

CONNECT

ANNUAL NEWSLETTER OF THE MRII

Issue 6 • September 2015

PRESIDENT'S WELCOME

Mr John Elliott, MRII President

NATIONAL CONFERENCE 2015

Thank you to our Sponsors

- Introduction to Biopharmaceuticals and Bioprocessing Training Course 2015
- MRII Awards 2015
- The Value of the Healthcare Sales Professional Visit
- Meet a Member
- An Interview with Justin Carty, CEO IMSTA
- Mindfulness
- Take Action
- MRII Celebrates 30 Years!
- Antibody Drug Conjugates



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Introduction to Biopharmaceuticals and Bioprocessing Training Course



Why should I attend this course?

Ireland is emerging as a leading location for biopharmaceutical companies. Since 2004, €9bn of capital investment has been committed to new biopharmaceutical facilities here. Manufacturing excellence in biopharmaceuticals is driving this growth, we have gone from two manufacturing sites in 2003 to ten in 2013 with a number of other facilities now under development. Are you up to date?

This is a 1 day training course, covering a series of specific sessions designed to meet the learning outcomes of attendees including a full tour of the NIBRT pilot production plant and associated utilities areas which will help to contextualise the theory sessions.

The principal objective of this training course is to provide an understanding of the bioprocesses and disciplines necessary to produce biologic products and the implications such products have on facility design and operation.

This course will provide trainees with an overview of the biopharmaceutical production process, from cell line creation, to large scale drug production, to harvesting, purification and finally to formulation-final filling of drug product.

PRESENTER:

Mr John Milne PhD,
Training Director (NIBRT)

Date: Friday 16 October 2015,
8.30am – 5.00pm

Cost: €300 MRII Member (€395 Non Member), per person includes lunch and NIBRT certification following completion of the course.

Priority will be given to members for places. Non-member bookings are subject to availability. Discount available for an attendee (Member) if currently out of work.

Venue: National Institute for Bioprocessing Research & Training (NIBRT), Mount Merrion, Dublin 4.

Course Outline

Time	Content
08:30 - 08:50	Arrival at NIBRT
09:00 - 09:15	Welcome, Introductions and Course Overview
09:15 - 10:15	Introduction to the Biopharmaceutical Industry - Current Options and Future Trends
10:15 - 11:15	Production of Biologics (Cell Culture and Protein Purification Operations)
11:15 - 11:30	Break
11:30 - 13:00	Interactive Tour of NIBRT Production Plant
13:00 - 13:45	Lunch
13:45 - 14:45	Aseptic Processing and Contamination Control
14:45 - 15:45	Single-use Technologies and their implication for Facility Operation
15:45 - 16:00	Break
16:00 - 16:45	Interactive Discussion/Open Forum on opportunities MRII attendees
16:45 - 17:00	Course Summary and Feedback



email info@mrii.ie
to book your place today

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info@mrii.ie
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IPHA Medal Winner 2015



Mr Philip Hannon, Communications and Public Affairs Manager, Irish Pharmaceutical Healthcare Association (IPHA) and Ms Claire Leonard, MRII. Ms Leonard was the IPHA Medal winner for the highest scoring candidate in the MRII Examination 2015.

President's Welcome

John Elliott, MRII President



I am delighted to welcome you to this issue of CONNECT, the annual newsletter of the MRII.

I took up the Presidency of the MRII in May of this year. I very much look forward to working with Council on behalf of our members and their companies. I also look forward to working with our sponsors whose participation with the Institute is so valued.

The MRII is in its 31st year, I am honoured to take this role and build on the hard work that continues to ensure that we continually improve our service to our members.

One of the first tasks that Council and I decided upon was to poll our members, and also Managers, to establish how best the MRII can serve all. We know we are working in an ever changing industry and we felt it was a good time to provide this opportunity for communication to us from our members and their companies. The responses will enable us to align our activities with what best suits our membership's needs. The results are currently being analysed and will be made available to our members in September.

Our National Conference will be held on the afternoon of Friday April 15th 2016, in the Radisson SAS Hotel, Athlone. The change in format to a one day only was introduced to allow those who are unavailable for a greater portion of time over the weekend to attend. Our National Conference provides quality educational and networking opportunities for our members, the success of the conference relies on attendance. I have written to management to seek their support for your attendance.

The Institute relies heavily on many factors, our sponsors are crucial to our survival. This year we are very fortunate to have Volvo on board as our major sponsor. We also have another 15 businesses who sponsor us this year. I saw first-hand at our National Conference this year the level of time and effort they bring to this event. The last page in this publication is a perforated listing. All members are encouraged to keep this listing to hand and utilise these businesses, where possible.

As your President I need your support by engaging with us throughout the year and participating in Institute activities. Feedback is always welcome and we can serve you best when made aware of what your need may be as and when necessary. I am always contactable at president@mrii.ie

I look forward to bringing you further updates throughout the year on Institute activities and I wish all continued success in their individual roles going forward.

John Elliott



VOLVO CAR IRELAND'S AFFINITY OFFER



MRII members (with membership of 6 months or more) can avail of Volvo Car Ireland's Affinity Offer.

This is a discount offered to an MRII member who is purchasing the car for personal use or who is in receipt of a monthly car allowance.

Full details are available on www.mrii.ie (under Membership/Benefits).

A password is required to access this page. Eligible members who wish to access the offer should request the password from info@mrii.ie



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This presentation will include discussion on:

- **Pharmacy Interaction**
- **Educating and Screening**
- **Compliance and Adherence**
- **Polypharmacy**
- **Collaboration with General Practitioners**
- **Facilitating and Supporting**

September 16th, 5.30pm, River Lee Hotel, Cork

SPEAKER:

Darren Breathnach,
Pharmacist, Pharmacy First Plus, Cork

To book please email meetings@mrii.ie

There is no charge for MRII members to attend
€25 charge for non members to attend



MRII Council

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EAST MEMBER

Pfizer Healthcare Ireland

Neil Mac Court

EAST MEMBER

Ashfield

Pamela Large

EAST MEMBER

Boehringer Ingelheim

Institute Fellows

Noeleen Byrne, John Carr, Donal Curran, Paddy Dyar, Kevin Kelly, Peter Sheedy, Pamela Large.

