

8TH ANNUAL

PHARMACEUTICAL REGULATORY AFFAIRS ASIA

Part of:

PharmaCon
Pharmaceutical Congress Asia

3-6 August 2015

**Grand Copthorne
Waterfront Hotel,
Singapore**

Accelerating Regulatory Approvals to Fast Track your Drugs to the Market

2015 Expert Faculty Include:



Churn-Shiouh Gau
Executive Director/Center for
Drug Evaluation,
Taiwan FDA



Maria Victoria P. Calub
Food-Drug Regulation
Officer IV,
FDA Philippines



Andrea Laslop
Head of Scientific Office, Austrian
Agency for Health and Food
Safety (AGES) PharmMed &
Member, (CHMP), European
Medicines Agency (EMA)



Chau Giang Le
Vice President, Regulatory
Affairs and Scientific
Engagement APAC,
Johnson and Johnson,
Singapore



Koichi Miyazaki
Senior Director, Regulatory
Affairs Group, Asia
Development Department,
Daiichi Sankyo, Japan



Nguyen Ngo Quang
Deputy Director, Administration
of Science, Technology and
Training (ASTT),
Vietnam Ministry of Health,
Vietnam



Dr Noppadon Adjimatera,
SEA Regional Regulatory and
Medical Affairs Director,
Reckitt Benckiser, Thailand



Ikhsan Rambia
Head of International
Regulatory Affairs,
Sanbe Farma, Indonesia



Premnath Shenoy
Regulatory Affairs Director,
AstraZeneca, India

Key Themes for 2015

- ▶ Latest Country-Focused Updates, Regulatory Convergence Trends, Adaptive Licensing and Future Trends
- ▶ Key Product-Focused Regulatory Advice and Strategies in Various SEA Key Markets
 - OTC drugs
 - Generics
 - Biosimilars
 - Vaccines
 - Medical Devices & Combination products
- ▶ Clinical Regulatory Strategies such as Overcoming Challenges in NDAs, MRCTs and Bridging Studies Across the Region
- ▶ Implementing an Effective Global Regulatory Strategy (GRS) and Global Dossier Submission Best Practices
- ▶ Post Market Surveillance Essentials and Compliance

Pre-Conference Workshop: 3 August 2015

Registration in the ASEAN Region: Overview of Dossier Requirements, Time-Frames and Registration Procedures



Post-Conference Special Focus Day: 6 August 2015 Regulatory Strategies for Clinical Trials

Co-located with: **Clinical Trials** 2015



MARKET ACCESS 2015

MEDICAL AFFAIRS FORUM ASIA 2015

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- 8:00 **Registration Opens & Morning Coffee**
 8.45 **Welcome from IBC Asia & Speed Networking**
 8.50 **Chairman's Opening Address**

Asia Pharma Market Outlook

- 9.00 **What are the Key Commercial Considerations for Successful Drug Investment and Development in Asia?**
- Competitive outlook for the Asian pharmaceutical sector: Diversify or focus on core segments?
 - Commercial challenges, issues and potential solutions for successful drug development in Asia
 - Examining the Asian R&D and commercial pathway for a big pharma
 - Incorporating changes in big pharma organizational structures for the integration of Asia R&D
 - Establishing central trial coordination operating models for the Asia-Pacific R&D trial portfolio
 - Exploring collaboration models in Asia for successful drug development
 - Commercial and market challenges for profitable drug development and portfolio development in Asia

Panelists:

Yariv Hefez, Vice President, Strategic Development, Business Development, Portfolio Management and Partnering, Biosimilars, **Merck Serono**, Switzerland
Stewart Geary, Chief Medical Officer, Senior Vice President, General Manager, Corporate Medical Affairs Headquarters, Global Safety Board Chair, **Eisai**, Japan
James Garner, Head, Unit Development Operations, **Sanofi**, Singapore

- 9.30 **What is the Impact of Globalization on Drug Development for Biotech and Local Pharma?**
- Drug development scenario in Asia from regional pharma and biotech
 - Examining the clinical development pathway for regional pharma in Asia
 - How do you bring products to different markets quickly and cost effectively?
 - Current issues and challenges for biotech and local pharma in terms of drug development and approvals in Asia
 - Biotech: Capitalizing on data from human genome projects and improving success rates with bringing products to market
 - Local Pharma: Transitioning from minimal margins with small molecules to new business models in biologics
 - What is the future of drug development in Asia?

Panelists:

Tadashi Fujisawa, Chief Executive Officer, **Mebiopharm**, Japan
Robert Braithwaite, Founder & CEO, **Luqa Pharmaceuticals**, China
Jin-San Yoo, President & CEO, **PharmAbcine**, South Korea
Carl Firth, Chief Executive Officer, **Aslan Pharmaceutical**, Singapore

- 10.00 **Regulatory Convergence, Drug Development Pathways and Access in Asia**
- APAC regulatory convergence, regional harmonization initiatives and future trends
 - Practical advice on how industry can prepare for further ASEAN harmonization initiatives
 - Updates and key considerations in clinical and drug development regulatory pathways in Asia
 - Remaining challenges for existing harmonization initiative
 - Expected future developments- Asia vs TPP vs EU-US TTIP, what else is expected to come?

