



PHARMACEUTICAL IRELAND

2ND ANNUAL FORUM ON INNOVATION, CREATIVITY & INTELLECTUAL PROPERTY

*Evolution of process development in Irish
Pharmachem Sector*

**Matthew Moran – Pharmaceutical Ireland
Mumbai, February 2008**

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PHARMACEUTICAL IRELAND PRESENTATION

1. PharmaChem Sector in Ireland
2. Evolution from pure manufacturing
3. Future prospects



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OVERVIEW

- Most valuable sector in Irish economy
- Established in late 1960s
- Dominated by US based companies

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EARLY YEARS

- IDA strategy to attract knowledge based industries
- Ireland marketed aggressively
- Tax incentives key
- USA targeted



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DEVELOPMENT OF THE SECTOR

- Industry took off in the 1970s
- Ringaskiddy/Little Island targeted
- Significant multi-nationals attracted to Ireland
- Critical mass developed



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PRESENT SITUATION

- Pharmachem sector consolidated
- Very stable sector
- 16 out of the top 20 pharmaceutical companies operate out of Ireland
- Most plants are benchmarks for rest of world



World's Leading Drugs Produced in Ireland

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WORLD RANK	PRODUCT	COMPANY
1.	Lipitor	Pfizer
2.	Zocor	Merck & Co.
6.	Zyprexa	Eli Lilly
7.	Seroxat/Paxil	GlaxoSmithKline
8.	Prevacid	TAP Holdings
10.	Zoloft	Pfizer
15.	Neurontin	Pfizer
17.	Fosamax	Merck & Co.
19.	Risperdal	Johnson & Johnson
20.	Effexor XR	Wyeth
23.	Claritin	Schering-Plough
25.	Premarin	Wyeth

Source: Deutsche Bank and IDA Ireland 2002

INDUSTRY CHARACTERISTICS

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- Dominated by pharmaceuticals/fine chemicals
- High tech
- Excellent environmental compliance record
- High levels of regulatory compliance with IMB/FDA



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RELEVANT STATISTICS - 1

EXPORTS

1973 €100.31 million

1995 €6.40 billion

1998 €18.3 billion

1999 €21.08 billion

2000 €27.22 billion

2001 €32 billion

2002 €39 billion

2003 €35.7 billion

2004 €37.5 billion

2005 €40.3 billion

2006 €41.7 billion*

* 45% of total exports for Ireland

Source : CSO



RELEVANT STATISTICS - 2

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BALANCE OF PAYMENTS

1982	€139.7 million
1995	€3.12 billion
1998	€13.72 billion
1999	€16.13 billion
2000	€21.15 billion
2001	€26 billion
2002	€32.3 billion
2003	€28.9 billion
2004	€30.3 billion
2005	€33.1 billion

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Source : CSO





RELEVANT STATISTICS - 3

Year	Nos. Employed
1992	15400
1993	15100
1999	22200
2002	24100
2003	24000
2005	24500





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CURRENT/FUTURE SITUATION - 1

- Majority of major players in Ireland
- Significant re-investment has taken place
- Broad spectrum of activities now evident



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CURRENT/FUTURE SITUATION - 2

- IDA seeking to further embed companies
- Value adding / knowledge intensive activities prioritised
- Global consolidation



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TECHNOLOGY FORESIGHT

- Prioritised ICT, Biotechnology
- Science Foundation Ireland established
- Will invest €686 million in basic research
- Programme for Research in third level Institutes (PRTLTI) €250 in Life Sciences.



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FUTURE

- Emphasis on Biotechnology
- Development of Research Infrastructure
- Promotion of Science



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RECENT INVESTMENTS

<u>Expansions</u>	<u>€m</u>	<u>Employment</u>
Pfizer Ireland	609	350
Merck Sharp & Dohme	171	50
Organon Ireland	25	170
GlaxoSmithKline Beecham	317	100
Wyeth Medica	57	170
Elan	209	n/a
Servier	184	150
Eli-Lilly	400	180



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RECENT INVESTMENTS

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GREENFIELD

	<u>€m</u>	<u>Employment</u>
Wyeth Biopharma	1269	1300
Bristol-Myers Squibb	380	250
Genzyme	317	480
Alza	152	80
Abbot	406	200
Gilead	62	na
Taro	n/a	300
Recordati	28	60
Centocor	700	350
MSD	200	110



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DEVELOPMENT OF A RESEARCH BASE

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- Prioritisation of Biotech by Science Foundation Ireland (www.sfi.ie)
- PRTL Initiative
- Critical for long term success of sector



