INCON

ISA Ireland Section

Pharmatex Conference and Learning Program

This year PHARMATEX 2008 hosted the 19th International Confederation of Contamination Control Societies Symposium.

This industry, at the corner stone of Ireland's knowledge economy, is hungry for information, innovation and excellence.

The three day Conference and Learning Programme was divided into eight tracks ranging from the Heads of Industry, Disposables in Bio Manufacturing, Industrial Communications, Training and Re-Skilling Workshop and The Next Step in Automation.

ISA Ireland Section Golf Outing

The ISA Ireland Section Golf Outing 2008 took place at the end of August in Harbour Point Golf Club in Cork.
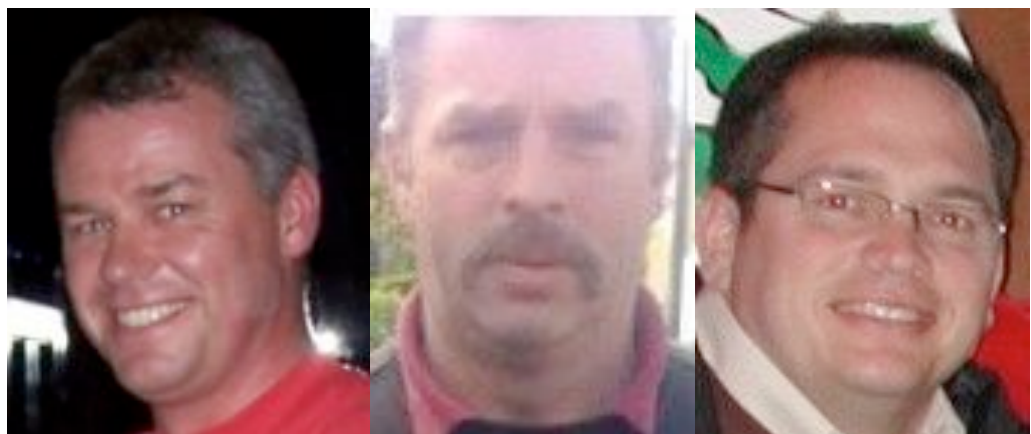
The event was well supported by the event sponsors and by the participants who turned out on the day.

The event sponsors included:
   ESI Technologies
   FESTO
   HA O'Neills
   Janssen Pharmaceuticals
   NTRON
   O'Sheas Electrical
   ProsCon

After a wet and windy week leading up to the event, the weather improved for the day – which was reflected in the scoring.

It was a team event and the winning team clinched victory by all three players getting

Golf outing first place winners, left to right - Mr. Ray Wolfe, Mr. Denis Foley and Mr. Brian Bridgewater

birdies on the tricky par 5 finishing hole.
The final results were :-
1st Brian Bridgewater / Ray Wolfe / Denis Foley
2nd Eamon Bradfield / Joe Redmond / Frank Corrigan
3rd Brian Curtis / Tony O'Flynn / Tommy Flynn

Nearest the Pin was Declan Lordan. Longest Drive was Ray Wolfe.

The prizes were presented by ISA Ireland Section President Mr. Mick Meade at the 19th hole, where all the near misses and putts lipping out

were discussed in detail.

Next years proposed golf outing is being scheduled for May 2009. For further information / comments contact E a m o n   B r a d f i e l d (eamonis@gmail.com)

Section Performance Award Submission 2008

Special Accomplishment - Joint Organisers of PHARMATEX 2007

Date: 27 May 2008
Section: Ireland
District : 12

Reference: Special Accomplishment / Training & Education Programme

Joint Organisers of the PHARMATEX Conference & Learning Programme which was held from 11 – 13 September 2007 in the Radisson Hotel, East Gate, Little Island, Cork, Ireland.

Mr. Mick Meade (left) President of ISA Ireland Section with Mr. Declan Lordan (centre) and Mr. Billy Walsh (right) at the recent Pharmatex Conference and Learning program 16-Sep-2008.

Dear SPA Evaluation Committee,

Four of the nine member joint organising Conference Committee were leading members of the ISA Ireland Section Committee, namely, Kevin Dignam, Declan Lordan, Eoin O'Riain and Billy Walsh.

