2nd ICIP 2016

INTERNATIONAL CONFERENCE ON INDUSTRIAL PHARMACY

Generics and Biosimilars

15th -16th August 2016

INTERNATIONAL ISLAMIC UNIVERSITY MALAYSIA, KUANTAN

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2nd ICIP 2016
INTERNATIONAL CONFERENCE ON INDUSTRIAL PHARMACY
Generics & Biosimilars

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Organized by
Kulliyyah of Pharmacy, International Islamic University Malaysia

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FOREWORD

In the Name of Allah, The Most Gracious, The Most Merciful

In Portugal, the generic market grew from almost non-existent in 2000 to 30% in volume with a corresponding 23% growth in value in 2011 .

The contribution of India to the production of generic drug is definitely an understatement. It was reported by Doctors Without Borders that 80% of the drugs they used for the treatment of HIV/AIDS are generic produced by Indian companies . Other Indian generic drugs used are for the treatment of TB, malaria and infectious diseases.

Despite the relatively affluent Japanese, the government is strategising to minimise medical expenditures by substituting innovator products with generic drugs . The target is to have 60% share by volume comes March 2018. This strategy involves the revision of pricing scheme that intends to lower the generic drug price by 50% compared to originator.

Worldwide, the pharmaceutical market revenue increases from USD427.6 billion in 2002 to more than a trillion in 2014 . If the Japanese target is something to be reckoned with, this is a strong driving force for the growth of the generic and biosimilar pharmaceutical industry.

In reflection, if the Japanese who are wealthy enough has a strategy to reduce cost by using generic drugs, the motivation should be even stronger with developing countries in Asia including the Indian sub-continent and Africa. We can expect increasing number of manufacturers and manufacturers increasing their capacity. With these activities, quality could be forsaken if regulatory bodies could not keep up with the escalating volume of products. Best practices in industrial pharmacy must be encouraged, data integrity is sanctified and basic requirements must be adhered.

Most importantly however, is how we react to socio-economic challenges. In times of economic tribulation throughout the world, we are also put to tasks with infectious diseases that call for new therapies and vaccines. As we have witnessed, the Zika virus and the Ebola virus for instance, struck nations that are trying to climb the economic ladder. These are nations having people in the income poverty category and perhaps a few in the extreme poverty category of sustaining with less than USD1 a day . To these people, quality of life is an alien concept what more sophisticated medicines.

FOREWORD

As educators, scientists, industrialist, regulators and responsible people who contribute to industrial pharmacy, we must see the industry beyond stature and monetary gains. It is undeniably a social issue. Medicines should reach all shores and never discriminatory in any way. It is a sacred obligation to save life, intellect and progeny. While generics and biosimilars should be encouraged to reduce costs, over prescription, ineffective patient-counselling resulting in wastes and unethical practices downstream are real issues, which must be dealt with, that defeat the purpose of having generics and biosimilars in the first place.

Thus it has been said.

On behalf of the organising committee,

"Welcome to the 2nd International Conference on Industrial Pharmacy."

We hope that all of us have a wonderful time meeting each other, sharing our ideas and contribute to the body of knowledge passionately and wisely for the sake of humanity.

Smile and you will get a smile in return!

Thank you to our invited speakers and honourable guests for your participation.
We value your presence and finding time to be with us in spite of your other commitments.
Let us together shape industrial pharmacy as an ethical, a socially-sensitive and a responsible industry.

And we hope to see you again in 2018.

Thank you to all my lovely friends who have unrelentingly, tirelessly and indefatigably worked to organise the conference. May Our Creator The Most Gracious grant you with more energy and everything good in this World and in the Hereafter. We appreciate very much the support given by the university and our partners in research and education.

Pisang emas bawa belayar,
masak sebiji di dalam peti.
Hutang emas boleh dibayar
hutang budi dibawa mati.

May Allah The Bestower, The All-Seeing, The Most Gracious, accept our effort as good deeds.

Kausar Ahmad
Chair
ICIP 2016

PRE-CONFERENCE WORKSHOP

GMP IN QC LAB

14TH AUGUST 2016 | SUNDAY

VENUE : IKOP QC Chemistry Lab

Instructor: Puan Rohani Mohammad (Affiliate Manager ISPE Malaysia)

0830-0900	Registration
0900-1000	GMP requirements in QC Laboratory
1000-1030	Morning Break
1030-1130	GMP Audit findings in QC Laboratory
1130-1230	Common Audit findings in QC Laboratory
1230-1300	Q&A Session
1300	Lunch - End of Session

CONFERENCE DAY 1

15TH AUGUST 2016 | MONDAY

0830-0900	**Registration** **Breakfast & Poster Prep**	**Banquet Hall** **Grand Hall**
0900-0915	**Opening Ceremony** **Recitation of Quran** *Bro Muhammad Badri Abdul Kudos*	**Banquet Hall, Ground Floor**
0915-0930	**Welcoming Address** *Prof Dato' Dr Tariq Abdul Razak* *Campus Director, IIUM Kuantan*	**Banquet Hall, Ground Floor**
0930-1000	**Photography Session**	**OCD Staircase**
1000-1030	**Tea Break & Networking**	**Grand Hall, Level 1**
1030-1120	**Plenary Session 1** *The Development of the Malaysian Generic Industry - A Practitioners' Perspective* *En Azhar Hussain* *President, ISPE Malaysia Affiliate Board*	**Banquet Hall, Ground Floor**
1120-1210	**Plenary Session 2** *Bringing Research to Industry: Environmentally Benign Commercialization of Supercritical Fluid Technology* *Prof. Kenji Mishima* *Head-Research Center of Composite Material, Fukuoka University, Japan*	**Banquet Hall, Ground Floor**
1210-1235	**Poster Presentation 1**	**Grand Hall, Level 1**
1235-1300	**Poster Presentation 2**	**Grand Hall, Level 1**
1300-1400	**Lunch**	**Grand Hall, Level 1**
1400-1430	**Invited Session 1** *Curcumin-Loaded Nanoemulsion for Pharmaceutical Applications* *Dr. Heni Rachmawati* *Associate Professor - Pharmaceutics* *Bandung Institute of Technology, Indonesia*	**Banquet Hall, Ground Floor**
1430-1500	**Invited Session 2** *The Biotechnology Industry – Past, Present and Future* *Ms. Michelle Peake* *Principal Consultant - Synertec Asia*	**Banquet Hall, Ground Floor**

1500-1530	**Invited Session 3** *Pharmaceutical Industry Outlook in Korea* *Mr. Jae Hwang* *Chief Executive Officer* *JH Biosystem, Korea*	**Banquet Hall, Ground Floor**
1530-1600	**Invited Session 4** *Clinical Drug Design* *Prof. Basavaraj K Nanjwade* *Professor* *Department of Pharmacy Practice* *The Oxford College of Pharmacy, India*	**Banquet Hall, Ground Floor**
1600-1700	**Parallel Session 1**	**Banquet Hall, Ground Floor**
	Parallel Session 2	**Seminar Room 2, Ground Floor**
	Parallel Session 3	**Seminar Room 3, Ground Floor**
1700	**Afternoon Tea**	**Grand Hall, Level 1**
2000-2300	**Conference Dinner** *Welcoming Speech* *Dr Siti Hadijah Shamsudin* *Dean, Kulliyyah of Pharmacy, IIUM*	**Grand Hall, Level 1**

CONFERENCE DAY 2
16TH AUGUST 2016 | TUESDAY

0830-0900	**Registration & Breakfast**	**Grand Hall, Level 1**
0900-0950	**Plenary Session 3** *Industrial Pharmacy - The Pharmacy Profession's Dilemma?* *Mr. John C P Chang* *Deputy President,* *Balai Ikhtisas Malaysia*	**Banquet Hall, Ground Floor**
0950-1020	**Tea Break**	**Grand Hall, Level 1**
1020-1110	**Plenary Session 4** *Challenges and Opportunities in the Pharmaceutical Biosimilar Industry* *Dr Abdul Manaf Mohd Radzi* *Chief Executive Officer* *University-Industry Partnership,* *Malaysian Bioeconomy Development Corporation Sdn Bhd*	**Banquet Hall, Ground Floor**

1110 - 1140	**Invited Session 5** *Proteins and Enzymes in Drug Delivery* *Prof. Hamzah Salleh* *Professor - Biotechnology Engineering,* *International Islamic University Malaysia*	**Banquet Hall, Ground Floor**
1140 - 1210	**Invited Session 6** ***10 Simple Steps for Equipment Qualification Compliance for Pharmaceutical Industries*** *Ir. Dr. Nizamil Fairuz bin Yahya* *Managing Consultant* *PharmEng Technology, Malaysia*	**Banquet Hall, Ground Floor**
1210 - 1240	**Invited Session 7** *Replacement of Toxic Solvents Used in the Pharmaceutical Industry with Safe and Renewable Mixed-Solvents* *Prof. Richard Smith* *Graduate School of Environmental Studies* *Tohoku University,Japan*	**Banquet Hall, Ground Floor**
1240 - 1300	**Poster Presentation 3**	**Grand Hall, Level 1**
1300 - 1400	**Lunch**	**Grand Hall, Level 1**
1400 - 1500	**Parallel Session 4**	**Banquet Hall, Ground Floor**
	Parallel Session 5	**Seminar Room 2, Ground Floor**
	Parallel Session 6	**Seminar Room 3, Ground Floor**
1500 - 1600	**Parallel Session 7**	**Banquet Hall, Ground Floor**
	Parallel Session 8	**Seminar Room 2, Ground Floor**
	Parallel Session 9	**Seminar Room 3, Ground Floor**
1600 -1700	**Closing Ceremony & Presentation of Awards** *Dr Juliana Jaffri* *Head, Department of Pharmaceutical Technology,* *Kulliyyah of Pharmacy, IIUM*	**Banquet Hall, Ground Floor**
1700	**Afternoon Tea - Conference Ends**	**Grand Hall, Level 1**

Mr. Azhar bin Hussain
President, ISPE Malaysia

Mr. Azhar Hussin is the current President of ISPE Malaysia affiliate (International Society of Pharmaceutical Engineers). Graduated from the University of Wales, UK with a degree in Pharmacy, he has carved his way to become one of the most respectable figures in the Malaysian Pharmaceutical Industry.