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Funding R&D in Ireland



R&D Ireland Budget
€2.4bn over 7 years

PRTL - €508m
University Research
Infrastructure

Science Foundation
Ireland - €646m
Investing in the best
Researchers

R&D Capability / RTI
& EU- FP6
Industry Programmes

Academia

Industry

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INDUSTRY PERSPECTIVE

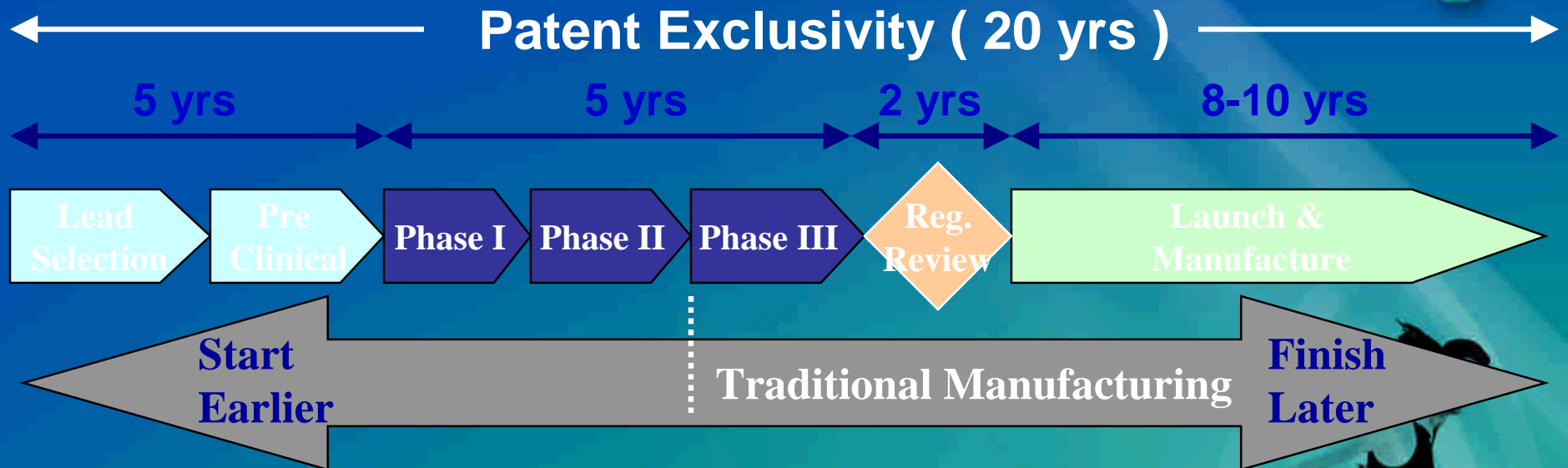
- Focus on development & manufacturing
- Process development/optimisation



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Pharma Product Life Cycle

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- **Start Earlier, Finish Later**
- **‘Receiver’ to ‘Co-Creator’**
- **Must Have Clear Competitive Advantage over Sister Sites**

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Moving Up the Value Chain

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- Manufacturing as the Foundation
 - Delivery
 - Compliance
 - Return on Investment
- Research Capability
- Research Infrastructure
- Workforce Skills
 - Quality vs Quantity