Past Presidents of the MRII

Tom Collins (RIP);	1984 - 1986	John McCarthy;	1999 - 2000
Jack Kinsella;	1986 - 1987	Daragh Moran;	2000 - 2001
John McCarthy;	1987 - 1988	Howard Simpson;	2001 - 2002
Kevin Kelly;	1988 - 1989	Nuala O'Connell;	2002 - 2003
Paddy Dyar;	1989 - 1990	Donal Curran;	2003 - 2004
Pat Kinsella;	1990 - 1991	Ciaran MacFadden;	2004 - 2005
Ciarán O'Kelly;	1991 - 1992	Mary Thérèse O'Connell;	2005 - 2006
Sinéad Cadden;	1992 - 1993	John Fenlon;	2006 - 2007
Michael O'Brien;	1993 - 1994	Tony Glynn;	2007 - 2008
Robin Ward;	1994 - 1995	Pamela Large;	2008 - 2009
Peter Sheedy;	1995 - 1996	Kelvina Galavan;	2009 - 2010
Andrew O'Regan;	1996 - 1997	Gareth Fair;	2010 - 2011
Noeleen Byrne;	1997 - 1998	Alison O'Keefe;	2011 - 2013
John Carr;	1998 - 1999	Linda McMahon	2013 - 2015

MRII Awards 2015

Fellowship Award



John Elliott, President MRII, with Pamela Large, Boehringer Ingelheim, the recipient of a Fellowship Award

Ambassador Of The Year



MRII Ambassador of the Year
Vanessa Hardy, A. Menarini Pharmaceuticals

MRII Rep Of The Year



John Elliott, President MRII, with Eddie O'Callaghan, MRII Representative of the Year (Lundbeck Ireland)

New Members



Recently appointed Full Members of the MRII, Niamh O'Regan, Ashfield, Conor O'Daly, Kora Healthcare and Zara Crofton, Covidien, pictured with John Elliott, President MRII

The Value of the Healthcare Sales Professional Visit

Yes, there is life after the loss of the flashy pens and sticky pads!



Dr Tony Cox

Dr Tony Cox is a GP in Ennis, Co Clare where he has lived for 24 years. Tony is married to Denise, a fellow GP (Dr Denise Crowley). She works with Tony in the same practice. They have 2 sons Colm and Eoin. Both are in College in UCC.

Dr Cox has been a GP Trainer with the Mid Western GP Specialist Training Scheme since 2001. Dr Cox is an MICGP Examiner and was was Chair of the MICGP Examination Committee for 4 years.

Dr Cox was President of the ICGP, 2014 – 2015 and is currently the Immediate Past President of the ICGP.

The Healthcare Sales Professional (HSP) who calls to the surgery has been a part of my life since I commenced in General Practice in Clare 24 years ago. I have always maintained an open door policy towards HSPs and continue to welcome their visits. I see one HSP per day because at the end of the day GPs need to get on with their consultations with their patients. But the HSP knows that they are welcome in my practice on any given day.

Why would I as a busy GP welcome a Healthcare Sales Professional into my practice?

First and foremost I have become very friendly with many HSPs over the years. These are invariably interesting, intelligent and understanding people. They understand the stresses and the challenges of General Practice and they blend in seamlessly with whatever the prevailing mood is in the practice on any given day. The HSP will always have up to date information about the medications that they are promoting. They can often act as the provider of that little bit of information that you were seeking on a particular drug and its safety and potential interactions. Their information is always presented in an impartial fashion and they never challenge the merits or otherwise of

competing drugs. They provide up to date articles and research details on the medications in question and will always offer to get the extra information or further details that you request from their medical team in head office. Of course the HSP's information and detailing is not the GPs primary source of information but it is an important part of the total information package available to us GPs.

HSPs will often provide placebo devices for their company's products. For example with the explosion of medications available for the COPD patient and the various new delivery devices it has become more than a little confusing for the GP as well as the patient. Having a dummy device helps the GP to become au fait and comfortable with the use of the new device and enables us to educate our patients in a confident and effective fashion. It also allows us to let the patient make their own informed choice of which device and medication works best for them.

Samples of the newer medications can be invaluable in the first two years and having a reasonable supply of these from the HSP is often very helpful.

The HSP also organises local educational meetings and provides us with regular opportunities to meet with our GP colleagues and local consultants in a collaborative and supportive environment. The information that can be accessed at these meetings is often very helpful to a

GP in deciding on the merits and suitability of any new or existing medication. Hearing our GP and Consultant colleagues speak of their experience of using these medications can often be the stimulus to provide us with the confidence to prescribe these drugs.

Recent changes: Good or bad?

In recent years HSPs have been using the ubiquitous iPad more and more as their mode of delivery of their information package. I am not quite sure that this is something that appeals to many GPs. I feel that perhaps some of these presentations could be amended so that they are more specific and not so lengthy.

Also a number of companies have scheduled a "virtual visit" by internet connection and telephone. I have participated in two of these out of curiosity and a willingness to try out new technology. In my opinion there is no substitute for the personal visit where trust and mutual respect develops over a number of visits. The HSP who is aware of the GPs availability and time pressures will tailor their visit to fit in perfectly with whatever conditions prevail in the surgery that day. That cannot be achieved over an internet and telephone connection as well as can be achieved face to face.

I am sure that it can often be a challenging job working as a Healthcare Sales Professional. Sitting patiently in a doctor's waiting room must be difficult at times. I hope that HSPs understand that they are very welcome in the vast majority of GPs surgeries in Ireland. Many GPs will do their best to allow the HSP their opportunity to have a fruitful and rewarding visit. We are all on the same team and I certainly hope that the HSP visit as it stands will continue into the future.



We welcome membership from those engaged (or who propose to be engaged) in the profession of healthcare sales (primary/secondary care and OTC).

Our members represent branded and generic pharmaceutical companies and medical device companies. We currently have 500 members representing 80 companies across the Life Sciences sector in Ireland.



Apply for membership at www.mrii.ie

Meet a Member



Anthony J. Carroll

What does your role involve?

I work for Bristol-Myers Squibb Pharmaceuticals (BMS) as a Key Customer Manager for Virology/HIV and to understand my role it is important to know a little background about our operations in Ireland. BMS is a global BioPharma company firmly focused on its mission to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. BMS's operations in Ireland include two Active Pharmaceutical Ingredient Manufacturing sites, a Global Biologics Drug Product Testing Laboratory and an External Manufacturing division. Last November BMS announced plans to construct a new state-of-the-art, large-scale biologics manufacturing facility in Cruisera, Co. Dublin that will produce multiple therapies for the company's growing biologics portfolio.

My role captures the very essence of account management including developing appropriate business relationships with customers/Health Care Professionals (HCP's) involved in budget management, formulary and guideline setting, patient diagnosis and management, and supply and distribution. I collaborate with HCP's

through meetings and other interactions which have an educational and scientific value. To perform effectively I need to champion account management approaches and behaviours, particularly in terms of collaboration both internally and externally. My job is immensely rewarding as I passionately believe that I help to inform healthcare professionals about my product which assists when they treat their HIV patients.

What do you see as the challenges in HIV in Ireland?

While there has been a significant and welcome improvement in treatment for HIV, we also know there is great cause for concern in the rising numbers of newly diagnosed - 344 people in 2013, 377 people in 2014 (11% increase on 2013) and 168 people to date in 2015 (HSE Health Protection Surveillance Centre data). These figures show that HIV continues to disproportionately impact men who have sex with men (183; 49%). There remains a sizeable number of heterosexual people contracting HIV in Ireland (125; 33%) and it is worrying that a recent trend of reducing HIV infections amongst people who inject drugs has seen an unexpected reversal (27; 7%).

