

# Newsletter

technology transfer initiative

an innovative support structure for indigenous companies in the west, midwest, and southwest

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## Medical Device FDA QSR & QSIT Seminar

The TTI in NUI Galway, in association with the BESTNet Accel project, held a very successful 2 day training course on the FDA directive. The event was targeted at QA personnel responsible for design and implementation of Quality Systems, manufacturing and process engineers and senior management. It was attended by a cross section of small to medium sized medical device companies across the BMW region.

This session was presented by Mary Rose O'Mahony, who has 16 years experience in the healthcare industry. She has extensive experience working in FDA, IMB & ISO regulated bodies and has established and managed plant -wide validation programmes.

The 2-day session was a classroom based course, highly interactive with the use of practical exercises and case studies to reinforce learning. The workshop identified the key challenges that each individual company faces with the following objectives:

- To gain a greater knowledge and understanding of the FDA Quality System regulations
- To understand the FDA audit approach following the Quality System Inspection technique – QSIT
- To gain an appreciation of the Quality System guidance documents provided by the FDA
- To review FDA citations using group discussions and workshops

Feedback from the participants was extremely positive with all rating both the content and presentation very highly.

**Watch out for the upcoming seminar/workshop on the European Regulatory Affairs which is scheduled for June timeframe.**

Contact the TTI for further details.



## Notice Board: Up & Coming Seminars

IP, Patent & Licensing for Biomedical Sector  
April 30<sup>th</sup> 2007

Medical Device European Regulatory Affairs - June '07

Do you have a topic you'd like covered at a future seminar ?

## Enterprise Ireland Innovation Vouchers Initiative

Do you own or manage a small company?  
Do you have a business opportunity or problem that you want to explore?  
Then why not apply for an Innovation Voucher worth €5,000?

The Minister for Enterprise, Trade & Employment Micheál Martin TD announced on Wednesday 21st March a €10m fund to assist small Irish firms to become more innovative.

Small companies\* with a business opportunity or problem they want to explore can exchange the voucher for advice and expertise from knowledge providers, one of which is **NUI, Galway**.

Innovation Vouchers can be used for any kind of innovation, some of which are outlined below:

- New business model development
- New service delivery and customer interface
- Preliminary research/literature research
- Innovative or Technology audit
- New Product Design/ Development
- New or Improved production process.

Enterprise Ireland is managing the initiative and will allocate **200** vouchers worth **€5,000** each in this initial pilot phase. Applications will close on **Monday 30<sup>th</sup> April 2007**.

The online application form and further information on the Innovation Vouchers Initiative can be found on the Enterprise Ireland website <http://www.enterprise-ireland.com/InnovationVouchers/>

**If you have any questions on this initiative, you can contact us here at the TTI, NUI Galway.**

*\*A small company is defined as an enterprise that has fewer than 50 employees and has either an annual turnover and/or an annual Balance Sheet total not exceeding €10m.*

## A Programme of Research Briefings for Innovative Companies

NUI, Galway is about to launch a series of research briefings designed to help companies get involved in R & D activities, with a special emphasis on optics, lasers and applied photonics. Sponsored by the ERDF and administered in Ireland by the BMW Regional Assembly, the work programmes will be delivered by LightHouse, a collaborative initiative of the National Centre for Laser Applications ( NCLA ) and the Applied Optics Group, both based in NUI Galway. Between them, the groups have a broad expertise in the industrial applications of lasers and optics and have a critical mass in terms of combining fundamental and applied research with technology transfer and industrial outreach.

The two groups recognise the opportunities that exist for an outreach activity with a regional and national impact, focussed on disseminating optics-related information to industry. Laser and Opto-electronic technologies have developed at a remarkable pace over the last 40 years, and the application of photonic tools have been extensive in biomedical science, ICT, Manufacturing, Communications, lighting, displays, lasers, sensors, machine vision, life sciences, environment and many other fields. The enormously enabling aspect of lasers/optics to industrial processes will mean that enhanced knowledge of this field will be of benefit to industry.