Panelists:

Churn-Shiouh Gau, Executive Director, Center for Drug Evaluation, **Taiwan Food and Drug Administration (FDA)**, Taiwan
Maria Victoria Calub, Food-Drug Regulation Officer IV, **Food and Drug Administration (FDA)**, Philippines
Andrea Laslop, Head of Scientific Office, **Austrian Agency for Health and Food Safety (AGES) PharmMed & Member, Committee for Medicinal Products for Human Use (CHMP), European Medicines Agency (EMA)**, Austria
Nguyen Ngo Quang, Deputy Director, Administration of Science, Technology and Training (ASTT), **Vietnam Ministry of Health**, Vietnam

- 10.30 **Morning Networking and Refreshment Break**

- 11:15 **Chairperson's Opening Remarks**
Michel Mikhail, Expert in International Global Regulatory Affairs, **Germany**

Country-Focused Regulatory Updates & Clarification of Guidelines

This session features latest country-focused regulatory updates and advice from some of the key authorities and industry opinion leaders in Asia. Each presentation will be followed by Q&A sessions where you are encouraged to voice your pressing queries.

Latest Country Updates & Regulatory Environment Overviews

- Latest updates related to each country's respective regulatory requirements
- Brief overview of each respective regulatory environment
- Challenges faced or common questions asked to authorities
- Tips in dealing with/negotiating with authorities

- 11:20 **Taiwan: Churn-Shiouh Gau**, Executive Director/Center for Drug Evaluation, **Taiwan FDA**

- 11:50 **Philippines: Maria Victoria P. Calub**, Food-Drug Regulation Officer IV, **FDA Philippines**

- 12:20 **Vietnam: Thao Nguyen**, Regulatory and Government Affairs Director, **Roche**, Vietnam

12:50 Networking Lunch & VIP Tables

VIP Table 1: Churn-Shiouh Gau, Executive Director, Center for Drug Evaluation, **Taiwan Food and Drug Administration (FDA)**, Taiwan

VIP Table 2: Maria Victoria Calub, Food-Drug Regulation Officer IV, **Food and Drug Administration (FDA)**, Philippines

VIP Table 3: Andrea Laslop, Head of Scientific Office, **Austrian Agency for Health and Food Safety (AGES) PharmMed & Member, Committee for Medicinal Products for Human Use (CHMP), European Medicines Agency (EMA)**, Austria

Exchange business cards and have an informal chat with the above guests during the networking lunch

- 2:00 **Indonesia: Ikhsan Rambia**, Head of International Regulatory Affairs, **Sanbe Farma**, Indonesia

- 2:25 **Thailand: Dr Noppadon Adjimatera**, SEA Regional Regulatory and Medical Affairs Director, **Reckitt Benckiser**, Thailand

- 2:50 **Japan: Koichi Miyazaki**, Senior Director, Regulatory Affairs Group, Asia Development Department, **Daiichi Sankyo**, Japan

- 3:10 **China: Victoria Elegant**, Vice President, Medical, Clinical and Regulatory Affairs, **Baxter Healthcare**, China

- 3:30 **India: Premnath Shenoy**, Regulatory Affairs Director, **AstraZeneca**, India

3:50 Afternoon Networking & Refreshment Break

4:30 Accelerating Patient Access to Medicines via Adaptive Licensing and Approval Pathways

- Established approval pathways for innovative pharmaceuticals in EU
- Latest EMA program on 'Adaptive Licensing' and 'Adaptive Pathways' focus
- Comparisons with FDA's and PMDA's new approval pathways
- Advanced Therapy Medicinal Products (ATMP), Individualized Medicines, Rare Diseases

Andrea Laslop, Head of Scientific Office, **AGES, PharmMed, Austria and Austrian member at CHMP at EMA (European Medicines Agency)**

5:00 Roundtable Discussions

Each leader will facilitate the discussion for 40 minutes. Leaders will then share key takeaways on the stage for 5 minutes each. Choose your table now! Email sonia.jaya@ibcasia.com.sg

Comparisons of CMC Variations in the Region & Managing Complications

Tong-Lay Crystal Lau, Senior Technical Regulatory Specialist (Global), **GSK**, Singapore

Strategies for Handling Products in Multiple Countries

Jack Wong, Director, Regulatory Affairs Asia Pacific, **Terumo BCT**, Singapore, Founder of **Asia Regulatory Professional Association (ARPA)**

Regulatory Intelligence when Developing Regulatory Strategies for a Global Market