Where do you see opportunity to reduce the rise in HIV in Ireland?

As HIV figures increase we cannot afford to stand still. There have been calls for the publication of the National Sexual Health Strategy so that a clear policy framework can support work in this area. The publication of a new strategy will go a long way in supporting the partnership of the Sexual Health Communications Network chaired by the HSE Crisis Pregnancy Programme. Across Ireland extra resources are needed for testing services, for training and education, for treatment and prevention work. One area that needs continuous improvement is sex education in our schools; evidence would suggest that this would impact positively on how young people behaved towards sex.

What are your personal strengths?

I am motivated by challenge. I was awarded my MBA from Dublin City University Business School in 2011. This qualification is seen as an industry standard for aspiring leaders so wherever it takes me I am delighted to have achieved it. There is no doubt the qualification gives one broader business 'know-how' and skills to take a 'helicopter' perspective to any given situation. It also helps when working cross functionally. I am able to generate ideas while maintaining an ethical approach to business which in the dynamic and compliance driven pharmaceutical sector is a huge skill. On the main I will dismiss the negatives and am eager to achieve the task. I put a lot of energy into building both professional and personal relationships - I get a constant infusion of energy from being around other energetic people.

Are you looking forward to your term as an MRII Council Member?

I was honoured to have been asked by the recently appointed president of the MRII to serve as a council member for 2015/16. The MRII Council work with our President, on behalf of members, to advance the promotion of professionalism and best practice for all Healthcare Sales Professionals and to provide educational and social opportunities for all members of our Institute. I recently represented our President by attending an IPHA organized conference on Innovation and Partnership. It was truly gratifying to hear the significant impact that patient organisations make to the lives of patients with diseases ranging from Multiple Sclerosis to Crohn's Disease. Additionally, through unconditional financial support from the pharmaceutical sector these organisations significantly help the patients that utilise their services. Through my membership of the MRII Council I endeavour to impact in a positive way the professionalism of Healthcare Sales Professionals.



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Why did you volunteer in Malawi?

My MBA thesis project explored the importance of emotional intelligence (EI) to business. Cognisant of this I worked with life coach Pat Meehan with the simple aim of further developing my EI and to make each and every interaction meaningful and worthwhile, crucial in business relationship development. EI is said to be paramount for management success. In addition, as part of my EI journey I worked for almost six months as a volunteer in 2012/13 at The Billy Riordan Memorial Clinic in Malawi, Africa. This was a significant and



life changing time for me. I was inspired to work and help families who pretty much had nothing relative to developed world standards and to see how these beautiful people could still be so upbeat and afford amazing smiles. My favorite photograph of my time in Malawi is here of this young child who has the most amazing eyes. Each time I look at this picture I read her mind in different ways. My time in Malawi allowed me to develop many skills, from EI to resilience to not fussing about the small things.

What is your favourite holiday destination?

I have been very fortunate to have had many opportunities to travel during my free time. A highlight for me was a time when I decided to save for the holiday of a lifetime and stayed at the seven star Burj Al Arab in Dubai, this was absolutely amazing. However I was also very happy to stay in a hostel in Berlin. Often people think too much about the quality of their accommodation. I have been told I am a man of extremes!!!

While a country man by birth, my personality aligns best to city life. Hence, I prefer city breaks over long beach holidays. I have travelled extensively on holidays, but Hong Kong sits as one of my favourites. This enigmatic city of skyscrapers, ancient traditions and heavenly food will fascinate no matter how often one visits. Victoria peak at night offers an amazing view of the city; the 5 star Peninsula is a great treat for afternoon tea; Ngong Ping Cable Car is a spectacular 5.7km bi-cable ropeway linking Tung Chung and Ngong Ping (where the Po Lin Monastery and Tian Tan Buddha are located – the largest Buddha in the world). Also, amazing food at Spoon restaurant where you can have a table to see the nightly Symphony of Lights – a famous laser lights and music show in Hong Kong.

Do you have a favourite place to stay in Ireland?

As a graduate of National University of Ireland in Galway my heart begins to smile when I arrive in the city. Through my work I often have to stay in the city of the tribes. I keep going back to The Harbour Hotel, located a short stroll from Shop Street. The staff are amazingly nice, especially the warm and welcoming receptionist staff (tell Marie I sent you!!) who always remember my name. The hotel is perfect for lounging, having a drink or snacking in the very nice bar area. While the bedrooms are basic, they are always very clean and the beds are comfortable. The Harbour Hotel is always a winner for me on price, helpful staff and proximity to city life.

What are your interests and hobbies?

In case you haven't guessed good food and travel are key sources of enjoyment for me. I will endeavour to get the best for half the cost. I like value for money. I am a member of the Irish Management Institute and The MBA Association and love to attend lectures and in particular network at these events. I try with effort to attend Kettle Bell classes at least once a week and it is not uncommon to see me at an antiques auction near you! On the sporting side, I follow Munster Rugby and the Cork Hurling team. I also love politics and am passionate about equality for men and women at work. I want to see equality for unmarried fathers and I would like legislatively protected time away from work for those who volunteer abroad with NGO's.

Have you a favourite quote?

Tell me and I forget; teach me and I remember; involve me and I learn. (Benjamin Franklin).

The information and views set out in this article are those of the author and not Bristol-Myers Squibb

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An interview with Justin Carty



Chief Executive, The Irish Medical and Surgical Trade Association (IMSTA)

When and why was IMSTA founded?

The Irish Medical and Surgical Trade Association (IMSTA) was established in 1982 to represent the Medical Technology supply industry in Ireland.

Medical Technology encompasses technologies (application of science and technology) that are improving the quality of healthcare delivered and patient outcomes through earlier diagnosis, less invasive treatment options and reductions in hospital stays and rehabilitation times.

IMSTA member companies produce and market medical devices, diagnostic products and health information systems that are transforming healthcare through earlier disease detection, less invasive procedures and more effective treatments.

How many members have IMSTA?

We currently have in excess of 100 member companies.

What type of companies seek membership of IMSTA, name a few?

Typically IMSTA members are distributors (e.g. Fannin, United Drug, PEI) but we also have manufacturing company members who supply directly (e.g. Medtronic, J&J, Abbott, Baxter)

What makes a good Medical Devices Sales Professional?

What makes any good sales professional? In our sector a good knowledge of your specialisation and the ability to be a resource to your target audience go a long way towards a successful medical device sales professional. A medical device sales professional tends to be very commercially aware and has an in depth knowledge of the tendering process. They also need to be very confident in demonstrating medical devices/instrumentation in theatre. They

would always seek to learn about the newest technologies available on the market and seek opportunities to broaden their product portfolio.

