



## Dublin City University Pharmaceutical Regulatory Symposium & Webinar

### *“Exploring Current Trends in Active Pharmaceutical Ingredients Manufacture, Control and Regulation”*

DCU Alpha Campus, Dublin – 09th May 2018

Regulatory Science Ireland (<http://www.regulatoryscienceireland.com>), in partnership with Dublin City University ([www.dcu.ie](http://www.dcu.ie)), and DCU Alpha ([www.dcualpha.ie](http://www.dcualpha.ie)) are pleased to present the second annual symposium on Active Pharmaceutical Ingredients on **09<sup>th</sup> May 2018**, in Dublin, Ireland.

Now in its second year, this not for profit initiative aims to bring together regulators and industry experts to discuss the current trends in the manufacture, control and regulation of active pharmaceutical ingredients (API's).

The symposium will serve as a unique discussion platform for industry and regulatory professionals, as well as providing a valuable learning opportunity for junior professionals, junior regulators, and members of academia.

By inviting regulators, academics and industry experts to participate in this forum, the organisers and speakers aim to promote an open discussion with participants, which will ensure an engaging and interactive event for all attendees.

The theme of this year's event will explore newly published regulatory guidance (including the ICH Q11 Q&A document) and investigate emerging trends and their regulatory implications (e.g. API starting material definition, flow chemistry and continuous manufacturing).

Participants can attend the symposium on the day at the DCU Alpha campus, or can register online to view the event as a webinar.

Register your interest today by contacting the team at [APIsymposium@dcu.ie](mailto:APIsymposium@dcu.ie)



*“Exploring Current Trends in Active Pharmaceutical Ingredients Manufacture, Control and Regulation”*

## **Key benefits - why should you attend?**

This symposium will serve as a forum to discuss the latest regulatory guidance and emerging trends, presented by European regulators and industry experts.

The event will appeal to regulatory professionals, healthcare regulators, members of academia, and scientists interested and/or involved in the manufacturing and regulation of active pharmaceutical ingredients.

In addition, the symposium aims to be an open and inclusive event which will present a unique opportunity to network with regulators, industry professionals, and academics working in emerging fields.

Attendees will have the opportunity to learn about a wide range of topics which include:

- Latest developments on regulatory aspects of API manufacture
- The use of “risk management” as a tool when developing a control strategy for a drug substance.
- Translation of process knowledge into a regulatory dossier to reduce probability of deficiency letters.
- Use of the recently published ICH Q11 question and answer document to help you define an appropriate starting material for your process.
- Identification and control of risks associated with mutagenic impurities and/or elemental impurities during the manufacturing process.
- Emerging technologies and application of continuous manufacturing and flow chemistry in API manufacture.

Register your interest today by contacting the team at [APIsymposium@dcu.ie](mailto:APIsymposium@dcu.ie)



*“Exploring Current Trends in Active Pharmaceutical Ingredients Manufacture, Control and Regulation”*

## **Theme, Topics & Speakers**

This year’s event will explore both current hot topics in API manufacture as well as the exploration of emerging trends within the pharmaceutical industry and regulatory environment.

For the 2018 edition, topics have been selected in order to address the most common issues encountered in active substance master files and/or CEP applications.

Some topics delve further in order to discuss new guidance recently published in the last year (e.g. application of the ICH Q11 question and answer document).

In addition, we will also explore the emerging trend of continuous manufacturing and the potential impact in API manufacturing control and regulation.