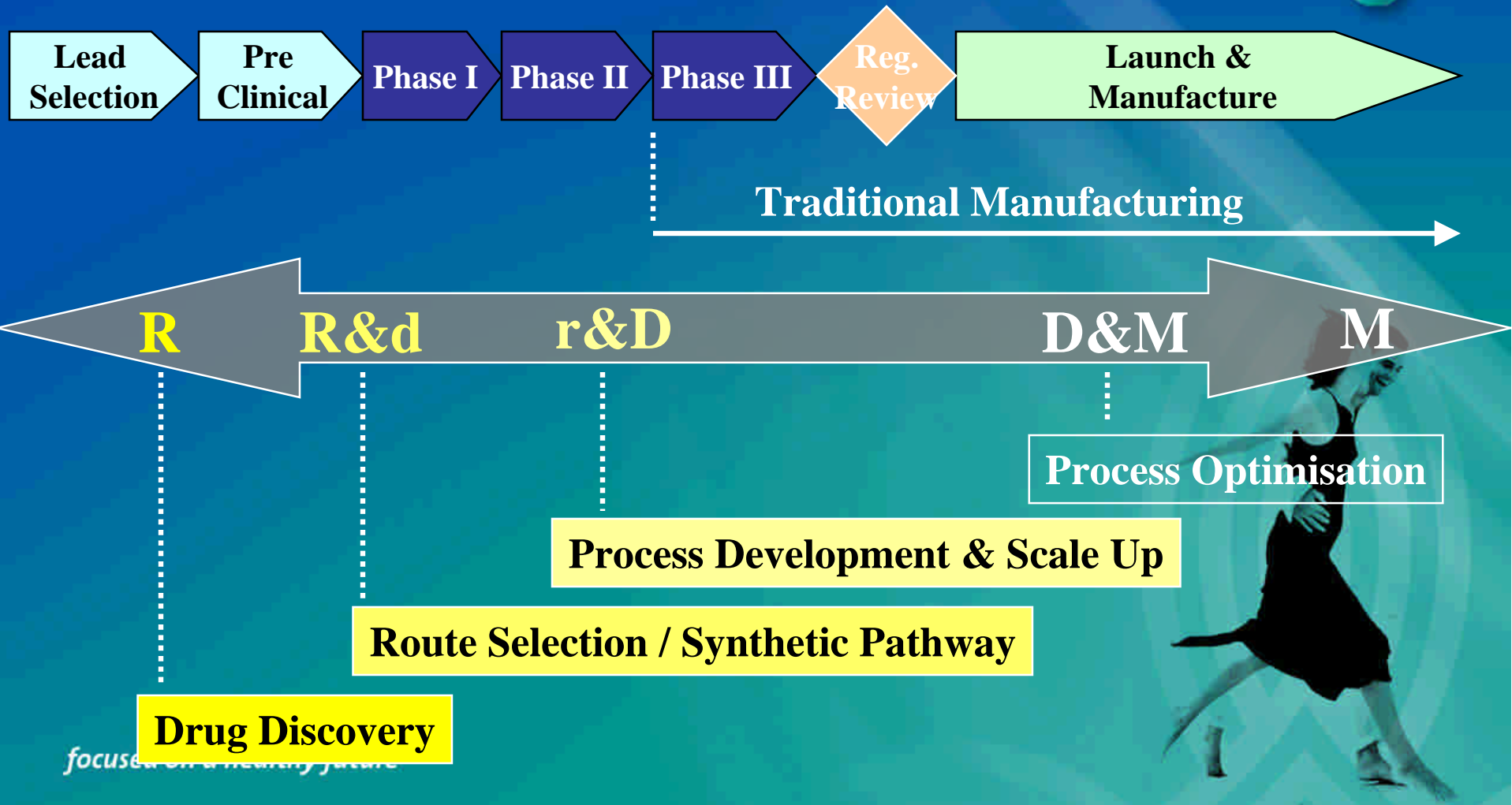
} Reliability & Repeatability



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Pharma R&D Value Chain

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- **IDA Strategy for R&D, 2005 – 2008:**
 - 75% of companies with Process Development capability
 - 5% of employees
 - 3 significant Industry / Academic Research Partnerships
 - First stand alone corporate R&D centre
 - 9 R&D Capability schemes approved
 - 3 Technology Platform companies
- **Skills Required:**
 - Traditional:
 - Organic / Analytical Chemists, Chemical Engineers
 - Emerging Needs:
 - Physical Chemists, NanoTechnologies, PAT
 - Pharmaceuticals, Medicinal Chemists
 - BioChemists, BioChemical Engineers, Microbiologists

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The Way Forward

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- **From Manufacturing to D&M / R&D / R&D**
 - Supply of talented scientists critical
- **Increased Government focus on Pharmachem R&D:**
 - Action Plan from Task Force on the Physical Sciences
 - SFI – equal support to Pharmachem & Biotech
 - 70% of drugs sold in 2008 will be ‘small molecule’
 - Financial supports must be attractive vs. Competition
- **Third level sector & industry must work together**
 - Industry Relevant Research
 - Industry ‘Savvy’ students - Graduates & Post Graduates
 - Improved Support from Industry



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Industry / 3rd Level Initiatives



- **Skills:**
 - Primary / post-Primary Focus
 - Internships during PhD program
 - Relevant post Graduate top-up courses
 - BSc to MSc programs, New / Emerging Technologies
 - Targeted Process Development initiatives
- **Shared Learning:**
 - Research Seminars / Workshops
 - Direct Industry / 3rd Level Research Partnerships
 - Access to Infrastructure / Resources / Databases
 - Ensure IP not a barrier



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GOVERNMENT INITIATIVES

- National Institute for Bioprocessing Research and Training (MCRT)
- Centre for Bio-Analytical Sciences.
- Biomedical Diagnostics Institute
- Regenerative medicine Institute
- Alimentary Pharm-biotec.



