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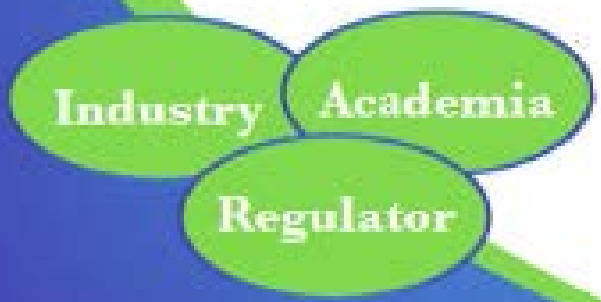
Regulatory Science Ireland (RSI)

mission, plans and future direction

Professor Caitriona O'Driscoll, UCC



www.regulatoryscienceireland.com

What is Regulatory Science?

- No formal definition exists …. Commonly described as
  - The science of developing new tools, standards and approaches to assess the safety, efficacy, quality and performance of drug products (FDA)

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Why? Regulatory Science

- The challenges of modern product development and globalisation underscore the critical importance of modernizing and advancing regulatory science to match advances in basic and applied science and technology – FDA, 2011

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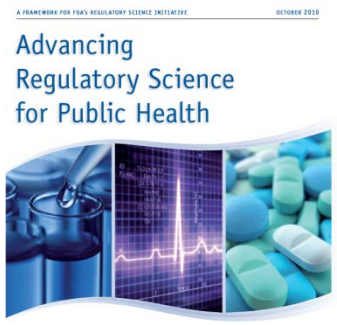
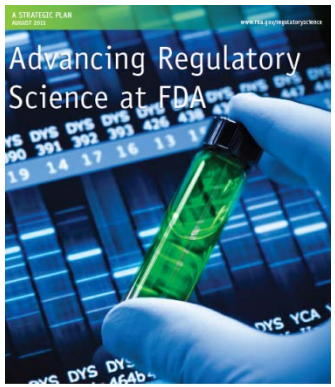
Evolution of Regulatory Science



FDA



FDA

EUROPEAN MEDICINES AGENCY
SCIENCE · MEDICINES · HEALTH

2010 2011 2012 2013 2014

M-CERSI Science that speeds health innovation

CIRS Centre for Innovation in Regulatory Science

Georgetown University
CERSI
Center of Excellence in Regulatory Science & Innovation

STATE OF THE ART nature publishing group

Research at the interface of industry, academia and regulatory science

William B Mattes[1], Elizabeth Gribble Walker[1], Eric Abadie[2], Frank D Sistare[3], Jacky Vonderscher[4], Janet Woodcock[5] & Raymond L Woosley[1]

VOLUME 92 NUMBER 4 | OCTOBER 2012 | www.nature.com/cpt

VOLUME 28 NUMBER 5 MAY 2010 NATURE BIOTECHNOLOGY

Advancing the Science of Medicines Regulation: The Role of the 21st-Century Medicines Regulator

MM Lumpkin[1], H-G Eichler[2], A Breckenridge[3], MA Hamburg[1], T Lönngren[2,5] and K Woods[3,4]

NATURE MEDICINE VOLUME 17 | NUMBER 12 | DECEMBER 2011 1535

Efficient drug approval and monitoring must rely on sound regulatory science

OPINION

Emma A Meagher & Garret A FitzGerald

UNIVERSITY OF MARYLAND
MPOWERING THE STATE

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M-CERSI Center of Excellence in Regulatory Science and Innovation
Science that speeds health innovation

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Research

Strategy

The M-CERSI creates new mechanisms for scientific exchange, education and training, as well as regulatory science research. The center brings together diverse thoughts and ideas around emerging technologies and methodologies for regulatory science. The sum of these interwoven activities is a vibrant, cutting edge center that stimulates innovative thought, disseminates understanding of regulatory science and practices, and generates new knowledge in support of the FDA's fundamental mission -- to promote and protect the public health -- under current priorities and initiatives.

