.

Registration is necessary for those carrying out lobbying activities, such as:

- ◆ Communicating either directly or indirectly with a designated public officials, including Ministers, Ministers of State, TDs, Senators, MEPs, members of local authorities and special advisers.
- ◆ Communication is about a relevant matter, as described in the legislation
- ◆ The communication is not specifically exempted
- ◆ You are one of the following: professional lobbyist being paid on behalf of a client, employer with more than employees, representative body, any person communicating about the development of zoning of land.

Ibec is working closely with the regulator, the Standards in Public Office Commission to ensure that the new web-based register is fit-for-purpose.

A briefing session for members on the Act will be held in Ibec offices on 22 June. The session will consist of a presentation by Aidan Moore, The Standards in Public Office Commission followed by a questions and answers session.

For more information [www.ibec.ie](http://www.ibec.ie)

## Bringing Together the Who's Who of the Pharma Sector Under One Roof

For the second year PCI will partner with Event Strategies to run The Pharma Industry Awards. The Awards cater for entrants ranging from researchers and marketing strategists to process and formulation engineers, from campus start-ups to the biggest names in the Pharmaceutical industry

Visit [www.pharmaawards.ie](http://www.pharmaawards.ie)

### 2014 Award winners



Matt Moran, Director, PharmaChemical Ireland, presents the Overall Pharmaceutical Excellence Award to Tim Buckley, Quality Director, Bristol-Myers Squibb.

Matt Moran, Director from Pharmachemical Ireland, presents the award for Pharmaceutical Leader of the Year to Dave Cagney, site lead, Pfizer.

## Science Educator of the Year 2015 Award

Pictured is Siobhan Dean presenting the PCI/ISTA science educator of the year award 2015 to Sheila Porter at the ISTA conference held last March in UCC. Sheila the founder of Scifest is a worthy recipient of the award. Since 2008 more than 28,000 second level students have participated in the Scifest programme. Last year over 6000 students participated, making Scifest one of the largest science fairs of its kind in Europe.



## Ambitious New Innovation Strategy Required

The Department of Enterprise, Jobs and Innovation is currently drafting a revised national strategy for science, technology and innovation. Ibec, on behalf of business, is calling on the Government to think big and be brave with strategic investments, while at the same time introducing new policy measures that support innovation.

### Ibec recommendations for a Strategy on Science, Technology and Innovation:

**Reinstate the 3% of GDP by 2020 investment target:** The strategy should be the comprehensive, overarching framework from which all complementary policy and initiatives to support RDI activity in Ireland should be linked in order to foster a strong innovation system and develop the knowledge-based economy and society.

**Establish an independent advisory committee** on a permanent basis to review, evaluate and inform the strategy as it evolves. While the strategy may be Government led it will require significant investment and commitment from the business and research community for it to succeed.

**Invest in highly trained and educated people:** The next strategy for science, innovation and technology must further emphasise the connection between research and skill development at all levels. A strong research base, rooted in excellent science, gives educators the authority, assurance and confidence to educate and train the next generation of business leaders, scientists, technologists and engineers.

**Develop a balanced portfolio** of basic and closer to market, applied research, across all disciplines including science, social, humanities and engineering. This approach is a feature of some of the most dynamic and productive innovation systems internationally.

**Provide business supports:** To build the innovative capacity of SMEs and less R&D active businesses, including their ability to increase knowledge and competence in bringing innovation closer to the market place, specific SME incentives and supports will need to be incorporated to the strategy.

For further information, please contact Claire McGee, Ibec Innovation and Education Policy, [claire.mcgee@ibec.ie](mailto:claire.mcgee@ibec.ie).

## Recent Investments



Dr. David Keenan, Vice President, Global External Supply & Managing Director Mallinckrodt Pharmaceuticals Ireland with the American Ambassador Kevin F O'Malley, President & CEO of Mallinckrodt Mark Trudeau, and Joan Burton An Tanaiste and Minister for Social Protection, and Leader of the Labour Party

**Mallinckrodt plc**, announced a €45 million investment to expand its Dublin-based operations. A new state-of-the-art manufacturing facility and office building are to be located at College Business and Technology Park, Blanchardstown, Dublin 15. The development will provide 300 jobs during the two-year construction phase and 45 skilled full-time positions once the construction is completed.

Mark Trudeau, Chief Executive Officer and President of Mallinckrodt, added, *"We are proud to have had a significant presence in Ireland for over two decades, and today marks an important step for the company. Our Irish workforce has served as a tremendous asset to our global operations to date. We are particularly pleased to be making this sizeable capital investment today, continuing our long-standing operations in Ireland."*

**Alexion Pharmaceuticals** announced plans to significantly expand its operations in Ireland by constructing the Company's first ever biologics manufacturing facility outside the United States. This €450 million, four-year project, which will be constructed at Alexion's College Park site in Blanchardstown, is expected to create approximately 200 additional full-time jobs on completion, which will bring Alexion's total workforce in Ireland to almost 500 employees. Since first entering Ireland in 2013, Alexion has invested €130 million in two facilities – a vial fill-finish facility in Athlone and a Global Supply Chain facility at College Park. Phase 1 of the College Park facility, comprising Global Supply Chain HQ, laboratories, packaging and warehousing operations is expected to be operational by year-end. Approximately 560 construction workers are involved in the development of the current Athlone and College Park projects, and the planned expansion of College Park will also create over 800 construction jobs.

**GSK** recently announced their Ireland IMPACT Awards, designed to recognise and reward community-based charities that are doing excellent work to improve people's health and wellbeing in Ireland. GSK have been running these awards in the UK and US for 18 years.

## Science week 2015



The aim of Science week is to promote the relevance of science, technology, engineering and math's (STEM) in our everyday lives and to demonstrate their importance to the future development of Irish society and to the economy. This November the PCI regional education working groups will host chemistry roadshows in post primary schools.

These roadshows will highlighted the relevance of science to the students in their everyday lives covering subjects they are familiar with, like the food they eat and medicines they take.

For further information on how to get involved in science week contact Siobhan at [Siobhan.dean@ibec.ie](mailto:Siobhan.dean@ibec.ie)



Siobhan Dean presenting the Pharmaceutical Ireland best chemistry award to Domhnall O'Farrell from Mountrath community school Co Laois at SciFest WIT. For his project "To compare the level of fluoride in potable tap water and store-bought water"





## Upcoming events

**Briefing on the Regulation of Lobbying Act 2015**  
22 June Ibec Dublin

**PCI Round table on skills**  
6 July Ibec Dublin

**Public affairs/education**  
wg 30 June Conference call

**Ibec President's Dinner**  
17 Sept, RDS Dublin

**PharmaChemical Ireland/ PDA/ISPE Quality and Innovation Conference** 23 & 24 Sept 2015 Radisson, Little Island, Cork

**BioProduction 2015: Benchmark Technological Developments and Explore Best Practices in Biomanufacturing**  
14 /15 Oct 2015 Citywest hotel conference & events Centre  
[www.bio-production.com](http://www.bio-production.com)

**Ibec HR Leadership Summit 2015** 21 October, Royal Hospital Kilmainham

## Upcoming Training

Course	Location	Date
Developing Standardised Work	Ibec	23/24 June
Residential in Toyota	Deeside	7-11 Sept
Maintenance	Deeside	29 Sept
Lean Management Introduction	Deeside	30 Sept
4S-Organisation and Cleanliness	EI	27 Oct
Practical Problem Solving	EI	28 Oct

Register today!  
Contact Nessa Fennelly  
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