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## Process Technology Transfer solutions in Pharma Manufacturing

Hovione Plant, Loughbeg, Ringaskiddy, Co. Cork (15 minutes from Jack Lynch tunnel)

**Thursday May 11<sup>th</sup> 2017**

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One of the technical challenges for the pharma industry is the transfer of process technology between production sites, or from development units to full manufacturing scale. The goal is to produce a product that is exactly the same as the original formulation, but at the volume required by the market. The faithful scale-up or transfer of a production process and its associated analytical methods, documentation systems and knowledge presents difficulties. However, it is essential in maintaining product quality, and in ensuring regulatory compliance. This meeting will outline all of the issues related to this process, and review the solutions currently available. Attendees will also have an opportunity to visit the Hovione plant. The meeting is kindly sponsored by Hovione.

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### Agenda

- 2.30** Registration
- 3.00** Welcome and introduction
- 3.10** Presentations
  - ***Risk Mitigation in technical transfer***  
Brian Harrison HiTech Health, Dublin
  - ***Scale-up and Modelling tools: Difficulties and Advantages***  
Rui Loureiro, Process Development Director, Hovione, Portugal
  - ***Techniques to overcome solubility challenges during process development and transfer***  
Marcio Tentem, Hovione, South Carolina
- 4.30** Open Mike Session (3-minute presentations)
- 4.45** Q&A
- 5.00** Network Reception hosted by Hovione

**Tours of Hovione plant:** (Groups of 15 max) are available after the meeting.  
Please indicate your interest on registration.

To register go to [www.enterprise-ireland.com/bioconnect](http://www.enterprise-ireland.com/bioconnect)

## SPEAKER PROFILES



**Brian Harrison**  
Managing Director  
HiTech Health, Dublin

**Brian Harrison** has over 25 years of extensive technical leadership experience. As Vice President of Chemical Development with Bristol Myers Squibb, Brian was responsible for the transfer, scale-up and registration of multiple new products in a range therapeutic of areas including oncology, virology and antibiotics. His achievements included undertaking the due diligence and successfully transferring an entire portfolio of drugs from a single manufacturing site and outsourcing the production to multiple different CMOs in various countries. Brian has also significant operational expertise having been general manager of a manufacturing facility for BMS.

Brian recently supported Science Foundation Ireland in the effective management of funding programmes across diverse areas including life sciences, ICT and sustainable energy. He serves as a pro bono Board member of Debra Ireland, the charity supporting families and patients with the debilitating disease, epidermolysis bullosa. Brian holds a BSc and PhD from University College Dublin, Ireland as well as Diplomas in Management, Finance and Corporate Governance.

**Rui Loureiro** obtained his first degree in Physics and Chemistry in the University of Algarve where he carried out research under the guidance of Professor Lurdes Cristiano. He then moved to Liverpool UK to carry out a Ph.D. in organic chemistry under the guidance of Professor Johnstone developing amphiphilic polymers as drug delivery agents.

After completing his PhD, he continued in the University of Liverpool as a post-doc fellow before joining Lintfield Ltd as a process chemist. In 2008 Hovione launched a welcome back program to bring Ph.D. students back to Portugal and he joined Hovione as process chemist in that year.

In Hovione he has been a group leader and currently is director of the R&D Process Chemistry area where is responsible for the development and scale-up of processes to produce active pharmaceutical ingredients under development.

In his work Rui has published ten papers in peer review magazines and is author of four patents. Currently his interests are scaling-up processes to produce and purify APIs under a quality by design approach, flow chemistry and process modelling



**Rui Loureiro**  
Process Development  
Director, Hovione,  
Portugal



**Marcio Tentem**  
Hovione  
South Carolina

**Marcio Tentem** joined Hovione in 2008 and has since been involved in the development of the Particle Design and Drug Product Business of the company. In the role of a scientist, group Leader or manager, Marcio has been involved in the development of multiple commercial and late stage programs in the field of solubility enhancement, particularly in the area of amorphous solid dispersions by spray drying, taste masking by spray congealing, microfluidization assisted processes and jet milling.

Marcio is currently Associate Director for Drug Product Development at Hovione leading the R&D efforts in the field of particle engineering, oral solid dosage forms and inhalation.

Marcio is PhD in Chemical Engineering with several papers and patents published in topics such as Green Chemistry, Controlled Release, Inhalation, Drug Product, Particle Engineering and Solubility enhancement.

This BioConnect Ireland Event is sponsored by:



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