Visiting Scientists

A critical component of center success is establishing, promoting, and facilitating two-way connections between UM and FDA staff. The M-CERSI will invite visiting scientists from the FDA and from industry to engage with the new Center and to engage in scientific exchange. Also, M-CERSI will provide continuing education (CE) training for FDA personnel.

Creating New Opportunities for Collaborative Regulatory Scientific Research

- **Center-Wide Regulatory Science Activities** - The M-CERSI will execute in parallel three regulatory science projects reflecting the collective strengths of UM campuses in College Park and in Baltimore. The Scientific Exchange, Research and Training Activities for each project are managed by project leaders.
- M-CERSI sponsors a small regulatory science research component that is unattached to its projects. Several small Innovation Awards will help build its program in the future.
- **Specific Regulatory Science Activities** - M-CERSI focuses on three project areas, each corresponding to an FDA-specified focus. Each major project area includes training and exchange, as well as a research component. Each major project will support at least two graduate students / fellows, who will benefit from FDA advice and guidance. The Executive Committee, comprised of UM and FDA leadership, will solicit proposals from UM faculty and develop a specific plan for each project area. In this way, priorities can be identified and appropriate investments can be made. Additionally, this will provide a mechanism for project renewal and/or new project development as the Center grows and matures.

2011-2012

FDA Chief Scientist Jesse L. Goodman on the importance of the CERSI

The Fischell Department of Bioengineering was honored to welcome FDA Chief Scientist and Deputy Commissioner for Science and Public Health, Jesse L. Goodman, M.D., M.P.H., to the 2011 Fischell Festival as our Keynote speaker. Goodman discussed what the new partnership would mean for the approval processes applied to new drugs and biomedical devices.

Goodman's address introduced guests to the FDA's new strategic plan for advancing regulatory science, and how building partnerships with academia and industry—like the establishment of the new CERSIs with the University of Maryland and Georgetown University—will be critical to advancing its goals.

Addressing the criticisms leveled against the agency, Goodman explained how difficult its job can be. "The FDA regulates products that relate to 25% of the nation's economy," he told the audience, "so you can see how the potential to do good in terms of promoting innovation, to do harm if you unnecessarily slow it, or to do harm if you make decisions that allow unsafe products on the market, is tremendous."

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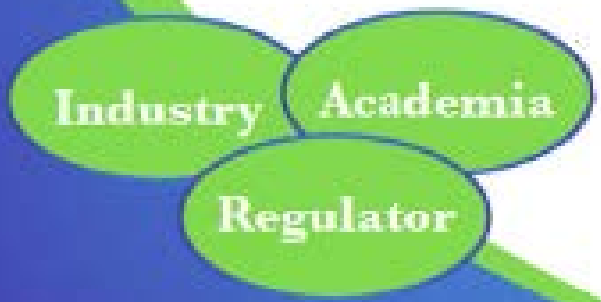
Regulatory Science Ireland (RSI)

A Company Limited by Guarantee,
registered in Ireland with Company Number 565753



RSI Board of Directors:

REPRESENTATIVES

- Regulator: HPRA
- Academia: UCC & DIT
- State Agencies: IDA & EI
- Pharmaceutical Sector: PCI & Specific Companies
- Medical Device Sector: IMDA

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What is RSI - mission?

Regulatory Science Ireland is a *network of interested parties* from:

- Academia
- Pharmaceutical Industry
- Medical Devices Industry
- Regulatory Body (HPRA)
- Government Agencies

Who are committed to the development of an integrated *Irish response* to the Global Regulatory Science effort in the fields of:

- Research
- Education and Training
- Knowledge sharing

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What RSI will provide?

