QUARTERLY NEWSLETTER
Q2 2015

Welcome to the latest edition of the information sharing newsletter from the Maynooth University Commercialisation Office. Our goal is to share relevant market news and activities on the commercialisation of Maynooth University research. We hope you enjoy this newsletter. For more information visit: **maynoothuniversity.ie/commercialisation**

TECHNOLOGY TRANSFER SUMMIT GLOBAL INITIATIVE

BUSINESS DEVELOPMENT UPDATE

To stay abreast of developments in the biotech arena our Commercialisation Executive Dr Paul Tyndall, a specialist in this space, takes in a global conference every other year. In April this year Paul attended the Technology Transfer Summit (TTS) Global Initiative Conference in Barcelona, Spain. The TTS Global Initiative is the key platform and think tank focusing directly on dialogue, partnering, licensing and technology transfer between public sector biotech research TTOs, early stage start-ups, SMEs and senior industry licensing and business development executives, patient organisations and other key stakeholders.

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The TTS Global Initiative was launched in 2007, emerging out of a working group of the heads of the leading trade lobbies and associations in Europe for Biotechnology, Pharma, Bio Industry, and Venture Capital, along with key European institutions, all of which sought to undertake a new initiative to foster the more efficient translation of leading biotech and healthcare sector research to the market and to patients.

Download full TTS article

MAYNOOTHWORKS BUSINESS INCUBATION CENTRE

MAYNOOTH UNIVERSITY UPDATE

The Maynooth Business Incubation Centre "MaynoothWorks" will be open for business from July 2015 and represents an exciting opportunity for the University and local entrepreneurs. Designed by Coady Architects the Centre's generous office and networking spaces provide a great environment for the modern entrepreneur. The management team of Owen Laverty and Sharon Comerford will be in place shortly. Owen has been a Commercialisation Executive in the Commercialisation Office for the last 8 years and brings a wealth of experience. Owen previously ran his own start-up company, and was actively involved in the management of over 10 spin-out companies from Maynooth University. Sharon comes from the Maynooth University Edward M. Kennedy Institute where she has successfully supported the Institutes activities.

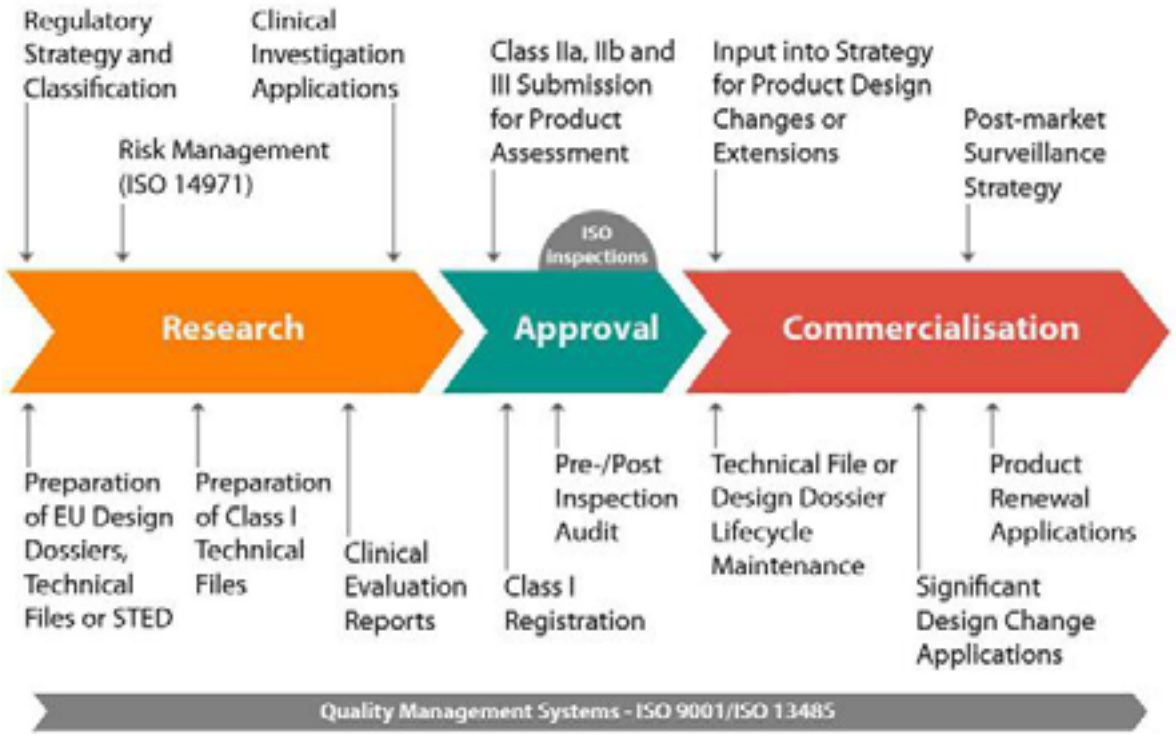
We are interested in meeting entrepreneurs who would like to move to our MaynoothWorks facilities and particularly those who could benefit from the research strengths of the University.

For all enquires on MaynoothWorks please contact: **owen.laverty@nuim.ie** (01) 708 6589

In February Enterprise Ireland and Molecular Medicine Ireland jointly hosted a seminar on the use of software as a medical device: the regulations and their impact on your business.

The objective of the seminar was to give participants from academia, manufacturing, software developers and clinicians greater understanding of the regulatory environment, quality management system required and processes and procedures required during the development of a medical device that incorporates software.

Increasingly medical devices are becoming "smart" meaning that they incorporate some form of sensing/controlling technology. Depending on how these devices interact with the user, the software that is incorporate in the device may also have to be classified as a medical device. Paul Scannell of NSAI empathised this point in the definition of a medical device as "including the software intended by its manufacturer to be used specifically for diagnostic and/ or therapeutic purposes and necessary for its proper application". Diarmuid Cahalane of Open Innovation Partners outline that implementing well defined and traceable development processes was key. He emphasised that the main additional requirements for software as a medical device are: 1) A formal rationale for any changes during design and development and 2) the approval of an authorised individual prior to the implementation of any design changes. Peter Donnelly of BioBusiness looked at the need to take close account of the regulations as they apply to software and the impact that they have on business.



Developers need to be aware of the international standards that apply to software's use in a medical device: ISO 13485 (Quality Management System), ISO 14971 (Risk Management) and IEC 62304 (Software Development lifecycle for medical devices). Implementing these standards will allow the developer to put their product forward for Conformity Assessment meaning that they can demonstrate that this product meets the appreciable requirements for the current medical device directive (the device can be CE marked).

Things to bear in mind:

- 1 in 3 medical devices that incorporate software require for operation have been recalled due to a failure (bug) in the software.
- Between 2005 and 2011 19.4% of medical device recalls were related to software.

Comments & Questions to
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