The research briefings will address the main barriers to embarking on cost effective R & D, through a number of themed sessions, as follows:

- Photonics 21-Europe's Photonics Strategy and how it will impact Irish industry.
- Laser and optics. Enabling Technologies for Irish Industry
- Access to Photonics Research Services, regional and national
- Access to Photonics Research Services, International.

**Participation in the programme is free.** Anyone wishing to participate in the programme should contact Mr. Tony Flaherty at (091) 493595 or email [tony.flaherty@nuigalway.ie](mailto:tony.flaherty@nuigalway.ie)

## Fund your Innovative Research projects with the Innovation Partnership Initiative

The Innovation Partnership Initiative is one of the funding packages available to Irish Industry and 3<sup>rd</sup> level colleges to work together on innovative research projects. The key to this programme is that companies can avail of the opportunities to develop innovation through collaborative research with the colleges which can lead to greater market share and increase profits. The Innovation Partnership initiative supports and encourages industry to become aware of the skills and expertise in the 3<sup>rd</sup> level institutions.

### What's in it for you?

- Financial assistance for the cost of the 3<sup>rd</sup> level research and development expertise
- Access to knowledge, expertise and skills bank
- A new perspective for your business through collaboration.

### You qualify if:

- Your company is involved in manufacturing, processing or internationally tradable services with an operating base in the Republic of Ireland
- Your business needs innovative research carried out
- Your research has a commercial impact in Ireland and does not duplicate work already in the public domain
- Your project has a scientific and technological emphasis

### How does it work?

- The college and company agree on whether the project should be a feasibility or a full proposal
- An outline proposal is submitted to Enterprise Ireland for assessment of project eligibility
- Feasibility Funding (100% of costs up to € 9,000 )
- Full Proposal Funding (50-70% of costs up to €190,000)
- Full proposals may be subject to a technical and commercial peer evaluation. The evaluator will work with the college and company to help clarify any concerns / issues.

**2** The proposal submission and all routine project administration is handled by the 3<sup>rd</sup> level college on your behalf. Applications are usually processed within 4-6 weeks. To Apply: Contact the TTI.

## Company Profile



Sigma-X Ltd was founded in 2004 and has its headquarters in the incubation centre on the National University of Ireland Campus.

Sigma-X develops and markets analysis and design software solutions for the structural engineering industry. The software applications are designed to serve as standalone or additional components to any finite element (FE) analysis software programme.

### Mission

Sigma-X aims to become the leading provider of software solutions for the structural engineering industry by researching, developing and marketing high quality software, with a particular focus on pre- and post-tensioning software.

### Products

To date Sigma-X has successfully developed **Sigma-X Section** (a section properties calculator) and **Sigma-X Post Tension Floor** (for the analysis and design of post-tensioned concrete floor slabs).

### Capitalising on change

Timing is everything and for Sigma-X the timing could not possibly be better! There is currently a unique convergence of two separate factors causing unprecedented change in the structural engineering software market. Sigma-X is poised to exploit both to its advantage.

Firstly, a single European set of codes and standards for structural engineering design is in the process of being introduced across Europe. The old national codes will be obsolete within the next 18 months, as will many of the software applications originally designed, often on old black box technology. Whilst competitors have been engaged in expensive software re-writes, the playing pitch has been levelled as Sigma-X has been incorporating the Eurocodes into its technology since the beginning.

Secondly, for supply reasons, steel as a building component, is quickly losing ground to concrete and large span flooring systems. More often structures from multi-story car parks to bridges are being designed in concrete using the post-tensioning method. In the UK alone growth rates of in excess of 100% year on year have been the norm for the past few years. **Sigma-X Post Tension Floor** is uniquely placed as the only accessible European solution for post tension design.

### Management Team

James Lee, Managing Director – James holds a PhD involving the experimental and numerical analysis of bridges and has over 20 years experience in the structural engineering industry

Maria Moynihan, Business Development Director  
- Maria holds a B.Comm from NUI Galway



[WWW.SIGMA-X.NET](http://WWW.SIGMA-X.NET)



*Dr. James Lee, Managing Director, Sigma-X*

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