What is the current position within the Medical Device Industry regarding job opportunities?

The market has had 6+ really tough years but it is recovering, so growth and prospects are improving. In a recent survey of IMSTA members 18% of companies indicated that they expect to grow their sales force in the next 12 months.

Have you any current updates on new device developments here in Ireland?

IMSTA has submitted a Health Policy Proposal to Government which could stimulate device innovation at hospital level. There are always new products being launched, c. 300 / 400 per year globally. Ireland is a global centre of Medtech development and there is intensive investment in R&D / manufacturing here. As the market is largely serviced by distributors, new products will invariably come via trade fairs like MEDICA, but new products will also come from manufacturers selling direct too.

How many Medical Device companies have a sales force presence in Ireland?

Approximately 16 have direct sales operations in Ireland.

What is the value of the Medical Device market in Ireland?

Export sales from manufacturers is c. €8 billion. Sales in the Irish market c. €750 million.

How many Medical Device companies have a manufacturing base in Ireland?

Approximately 14 IMSTA members have manufacturing facilities. Speaking at 'Manufacturing to win on the world stage', in April of this year, Director of the Irish Medical Devices Association (IMDA) Dr Sinead Keogh said: "We are now seeing a real opportunity for recovery. Output in traditional manufacturing was up 6.3% in 2014, and Irish goods are competing strongly with UK counterparts. Employment in manufacturing will be 6,000 higher this year compared to last".

Are there any new companies setting up in Ireland?

Yes, a continuous stream of foreign direct investment means existing manufacturers are growing their presence and new ones arriving every year.

What are the IMSTA Awards?

This is an opportunity for companies to highlight the quality of their products / services and excellence. The annual awards event is a platform for the supply industry to showcase the state-of-the-art medical technologies they bring to the market and demonstrate the valuable contribution our industry is making to healthcare in Ireland.

In 2016 we hope to work with the MRII to introduce a new award category.



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Eilish Wall, the Lodge at Ashford Castle.



Eoin Newell from MDT.



Caroline Spollen and Stuart Thornton from Hotel Solutions.



Catherine Bodley and Amy Brennan from O'Callaghan Hotels.



Hazel Whelan and John Reidy from Recruitment Plus.



Catriona Murphy; Darragh O'Connor and Norina O'Callaghan from Dalata Hotel Group

ational Conference 2015

Brendan Lyon Photography - 01 805 3927



Siobhan Monaghan from Sweet Cicely



Fergus McCauley, Nólín O'Hora, Ciarán Collins, PMI



Anita Sherlock from Quintiles.



Muireann King from Croke Park Hotels.



Caroline Donnelly from Pharmaforce.



Kim Bevans and Lorna Hennebry from Citywest/Kilashee Hotels



Yvonne McNamara and Aisling Foley, St Helen's Radisson Blu Hotel and Radisson Blu Royal Hotel



Sheena McCann, Mount Wolseley and Lil Grant, Mount Juliet.



TEACHING WHAT CANNOT BE TAUGHT CONVENTIONALLY

1975	Programme launched
250	Senior leaders and CEO's transformed
40+	Average age
15+	Average years of experience

A unique experience



A past participant of the IMI MSc in Management Practice, Dermot Duff gives his perspective on the benefits of the programme to you and your organization.

The MSc in Management Practice Programme (MPP) is a two-year post-graduate master's programme aimed specifically at chief executives and senior managers validated and awarded by University College Cork.

It is designed exclusively for experienced senior people who need to develop their understanding of the complex management issues facing them and their organisation, but find it impossible to go on either a full-time master's programme or a part-time programme which is not directly related to their own organisation and role.

The MPP is a flexible programme made to match participants' emerging needs, rather than restricting them to a pre-made curriculum or agenda.

Conventional teaching

Management is situational, contextual and highly nuanced. For these reasons, the development of management skills needs to be rooted in experience. This experience should be brought to others for understanding and learning or mined for the lessons it contains. It needs to be a guided experience, with help and encouragement to increase the manager's ability to purposefully reflect on the experience and

consciously develop new perspectives and new competences. Management, in a sense, is therefore highly personal.

Leading on from this, it can be seen that attempting personal and organisational change is best done using the participant's own environment, provided the risks can be managed and the benefits for the organisation are sufficient. Text-book change, though having value, is ultimately anodyne, disconnected from reality.

The MPP bridges these risks by ensuring that plans are well thought through, that the participant is prepared to lead the change initiative in an authentic way, and that the programme itself shares the risks by adjusting to meet the individual needs of the practising manager as they emerge.

Flexibility

While the programme has a core common curriculum, it also has enough bandwidth to make sure that individual and group circumstances are catered for; some of this flexibility comes from having very small class sizes (maximum 12 participants), thus allowing for individual attention. More significantly participants can determine in the latter

part of the programme who they would like to engage with to enhance their learning experience.

An individual will benefit more if the peer group shares a common goal and act supportively. In the best programmes, participants learn as much from their colleagues as their lecturers. While there is nothing contrived about the group bonding, it emerges from the ethos of the MPP and its deliberately small class size. The peer review mechanisms also help to strengthen these bonds, as does the social dimension of belonging to a group with the energy and power to make things happen.

Further individualisation

The tutor is an experienced academic with a business background that essentially guides you through the process and helps you navigate the changes you are attempting in the organisation and in your own outlooks. The tutor stays with the participant throughout the learning journey, and acts as a personal guide, meeting participants as needed.

In this context they argue that the programme will change both themselves and their organisations in a way they never thought of before and fundamentally forever.

Next programme date: 09 October 2015

For more information talk to the programme director, Dr Mary Hogan:

w: imi.ie

e: mary.hogan@imi.ie/

programmeadvisors@imi.ie

t: 01 207 8551 / 1800 223 388

National Conference 2015

Brendan Lyon Photography - 01 805 3927



Eoin Newell, MDT and Dr Mark Rowe, Conference Speaker.



Kevin Hynes and James Corcoran, Sanofi



Lorette Jackson, A Menarini and Peter McGarry MRII



Hazel Whelan, Recruitment Plus and Mark Cumisky, UCD Career Development.



Zara Crofton, Covidien and John Reidy, Recruitment Plus.



John Milne, NIBRT and Yvonne McNamara, Radisson Hotels.



Brian Forde, Pfizer and Tom Malone, Ashfield.



Niall Ryan, MRII and David McCarthy, Lundbeck.



Clare Fitzpatrick, New Altra and Keith Duggan, Pfizer.



Anthony J. Carroll, BMS and Grainne Lee, Medical Rep.



Lee Corbett, Grunenthal and David Brady, Amgen



Mick Fleming Janssen and John Elliott, Pfizer



Kevin Kelly, MRII, Lorette Jackson, A Menarini and Pearse O'Doherty, MRII



Mark Kelly, Hospira and Eddie O'Callaghan, Lundbeck.