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National Institute for Bioprocessing Research & Training (NIBRT)

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Bioprocessing Research:

- Monitoring and control of Bioprocess.
- New technology for downstream process.
- Comparative studies.



Education and Training:

- MSc and Ph.D. programmes in Bioprocessing.
- Range of undergraduate and post graduate training in GMP and regulatory affairs.
- Short-term / bridging courses.



Services and Resources:

- cGMP Plant.
- Pilot Manufacturing services for early clinical trials
- Access to specialised equipment.
- Trained Personnel.



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Centre for Bio-Analytical Sciences

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- Collaborative biopharmaceutical research.
- Partners include Bristol-Myers Squibb, Dublin City University and National University of Ireland, Galway.
- BMS will locate a research team in both universities.
- 32 researchers (25 academics and 7 BMS).
- Developing new technologies and methods for BMS biopharmaceutical products and processes.
- Investment of €9.645m.



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Academic/Industry Collaborations

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BDI – Biomedical Diagnostics Institute



Biosensors, bio receptors, microsystems and instrumentation. The programmes range from fundamental studies of molecular recognition through the commercialisation of applications-driven devices

Director: *Prof Brian MacCraith*

- DCU, UCD and RCSI.
- Becton Dickenson, Hospira, Analog Devices, Inverness medical, Omic, Enfer.
- Industry meetings and partner delivery.

Funding: €12m (HEA), €4m (SFI) & \$16m CSET award.

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Regenerative Medicine Institute (REMEDI)

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- World-class biomedical research centre.
- Focus on gene and cell therapy for tissue repair and regeneration.
- Established in 2003 and based in the National University of Ireland, Galway.
- SFI (CSET) award and industry funding including MedtronicVascular (Galway).
- Investment of €15m.
- Concentration on cardiovascular, orthopaedic and neuronal diseases.



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Alimentary Pharmabiotic Centre

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- World-class research centre.
- Focus on impact of intestinal bacteria and probiotics on GI disorders.
- Established in 2003 and based at University College Cork.
- SFI (CSET) award and industry funding including Proctor & Gamble
- Investment of €16.5m.



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Evolution of Process Development in Industry

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Some Examples

- GSK – ongoing investment
- Pfizer – biocatalysis.
- Schering Plough – organic synthesis
- Merck Sharpe & Dohme - €100m – investment in formulation R&D and clinical trials manufacture
- Wyeth – Biopharma-€25m
- Allergan-€10m- Botox Facility
- Wyeth Process Development Centre-€24m

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R&D / Process Development

GLAXOSMITHKLINE

- Sole production site for several blockbuster products including 'Seroxat' with sales of \$1.84 billion in 2004
- State-of-the-art research facility
- €600 million investment employing over 1,400 people in Ireland

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PFIZER

- Global Process R&D Centre – 25 People.
- Developing prioritised API entities.
- Co-development programmes with Group R&D.
- New Project
High Containment Development Facility.
- Investment €20m – 27 People.



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R & D / Process Development

WYETH BIOPHARMA

- Product and Process R&D Facility – 2,500 sq.m
- 40 people.

- Development of biotechnology processes.

- New Project – Wyeth Research

Bio-therapeutic drug discovery focusing on product discovery, pre-clinical research and drug discovery technology development.

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Wyeth

OLYMPUS

- Sole global site in the Group for the development and production of clinical chemistry reagents. Employs 44 – Ph.D., MSc, BSc.

- New Project

Sole global responsibility for immunoassay reagent development

22 Biochemists – Ph.D, MSc, BSc. - €9m investment.



OLYMPUS

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Why locate in Ireland

- **Availability of skilled workforce**
- **Low Corporate Tax**
- **Significant Lifesciences Cluster**
- **Track Record – FDA Compliance**
- **Financial Incentives**
- **Political Stability**
- **Temperate Climate**
- **Expatriate Ease**
- **Industry/Academic Collaboration**
- **Site Availability**
- **Strong Local Management**
- **Project Execution**

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Conclusion

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‘You must have more and more capabilities on site, it’s not enough just to have Ireland’s lower tax rate, because other jurisdictions have lower tax rates’.

‘The technical capability and the people become a far more critical piece’

B. O’Leary (IDA)



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