Mr Azhar has worked and led reputable companies in the local pharmaceutical industry arena, with 18 years of invaluable experience with Glaxo Malaysia (1976-1994) - rising to the Board of Directors in 1993; 12 years with Pharmaniaga (1994-2006) - with his last position as the Managing Director; a Senior Director of the UEM Group (2007-2008) where he was responsible for the development of the Pharmaceutical and Healthcare business; and three years with TPM Biotech Sdn Bhd. (2008-2010) where he lead the TPM Herbal Biotech Centre in Raub . He also acted as the Director for IKOP Sdn Bhd from 2013-2015.

At present he is the Chairman and Director for Kotra Industries Berhad and Neoconsult Sdn Bhd. As the past president of the Malaysian Organisation of Pharmaceutical industries (MOPI), Mr. Azhar has committedly facilitated and encouraged the development of the pharmaceutical industry in Malaysia.

The Development of the Malaysian Generics Industry – A Practitioners' Perspective

Azhar Hussain
ISPE Malaysia
E-mail: hsazhar@gmail.com

ABSTRACT

The Government views the Pharmaceutical Industry as one of the areas targeted for promotion not only for economic benefits but also as a key driver for contributing to the well-being of the population and a strategic initiative to achieve self-sufficiency in the country's drug needs.

This paper presents views from a practitioners' perspective, starting with a brief historical account of the industry during its formative period in the early years of the country's independence, highlighting the challenges faced by the few players operating then, amidst the prevailing economic, social and political environment at the time and how these were mitigated.

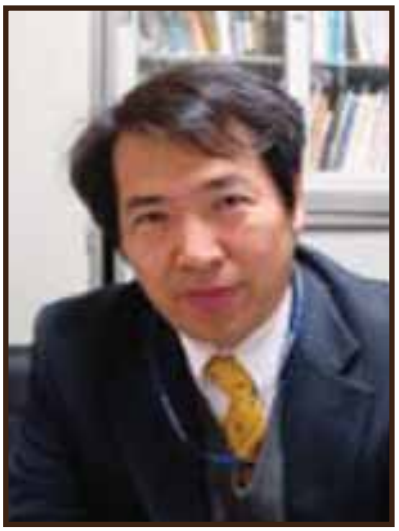
The subsequent introduction of the Codes of Good Manufacturing Practice and the enforcement of Drug Registration and Licensing in the eighties has a very significant impact on the industry and how it helped in shaping the industry to what it is today. The enforcement of these regulations also helped mitigate the misconceptions and negative perception about generic medicines, which largely had been a barrier to the utilization of generic medicines.

This paper also highlights the various 'critical milestones' in the development of the industry and how they help grow and shape the industry to what it is today. Significant events in the country affecting the industry such as the introduction of the Code of GMP, removal of import tariffs on pharmaceuticals, the introduction of Drug Licencing and Registration, the Privatisation of Drug Procurement and Distribution for the Ministry of Health hospitals, the Initial Public Offers (IPOs) by Malaysian Pharmaceutical companies, Malaysia's acceptance into the PICs and lastly but not least, our very own M&As.

Nonetheless, the journey travelled has never been a smooth-sailing one for the local pharmaceutical industry. It had faced numerous challenges, impediments and intense competition even to this day. Challenges in meeting the needs of ever growing stringent regulatory requirements amidst rising costs of doing business could not have been worse. Intense competition from not only the regulated markets but also from regional players in ASEAN, India and China calls for astute business capability and technological competence.

With all these challenges, shortcomings, inadequacies and impediments within the industry left unresolved fully, and the prevailing intense competition from both within the country and internationally, one cannot help but ask the question" is there a future for the Malaysian pharmaceutical Generics Industry?"

This paper attempts to provide some of the answers and hopefully solutions to tackle those challenges. The local pharmaceutical industry stakeholders need to do 'more' in going forward not only to remain relevant in Malaysia as a significant healthcare provider but also in playing a part in reducing the sectoral deficit and contributing to the nation's economic gains.



Professor Kenji Mishima
Head of Composite Material Research Center
Department of Chemical Engineering,
Fukuoka University, Japan

Prof. Kenji Mishima is the Head of Composite Material Research Center, from the Department of Chemical Engineering, Fukuoka University, Japan. He graduated from the Himeji Institute of Technology with BSc in Chemical Engineering in 1981, then in 1983 obtained his Master's Degree in Chemical Engineering from Kobe University. In 1986 he completed his PhD degree on Internal Phenomena with Solvent Extraction. He is an experienced and well respected researcher and academician with 269 publications, 32 patents and has written 16 books. His research interests lies in the Development of Drug Delivery System, Development of Supercritical Fluid Technology, Prediction of Physico-Chemical Propertiesof Liquids and Gases, Development of Recovery Process for Bioproducts, Experimental and Theoretical Studies on Phase Equilibria of Polymer Systems and the Development of Materials in Regenerative Medicine.

Prof Mishima is an active member of many professional bodies. Amongst his list of professional memberships include: The Society of Chemical Engineers, Japan, the Chemical Society of Japan, American Institute of Chemical Engineers, the Japanese Society of High Pressure Science and Technology, and the Japanese Society of Thermophysical Properties. He is also actively involved in professional activites such as being a member of the Regional Science Promoter Program at Fukuoka Prefecture and a member of the Committee of Clean Japan Center.

Bringing Research to Industry: Environmentally Benign Commercialization of Supercritical Fluid Technology

Kenji Mishima
Department of Chemical Engineering,
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ABSTRACT

Feasibility of supercritical fluid technique for environmentally benign commercialization of supercritical fluid technology was considered as an example of 'bringing academic research to industry'. We applied supercritical fluid technology to control the microstructure of composite material.

The rapid expansion from supercritical solution with a non-solvent (RESS-N) and the pressure-induced phase separation (PIPS) of $scCO_2$ solutions are applied to forming polymeric microcapsules. Supersonic was applied to control the structure in supercritical carbon dioxide under the condition of high pressure. A suspension of target material in carbon dioxide containing a co-solvent and dissolved polymer is sprayed through a nozzle to atmospheric pressure. After rapid expansion of the solution, polymeric micro-composites were formed according to the precipitation of the polymer caused by the decrease of solvent power of carbon dioxide.

This method can offer three advantages. Using this method, we can dissolve enough amount of the coating polymers, which are insoluble in pure carbon dioxide, encapsulate micro-particles of the target material without adhesion between each particles as, which is the result of utilizing a non-solvent as co-solvent and the removing of co-solvent remaining in the mixtures by gasification of carbon dioxide, and control the polymer-coating thickness with changing the feed composition of the polymer.

Mr. John Chang
Deputy President
Balai Ikhtisas Malaysia

Graduated from the National University of Singapore, 1969, John started his career in Industrial Pharmacy setting in pharmaceutical manufacturing and later held corporate positions in sales, marketing and management in multinational companies for more than 20 years before settling into management and healthcare communication consultancy.

His active interest in the pharmaceutical and pharmacy sector saw him elected President, Pharmaceutical Association of Malaysia (PhAMA) from 1983 -1986. He participates actively in the Malaysian International Chamber of Commerce Trade & Industry committee looking at issues concerning the WHO Essential Drug List, Drug Registration Act, new Patents Act in Malaysia. He was a member of the Poisons Board Malaysia.

His strong interest in pharmacy leadership and advocacy saw him ascending to the position of President of the Malaysian Pharmaceutical Society from 1996–2008, and is still in the Council. He participates in various governmental and NGO committees pursuing issues concerning pharmaceutical and healthcare matters, and often as invited speakers, locally and abroad.

He engaged himself as officials in international pharmacy-related organisations such as the Commonwealth Pharmaceutical Association (CPA), FIP Western Pacific Regional Organisation, and the Federation of Asian Pharmaceutical Associations (FAPA) as councilor for over 20 years, vice-president, president-elect, president and now the immediate past-president. He was engaged in many issues on pharmaceutical and pharmacy in the international arena.