The symposium will focus on 5 core topics:

- 1. The principles of Quality Risk Management as Outlined in ICH Q9**  
Dr. Ciara Turley (HPRA)
- 2. Definition of an Appropriate Starting Material for Your Active Substance: Interpretation and Application of the ICH Q11 Question and Answer Document.**  
Dr. Matt Popkin (GSK). Invited EMA Speaker to be confirmed
- 3. Strategies for Management of Potentially Genotoxic/Mutagenic Impurities as per ICH M7**  
Mr. Ciarán Feeney (EDQM / Symposium Organising Committee)
- 4. Strategies for Management of Elemental Impurities Using the Principles Outlined in ICH Q3D**  
Dr. Michael James (Consultant / Symposium Organising Committee)
- 5. Quality Considerations in Continuous Manufacturing in API Manufacture and Control.**  
Dr. Aoife Corrigan (Eli Lilly)

**Dublin City University Pharmaceutical Regulatory Symposium & Webinar**  
**09<sup>th</sup> May 2018**

*“Exploring Current Trends in Active Pharmaceutical Ingredients Manufacture, Control and Regulation”*

## **Programme of Events and Timetable**

This event will be hosted as a one-day one day symposium for attendees arriving on the day.

For attendees unable to visit in person, this event will also be broadcast as a webinar.

A detailed timetable of events will be made available closer to the date of the symposium.

## **Price**

The price lists for attendees are as follows:

**Single Attendee:** \_\_\_\_\_ **€350**

**Webinar Attendee Only:** \_\_\_\_\_ **€250**

**Young Graduates / Student:** \_\_\_\_\_ **€175\***

\* Proof of status required to avail of this rate. Please contact the organising committee for more information.

**Exhibitors (Limited Space Available):** Please contact the organising committee for further details.

**Note:** Concessions for returning attendees or affiliated organisations may be available. If eligible, please contact the organising committee for more information.

Register your interest today by contacting the team at [APIsymposium@dcu.ie](mailto:APIsymposium@dcu.ie)



©DCU 2018



Contact: [APIsymposium@dcu.ie](mailto:APIsymposium@dcu.ie)

**Dublin City University Pharmaceutical Regulatory Symposium & Webinar**  
**09<sup>th</sup> May 2018**

*“Exploring Current Trends in Active Pharmaceutical Ingredients Manufacture, Control and Regulation”*

## **Practical Information**



**09th May 2018 - DCU Alpha Campus, Glasnevin, Dublin 11, Ireland.**

DCU Alpha is the innovation hub of Dublin City University which fosters an environment of invention, innovation and research. This state of the art facility complete with a comfortable 100 seat auditorium, is easily accessible from both Dublin City Centre and Dublin Airport.

<http://www.dcualpha.ie/our-story/>

## **Getting There**

DCU Alpha Campus, Glasnevin, Dublin 11, Ireland. (See map at bottom of page). This event will take place in DCU Alpha (Dublin City University's Innovation Campus). View map (at bottom) for exact location of the campus.

Dublin Bus 83 stops at the campus gates and a wide variety of bus stops are within short walking distance from the facility. There are also parking spaces available for those wishing to travel by car.

Dublin City University and its research, entertainment and fitness facilities are 800 metres from the event space.

Parking is available in the visitor's car-park via the Old Finglas, this is managed on a first come first served basis.



©DCU 2018



Contact: [APIsymposium@dcu.ie](mailto:APIsymposium@dcu.ie)

**Dublin City University Pharmaceutical Regulatory Symposium & Webinar**  
**09<sup>th</sup> May 2018**

*“Exploring Current Trends in Active Pharmaceutical Ingredients Manufacture, Control and Regulation”*

Register your interest today by contacting the team at **APIsymposium@dcu.ie**

**Organising Committee**

Mr. Ciarán Feeney – European Directorate for the Quality of Medicines and Healthcare (EDQM)

Dr. Michael Morris – Health Products Regulatory Authority (HPRA) Retiree

Dr. Michael James – Consultant

Dr. Kieran Nolan – Dublin City University School of Chemical Sciences



©DCU 2018



Contact: **APIsymposium@dcu.ie**

**Dublin City University Pharmaceutical Regulatory Symposium & Webinar**  
**09<sup>th</sup> May 2018**

*“Exploring Current Trends in Active Pharmaceutical Ingredients Manufacture, Control and Regulation”*

Register your interest today by contacting the team at **[APIsymposium@dcu.ie](mailto:APIsymposium@dcu.ie)**



©DCU 2018



Contact: **[APIsymposium@dcu.ie](mailto:APIsymposium@dcu.ie)**