RSI will create through relevant research, training and communication an environment that:

- ☑ Facilitates Irish contributions to an effective response to the increasing complexity of *Health Care Products* and their associated *Regulatory Systems*;
- ☑ Creates a cohort of Irish based Regulatory Science experts;
- ☑ Further strengthens the value proposition of Ireland as an attractive location for Health Care Product related activities
- ☑ Patient focused

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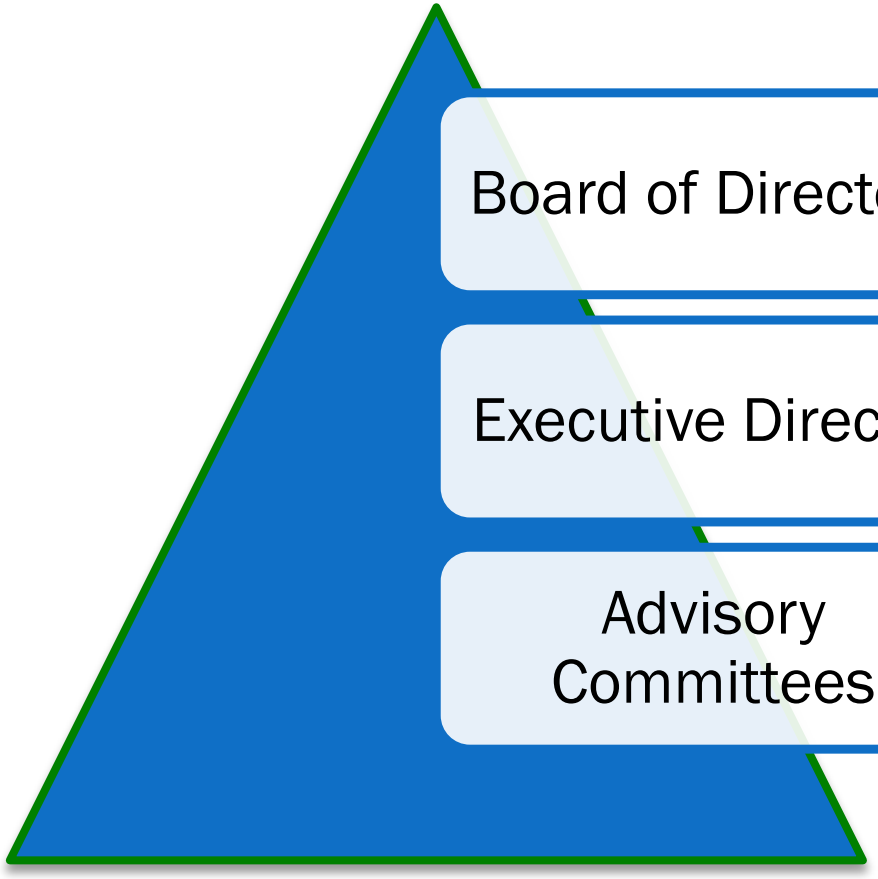
How RSI is organised



Academia/Industry/Agency/HPRA representatives approve the Annual Operating Plan and specific research topics

Executes Operating Plan and leads the RSI activities on a day by day basis

Representatives of stakeholders with specific interest areas to provide expert advice to Board of Directors

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RSI - Research Projects

Research scope is extremely wide so specific themes for focus will be determined by Board of Directors

RSI will also support individual investigators with projects in the Regulatory Science area

3 projects selected

- Quality Defects
- Biosimilars
- Medical Device Register

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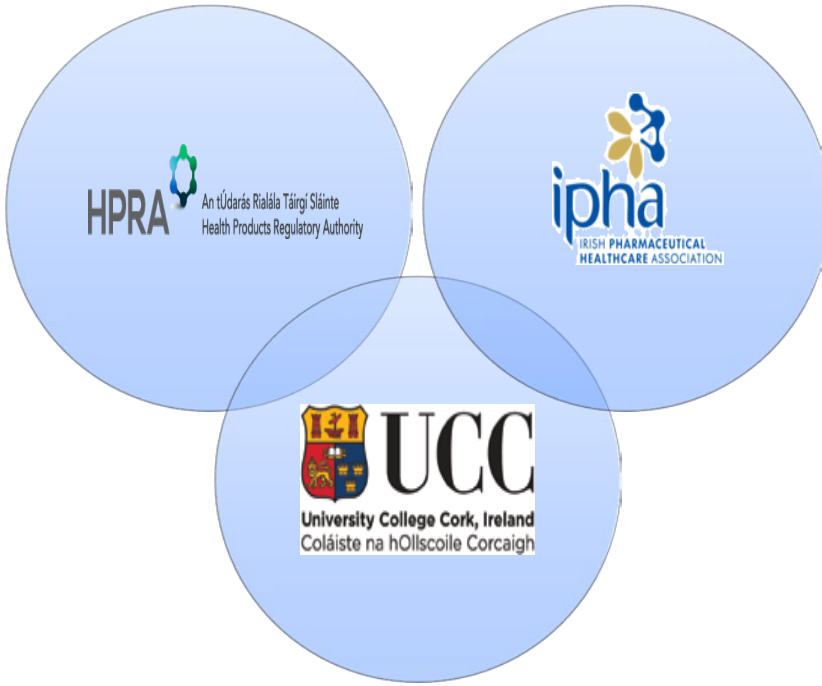
Biosimilars Research Project

