Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

School of Pharmacy & Pharmaceutical Sciences

QP Forum 2017 – Monday 24th / Tuesday 25th April

Monday 24th April

6.30-7.30 p.m. ***Evening Reception & Registration for those interested and available – this will be held in the BOI Premises, Hamilton Building, College***

Tuesday 25th April

9.00 a.m. **Welcome – MacNeill Lecture Theatre**

CART technology in the treatment of fatal diseases
Dr Thurloch O'Criodain, Novartis Switzerland

Product Quality Reviews – Value-adding or just another report that needs to be prepared? Ideas for making PQRs more useful for the QP
Dr Kevin O'Donnell, HPRA

Coffee

Being a QP outside Ireland - *Panel discussion with European Colleagues*
Led by Dr Frank Hallinan, Jazz Pharmaceuticals

Handling significant data integrity breaches…. why not go after the 'real' criminals*?*
Dr Kevin Sweeney, The Compliance Group

Light Lunch in Concourse

Afternoon

Parallel workshops/discussions – see overleaf for details

HPRA regulatory update and the implication for QPs
Deficiencies found in Inspections and QP Responsibilities
followed by Q&A with HPRA Inspector Panel

Reception in Concourse

Parallel Workshops/Discussions

There will be four parallel workshop/discussions held – each one will cover two of the topics requested by the survey. You may choose **one** session – see below.

1. **Marketing Authorisation Holder Responsibilities / Management of Contract Manufacturing Organisations**

   What is expected of a MAH…..what do the regulations say? – a practical example

   How can we deal with incomplete dossiers - liaising/cooperating with manufacturing sites and regulatory authorities?

   Stock out Management – MAH/Manufacturing Site interaction – critical product shortages

   Management of CMOs – which approach works best?

   What can be done for CMOs that are not delivering?

2. **Quality Risk Management / Metrics**

   - How we might apply QRM as an effective tool in Continuous Improvement
   - Meaningful metrics & their role in QRM
   - Examples, Discussion & Q&A

3. **Investigational Medicines / Serialisation**

   Investigational Medicines: likely topics to be covered will be

   - The level of GMP compliance for different phases
   - Process validation for different phases
   - Importation of IMPs
   - QP certification of IMPs
   - Problems encountered / solutions developed!

   Serialisation: likely topics to be covered will be

   - The state of implementation across different organisations / sites
   - Hurdles encountered to date
   - Any particular roadblocks which have to be lifted
   - Experiences with different Regulators.

4. **Coping with QP Responsibility**

   This workshop is designed for early career QPs and also those who are at present involved in study on QP Courses. Experienced QPs will lead the discussion on various scenarios that may arise in both sterile and non/sterile facilities.