Keenly interested in pharmacy education and concerned over the quality of graduates, he actively enrolled as a member of the Malaysian Qualification Authority, MQA/Pharmacy Board Evaluation Panel since its inception in 1998. Over the decades he had observed the gradual erosion of pharmacist's participation in the pharmaceutical industry. This has caused serious concern to the profession and indeed has become the pharmacy profession's dilemma in staying relevant in this sector. He is presently also the Deputy President of Balai Ikhtisas Malaysia (Malaysian Professional Centre), an umbrella body for professionals in Malaysia.

Industrial Pharmacy - The Pharmacy Profession's Dilemma?

John C P Chang
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ABSTRACT

Pharmacists have long been associated with the pharmaceutical industry for obvious reason that their education and practice whether in community, hospital or regulatory are closely associated with and considered a significant part of the industry. This association has historical link to the apothecary period involving the process of herbal formulation and preparation.

The development in healthcare and pharmaceutical industry, new healthcare transformation policies and the socio-economic factors in a globalized world, including advanced pharmacy education over the last few decades have impacted pharmacist's role, new and extended ones.

From what was once a science-based pharmacy education, the curriculum adopted globally has responded in shifting it towards more clinical oriented. Pharmacy graduates today are not well-informed and inadequately exposed to industrial pharmacy. Such emphasis on patient-oriented national healthcare system has undoubtedly created greater opportunities for clinical and community practice, despite the pharmaceutical industry continues to thrive and growing.

Amidst such development, there has been perceptible concern within the profession in many countries that attractive career opportunities in the sector maybe forsaken. Despite with the dramatic increase in pharmacist manpower everywhere corresponding with similar increase in pharmacy schools, few students have taken interest in industrial pharmacy even with effort to retain industrial biased-curriculum in some institutions. Graduates of other disciplines are replacing pharmacists who may eventually lose their close association with the industry.

Recently, the Malaysian Government has liberalized the PRP training to allow training in selected private institutions, partly to resolve shortage in the private sector amidst the public sector having attained almost full capacity for pharmacist employment. Will this rekindle interest thus rebalancing the equation now favoring clinical pharmacy?

What had gone amiss? Have the profession and its institutions made serious strategic mistake in focusing on patient-centered practice that pays better and missed out other opportunities? Would this gradual decline for Industrial Pharmacy by the profession begs the question "Is Industrial Pharmacy now the Profession's Dilemma". Would it lead to its eventual demise as a preferred career option undermining the traditional job scope for pharmacists? What would be the larger implication for pharmacists in the industrial sector which not only continues to expand but fast moving into the new world of biologics and biopharmaceuticals? Do we have the answer? Or do we do nothing and see it fading away from the grip of the pharmacy profession?

Dr. Abdul Manaf bin Mohamad Radzi

Chief Executive Officer
University-Industry Partnership
Malaysian Bioeconomy Development Corporation Sdn Bhd

Dr. Abdul Manaf bin Mohamad Radzi graduated with a BSc degree in Chemistry from Northern Illinois University in DeKalb, Illinois USA in 1977 where he majored in professional chemistry and minored in physics. He obtained his PhD degree from the University of Tennessee, Knoxville USA in 1987, majoring in physical chemistry and minoring in inorganic chemistry. He then pursued his studies in administration and obtained a Masters' degree in Business Administration from Ohio University in 1996.

Dr. Manaf joined the Malaysian Biotechnology Corporation Sdn Bhd (BiotechCorp), a government-linked company under the purview of the Ministry of Science, Technology and Innovation, Malaysia as the Senior Vice-President, Industrial Division in January 2010. Shortly after, he was re-assigned to head the Agriculture Biotechnology Division. He was responsible for extending the usage of biotechnology tools to elevate the agriculture industry, focusing in the areas of crops biotechnology, livestock, aquaculture, and natural products discovery and commercialisation.

At present, he is the Senior Vice-President handling University-Industry Partnership. The divisions' main responsibilities are to ensure that the industry benefit from the research and development work conducted in universities and research institutes; to create centres of excellence whereby a university is recognized for a certain area of expertise that will become a reference centre for the industry; and finally, to support bio-entrepreneurs by facilitating their incorporation to become a company, by assisting in securing relevant investments (i.e. ScienceFund, TechnoFund, Innofund and other funding instruments) and training (QB3-based training module like "Customer-Driven Technology Commercialization"), among others.

Dr Manaf has extensive experience in research, marketing, retailing and sales across various industries, including building and construction, IT, oil and gas, chemicals, fertilizers and pharmaceuticals and has worked in multi-national companies such as ICI and PETRONAS and public-listed companies like CCM Berhad and ACPI Berhad, .

Prior to joining BiotechCorp, he has held significant positions with CCM Berhad from 2005 to 2010, including as a General Manager to CCM Duopharma Biotech Berhad. He has led various subsidiaries within the company including CCM Pharmaceuticals Pte Ltd, the Singapore subsidiary of the group; Prima Health, the pharmaceutical retail arm of the group; and Innovax Sdn Bhd which conducts R&D of pharmaceutical products.

Challenges and Opportunities in the Pharmaceutical Biosimilar Industry

Abdul Manaf Mohd Radzi
Chief Executive Officer
Malaysian Bioeconomy Development Corporation Sdn Bhd
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ABSTRACT

Bioeconomy is an economic activity which focuses on using biological sources in generating a sustainable economic, social and environmental development. It is an economy which gives great opportunities and solutions to growing number of pressing global challenges such as climate change mitigation, energy and food security and resource efficiency, building a greener economy and gives an alternative for affordable healthcare. In terms of economic growth, it will increase the nation's income by exploiting the bio-resources to provide high value products using bio-based technologies. One of the bio-based industry that helps developing bioeconomy is biopharmaceutical. This industry has grown rapidly by generating global revenues of $163 billion and the annual growth rate is more than 8% of conventional pharmaceutical.

The increase in demand for biological drugs is estimated to grow from $289 billion to $445 billion by 2019. In the USA market for the year 2009, approximately 20% of all drugs were biologics. However, the availability of the biologic drugs is limited due to their high price; for example the drug Humira for Crohn's disease would cost patients USD51,000 on average annually. However, most of the patents for biological drugs will be expiring in several years. Thus, researchers have come with alternatives to sustain the availability of the drugs in the market with cheaper prices by introducing biosimilars. The market evolution of the biosimilar drugs is showing gradual uptake in the USA, Europe and Asia including Malaysia. Since July 2008, five biosimilar products have been approved to be marketed in Malaysia (SciTropin, Binocrit, Zarzio, Nivestim and Insugen).

In supporting national biopharmaceutical industry, Malaysia has collaborated with various biopharmaceutical companies including Biocon. Malaysia also is one of the earliest countries that develops the biosimilar guidelines and supports the development of biosimilar ecosystem. The development of biosimilar products will assist in creating talent bio-based industry that helps in the growth of bioeconomy in Malaysia.

Assoc. Professor Dr. Heni Rachmawati
Associate Professor in Pharmaceutics
Bandung Institue of Technology
Indonesia

Dr. Heni, is an Associate Professor in Pharmaceutics with the Bandung Institute of Technology (ITB), Indonesia. She obtained her first degree and Master's Degree from ITB before pursuing her PhD studies in the University of Groningen, Netherlands. Her research interests are in Drug Delivery system and Nanotechnology-based formulations with 32 International publications and 13 Indonesian publications, four book chapters and a patent on Curcumin nanoparticles.

Her post-doctoral studies saw her attached with the Institut für Pharmazeutische Technologie, Biotechnologie und NutriCosmetics Freie Universität Berlin, Germany where she worked on the Production and Characterization of Curcumin Nanocrystals. She also worked on a post-doctoral project with the Department of Chemical and Biomolecular Engineering, Faculty of Engineering, National University of Singapore on the Development of Ab-conjugated nanoparticle for cancer diagnostics and therapy. Her research work started with and continues to focus on Interleukins, Interferons, Curcumin nanocrystals and other works on drug delivery systems and nano-technology-based formulations.

Curcumin-Loaded Nanoemulsion for Pharmaceutical Applications

***Heni Rachmawati*[1]**, *Dahlia Permatasari*[1], *Miranti A.Novel*[1], *Irene S. Soraya*[1], *Risya M. Nisa*[1], *Guntur Berlian*[2], *Olivia M. Tandrasasmita*[2], *Annisa Rahma*[1], *Catur Riani*[1], *Neng F. Kurniati*[1], *Maria I. Iwo*[1], *Raymond R.Tjandrawinata*[2]

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ABSTRACT

Curcumin, a major active compound isolated from Curcuma species is known to possess a wide range of pharmacological activities. The main pathway of curcumin biological activities is via antioxidant. Scavenging activity of curcumin may be attributed to the high reducing power and higher total phenolic contents. This chemical structure is supporting its therapeutic action, however in other case bringing problem during formulation development. Low bioavailability due to low solubility of curcumin is identified as a major limitation in clinical application. We established a smart formulation to improve the pharmaceutical value of curcumin. A lipid-based nanoemulsion demonstrated a versatile approach not only enhancing curcumin solubility, but also skin permeation, chemical and biological stabilities. Various models of diseases were applied to prove the potential benefit of nanoemulsion encapsulating curcumin. The study was conducted both in vitro and in vivo.