Jointly funded by HPRA and IPHA

Dr Brendan Griffin, UCC
Joan O'Callaghan Research Scientist
HPRA



Objectives

- **Raise awareness** on Biosimilars among patients and healthcare practitioners (e.g. Surveys of stakeholders, scientific publications)
- Compare **international approaches** and emerging trends related to the safe and effective use of Biosimilars
- Develop position papers on international **best practise** approaches for providing safe and effective use of biosimilars

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Engagement with Healthcare Professionals

Prescribers

- Questionnaire - understanding, attitudes and behaviours towards biological medicines and biosimilars
- Currently being distributed via professional societies
- Survey results will facilitate further engagement with societies

General Practitioners

- Tailored questionnaire for GPs currently being distributed via ICGP
- Invited to provide an educational session on Biosimilar medicines at ICGP summer school (June)

Irish College of General Practitioners
Coláiste Dhochtúirí Teaghlaigh Éireann

Pharmacists

- Two publications on Biosimilar medicines (IPN and HPN)
- PSI have been approached re guidelines focusing on importance of traceability requirements for all biological medicines

IPN Irish Pharmacy News
HPN Hospital Pharmacy News

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Working Together for Better Patient Outcomes

Engagement with Patients

- Presentation - Biological and Biosimilar Medicines (Regulatory perspective) at IPPOSI event in April
- Currently preparing patient information materials on biosimilar medicines (intended for HPRA and RSI websites)
- Planned update to RSI website – dedicated RSI Biosimilars page
- Establish links with IPPOSI and patient organisations to get feedback on patient information materials and ensure maximum exposure

IPPOSI PATIENTS SCIENCE & INDUSTRY

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Outreach Activities

14th Annual Biosimilar Medicines Group Conference

Presented RSI Biosimilars Project during session 'Reducing the information gap on biosimilar medicines amongst stakeholders' London, April 2016

European Commission

- Participation in EC Stakeholder Event on Biosimilar Medicinal Products
- Brussels, June 2016

Smi 7th Annual Biosimilars Europe Conference

- Invited to speak about RSI Biosimilars Project
- London, Sept 2016

Quality Defects and Recall regulation in Europe – Role of the Irish Pilot Project

Jointly funded via PCI and HPRA

Key Questions.....

- Are certain defect types in medicines **recurring?**
- Where are the **key trends?**
- What kinds of **products and manufacturing processes** have been the most susceptible to different kinds of defects?
- Are certain types of **manufacturing processes, product types and pharmaceutical forms** more likely to generate/have defects?
- What kinds of **root causes** are being identified?
- How many QD investigations **fail to determine** the root causes?
- How often is **human error cited** as the root cause?
- What kind of **CAPA** actions are generally taken?
- How effective are the **CAPAs** that have been implemented?