Andrew Rea from ESRI Ireland



Andrew Rea, Head of Professional Services at ESRI Ireland, and a past participant of the IMI Henley MBA. He shares his story of how instrumental the IMI Henley MBA was to his career and his organisation.

Why did you choose the IMI henley MBA?

My role in ESRI Ireland involves managing the operational activities of the department (a team of nearly 40 people), providing strategic direction for the department and contributing to overall company strategy. I selected the IMI Henley MBA because I believed that this programme would help me to be more successful in this role and provide me with enhanced skills in leadership, in managing people, financial management and in strategic thinking.

The flexible approach combined with the applied learning style provided by the IMI Henley MBA was something that I thought would be very beneficial, I could achieve my MBA while at the same time applying the learning in a practical way within ESRI, and gain insights and learning from the experiences of peers on the course and from the IMI community.

What were the highlights?

It is difficult to pick highlights out of the MBA because it was all so applicable to my objectives and my career. If I were to pick one though, it was the opportunity to have an interaction with experts in the various subject areas. This, combined with, being able to share experiences with people in different industries made the experience really invaluable. Similarly, being able to apply the learning directly to my work environment through the

assignments was excellent and allowed me to demonstrate the value of the MBA to the organisation.

What were the challenges?

The biggest challenge for me was my own time, balancing work, personal life & study time. Maintaining a consistency with all of these factors across the three years required a lot of planning and sacrifice personally and from my family. Also, it had been a long time since I'd done anything academic and the prospect of launching into this was very daunting. In saying this, there was plenty of support to get through this from Henley and the IMI team.

What impact has the MBA had on your organisation?

The programme has had a direct impact on my organisation and one that started almost immediately. The MBA is structured so that you apply your learning to real work scenarios and therefore from the very first module until the very last, ESRI Ireland has and is benefiting from my Henley and IMI experience. The learning and development that has been brought to the organisation as a result of this MBA has impacted the performance of my team in achieving our margins, growing the team and increasing our value to our parent organisation.

What impact has the MBA had on your career?

It is still early days for me as I've just completed the programme. I can say though, that there has been a change in both my personal development and in my leadership in work. I know that I've grown as a leader and have developed a more rounded, authentic leadership style. My perspective has evolved to being more strategic in nature and is now focused on "leading" my department and ESRI Ireland as opposed to "managing" it. I now feel that I can rise to whatever opportunities and challenges lie ahead. It's an exciting time.

What is your advice to people planning further study?

If I were to provide any advice it would be to plan how you are going to balance all of the demands of your time, i.e. home, work, study etc. Sit down and agree this plan with your family. Make sure that it is something that you will enjoy and that you can see the benefits of, this will help get you through the times where you are exhausted and hitting that study wall. Also, listen to the people administering the course, it will be the first time you have done it but they've done it hundreds of times, heed their advice. I'll leave you with one thought which sums it up for me – in the words of Gail Devers "Every accomplishment starts with a decision to try".

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Next programme date: 17 October 2015

Mindfulness

The pace of modern life and business is often stressful, in this article Carmel Farnan of the Irish Mindfulness Academy discusses the theory of Mindfulness and some practical tips on how to deal with stress and advice to 'live in the moment'.

Have you ever noticed as you go through the day doing your normal activities, like driving your car, or performing some work related task, that your mind has drifted off, often many miles away and is pondering about something else? You may be daydreaming about your next holiday, worrying about a forthcoming sales meeting, or simply drifting off into random thoughts.

In all of these cases your mind is not on what's currently happening. This means you are in fact absent from your actual life and are therefore missing large parts of it. This way of operating is often referred to as automatic pilot mode - Mindfulness is the opposite of this.

The official definition of Mindfulness is "Paying attention in a particular way; on purpose, in the present moment, and non judgmentally".

Mindfulness is about experiencing the world that is firmly in the 'here and now'. Watch how various thoughts can flit through your mind uninvited "Why do things always go so wrong for me?" "Have I definitely finished preparing for this meeting correctly?" "It will be awful if the traffic is heavy, I can't be late again". Or you may notice your mind spends a lot of time dwelling in the past "If only I had made a different decision back then how different things would have turned out". Some people may spend time worrying about the future "What if, X, Y, or Z happens...?"

Because your thoughts make your feelings, when your mind thinks thoughts like those listed above, a corresponding negative emotional state is generated in your body. Research has shown that sad thoughts produce sad feelings, anxious thoughts produce anxious feelings and stressed thoughts produce stressed feelings (reference 1). Without learning how to use our minds correctly we can become victims of our own thinking, since a mind left to its own devices can generate many variations of subtle emotional suffering.

This suffering comes in different guises. Sometimes we worry about the future, feel sad or angry, or just feel bored, anxious or stressed. Sometimes it's very subtle—we "just don't feel great". In the extreme we can get so taken over by anxiety, depression, pain, or stress related symptoms that we find it difficult to even function.

So, why do our minds work like this?

The answer is down to evolution which through the ages has retained our bodies "fight or flight" response. Imagine a wildebeest grazing in the savannah when it is suddenly chased by a lion. Its "fight or flight" response is activated, flooding it's body with adrenalin and other stress related hormones to enable it to flee from the lion. Minutes later, the danger has passed and the wildebeest returns to grazing. Its mind also returns to grazing, which results in the body returning to its natural state. In contrast, had a human been chased by the lion, our minds would remain on constant alert. "What if the lion comes back?" "How can I defend myself more effectively?" In a modern day context, we as humans remain in a permanent "fight or flight" state as we ruminate on the past, "I should have said that differently in my email", dwell negatively on current events, or worry about imagined future events "What if I make a mess of the presentation?" "What if I don't reach my sales target this quarter?" Such thoughts produce a hyper vigilant state, causing stress hormones to constantly remain in the body due to this prevalence of negative over-thinking.



So, here's where Mindfulness is the key to rediscovering our innate happiness and well-being. Mindfulness practice allows us to train our brains to focus on our moment-to-moment experience, freeing us from the tyranny of over-thinking. Research from Stanford University indicates that our mind has approximately 60,000 thoughts per day, which can only happen in our heads one thought at a time (reference 2).

Mindfulness training allows us to see our thoughts as just that, simply mental events that occur in our minds and not facts. It teaches us to observe our thoughts as they pass through our mind, disengage from them, letting them pass on by, in the same way as the clouds continually move across the sky. This means that when our minds move into the realm of worrying about the next business meeting or paying that mortgage,

mindfulness practice helps us return to the safety of the present moment.



When our minds bemoan the cold, the practice of mindfulness allows us notice that it is our complaining thoughts about the cold, not the cold weather itself that is causing the negative feeling. It is not the situation itself, but our perception of it that creates our feelings. In helping us to observe how we create our own distress, mindfulness practice shows us how to let go of painful thought habits and replace them with more nourishing ones.