They assisted in organising the very successful three day Conference & Learning Programme that was held in Cork, Ireland during September 2007.

A three day major Exhibition was held in conjunction with the Conference & Learning Programme.

Several key people in Ireland attended Track A (Pharma and Bio-Pharma: The Next Ten Years) including Micheál Martin, Minister for Enterprise, Trade and Employment. Senior representatives from Irish State agencies such as IDA Ireland, Enterprise Ireland, Forfás were present as well.

The ISA Ireland Section

Committee members were involved in all aspects of the programme which took nine months to plan with meetings held every two weeks but they had complete control of Track C (Wireless Automation in Bio Pharma Plants) and Track G (Process Analytical Technology: The User Perspective). More than 250 delegates attended Tracks A, B, C, D, E, F, and G over the course of the three days.

This winning formula is been used again in 2008

with PHARMATEX 2008 which is been held from 16 – 18 September in Cork, Ireland, the only difference this year is that the associated Exhibition will be smaller in size, that is a table top format. Website:

http://www.pharmatex.ie

I include detailed supporting documentation for your perusal.
Respectfully Submitted by:

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Section President 2007 / 2008

ISA
ISA–The Instrumentation, Systems, and Automation Society

Presidents Corner - *Brother, Can You Spare a "Time?"*

A statistic which I had previously come across and often quote is "in a typical voluntary organisation only 3% of the membership offers to serve".

This perhaps gives some substance to the perceived view of "the same old faces on the committee" when put forward as a reason for ceasing membership of such an organisation.

Such attitudes are very obvious today across the spectrum of typical voluntary organisations — churches, sporting clubs, charitable bodies, professional societies, etc. Unfortunately ISA and the Ireland Section are no different in this regard.

This increased lack of volunteers is perhaps is also resultant from the current turmoil in the world as people feel, like our ancestors before, to retreat into the castle and pull up the drawbridge.

However I believe that the answer is in fact the opposite and in times of downturn these organisations are in more need of members and of the service by those members.

"Brother, Can You Spare a Dime?" (lyrics by Yip Harburg, music by Jay Gorney (1931), also sung as "Buddy, Can You Spare a Dime?", is one of the best-known American songs of the Great Depression.

When Bing recorded this song in October, 1932,

one out of every four Americans who wanted to could not find work.

The banking system was near collapse. Record sales had plummeted because Americans did not have the money for such luxuries.

This is arguably very reflective of the current situation in which the world now finds itself.

My belief is that time is the most precious non-renewable of all the world's resources because our personal possession of this resource is both indeterminate and cannot be increased.

Therefore such should be utilised very wisely indeed and so the giving of time freely for the benefit of others is to be much treasured.

Generally, volunteering is described as an unpaid activity where someone gives their time to help an organisation or an individual who they are not related to. Volunteering is therefore "…an activity that involves spending time, unpaid, doing something that aims to benefit the environment or individuals or groups other than (or in addition to) close relatives".

In our era of pop psychology and self-help, few things can make such a profound difference to an individual as a spirit of engaged service and volunteerism.

Studies have shown that a key motivation for volunteering is social exchange and obligation to society. Recent theories on volunteerism put forward some advantages as follows.

Postulates that people will search for environments that allow them to use their skills and abilities to express their attitudes and values.

Is considered to be integrative for both society and individuals and to provide direct ways for them to initiate change.

Suggests that it improves the happiness, life satisfaction, self-esteem and sense of mastery of people.

Provides physical and mental health benefits.

So in a parody of the lyrics of Yip Harburg, and with all that we still have,

I ask you "Brother, Can You Spare a Time?" for all those organisations, and including ISA Ireland Section, which are in need of your skills to enable a better world for the generations to come.

Michael Meade
President
ISA Ireland Section

30th ANNIVERSARY OF CHARTER DINER

The 30th Anniversary of Charter Dinner which will be held on Saturday 8th November 2008 at the Maryborough Hotel Cork.

Tickets will be priced at €75 each and the room layout will be for round tables of ten. Formal invitations including booking form are available.