Curcumin-loaded nanoemulsion exhibited better characteristics and effects in all models. In addition, to confirm the safety of using high concentration of surfactant to form spontaneous curcumin-loaded nanoemulsion, an acute toxicity data was also provided.

Ms Michelle Peake
General Manager and Principal Biotech Consultant
Synertech Asia

Ms Michelle Peake has been working in the field of biotechnology for over 20 years, after graduating with a BSc with Japanese from Griffith University, Australia. She has worked for companies in Australia, England and Malaysia, in all areas from research to process development, with her main experience in cGMP manufacturing for biopharmaceuticals. She has extensive experience in protein purification, analytical assays and fill/finish.

In December 2003 Michelle was appointed as the Director of Manufacturing for Alpha Biologics, a biopharmaceutical CMO in Penang, Malaysia, where she was responsible for the design and construction of the Alpha cGMP facility and equipment and establishment of the company. She was later promoted to Chief Executive Officer and to the Alpha Board of Directors and also holds a board position with a US publicly-listed company.

Michelle is currently with Synertec Asia as the General Manager and Principal Biotech Consultant. She is also a committee member of the Malaysian ISPE Affiliate and Industry Advisor to a Bioprocessing course at a Malaysian University.

The Biotechnology Industry – Past, Present and Future

Michelle Peake
Synertec Asia (M) Sdn Bhd
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ABSTRACT

The use of biological processes has been around since the 19th century when grains and nuts were used to make alcoholic beverages. World War 1 led to industrial fermentation, and then in the early 1980's, the use of biology for technology ie biotechnology, led to a new field called genetic engineering, which brought biotechnology to the forefront in healthcare research and development. Today most of the top-selling drugs are from the biotech industry, and we are now seeing their 'generic' counterpart's biosimilars, coming to the market. It is estimated that the cost to bring a biologics drug from research to market will take over 10 years and the company $2.5billion in areas such as development, clinical trials and marketing. The top selling biotech drug of 2014, Humira, brought in yearly revenue of $12.5 billion and teats diseases such as rheumatoid arthritis, psoriasis Crohn's disease, Ulcerative colitis and Psoriatic arthritis. While the medical/healthcare segment is the main industry in biotech, there is also activity in biofuels, industrial enzymes and genetically modifies crops.

Well, this is all very interesting, but what is the biotech industry really like and more importantly, what is happening with the biotech in Malaysia? What job prospects are there, what should I be studying, where do I want to end up, do I agree with genetically modified crops, with stem cell research – all valid questions to ask yourselves. But over the past few years Malaysia has new investment with international companies – are things looking up?

Mr Jae Hwang
Chief Executive Officer
JH Bio System, Korea

Mr Jae Hwang graduated from the University of Michigan and obtained his Masters' degree in computer engineering in 1990 and was immediately recruited into major ICT companies in the USA and Korea to begin what would be a fulfilling career in the ICT professional service.
In a career spanning 25 years, Mr Jae Hwang carved his niche and was extensively involved in the management and research in the field of ICT and Healthcare convergence. He acquired extensive experience in private sector management skills that became the hallmark of his career as an executive officer serving one of the most well-established companies in the USA and Korea.

Mr Hwang is now the CEO of JH Bio System. He is an accomplished Senior Technical Executive with over 25 years of experience in ICT and Healthcare industries including Healthcare Information System Integration, Software Engineering, Information Security, and Artificial Intelligence. His Korean and international leadership experiences concentrates on research and development, project management, international procurement and contract negotiation of organizations ranging in sizes from a dozen to 500 + employees. Mr Hwang has proven track records of successfully leading and managing emerging technology companies, expanding market share and profitability.

Prior to establishing JH Bio System, Mr Hwang was CEO of KTI Digital, a subsidiary of KTI group of Busan, Korea. KTI Group specializes in Marine ICT. Under Mr Jaes' direction, KTI Digital led the consortium of VTMIS (Vessel Traffic Management Information System) project (Contract amount: 150M Euro) for the Algerian Government.

Pharmaceutical Industry Outlook in Korea

Jae Sup Hwang
JH Bio System, Korea
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ABSTRACT

Korea accounts for 1.8% of the global pharmaceutical market in terms of sales revenue. Korea's pharmaceutical markets are small in absolute terms but have overtaken the global market in terms of growth rates. Korean pharmaceutical companies have mostly developed generic drugs. However, the development of new drugs is more important than ever to meet changes in the pharmaceutical environment. As such, industry players, especially major pharmaceutical companies, have strengthened their commitment to invest in new drug development.

The need to develop new drugs is gaining momentum due to government policies and changes in the domestic and foreign pharmaceutical market. Therefore, the commitment and investment of major pharmaceutical companies in new drug development are becoming more important.

Korean pharmaceutical companies have delivered achievements in biosimiliar and incrementally modified drugs (IMD), capitalizing on their know-how and research expertise, and made significant efforts to develop first-in-class drugs. As a result, Korean companies have exported technologies to multinational companies and conducted global clinical trials, earning recognition for their technological prowess. Hanwha Chemical exported its biosimilar version of Pfizer's blockbuster rheumatoid arthritis drug Enbrel, and Hanmi Pharmaceutical has licensed out its Poziotinib, a targeted anti-cancer treatment.

In addition, the average concentration ratio of the pharmaceutical industry increased from 6.24 in 2008 to 7.67 in 2012 in the R&D segment. Such an increase in R&D activities, which are essential to the development of the pharmaceutical industry, raises expectations that Korea will be able to enhance its competitiveness. Korean pharmaceutical companies made R&D investments worth KRW 967.2 billion in 2012. The R&D investment posted a high CAGR of 13.7% over the past five years, reflecting a growing commitment to R&D.

Korean pharmaceutical companies have actively sought partnerships with global pharmaceutical companies. Samsung BioLogics established a biosimilar joint venture with the U.S.-based Biogen Idec, enhancing comprehensive partnerships in areas such as R&D, manufacturing and marketing. As such, cooperation with multinational pharmaceuticals is expected to generate strong synergy effects. A strong global presence for South Korea's pharmaceuticals will be facilitated by the export-led developmental approach undertaken by the country. With a traditional focus on high-margin and easily transportable products, the local industry has been able to gain significant expertise that can be applied to the pharmaceutical sector. In addition, South Korea's strong ties with the US, a global leader in the medical sector, and a governmental emphasis on innovative industries, have created a favorable environment for the local pharmaceutical industry.

Professor Dr Basavaraj K. Nanjwade
Head of the Pharmacy Practice Department
The Oxford College of Pharmacy
Bangalore, India

Professor Basavaraj K. Nanjwade obtained MPharm and a PhD in Pharmaceutics. He is currently the Head of the Pharmacy Practice Department with The Oxford College of Pharmacy in Bangalore, India. Nearing 20 years of experience in academia and research, he has 143 publications (97 International and 46 National) and has written and issued text books and international reference books.

His research niche area revolves around Pharmaceutics particularly in Drug Formulation and Drug Delivery system with 1 Indian patent and another 15 patents awaiting approval. He has been an esteemed Visiting Professor and an invited speaker in several Asian countries including Nepal, Bangladesh, Thailand and South Korea. He is an active member of the pharmacy profession with professional affiliations with IPA, APTI, AAPS, CRS and FIP.

Clinical Drug Design

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ABSTRACT

The aim of the current research is to improve the desired properties in the lead compound and try to reduce the toxic or unfavorable effects. If the biological target is known, then the lead compound will be the natural ligand of this receptor or enzyme. The marketed drugs can be used as lead compounds.

Random screening approach is used if we do not know the biological target, whilst non-random screening approach tests compounds having some structural similarity to the active agents. Based on clinical observations, it is found that the drug candidate exhibits more than one pharmacological action.

Today, more systematic approaches are used such as high-throughput screening, which allows researchers to test thousands of potential targets with thousands of diverse chemical compounds to identify a new drug-target combination.

Rational drug design involves designing and synthesizing compounds based on the known structure of a specific target drug molecule. During high-throughput screening, hundreds of potential lead components are identified; many will be eliminated at the first round of testing.

Rational drug design develops fewer compounds compared to high-throughput screening for target. The compounds are very specific to the target and use computer-based modeling to achieve this specificity. During this round, compounds are tested in cultured cells or animals to find out how effective they are and whether they have any serious toxic effects.

Rational drug design has begun to replace the old methods. In rational drug design, biologically active compounds/molecule/drug are specifically designed or chosen to work with a particular drug target.

Professor Dr. Hamzah Salleh
Department of Biotechnology Engineering
Kulliyyah of Engineering
International Islamic University Malaysia

Hamzah Mohd. Salleh started his tertiary education at the Department of Chemistry, University of Waterloo, Canada in 1982. He completed his bachelor, masters and doctoral degrees at the same university in 1986, 1989 and 1994, respectively. Upon submission of his doctoral thesis, he spent about 15 months as a post-doctoral fellow at the College of Pharmacy, University of Michigan, Ann Arbor, USA. His interest in enzymes started in the final year project at Waterloo and this interest continues to the present day.