Often our lives become bogged down in a swamp of over-thinking. As we become lost in thought we are missing out on the moment to moment wonders of life. A good question to ask yourself to check if you are in the present moment is..."Am I thinking or am I living?"

With the current popularity of Mindfulness we might be led to believe that Mindfulness is a modern day "fad". This is not the case, since Mindfulness practices originated many centuries ago. However, the current popularity of Mindfulness is due to the fact that it is only in recent times that Mindfulness practices have been empirically backed by science. This validation has been attributed to the recent advancements in brain scanning techniques, specifically Functional Magnetic Resonance Imaging. These fMRI brain scans have shown remarkable changes in the brain after only eight weeks of Mindfulness training. A recent study showed significant changes in the brain regions involved in learning and memory processing. Additionally, brain scans illustrated increased activity in the brain regions responsible for emotion regulation and focused attention. All very worthwhile attributes leading to a greater sense of well-being in the workplace (Reference 3).

Mindfulness in the workplace

There are many case studies where Mindfulness has proved extremely beneficial in workplace settings. A mindfulness-based programme offered to workers at Transport for London resulted in major changes to the level of health related absenteeism. Days taken off due to stress, depression and anxiety fell by over 70% in the following three years. Course participants also reported significant improvements in their quality of life - 80% said their relationships had improved, 79% said they were more able to relax and

53% said they were happier in their jobs (reference 4).

These results were achieved by putting into practice the learnings from the mindfulness course. Mindfulness practice comprises two parts – the informal and formal practice. Informal Mindfulness means making your life a Mindful life, by simply paying attention, with all your senses to whatever you are doing at any moment in time. This could be brushing your teeth, drinking a coffee or driving a car. As you focus with deliberate attention on any of your daily activities Mindfulness becomes an integral part of your life, as opposed to it being another item on the “To-Do” list of an already overly busy life.

Mindfulness Practice

The other component of mindfulness is the formal Mindfulness practice. This involves setting aside a specific time in the day to partake in a meditation practice, perhaps observing your breath from moment to moment. As you pay attention to your breath you will notice that your mind naturally wanders. This wandering of the mind is not seen as a failure or a mistake, our minds are made to think. Mindfulness is not about stopping the thoughts, instead when the thoughts occur, one is encouraged to simply observe this wandering and then gently escort the mind back to focusing on the breath. This in time helps build a “Mindfulness Muscle” which research has found encourages the activation of the prefrontal cortex, the region of the brain necessary for complex planning and decision making. Research also has shown that Mindfulness strengthens the brain

networks that are responsible for your own emotions and allows you to make sense of the feelings of others – what we call empathy (reference 3). In modern business, empathy is considered a key leadership skill.

So, why not try the following 1 minute breathing meditation?

1. Start by sitting comfortably, with your back straight and eyes either softly open or closed.
2. Notice that you are breathing and feel the sensations of the breath.
3. If your mind wanders, no problem; just gently bring your attention back to the breath as it enters and leaves the body.
4. Pay attention to where you notice the breath the most, is it at the nose or....chest...ortummy? .
5. Stay with the sensations of the breath. Then when you are ready gently open your eyes.

Now, you have completed your first Mindfulness practice.

If you'd like further information on Mindfulness please see www.irishmindfulnessacademy.ie

Carmel Farnan is the founder of the Irish Mindfulness Academy and the British Mindfulness Academy. She is an International Mindfulness Trainer and Psychotherapist and completed additional

training as a Psychologist. She has personally practiced Mindfulness from a young age and this interest led her to study Mindfulness over the past 16 years under international leaders in this field. Her most recent Mindfulness study has been the Mindfulness Based Stress Reduction Program (MBSR) from the University of Massachusetts.

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The official launch of the MRII in October 1984, at Jury's Hotel, Dublin



The Council seen prior to the first A.G.M. (Left to Right) Michael Kenny, Jimmy Mallon, Tony Crowley, Tony Kelliher, Tom Collins, Jack Kinsella, Ger Lavin, Michael Clarke, Brian McLean



Enjoying MRII 30 Year Celebrations in October 2014, Pat Kinsella, Neil Mac Court, Jack and Imelda, Kinsella, Michael O'Brien

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Our objective is to have full MRII membership from all Healthcare Sales Professionals in customer facing roles and to have a clear communication channel between the MRII and all companies. This role has quickly been established as prestigious involvement in leadership within the industry. We are mindful of everyone's workload and do not wish to add to this. Ambassadors have full support from Council and our office.

If your company is not listed here and you wish to be considered for this role (you must be a Full MRII member) please email info@mrii.ie

The role will include:

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Des Joyce R I P

..... 1950 – 2015

I first met Des in 1969 when he joined the Leaving Cert class in "The Bish", St Joseph's College Galway City. Neither of us could have imagined that we would be lifelong friends 'till his untimely death. Des passed away on the 19th June last after a short illness. His family lost a loving husband and father and many in the pharmaceutical industry lost a loyal friend.

Des chose to work in the insurance industry after his Leaving Cert, a training that stood him in good stead for life. He transferred to pharma in 1976, joining Mead Johnson of the then Bristol Myers Group. He served there for several years before a reorganisation led to an offer to transfer to Dublin. Des and Genevieve had just completed their new home at Maree Cross Oranmore. It was a fine residence on its own grounds that Des had lovingly landscaped.

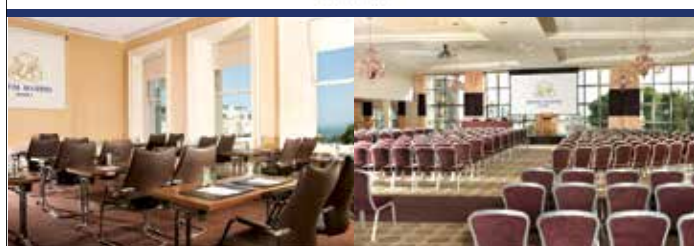
He and Genevieve decided to seek new opportunities in the West of Ireland. I recall him telling me his father was not impressed as that generation considered that one's job was paramount and ought to be treasured. His decision led to his appointment to Rowa / Rowex. He retained this position up to his retirement and was held in such esteem by management there that he was twice invited to return to complete specific assignments.

Des had a great concern for the welfare of his country and its citizens. He took an active interest in politics both local and national. At his funeral and his month's mind masses, both priests spoke of Des Joyce's strong community involvement. He willingly undertook tasks over many years that led to the enhancement of his area and the welfare of his neighbours.

To Genevieve and family and his siblings we offer our sincerest sympathy on their huge loss. Des, may your noble soul rest in peace. (B O'B)



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Take Action



Success belongs to those who do more than wish and hope, plan and pray,

intending to do something, someday. Success comes to those who take action!