The intent of the dinner will be to recognise and honour thirty years of growth, development and consolidation by the ISA Ireland Section and especially the members who enabled such in the intervening period.

The respective histories of the United States and Ireland are inextricably linked and receipt of our charter from ISA has inevitably led to increased interface between both countries. Increased globalisation has seen ISA expand from the United States into a truly worldwide organisation and the Ireland Section takes a very proactive and direct part in the functioning of ISA at European District level.

We have negotiated special rates with the Maryborough Hotel for the function at €49 per person sharing and €74 for single occupancy. Should you wish to avail of these rates, please contact the hotel reservations directly at (021) 4918307 quoting ISA as a reference.

ISA Technical Talk - Athlone

The talk was entitled "Project Management, Best Practice to Achieve Project Success".

Presenter Mr. Karl Lawler gave the technical talk to ISA members at the Creggan Court Hotel in Athlone, Co. Westmeath on the 27th May.

There was an appreciative audience for a superbly presented talk which was well attended by members from several corners of the country.

Mr. Jim Long (left) making presentation to speaker Mr. Karl Lawlor (right) of Biokinetics.

Group Photo L - R : taken by Brian Curtis Frank Maher - (retired) ESB ,Charles Smith - Allergan, Gordon Blakeney - Ntron Europe, Jim Long - HSE, Douglas Christy - G&P Systems, Karl Lawler (speaker) - Biokinetics, Billy Walsh - UCC, Daniel McGuinness - APV Ireland, David Barbour - Epsilon Consulting.

MES - Facilitating the Metamorphosis of Biopharma Manufacturing

The following report is courtesy of Mr. Seamus Cotter who presented the report at this years Pharmatex Conference and Learning Program 2008.

This is brief story about the industry and technology. Where is the industry now? Why do Technology Projects Fail?

How should Technology Projects Facilitate the Metamorphosis?

Industry Summary
Pharmaceutical and Biotech industry must contend with an increasingly difficult economic climate 56 products have been lost in phase III of development from 2002 – 2005

Between 1997 and 2004 safety based withdrawals lead to loss in sales of $13,5bn.

By year end approx $35.5bn worth of products will have lost blockbuster status since 2005.

In 2003 The wall street Journal published an article informing the world that 'Manfacturing Techniques lag far behind those of potato chip and laundry soap makers.'

Since 2003 improvements have been made however manufacturing defects account for almost 75% of all drug recalls

FDA benchmarking outside the industry – 'You need to improve …. Other high tech industries (electronics, medical devices) have achieved enormous productivity gains in manufacturing in the last 25 years. We should expect nothing less from the pharmaceutical industry.

Industry Summary Benchmarking Standard Manufacturing Benchmarking

Some reasons for the Differences

30-60% of all labor (Direct and Indirect) in a Bio-Pharm plant can be spent on completing, managing, reviewing, and correcting paperwork. The Paper can cost as much in labour as the product. 25-75% of manufacturing cycle time is because of waiting for paperwork activities to be completed.

The Paper can take longer to make than the product 25-50% of Work In Process Inventory is because of the paper. There can be twice as much inventory of the

ISA Ireland Section

product because of the Paper.

Industry Direction – FDA GMP's for the 21st Century Product quality and performance achieved and assured by design of effective and efficient manufacturing processes. Product specifications based on a mechanistic understanding of how formulation and process factors impact product performance

• Continuous "realtime" assurance of quality

• Regulatory policies and procedures tailored to recognize the level of scientific knowledge supporting product applications, process validation and process capability

• Risk-based regulatory scrutiny that relates to the level of scientific understanding of how formulation and manufacturing process factors affect product quality and performance, and the capability of process control strategies to prevent or mitigate risk of producing a poor quality product.

Technology has a role to play in these (Facilitating Process Knowledge, PAT, Scientific Understanding)

Where Should the Industry be going?
Lean – Six Sigma – Right First Time Continuous Processing (Process Analytical Technology), Process Knowledge, Operational Excellence, Innovation.