Hamzah Mohd. Salleh joined the International Islamic University Malaysia (IIUM) in 1993 as a lecturer while pursuing his doctorate qualification in Canada. Upon returning to Malaysia in 1995, he was affiliated with the Faculty of Engineering, IIUM but was assigned to teaching – chemistry and foundation of science (a philosopy of science subject) courses – and academic administration at the Engineering Department, IIUM Matriculation Centre in Kuala Lumpur. In between teaching, research–supervision and academic administration duties, Hamzah took leave of absence from the university and spent the sabbatical at the Chemistry Department, University of British Columbia, Vancouver in 2001-2002 and again in 2014, to renew his interest in enzymology. He is currently also contributing in the development of biotechnology in the country by making himself available as a resource person for vetting research proposals at the university level as well as for the Industrial and Environmental Biotechnology focus area at the Ministry of Science, Technology and Innovation (MOSTI), Malaysia.

Hamzah is currently attached at the Department of Biotechnology Engineering, IIUM and at present he has keen research interests on several hydrolytic enzymes, research for the utilization of agro-residues, as well as scientific research related to the halal industry and agarwood-based natural products. He is a very active member of several research groups including the Bioenvironmental Engineering Research Centre (BERC), Bioprocess and Molecular Engineering Research Unit (BPMERU) and the International Institute for Halal Research and Training (INHART), all at IIUM.

Proteins and Enzymes in Drug Delivery

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ABSTRACT

Proteins and enzymes are crucial in body functions and cellular processes that sustain life; they are also responsible to many undesirable pathological conditions in humans. Protein therapeutics are medical drugs produced using biotechnology techniques such as recombinant DNA technology and hybridoma technology, and their manufacture relies on the use of genetically modified organisms (microorganisms, mammalian cell cultures or plant bio-factories) or biocatalysts that living organisms produce, and involve extensive bioprocessing on a large scale. Protein-based drugs are fundamentally different in structure and size from the conventional small molecule organic chemical drugs; they have complex molecular architecture (primary, secondary and tertiary structures) and potential heterogeneity from post-translational processes.

Therapeutic proteins offer the advantages of high specificity and potency compared to conventional small organic molecules. These features arise from protein's macromolecular nature, which affords the structural complexity that is vital for specificity. On the other hand, this structural complexity also makes protein drugs some of the utmost challenging molecules to formulate and deliver. The formulation and delivery of therapeutic proteins including recombinant enzymes and monoclonal antibodies, cause substantial challenges owing to their large size, charge and susceptibility to degradation. There is also risk of antibody formation as a result of immunogenic response to the in vivo presence of the protein therapeutics.

Some of the most common routes of drug administration include non-invasive peroral (through the mouth), topical (skin), transmucosal (nasal, buccal/subligual, rectal, vaginal and ocular) and inhalation routes. However, protein-based drugs may not be suitable to be delivered using these routes because they might be susceptible to enzymatic degradation or can't be efficiently absorbed into the systemic circulation due to molecular size and charge issues that may render them therapeutically ineffective. Injection is perhaps the route of choice for protein drug delivery. The advantages and limitations of the common routes above will be presented. In addition, new and emerging formulation and delivery strategies such as nanoneedle array injection, microspehere controlled-release technologies, protein modification approaches and genetic manipulation of protein-based drugs, among others will be discussed.

Ir. Dr. Nizamil Fairuz Yahya,
Director & Managing Consultant
PharmEng Technology Sdn Bhd

Ir. Dr. Nizamil graduated with B.Eng (Hons) in Mechanical Engineering from the University of Glasgow, Scotland and subsequently obtained his Master of Engineering (Mechanical Engineering) degree from University Technologi Malaysia before pursuing his PhD in Quality Management from Western Illinois University, USA. He has 18 years of working experience in the field of Engineering & Technology Transfer, Quality Engineering & Validation and Quality Systems.
As a Professional Engineer (P.Eng) in Mechanical Engineering Division, he specializes in Equipment Fabrication & Process Design. Vastly experienced in Pharma & Medical plants start-up and responsible for the establishment of state-of-the-art GMP Design & Built facilities in Malaysia.

Currently, he is with PharmEng Technology Sdn. Bhd. Malaysia as the Director & Managing Consultant for QA & GMP Operation Compliance for South East Asia Region covering Malaysia, Singapore, Indonesia, Brunei, Vietnam and Thailand. His other responsibilities include overseeing the ongoing operation projects by providing technical support, as well as coaching the engineers in various Pharmaceutical, Medical Devices & Biotech Industries such as Alcon-CIBA Vision, Novartis, Biosensors, B.Braun, CCM Duopharma, Pfizer, Pharmaniaga Life Science, iNova Pharma, Leica Life Science, Thomson Reuters, Johor-Biotech, Fresenius and many others. Prior to PharmEng Tecnology Sdn. Bhd., he has served with Alcon, Ciba Vision Johor as a QA Compliance Manager, a Quality Systems Manager and a Quality Engineering Manager. With Polycore Optical (M) Sdn. Bhd., he acted as the Process Engineering Manager and Operations Manager. Earlier in his career he was a field engineer with Sclumberger WTA and an R&D Engineer with Universiti Teknologi Malaysia.

Ir. Dr. Nizamil's past and present affiliations has made him to be extensively experienced with international technology transfer projects, over-seeing & coordinating the overall Design & Built from facilities design drawings, start-up commissioning, qualification & validation projects and compliance aspect from construction stage through the approval by ISO and FDA.
His vast Quality Systems and validation experiences include lab equipment qualification, boiler, pure steam generator, facilities and utilities commissioning, equipment validation, packaging and labeling machine, Steam Autoclave and Process Validation for Medical Devices Industries.
He is a Specialist in Quality Systems compliance activities; from Quality Manual gaps analysis and implementation, non-conformance & CAPA reviewing and approval, document change control process and customer complaint.

10 Simple Steps for Equipment Qualification Compliance for Pharmaceutical Industries

Nizamil Fairuz Yahya
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ABSTRACT

Compliance of implementing equipment qualification for pharmaceutical industries is critical. These 10 simple steps would invite ways of driving employee quality compliance mind-set. This could influence the economic growth for investor confidence by improving its qualification strategies & approaches to ensure compliance to international standard.

PIC/s requirement does not specify clearly how to implement an equipment qualification. It is specified as a subset of validation which defined as “Equipment Qualification provide documented evidence that the process of establishing confidence that the equipment is capable of consistently operating within its established limits or its critical process parameters repeatedly & reliably”.

The 10 simple steps to ensure compliance for equipment qualification for pharmaceutical industries are discussed.

INVITED SESSION 7

Professor Richard L. Smith, Jr.
Graduate School of Environmental and
Research Center of Supercritical Fluids
Department of Chemical Engineering.
Tohoku University, Sendai, Jalan

Professor Richard Lee Smith Jr., obtained his PhD degree in Chemical Engineering from Georgia Institute of Technology in 1985. He is a professor at Tohoku University in Sendai, Japan since 2002 and holds posts at the Graduate School of Environmental and Research Center of Supercritical Fluids in the Department of Chemical Engineering. He has 200+ publications in environmental and chemical fields, 12+ patents and has published several books including a textbook on supercritical fluids. He is the Asia Regional Editor for the Journal of Supercritical Fluids.

Replacement of Toxic Solvents Used in the Pharmaceutical Industry with Safe and Renewable Mixed-Solvents

Richard L. Smith, Jr.
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ABSTRACT

The pharmaceutical industry creates the largest amount of hazardous waste per kilogram of product in the chemical sector.

To address this issue, the American Chemical Society Green Chemical Institute (ACS GCI), the Innovative Medicines Initiative (IMI-CHEM21) and others have developed solvent guides to allow researchers and companies to select or consider substitute solvents in reaction and separation sequences used in pharmaceutical syntheses.

The direct replacement of one solvent for an undesirable solvent (toluene for benzene, heptane for pentane) is possible in many cases for non-polar solvents, however, for solvents that have specific interactions, such as N-methyl-2-pyrrolidone (NMP), which is an aprotic polar solvent that can have specific solvent-solute interactions, direct replacement with a safer solvent is a challenging task.

Recently, we have proposed a method for replacing a hazardous solvent that has specific solute-solvent interactions with a solvent mixture (mixed-solvent). In the method, a solubility window is determined for the specific solute based on the Hansen solubility parameter (HSP). Then, Kamlet-Taft solvatochromic parameters (KT-SP) are used to characterize candidate solvent mixtures according to acidity, basicity and polarity of the mixed-solvent composition.

In this work, we consider a set of undesirable solvents being used in the pharmaceutical industry and consider their substitution by mixed solvents. For example, NMP has an HSP of 22.9 MPa0.5 and KT-SP acidity, basicity and polarity of 0, 0.72 and 0.92. NMP can be replaced by a mixed-solvent of □-valerolactone (95%) and water (5%) that has an HSP of 25.0 MPa0.5 and KT-SP acidity, basicity and polarity values of 0.18, 0.61 and 0.93.

The reason why the mixed-solvent can be used to replace the hazardous solvent can be attributed to the favorable mixed-solvent basicity that is caused by local composition enhancement and the sufficiently low acidity for the given solute of the application. Other solvent replacement examples will be discussed in the lecture.