The world belongs to those who reach out and grab it with both hands. It belongs to those who do something more than wish and hope and plan and pray, intending to do something someday, when all conditions seem just right. Successful people are not necessarily those who make the right decisions all the time. No one can do that, no matter how smart he or she is.

Once successful people have made a decision, they begin moving step-by-step toward their objectives, and they begin to get feedback or signals to tell them when they are on course and when course corrections are necessary. As they take action and move toward their goals, they continually get new information that enables them to adjust their plans.

It is important to understand that life is a series of approximations and course adjustments. Let me explain.....

When an airplane leaves Dublin for London, it is off course 99% of the time. This is normal and natural and to be expected. The pilot makes continual course corrections, a little to the north, a little to the south. The pilot continually adjusts altitude and throttle. And sure enough, the plane touches down at exactly the time predicted when it first became airborne upon leaving Dublin. The entire journey has been a process of approximations and course adjustments.

Of course, there are no guarantees in life.

You can never be completely sure that any action or behaviour is going to bring about your desired result. There is always a risk. And where there is risk, there is fear. And whatever you think about grows in your mind and heart. People who think continually about the risks involved in any undertaking soon become preoccupied with fears and doubts and anxieties that conspire to hold them back from trying in the first place.

At Babson College, Boston, a 12-year study was conducted to discover the reasons for success. The researchers concluded that the difference between

The Confucian saying "A journey of a thousand leagues begins with a single step" simply means that great accomplishments begin with your willingness to face the inevitable uncertainty of any new enterprise and step out boldly in the direction of your goal.

If you want to be more successful faster, just do more things. Take more action; get busier. Start a little earlier; work a little harder; stay a little later. According to the law of probability, the more things you try, the more likely it is that you will try the one thing that will make all the difference.

I have found that luck is quite predictable. If you want more luck, take more chances. Be more active. Show up more often.

Tom Peters, the bestselling author of *In Search of Excellence*, found that a key quality of the top executives was a "bias for action." Their motto seemed to be "Ready, fire, aim!" Their attitude toward business was summarised in the words "Do it, fix it, try it." They realised that the future belongs to the action-oriented, to the risk taker.

Successful people know, as General Douglas MacArthur once said, "There is no security on this earth. There is only opportunity."

And the interesting thing is this: If you seek opportunity, you'll end up with all the security you need. However, if you seek security, you'll end up with neither opportunity nor security.

There is a "momentum principle" of success, which is derived from two physical laws, the law of momentum and the law of inertia, and it applies equally well to everything that you accomplish and fail to accomplish. In physics, the law of momentum says that a body in motion tends to remain in motion unless acted upon by an outside force. The law of inertia, on the other hand, says that a body at rest tends to remain at rest unless acted upon by an outside force.



the successes and the failures in their study could be summarised by one word: launch! Successful people were willing to launch themselves down the track of opportunity without any guarantee of success. They were willing to risk uncertainty and overcome the normal fears and doubts that hold the majority in place.

And the remarkable thing is that as you take risks in life, new opportunities emerge all around you. However, you would not have seen those opportunities if you had not taken action. They would not have materialised for you if you had waited for some assurance of the outcome before acting.

In their simplest terms, as they apply to you and your life, those laws say that if you stay in motion toward something that is important to you, it's much easier to continue making progress than it is if you stop somewhere along the way and have to start again. Successful people are very much like the plate spinners in the circus. They get things spinning, knowing that if a plate falls off, or something comes to a halt, it is much harder to get it restarted than it is to keep it going.

Once you have a goal and a plan, get going! And once you start moving toward your goal, don't stop. Do something every day to move yourself closer toward your goal. Don't let the size of the goal or the amount of time required to accomplish it hold you back. During your planning process, break down the goal into small tasks and activities that you can engage in every day. Every day, every week, every month you should be making progress by completing your predetermined tasks and activities in the direction of your clearly defined objective.

And here is where the rubber meets the road. One of the most important single qualities for success is self-discipline. It is the ability to make yourself do what you should do, when you should do it, whether you feel like it or not.

Let me break down that definition of self-discipline. First, "the ability to make yourself." This means that you have to use strength and willpower to force yourself into motion, to overcome the power of inertia that holds you back. Second, "do what you should do when you should do it." This means that you make a plan, set a schedule, and then do what you say you will do. Do it when you say you will do it. Keep your promises to yourself and to others. The third part of this definition is: "whether you feel like it or not." You see, anyone can do anything if he feels like it, if he wants to do it because it makes him happy, if he is well-rested and has lots of time.

However, the true test of character is when you do something that you know you must do whether you feel like it or not — especially when you don't like doing it at all.

In fact, you can tell how badly you really want something, and what you are really made of as a person, by how capable you are of taking action in the direction of your goals and dreams even when you feel tired and discouraged and disappointed and you don't seem to be making any progress. And very often, this is the exact time when you will break through to great achievement.

As Ralph Waldo Emerson wrote, "When the night is darkest, the stars come out." Your ability to endure, to continue taking action, step by step, in the direction of your dreams, is what will ultimately assure your success.

Adapted by Patrick Meehan from the Psychology of Achievement by Brian Tracy.

Patrick Meehan is a FocalPoint Executive Coach and a Brian Tracy International Certified Trainer.

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Antibody Drug Conjugates

– a 21st century take on an old story



John Milne, Training Director, National Institute for Bioprocessing and Training, (NIBRT)

As schoolchildren most of us were told the story of the wooden horse of Troy. As the story goes the Greeks were laying siege to the city of Troy for several years but due to the resistance of the locals they were unable to gain entry.

Odysseus a Greek general devised a plan whereby the Greeks would build a wooden horse which they would leave outside the gates as a gift to honour the Trojans for defending their city. As the Greeks set sail pretending to depart the Trojans celebrated and found their "gift" outside their gates. They moved the horse inside the gates exactly as Odysseus had suspected. Later that night as the Trojans were sleeping, soldiers hiding inside the "hollow" wooden horse climbed

out and opened the gates. The Greek army who had returned under cover of darkness entered the city and as the story goes that was the end of Troy. This article will suggest a modern day take of this old story.

In recent years the global market for therapeutic proteins and more particularly antibody-based therapies has increased significantly. Annual biopharmaceutical growth rates of 10% have been achieved and future growth predictions are equally promising. The development of personalised therapies and more potent and effective drugs is also of obvious interest to drug companies. Antibody

based therapies offer the advantage of unique specificity of the antibody for its biological target. Monoclonal antibodies (mAb) now dominate the biopharmaceutical market with many

hand generally display little selectivity and often substantial toxicity to normal tissues. Therefore the logic behind combining the more advantageous properties of monoclonal antibodies

with the greater cytotoxicity of potent drugs is clear in that the resulting combination product might ultimately be of more therapeutic benefit to patients. The development of antibody drug conjugates (ADCs) has gained significant momentum in recent years, with two oncology therapies (brentuximab vedotin, Adcetris®, from Seattle Genetics, Inc., codeveloped and marketed by Millenium/Takeda and ado-trastuzumab emtansine,



more products currently in development targeting oncology, cardiovascular disease and immune disorders.