Technology is becoming increasingly important in the search for competitive advantage yet many companies which have invested in new technologies have been disappointed with the results – why?
Pitfalls
Sainsbury's
'In 2006 the giant British food retailer had to write off its US $526 million investment in an automated supply-chain management system. Merchandise was stuck in the company's depots and warehouses and was not getting through to many of its stores. Sainsbury was forced to

MES - Facilitating the Metamorphosis of Biopharma Manufacturing

ISA Council of Society Delegates Approves Name Change

The Council voted to rename the Society from ISA – The Instrumentation, Systems and Automation Society to the International Society of Automation. The Council of Society Delegates controls the policies of the Society, and Members are represented by one delegate for each geographic ISA Section…..more in the next issue of INCON.

hire about 3000 additional clerks to stock its shelves manually. '

Terminal 5 Heathrow
'Amazing, it was a high profile and expensive project requiring state of the art technologies and methods in all areas (architecture, logistics, ICTs, security, construction, etc...) forgot to effectively deal with a key component: the people that will have to work in this new place!''
Source

www.spectrum.ieee.org

delivery as hopelessly inadequate.

Many others will arrive late and over budget or require massive reworking. Few IT projects, in other words, truly succeed. '

Source
www.spectrum.ieee.org

Why the failures ?

Why the Pitfalls
Unrealistic or unarticulated project goals Inaccurate

management
Commercial pressures
Stakeholder Politics
Poor Management Commitment if any
No Training on Handover

Technology – Beating the Trend – Suggested Way Forward
Technology Definition – Three Components

Knowledge (Collection of Know-How)

Pitfalls
'There is history of [software] projects gone awry. Most IT experts agree that such failures occur far more often than they should.

What's more, the failures are universally unprejudiced: they happen in every country; to large companies and small; in commercial, nonprofit, and governmental organizations; and without regard to status or reputation. The business and societal costs of these

estimates of resources required
Badly defined system requirements

Setting the Standard for Automation™

Poor reporting of the project's status
Unmanaged risks
Poor communication among customers,

An artefact system with control – (A physical Item – The System)

A process of Enquiry or Action (Human activity of discovery and use)

Lets call it KAP. (Knowledge, Artefact, Process)

If all three are not considered then the risk of failure is increased.

Technology – Knowledge

failures—in terms of wasted taxpayer and shareholder dollars as well as investments that can't be made—are now well into the billions of dollars a year.'

'The problem only gets worse as IT grows ubiquitous. This year organizations and governments will spend an estimated $1 trillion on IT hardware, software, and services worldwide. Of the IT projects that are initiated, from 5 to 15 percent will be abandoned before or shortly after

developers, and users
Use of immature technology
Inability to handle the

project's complexity
Sloppy development practices

Why the Pitfalls
Poor project

Element
Project Management Knowledge

Knowledge of the Artefact (Hardware Software and Infrastructure)

Choose the Software Integrator Wisely:
Cost
Quality System
Track Records
Knowledge, Skills, Ability
Long Term Support

MES - Facilitating the Metamorphosis of Biopharma Manufacturing

Capability
Knowledge of the Business – Bio Pharma

Knowledge of the Requirements – All Stakeholders – need to be involved (IT, Users, Management, QA, H.R. Supply Chain, Finance - do not ignore any stakeholder who may have a potential say in its use)

Leverage the Knowledge from Stakeholders, remember one ignored is a lost opportunity for a more comprehensive solution

Technology – Artefact Element
Infrastructure needs careful consideration
Think of future capacity requirements

Security and Access Control
Enterprise Solution – Corporate vs Local Collaboration
Simple Structure
Standardised Interfaces with DCS and ERP Systems
Avoid Customised Solutions
Location

Support Agreements
Training – Customised or Standard ?

Technology – Process of Enquiry and Action
User Requirement Specification
Input from all Stakeholders
Clear Unambiguous definitions – The System will ……

All stakeholders need to define what one wants up front, collaborate agree and move on.

It is too late if disagreements arise during design
System Integrator to deliver Compliance Matrix against URS – it is important to know as soon as possible if the 'The System cannot do … or that the system scope does not allow for' ..

Have the cannot's, will not's and cost too much discussions early. This allows focus on the solution during design and implementation and allows harmony to prevail!