Mdm. Rohani Mohammad
Principal consultant
Neoconsult Sdn Bhd

Mdm. Rohani obtained her BSc degree from North London University in 1978 and Masters' degree in Radiopharmaceutical Chemistry in 1983. She is the Principal consultant for Neoconsult Sdn Bhd, an ISPE Malaysia affiliate, with more than 25 years of working experience in quality management with the pharmaceutical industry, both multinational and local organisations.

Her early involvement in the pharmaceutical industry since the early 80's concentrated on quality control laboratories; and the development of laboratory operations and management systems. From the early 90's to the year 2000, her focus progressed to quality assurance mainly in multinational pharmaceutical companies, and later she took on the responsibility for quality assurance in a local pharmaceutical company.

Since 2003, she is a lead figure in Quality Management with her areas of expertise being Quality Management (PIC/S cGMP, GDPMD), ISO Certifications (ISO 9000, ISO 18000 and ISO 14000), ISO Certifications – ISO 9000, ISO 18000 and ISO 14000 and ISO/IEC 17025 Accreditation. Amongst the significant initiatives of Rohani and her team include successfully obtaining the regulatory approval for the Cephalosporin Sterile Facility in 2004; the implementation of the Laboratory Information Management System (LIMS) in the QC laboratory of the Bangi Plant; and being responsible for all aspects of Quality Assurance, Quality Control, Quality Engineering (validation and qualification activities) and GMP compliance for pharmaceutical plants.

Synopsis

SESSION 1

In this session, the participants will be introduced to the basic requirements that any regulated QC laboratory will need to understand and follow. Each basic element in the applicable standards will be discussed to give an overview of the overall requirements to ensure compliance to basic GMP requirements for QC laboratory. This session will also introduce the concept of Good (QC) Laboratory Practice.

SESSION 2

Here, the focus is on the auditing for compliance to the requirements of GMP in QC laboratory. The concept of auditing will be explained together with brief descriptions of the audit processes. The roles of the auditees and the auditors will be discussed to give some understanding of what is required when conducting an audit.

SESSION 3

The third session will consist mainly the sharing of some common audit findings in QC laboratory. This will show how the requirements learnt in Session 1 and the auditing processes learnt in session 2 culminate into the audit results which is the audit findings. By sharing the common audit findings, the participants are warned of the most common pitfalls during daily QC operations and thus, will take care to avoid the usual mistakes when performing their daily QC tasks.

Parallel Session 1 (Product Development, Scale Up and Manufacturing Processes)
Time : 1600-1700 (15th August 2016)
Venue : Banquet Hall, Ground Floor
Moderator: Dr. Juliana Md. Jaffri

ID	TITLE	SPEAKER	TIME
46	Budget Impact Analysis on the Introduction of Biosimilar Rituximab and Trastuzumab into Malaysia Market.	Norazrina Pakiman	1600-1620
51	Slow release of ibuprofen encapsulated in gellan gum hydrogel for dressing application.	Khairul Anuar Mat Amin	1620-1640
62	Nanoencapsulation of *Curcuma zedoaria /Allium sativum L.* extracts and their activity against lymphoma cells	Herianto Pandapotan	1640-1700

Parallel Session 2 (Regulatory Affairs and Compliance)
Time : 1600-1700 (15th August 2016)
Venue : Seminar Room 2, Ground Floor
Moderator: Dr. Che Suraya Haji Mohd Zin

ID	TITLE	SPEAKER	TIME
10	Perception of Malaysian Community Pharmacists towards the Impacts of Generic Substitution on Community Pharmacies Profits: A Pilot Study	Tarek Elsayed	1600-1620
52	The relationship of work motivation to production department productivity of PT. Nufarindo Pharmaceutical.	Indra Putra Taufani	1620-1640
53	Pharmacists Perception to the Introduction of the Automated Dispensing System in the United Arab Emirates Pharmacies.	Rana Sammour	1640-1700

Parallel Session 3 (Biopharmaceuticals and Biotechnology)
Time : 1600-1700 (15th August 2016)
Venue : Seminar Room 3, Ground Floor.
Moderator: Associate Professor Dr. Muhammad Taher

ID	TITLE	SPEAKER	TIME
12	Beneficial alteration of blood parameters by telmisartan-pioglitazone combination	Fuzianna Ibrahim	1600-1620
30	Screening and selection of potentially viable probiotics lactobacilli and evaluation of tolerance in acid and bile salt	Hassan Pyar	1620-1640
45	Approaches to modify the nature of xanthan gum and characterizations to improve its functionality	Mohammed Gulzar Ahmed	1640-1700

Parallel Session 4 (Product Development, Scale Up and Manufacturing Processes)
Time : 1400-1500 (16th August 2016)
Venue : Banquet Hall, Ground Floor
Moderator: Professor Zaidul Islam Sarker

ID	TITLE	SPEAKER	TIME
25	Physicochemical stability of *Sonchus arvensis L.* and *Lumbricus rubellus* tablets	Fitra Romadhonsyah	1400-1420
63	Optimization of the Formulation for Ibuprofen-loaded Self-Nanoemulsifying Drug Delivery System	Hannie Fitriani	1420-1440
72	In vitro Analysis of Total Phenolic Contents, Flavonoids and Free Radical Scavenging Activities of Black Cumin Seeds and Oil in Different Solvent Extracts	Mohammad Al-Mamun	1440-1500

Parallel Session 5 (Analytical Method Development & Validation)
Time : 1400-1500 (16th August 2016)
Venue : Seminar Room 2, Ground Floor.
Moderator: Dr. Abd Almonem Doolaanea

ID	TITLE	SPEAKER	TIME
11	Development and validation of a LC- MS/MS method for simultaneous quantitation of telmisartan and pioglitazone in rat plasma	Pinaki Sengupta	1400-1420
20	Development of a Liquid Chromatography Mass Spectrometry (LCMS) Method for Simultaneous Determination of Phosphodiesterase-5 Inhibitors	Nur Baizura Bujang	1420-1440
19	Analytical Method Validation for Pharmaceutical Industries	Nizamil Fairuz Yahya	1440-1500

Parallel Session 6 (Product Development, Scale Up and Manufacturing Processes)
Time : 1400-1500 (16th August 2016)
Venue : Seminar Room 3, Ground Floor
Moderator: Dr. Bappaditya Chatterjee

ID	TITLE	SPEAKER	TIME
08	Subcritical carbon dioxide extraction of *Stereospermum fimbriatum's* stem bark and the extract's potential as an anti-dermal infection agent	Anis Fadhlina Izyani Awang	1400-1420
09	Enriched extracts of antidiabetic compounds from neglected weed *M. pudica* using supercritical and subcritical carbon dioxide extractions and the corresponding *in vitro* study for diabetes mellitus	Tasnuva Sarwar Tunna	1420-1440
69	Optimization and formulation of glimepiride self-nano emulsifying drug delivery system (snedds)	Yandi Syukri	1440-1500

Parallel Session 7 (Biopharmaceuticals and Biotechnology)
Time : 1500-1600 (16th August 2016)
Venue : Banquet Hall, Ground Floor.
Moderator: Bro Muhammad Badri Abdul Kudos

ID	TITLE	SPEAKER	TIME
23	Anti hyperlipidemic activity of *Vigna Mung Linn*	Anjana Male	1500-1520
29	Antihelmentic activity of *Annona reticulata Linn* leaf extracts	Grandhi Surendra	1520-1540
74	Arborinine from *Glycosmis pentaphylla (retz.)* DC. induces apoptosis through activation of caspase-3/7 in Human Mammary Gland Adenocarcinoma (MCF-7) cell line	Nurlaili Najmie Mohd Hussain	1540-1600

Parallel Session 8 (Product Development, Scale Up and Manufacturing Processes)
Time : 1500-1600 (16th August 2016)
Venue : Seminar Room 2, Ground Floor
Moderator: Dr. Hazrina Ab Hadi

ID	TITLE	SPEAKER	TIME
07	Compatibility study between paracetamol and pharmaceutical excipients used in liquid dosage forms	Muhammad Salahuddin Haris	1500-1520
27	Microbiology stability of *Sonchus arvensis L.* and *Lumbricus rubellus* tablets	Mira Amaliasari Sitorus	1520-1540
32	Effect of process variables on the preparation of BSA loaded double-walled poly(lactide-co-glycolide) microspheres	Mokhlesur Rahman	1540-1600

POSTER PRESENTATIONS

Poster Presentation Session 1
Time : 1210-1235 (15th August 2016)
Venue : Grand Hall, 1st Floor.