Over a hundred years ago Paul Ehrlich coined the phrase "magic bullet" as a term to describe an ideal therapeutic agent that could be created that killed only the organism that it targeted. His original vision has now been realised by the advent of monoclonal antibodies as by nature and design they provide a unique binding affinity for their targets. However antibodies despite their specificity can often exhibit poor penetration into tumours and also poor cytotoxicity. Cytotoxic drugs on the other

Kadcyla®, from Genentech/Roche) receiving regulatory approval in 2013. In addition, more than thirty ADC molecules are currently undergoing different phases of clinical evaluation and with many more reported to be in preclinical development, this demonstrates that ADC development is rapidly expanding and increasing in importance within the biopharmaceutical area.

As an example in the case of oncology applications the aim of the ADC strategy is to deliver a cytotoxic drug to a cancer cell that possesses on its surface an antigen against which the antibody was raised in the first place. As long as

a target antigen can be identified that is somewhat unique or perhaps over expressed on the cancer cell as compared to normal healthy cells, the basis for an ADC therapy exists. An ADC consists of three distinct building blocks, an antibody, an associated small molecule drug and linker. Bifunctional linkers with sites of attachment for both antibody and drug are used to couple the antibody and drug together. Conjugation of the toxic drug to the antibody inactivates the drug so that it is not toxic while in circulation. When bound to the target receptor the ADC-receptor complex is internalised through receptor-mediated endocytosis. Once inside the cell the active free drug is released by cleavage of the linker or degradation of the antibody. The free drug can now interact with its own target within the cell, exert its cytotoxic effect and lead to the death of the cell. The key to a successful ADC product lies within the linker technology used to combine the antibody and drug. Specifically the drug to antibody (DAR) ratio is a key determinant of the effectiveness of the ADC. For first generation ADC molecules conjugation of drug via the linker to the mAb was achieved using linkers that were functionalised with reactive groups designed to specifically react with accessible nucleophilic amino acid side chains belonging to native amino acids such as lysine (amine) or cysteine (thiol). Both these processes are random and precise control of the process is difficult. In the case of lysine directed conjugations (e.g. Kadcyla®) heterogeneous mixtures containing a DAR of zero to eight drug molecules per antibody have been produced. To further complicate matters conjugates have been identified with attachment of drug occurring at up to forty lysine residues of the approximate eighty available lysine residues on a typical IgG1 antibody. In the case of conjugation to cysteine residues on the antibody (e.g. Adcetris®) problems can also arise with conjugates containing zero, two, four, six or eight drugs per antibody molecule. Typically a thiol group in a cysteine residue is paired with a thiol group in another cysteine residue (a disulphide bridge) and hence those disulphide bonds need to be broken to expose the free thiol groups

for conjugation to take place. Due to complete or partial reduction of disulphide bonds variable DAR moieties can result. To facilitate tighter control of the DAR, newer approaches involving site specific conjugation on the mAb are currently in development. Such site specific strategies focus upon either insertion of additional cysteine residues into the mAb sequence by mutation, insertion of an unnatural amino acid with a reactive functionality or "handle" or enzymatic conjugation to generate the ADC. These options are now the main drivers for the generation of the next generation ADC molecules.

Once the ADC-receptor complex has been internalised the clever part of the ADC strategy is how the free drug is released. Once again there are alternative strategies that can be used. The linkers used can be divided into two categories namely cleavable and non-cleavable. Acid-labile hydrazine linkers undergo hydrolysis in the acidic environment of cellular compartments. Disulphide linkers are cleaved inside the cells where

double-strand cleavage and hence programmed cell death (calicheamicins). Currently newer more potent cytotoxic compounds are receiving attention in next generation ADC molecules (a-amanitin and pyrrolobenzodiazepine dimers (PBD)).

For therapeutic use the three constituent components of an ADC must be manufactured according to the requirements of current good manufacturing practice. Within industry there is wide experience of manufacturing monoclonal antibodies and the technologies involved in such processes are mature with over forty therapeutic monoclonal antibodies now approved. The manufacture of the linker component is a specialised discipline and companies such as Seattle Genetics and Immunogen are the major licensing and reagent sources. The manufacture of the toxic drug is challenging and requires full isolated facilities in order to protect personnel. Indeed the conjugation of the antibody to the drug also requires the use of specialised isolated environments

to protect personnel from the toxic effects of free drug during the manufacturing process. Bioprocessing staff are also required to undertake specialised training to ensure their safety and avoid exposure to the "free" toxic drug. ADC molecules present many



the cytosol provides a more favourable reducing environment compared to the extracellular environment. Peptide-based linkers couple the drug to the antibody via a peptide bond which can in turn be cleaved within the target cell by lysosomal proteases. Non-cleavable linkers on the other hand rely on the catabolic degradation of internalised antibodies in the lysosomal and endosomal cell compartments. Thus the strategy depends on the complete degradation of the antibody after internalisation resulting in release of the drug with the linker attached to an amino acid on the protein backbone of the antibody. The cytotoxic agent linked to the antibody can vary but in general fall into two categories, those that disrupt mitosis by interfering with microtubule assembly (auristatins and maytansinoids) and those that directly target DNA structure by inducing DNA

options and challenges in both their design and manufacture, however, all indications suggest that they represent a class of molecule that affords very promising opportunities particularly within the oncology space where the vast majority of clinical trials are focused. An indication of this is given by the number of ADC products in development and the interest from companies and contract manufacturing organisations to invest in facilities in order to increase their capability to manufacture these molecules in the future. As manufacturers now look to develop their capability to generate more efficient and safer ADC molecules it is clear that these molecules provide us with a nice analogy of the old story of the "wooden horse" with a toxic drug hidden in the payload of a specific antibody which is released upon internalisation within a target cell.

A top-down view of a desk with various items: a black notebook with a gold cross symbol, a pair of black-rimmed glasses, a hand holding a black pen, and several brown envelopes. A white rectangular box containing the company logo is centered in the upper half of the image.

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Hotel Solutions	Michelle Thornton	01.6309211	michelle@hotel-solutions.ie
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*Delivery and related charges not included. Terms and conditions apply. Model shown is the Volvo S60 D2 SE. Manual priced at €34,995. ^oWith 6+ months membership. Fuel consumption for the Volvo Range in mpg (l/100km): Urban 26.9 (10.5) – 68.9 (4.1), Extra Urban 41.5 (6.8) – 83.8 (3.4), Combined 34.4 (8.2) – 76.3 (3.7). CO₂ Emissions 169 – 48 g/km. All new Volvo cars come with a 3 year warranty and 2 years' roadside assistance.