Technology – Process of

Enquiry and Action
Users must know as soon as is effectively possible about how this system will affect how they work
Management must face the
Work practice changes
Training and Up-skilling Needs
Redundancies ?
Work Flows and job re-fit
Job- Redesign
Users must agree to work with the new system, receive the necessary training and move forward.

Process of Enquiry and

Action – The most neglected Component
Excellent engineering of an application of technology of a system of manufacturing is a necessary, but not sufficient, condition for enabling it to fully realize the potential benefits of that technology.

The technology will only perform at its full potential if the utilization of the system's human resources is also engineered.

That is, so engineered as to enable all personnel to

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communicate and cooperate fully with each other. And failure to meet this condition cripples the technology.

Conclusion
The industry must change
Technology must accelerate this change to maintain competitive advantage.

Adopt all components of KAP to mitigate risk of failure.

Become early adopters and

innovators – no longer should biopharma manufacturing use the 'stifled by regulation' excuse.

Realise that Technology is a Strategic Tool not a Unit of Cost – broader financial justification techniques are required.

Listen to the next presentations on how MES if correctly implemented can help you with the Metamorphosis.

MEMBERSHIP BENEFITS

Technical Information

Free Standards
Receive free unlimited ISA standards. Accredited by the American National Standards Institute (ANSI), ISA has published more than 150 standards, recommended practices, and technical reports, through the dedicated efforts of a network of industry experts.

Free Web Seminars
Unlimited free access to a library of over 40 online pre-recorded web seminars covering today's hottest topics.

Technical Library
Access to unlimited downloads of ISA's library of over 2,500 technical papers published at ISA conferences and symposia.

InTech Magazine
Free qualified subscription to InTech, the premier monthly magazine for automation professionals.

Technical Division Membership
Join a network of automation professionals who share your technical interests. Student Members get two free memberships.

ISA Transactions
Free online access to current and past articles covering the latest advances in the science and engineering of measurement and automation.

A Snapshot Tour of Pharmatex 2008

MEMBERSHIP BENEFITS

Networking Opportunities

ISAJobs.org
Free online listing of your resume when you're looking for your next career move

Local Section Membership Network with automation professionals in your local area for meetings, training events, and more.

Professional Development

Leadership Opportunities
Develop your leadership skills by participating in ISA's free online Leadership Development Certificate Program.

Discounts
Take advantage of significant Member discounts on ISA products, training and event registration

Certification and Licensure
Take pride in supporting the Society that recognizes your profession through professional certification programs. ISA offers the Certified Automation Professional (CAP), Certified Control Systems Technician® (CCST), and the Certified Industrial Maintenance Mechanic (CIMM) programs and supports the development of the Control Systems Engineer (CSE) licensure program.

Mentoring Program
Connect online with, and learn from, experienced professionals and practitioners, and much, much more.

A Snapshot Tour of Pharmatex 2008

ISA Committee for 2008 / 2009

Front Row L to R: Brian Nolan, Seamus Cotter, Jim Long, Mick Meade (President), Tadgh Moriarty

Back Row L to R: Dave O'Brien, John Downey, Billy Walsh, Willie Cody

President - Mr. Mick Meade	Web Master - Mr. Eoin O'Riain
President Elect - Vacant	Standards and Practices Chair - Vacant
Secretary - Mr. Tadgh Moriarty	Honours and Awards Chair - Mr. Brian Nolan
Treasurer - Mr. Seamus Cotter	Past President - Mr. Jim Long
Education - Mr. Billy Walsh	Committee - Mr. Eamon Bradfield
Technical Program Chair - Mr. Terry Mc Carthy	Committee - Mr. Kevin Dignam
Membership Chair - Mr. John Downey	Committee - Mr. Willie Cody
Newsletter Editor - Mr. Dave O'Brien	Committee - Mr. Gary Hartnett

FEEDBACK

Section Committee Members can also be contacted at:

ISA Ireland Section P.O. Box 203, Togher Mail Centre, Cork

website: http://www.iol.ie/~isaire   email: info@isa.ie

The views expressed in INCON are not necessarily those of ISA or ISA Ireland