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Quality Defects and Recall regulation in Europe – Role of the Irish Pilot Project

Research Project Objectives:

- **Analyse** the quality defect and recall data available at the HPRA covering 2010-2014
- **Scope**: Human & Veterinary Medicines and APIs. Unauthorised Medicines included also.
- Do interim work on the **key questions** cited earlier
- Elicit **expert opinion** in relation to quality defects
- Produce a '**Proof of Concept**' report to support initiation of the larger pan-European project at EMA
- Work to establish a **common taxonomy** for quality defects and recalls to help inform the design of the pan-European project
- Present **recommendations** to the EMA for the pan-European project
- Report launched Feb 2016

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Quality Defects and Recall regulation in Europe – Role of the Irish Pilot Project

EMA Project – status

- **Q2 2015:** Funding secured
- **June 2015:** EMA researcher appointed – ***Ms. Maria Filancia***, a secondment from HPRA ☺
- Work is now well underway on

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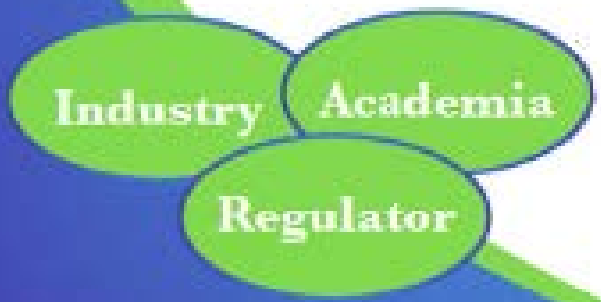
Regulatory Symposia