ID	TITLE	PRESENTER	TIME
03	Process validation for pilot-scale production of betamethasone 17-valerate emulsions using palm olein as topical drug delivery vehicle	Thazin Win	1210-1235
13	Characterization and stability evaluation of melt mixed solid dispersed nisoldipine with improved solubility	May Kyaw Oo	
31	Immediate release beads	A. Samah Hamed	
33	Tc99m DTPA: a tool in dynamic renal imaging	Mohamad Shahrir Abdul Rahim	
38	Swelling index, gel fraction, thermal and rheological properties of *Centella asiatica* hydrogel	Afnan Ahmed	
44	Effect of neutron irradiation on the physicochemical properties of Naproxen Sodium	Mohamed Awang	
54	Development and characterization of topical analgesic ointment-from lab to production scale	Noor Adibah Md Adib	
60	Fabrication of *Gentamicin* and *N. sativa* oil loaded PLGA Microspheres and The Comparison of Extended Release Profile Between Powdered and Compressed Forms	Farahidah Mohamed	
64	Optimization of thymoquinone-plga loaded nanoparticles by full factorial design	Luqman Muizzuddin Mohd Rosli	
71	Surface-active proteins in *Syzygium aromaticum* extract for the stabilisation of pal olein-in-water emulsion	Kausar Ahmad	
75	A study on rheological properties of various gelling agents for topical applications	Mohammad Nasrin Abdul Rahman	
76	Optimization of extraction method to obtain chitosan from squid pen	Hazrina Hadi	

Poster Presentation Session 2
Time : 1235-1300 (15th August 2016)
Venue : Grand Hall, 1st Floor.

ID	TITLE	PRESENTER	TIME
14	A review of phytochemical and pharmacological profiles of *Piper sarmentosum*	Nor Farahiyah Ghazali	1235-1300
24	Antimicrobial potential of various solvent extracts from leaf, stem and root of *Anisophyllea disticha*	Nurul Ashikin Abdul Bari	
28	Antioxidant capacities and phenolic profile of four Saudi Arabia date palms (*Phoenix dactylifera L.*) varieties	Nurfatin Nazirah Hamzah	
34	Anticancer properties of thymoquinone and dithiocarbamate metal complexes against oral squamous cell carcinoma HSC-3 and HSC-4 cell lines	Wastuti Hidayati Suriyah	
35	Antioxidant activity study and tyrosinase inhibitory screening of *Entada spiralis ridl.* leaves	Sharifah Nurul Akilah Syed Mohamad	
36	Phytochemical profile and free radical scavenging activity of *Entada spiralis Ridl.* stem bark	Fatimah Opeyemi Roheem	
37	Anticancer effects of *Eurycoma longifolia, Nigella sativa* and *Hibiscus sabdariffa* on ovarian cancer cells	'Afif Raihan Abdullah	
43	Isolation and identification of flavonoids from *Tetracera indica Merr. (dilleniaceae)* leaves	Alhassan Muhammad Alhassan	
50	Pharmacological activities and comprehensive metabolite profiling of *Clinacanthus nutans* extract and fractions.	Md. Ariful Alam	
55	Development and validation of high performance liquid chromatography method for analysis of Raloxifene HCL in rat plasma by liquid –liquid extraction	Syed Mahmood	
61	Cytotoxic study of *Knema laurina* and *Antidesma orthogyne* extracts on human breast cancer cell line MCF-7	Sama N. Shaban	
68	Antioxidant activities of five compounds isolated from the leaves of *Tetracera indica Merr.*	Qamar Uddin Ahmed	

Poster Presentation Session 3
Time : 1240-1300 (16th August 2016)
Venue : Grand Hall, 1st Floor.

ID	TITLE	PRESENTER	TIME
22	Cytotoxicity study of newly-synthesized carbonyl thiourea derivatives on pathogenic Acanthamoeba and its quantitative structure-activity relationship (QSAR) analysis	Maizatul Akma Ibrahim	1240-1300
26	Halal meat adipose tissue: a novel sources of adiponectin	Nuraniza Azahari	
40	*Phaleria macrocarpa* seed as alternative vegetable oil with nutraceutical values	Munzir Halib	
49	The role of polyamines in growth inhibition induced by *Momordica charantia* and *Gynura procumbens* in human lung adenocarcinoma cells, A549	Radiah Abdul Ghani	
56	Turning eel oil into gummy candies: A potential innovative nutraceutical product of eel (*Anguilla sp.*)	Desi Rahmawaty	
57	Development and validation of bioanalytical method for the detection of gliclazide in human plasma.	Mohamed Alaama	
59	Analysis of the influencing factors of *gentamicin-N. sativa* oil emulsions (GNE) characteristic using Plackett-Burmann design (PBD)	Mohd Affendi Mohd Shafri	
65	Understanding and perception towards generic medicines among final year pharmacy students, International Islamic University Malaysian: A quantitative Insight	Shazia Jamshed	
67	Preparation, characterization and factor effect screening of plasmid DNA loaded in PLGA/chitosan/ *Nigella sativa* oil microparticles	Mohd Fakhrul Radzi Mamat	
77	Sensory analysis of texture and appearance lip balm containing olive oil	Hazrina Hadi	
78	Influence of drug:polymer ratio in entrapment of salicylic acid into microsponge	Hazrina Hadi	
79	An evaluation of UNIFAC model for the prediction of solubility of mefenamic acid in organic solvents	Siti Kholijah Abdul Mudalip	

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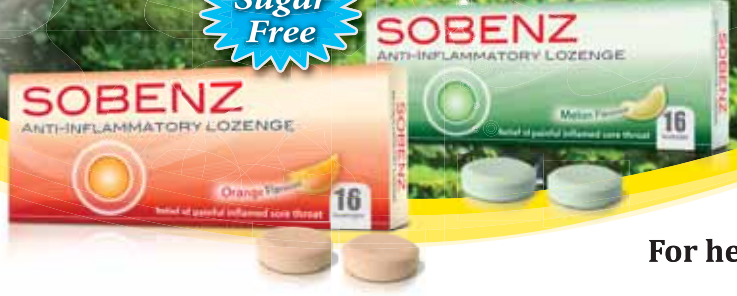

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5 Yankell SL, Welch CA and Cohen DA : Evaluation of Benzydamine HCl in patients with aphthous ulcers. Continuing Education Article

For healthcare professionals only

Full prescribing information available upon request.

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CCMPD/PMA(E)197-16/SOB/IIUM

RGS Corporation Sdn. Bhd.

(Company No: 864802-V)

Product Range:

- X-Ray Diffraction (Benchtop and High end system)
- Wavelength Dispersive X-Ray Fluorescence
- Energy Dispersive X-Ray Fluorescence
- Thermal Analyzer (TG-DTA, DSC, TMA, TG/DTA-MS, TDL)
- Raman Spectrometer (523nm, 785nm, 1064nm)
- Benchtop Nuclear Magnetic Resonance Spectrometer (^{1}H, ^{13}C, ^{19}F, ^{31}P)
- Scanning Electron Microscope (SEM, SEM/EDS)
- Atomic Absorption Spectrometer (Flame, Graphite AA, Hydride system)
- UV-VIS Spectrophotometer
- Sample Preparation Tools (Crusher, Mill, Sieve, XRF Fusior

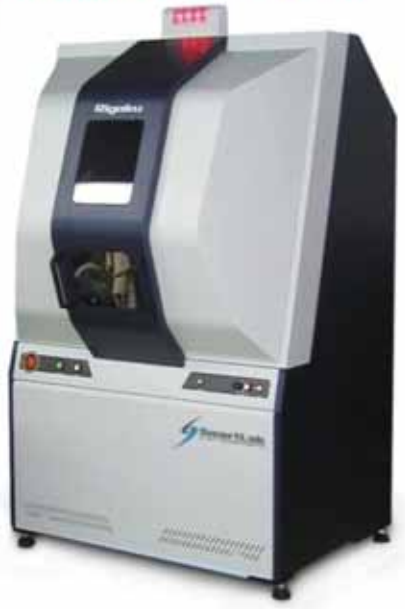
COXEM

Rigaku

nanalysis

technospex

Rigaku XRD Smartlab



Benchtop NMR

Benchtop SEM/EDX

RGS CORPORATION SDN BHD (864802-V)
SB15, Serdang Skyvillas,
Jalan SP 5/5, Tmn Serdang Perdana,
43300 Seri Kembangan,
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Email: info@rgscnet.com
Website: www.rgscnet.com

Rigaku EDXRF

µRaman

KOTRA PHARMA

FROST & SULLIVAN
2011 BEST PRACTICES AWARD
Malaysian Pharmaceutical Company of the Year
Generics Drug Category

FROST & SULLIVAN
2014 BEST PRACTICES AWARD
Malaysia Pharmaceutical Company of the Year
Generics Drug Category

KOTRA PHARMA (M) SDN. BHD.
WINNER OF
INDUSTRY EXCELLENCE AWARD
for
PHARMACEUTICAL CATEGORY
Organised By
NATIONAL PHARMACEUTICAL CONTROL BUREAU
MINISTRY OF HEALTH MALAYSIA
2012

Pharmaceutical Excellence Recognised

With over 30 years of pharmaceutical experience under its belt, Kotra Pharma is well on its way to achieve its mission to be the centre of excellence for the pharmaceutical industry. Having grown from a Malaysian brand to globally recognised in over 30 countries, Kotra Pharma's rapid progress did not go unnoticed.

Kotra Pharma received one of the highest forms of acknowledgement from the National Pharmaceutical Control Bureau, Ministry of Health Malaysia., whereby the company was nominated and awarded the inaugural *Industry Excellence Award 2012*, for its leadership in the field of Good Manufacturing Practice (GMP).