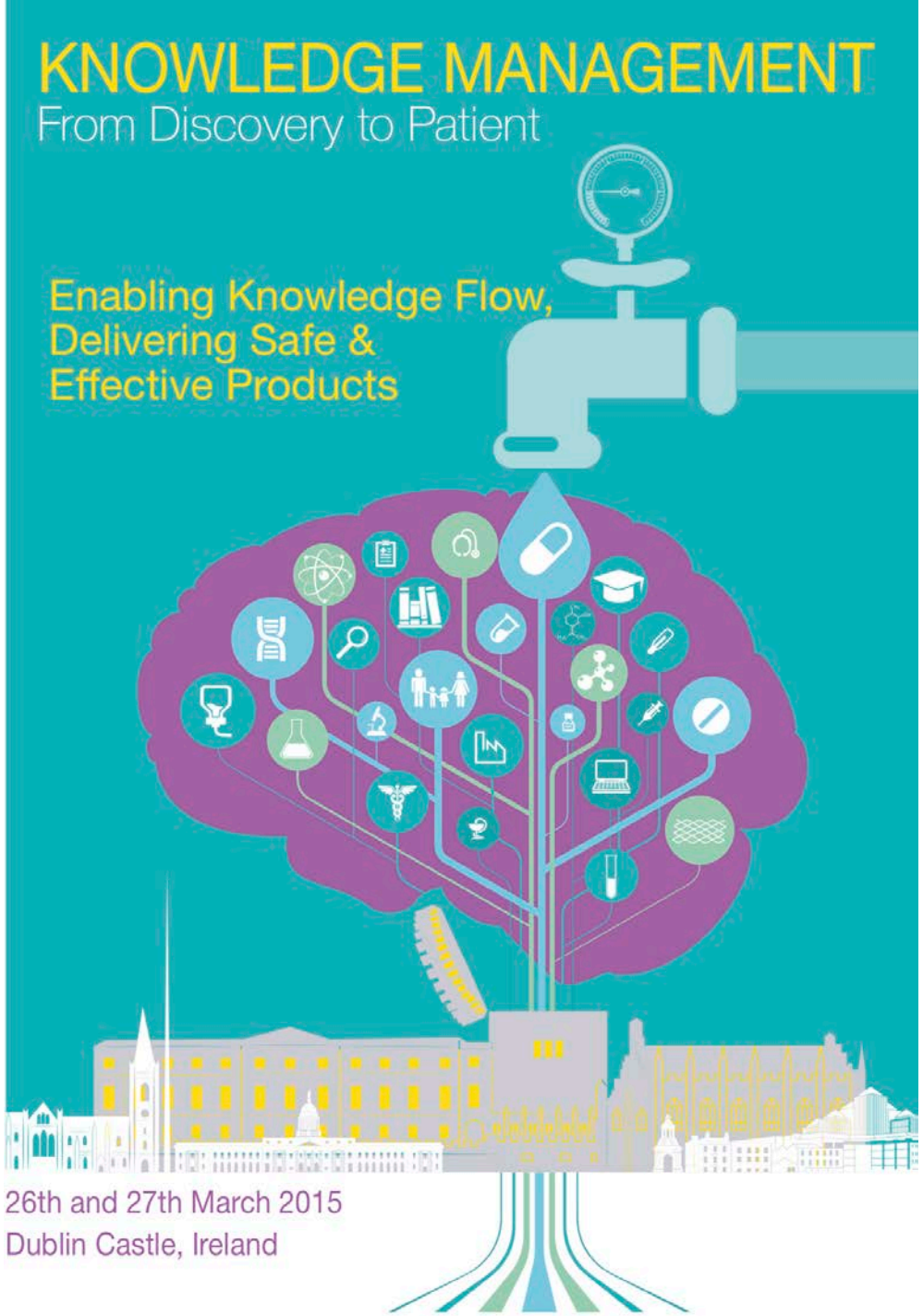
Cork and Dublin 2015/16



KNOWLEDGE MANAGEMENT

From Discovery to Patient

Enabling Knowledge Flow, Delivering Safe & Effective Products



26th and 27th March 2015

Dublin Castle, Ireland

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Regulatory Science Ireland information meeting –

Sept. 8th, 2015, Little Island Cork

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Launch of Quality Defects Report, 2016

Medicinal Products Regulation Research Report Launch

The DIT ***Pharmaceutical Regulatory Science Team*** in conjunction with the ***Health Products Regulatory Authority*** (HPRA) invites you to join them at the launch of an innovative Irish research study report, conducted in 2015, examining medicinal product quality defects and recalls in Ireland.

Medicinal Products QUALITY DEFECT AND RECALLS Pilot Research Project

HPRA An tÚdarás Rialála Táirgí Sláinte Health Products Regulatory Authority

D·I·T Dublin Institute of Technology Institiúid Teicneolaíochta Átha Cliath

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Pharma Chemical Ireland

Ibec

The Research

The EU Medicines Agencies *Network Strategy to 2020* identifies the handling of emerging events such as, quality defects or safety concerns as a major challenge for authorised medicines. Integration between EU member states on defect and product recall handling is crucial in addressing these emerging events and in driving behaviours toward prevention rather than cure.

This Irish research study, examining five years (2010 -2014) of medicinal products quality defect and recall data in the Irish marketplace, is the first of its kind in Europe. The initiative formed the basis of a pilot study to help inform a broader European study currently being undertaken by the European Medicines Agency (EMA).

The research was funded through Regulatory Science Ireland (RSI).

Program

12.30pm	Light Lunch St. Laurence Building
1.00pm	Welcome Address by DIT President *Professor Brian Norton*
1.15pm	Understanding the Context: Quality Defects and Recall Regulation in Europe–Role of the Irish Research Pilot *Dr Kevin O'Donnell, HPRA*
2.00pm	Key Findings and Recommendations from the QDR Research *Dr Nuala Calnan, PRST DIT*
2.45 pm	Update on Regulatory Science Ireland (RSI) Activities and Closing Remarks *Professor Frank Hallinan, UCC*
3.30pm	Tour of the new Greenway Hub Research Facility (All Welcome)

The Greenway Hub

24th February 2016

12.30pm – 4.30pm

Dublin Institute of Technology Presents:

Medicinal Products Quality Defects and Recalls Research

St Laurence Building,
Dublin Institute of Technology,
Grangegorman,
Dublin 7

There is no cost for this event but spaces are limited. To register please contact anne.greene@dit.ie

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RSI - Opportunities for Involvement?

- Influence direction of Research in RSI
- Ability to commission research – company/product specific or common need
- Communicate Training & Education needs
- Influence scope future legislation
- Interact with all the Stakeholders – different dynamic
- Direct access to Regulators / Government Agencies / Third Level institutions

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QUESTIONS?

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