Along with this recognition, Kotra Pharma was bestowed twice the title *Malaysia Pharmaceutical Company Of The Year* for 2011 & 2014 by Frost & Sullivan, a US-based consulting firm, for its leadership in customer value and innovation.

These accolades serve to further establish Kotra Pharma's presence within the pharmaceutical industry as well as encourage us as a company to continuously grow and seek better product innovation, manufacturing excellence and geographical expansion to bring accessible healthcare to all.

This effort, true to our vision of *Humanising Health where we believe everyone deserves a healthier tomorrow*, is further supported by Kotra Pharma's commitment to deliver quality medicines to healthcare providers worldwide by applying cutting edge pharmaceutical research and manufacturing technology.

To date, our pharmaceutical (Axcel® and Vaxcel®) and nutraceutical products (Appeton®), have globally benefitted patients and communities as we continue to grow, seeking new and improved ways to constantly fulfil our healthcare needs in an ever changing environment.

Committed to our vision, we have invested USD50 million in the first phase of a total USD150 million state-of-the-art manufacturing and research facilities, which constitute the largest single-investment in the Malaysia pharmaceutical industry to date.

At Kotra Pharma, your patient's health is our priority.

KOTRA PHARMA

Kotra Pharma (M) Sdn Bhd (90082-V)
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KOT/OTH/GEN/GEN/Sep14/29

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E-MAIL: sales@jentro.com.my

CATEGORY	PRODUCT NAME	CAS NO	STANDARDS	AUTHENTICATE
Anti-virus & Hepatitis	Daclatasvir dihydrochloride	1009119-65-6	In-hosue	DMF
	Dolutegravir	1051375-16-6	In-house	R&D
	Entecavir monohydrate	209216-23-9	In-hosue	GMP/DMF
	Ledipasvir Acetone	1441674-54-9	In-house	DMF
	Ledipasvir Copovidone	N/A	In-house	DMF
	Ribavirine	36791-04-5	CP/USP/EP	FDA/GMP/TGA
	Sofosbuvir	1190307-88-0	In-house	DMF
	Tenofovir alafenamide	379270-37-8	In-house	Pilot
	Velpatasvir	1377049-84-7	In-house	None
Prostaglandins	Alprostadil	745-65-3	EP	GMP
	Bimatoprost	155206-00-1	USP	DMF Preparing
	Dinoprost Trometamol	38562-01-5	USP	None
	Latanoprost	130209-82-4	In-hosue	None
	Cloprostenol sodium	55028-72-3	In-house	None
Cardiovascular	Ezetimibe	163222-33-1	In-house	Pilot
	Minoxidil	38304-91-5	USP	GMP
	Ramipril	87333-19-5	EP/USP	USDMF/ EDMF
	Diltiazem Hcl	33286-22-5	USP	None
	Telmisartan	144701-48-4	USP/EP/CP	GMP/DMF/ CEP
Antibiotics	Azithromycin	117772-70-0	USP/EP	GMP/FDA Approved
	Clarithromycin	81103-11-9	USP/EP	GMP/FDA/COS
	Fusidic sodium	751-94-0	CP/EP/BP	GMP/ DMF
	Metronidazole	443-48-1	CP/USP/BP	GMP/ DMF
	Polymyxin B Sulphate	1405-20-5	USP	DMF
	Posaconazole	171228-49-2	In-hosue	DMF
	Triamcinolone acetonide	76-25-5	USP	GMP
Antidepressant	Duloxetine hydrochloride	136434-34-9	In-hosue	USDMF/ EDMF
	Fluoxetine hcl	59333-67-4	USP/BP/EP	GMP
	Olanzapine	132539-06-1	USP/EP	GMP USDMF
	Tianeptine Sodium	30123-17-2	EP	None
	Venlafaxine Hcl	99300-78-4	EP	GMP
	Vilazodone Hcl	163521-12-8	In-house	Pilot
Antineoplastic	Fludarabine phosphate	75607-67-9	USP/EP	DMF/COS Approved
	Aprepitant	170729-80-3	In-hosue	None
	Capecitabine	154361-50-9	EP/USP	GMP
	Lenalidomide	191732-72-6	In-hosue	None
	Methotrexate	59-05-2	USP/EP	GMP/FDA
	Pemetrexed disodium 7H2O	357166-29-1	EP	DMF Preparing
Urinary System	Dutasteride	164656-23-9	EP/ In-house	DMF
	Finasteride	98319-26-7	USP/EP	DMF/GMP/CEP
	Tadalafil	171596-29-5	EP/USP	None
	Tamsulosin Hydrochloride	106463-17-6	EP	None

CATEGORY	PRODUCT NAME	CAS NO	STANDARDS	AUTHENTICATE
Corticosteroids	Clobetasol propionate	25122-46-7	CP/USP/EP	GMP/CEP
	Cyproterone Acetate	427-51-0	EP	GMP/CEP
	Epinephrine	51-43-4	USP/EP/BP	GMP/USDMF
	Fluticasone propionate	80474-14-2	USP/EP	None
	Hydrocortisone	50-23-7	EP/USP/CP	GMP
	Levonorgestrel	797-63-7	USP/EP/BP	GMP
	Mifepristone	84371-65-3	CP2010	DMF/GMP
	Prednisolone	50-24-8'	EP/USP	DMF/GMP
	Prednisone	53-03-2	EP/USP	DMF/GMP/CEP
	Progesterone	57-83-0	EP/USP/BP	DMF/GMP/CEP
Others	Adenosine Triphosphate Disodium (ATP)	987-65-5	CP	None
	Baclofen	1134-47-0	USP	GMP
	Bicalutamide	90357-06-5	In-hosue	DMF/EDMF
	Chloral hydrate	302-17-0	CP	None
	Dextromethorphan HBr	125-69-9	USP	GMP/DMF
	Diphenhydramine Hcl	147-24-0	BP/CP/ USP	GMP/SFDA/DMF
	Esomeprazole sodium	161796-78-7	USP/EP	DMF
	Indocyanine Green	3599-32-4	USP/CP	R&D
	Levothyroxine sodium	55-03-8'	USP	None
	Lorcaserin hydrochloride	846589-98-8	In-hosue	R&D
	Lurasidone hydrochloride	367514-88-3	In-house	R&D
	Menthol	2216-51-5	USP	Halal/GMP
	Mirabegron	223673-61-8	In-hosue	R&D
	Moxidectin	113507-06-5	EP	None
	Obeticholic acid	459789-99-2	In-hosue	R&D
	Oxytocin	50-56-6'	EP/USP	DMF Available
	Pentoxifylline	6493-05-6'	EP	GMP
	Phentolamine mesylate	65-28-1	USP	GMP
	Pimobendan	74150-27-9	EP	None
	Pirfenidone	53179-13-8	USP/In-house	None
	Pravastatin sodium	81131-70-6	EP/In-house	GMP
	Praziquantel	55268-74-1	USP	GMP
	Pregabalin	148553-50-8	USP	GMP/USDMF/EDMF
	Rapamycin(Sirolimus)	53123-88-9	In-house/ EP	DMF/GMP
	Tacrolimus	104987-11-3	CP/In-House	GMP DMF
	Tranexamic acid	701-54-2	BP	GMP

- Related intermediates are available upon request
- Intellectual property liability lies in the buyer where patents apply

ACKNOWLEDGEMENT

Our utmost gratitude to all who have
contributed to the realization of the
2nd International Conference on Industrial Pharmacy 2016

SUPPORTED BY

Malaysian Pharmaceutical Society

Background

The degree is a taught programme which invovels full-time coursework and classes. Foundation in the concepts, priciples and technologies of current pharmaceutical industrial matters, as well as management skills, are incorporated into the curriculum, to equip future industrial personnel who will be able to perform efficiently. The Kulliyyah pharmaceutical plant (IKOP Sdn Bhd) supports student learning particularly for practical & training sessions. The plant is GMP certified and is capable of producing solid, semisolid and liquid dosage forms.

Objective

To produce professionals who will be able to manage industrial activities through critical thinking and have the knowledge on current regulatory practice in manufacturing pharmaceuticals.

Admission Requirement

Bachelor of Science with good grades from IIUM and other IIUM recognized University both local and international.

English Language Requirement

Satisfactory proof of profiency of English Language by either:
Test of English as Foreign Language (TOEFL) with a minimum score of 500;
OR
International English Language Testing System (IELTS) with a minimum band of 5.0;
OR
IIUM administered English Placement Test (EPT) with minimum score of 5.0;
OR
Proof of attendance or prior education in universities that use English as the medium of instruction in English speaking countries (United Kingdom, United States of America, Australia, New Zealand and Canada);
OR
Prior education in IIUM.

Summary of the Programme

Core Courses	: 24 Credit Hours
Industrial Training	: 16 Credit Hours (1 Credit Hour/week)
Elective Courses	: 3 Credit Hours
Total Credit Hour for Graduation	: 43 Credit Hours
Duration of study	: 3 semesters (1.5 years)

Student Intake

Intake will in February & September.

Contact us :-

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NOTE

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