Michel Mikhail, Expert in International Global Regulatory Affairs, **Germany**

- 5:45 **Chairperson's Summary and End of Conference Day One**



9:00 Chairperson's Opening Remarks
Premnath Shenoy, Regulatory Affairs Director, AstraZeneca, India

Identifying Regulatory Pathways & Crafting Regulatory Strategies for Key Products

Overview of the Varied Regulatory Pathways and Crafting Regulatory Strategies for Implementing these Products into Different Asian Markets

9:10 Comparison of Regulatory Trends and Impact on Business Strategy: APAC vs International Regulatory Models – FDA/EMA

REGULATORY PANEL

- Key differences between the APAC regulatory systems vs International regulatory models
- How do the differences in US, EU and ROW affect marketing/commercial activities?
- Do Asian players have the winning formula to secure registrations and win in the US and EU market in the face of globalization?

Moderator:

Ng Cheng Tiang, Asia Regulatory Affairs Regional Director, Teva Singapore

Panelists:

Michel Mikhail, Expert in International Global Regulatory Affairs, Germany

Chau Giang Le, Vice President, Regulatory Affairs and Scientific Engagement APAC, Johnson and Johnson, Singapore

9:50 Regulatory Strategies for OTC Drugs

- Key challenges in OTC drug approvals
- Problems with registration package labelling
- OTC switches
- Innovation of OTC registration in Asia
- Developing an OTC regulatory strategy across Asia and beyond

Eva Kopečna, Head, Regulatory Affairs-Global OTC, Teva UK

10:30 Morning Networking and Refreshment Break

11:00 Strategies for Biosimilars & Vaccines – Key APAC Markets

- Overview and update on Biosimilar guidelines in key markets (China, Korea, India)
- Technical and regulatory challenges for different classes of products
- Regulatory strategy planning for similar biologics
- Overview and update on Vaccines guidelines in key markets (China Korea, India)
- Regulatory expectations of clinical evaluation of Vaccines
- Comparison of requirements for evaluation of biologics including vaccines

Premnath Shenoy, Regulatory Affairs Director, AstraZeneca, India

11:40 Generics Regulatory Pathways

- Generics/Supergenerics regulatory updates in key markets – Thailand, Vietnam
- Regulatory environment for generics in Asia
- Crafting a regulatory strategy for generics approvals in different markets across Asia

Krishna Prasad, Associate Director Regulatory Affairs, Actavis, Singapore

12:20 Regulatory Pathways for Medical Device and Combination Products in Asia

- Latest medical device and combination product regulatory updates
- Clarifying challenges in product classification
- How is Asia/ASEAN adopting to EU medical device standards?
- Post marketing surveillance issues
- Future initiatives and trends of medical device/combination products regulations across Asia

Jack Wong, Director, Regulatory Affairs Asia Pacific, Terumo BCT, Singapore, Founder of Asia Regulatory Professional Association (ARPA)

1:00 Networking Luncheon & VIP Tables

VIP Table 1: Vo Thi Nhi Ha, Vice Head, Division of Clinical Trial Management, Administration of Science, Technology and Training (ASTT), Vietnam Ministry of Health, Vietnam

VIP Table 2: Manish Garg, Medical Director, MSD Pharmaceuticals, Singapore

VIP Table 3: Jeonghoon Han, Regional Medical Director, APAC, Teva Pharmaceuticals, Singapore

Exchange business cards and have an informal chat with the above guests during the networking lunch

Regulatory Considerations for Clinical Development and NDA

2:10 Multi Regional Clinical Trials (MRCTs) for Accelerated Drug Development

- Understanding the diversity of different regulatory processes, requirements and approval timelines in different regions
- Comparing IND type analysis results and data in different countries
- Tips in negotiating with authorities and management of MRCTs

Shun Jin, Regulatory Policy & Intelligence Director, JAPAC, AbbVie Singapore

Yuko Kikuchi, Senior Director Asia Regulatory Affairs, Eisai, Japan

Koichi Miyazaki, Senior Director, Regulatory Affairs Group, Asia Development Department, Daiichi Sankyo, Japan

2:50 Overcoming Challenges in Filing for New Drug Application (NDA) Across Asia

- Considerations for new drug development and clarifying the differences in regulations in ASEAN
- Perspective on ASEAN harmonization
- Transparency, timelines and dossier requirements and the challenges faced
- Strategies for a smooth NDA filing in Asia
 - ~ CTD planning and building
 - ~ Preparing the drug label
 - ~ Dossier review responsibilities
 - ~ Translation issues

Bindoo Chahal, Regulatory Affairs Director, SEA, Lundbeck, Malaysia

3:30 Afternoon Networking and Refreshment Break

Achieving Operational Excellence in Delivering Dossier Submissions

4:00 Preparing Global Dossiers Effectively – Cross Regional Submission Advice

- Global regulatory environment and meeting requirements
- Preparing a global dossier and optimize efficiencies for preparing multiple dossiers
- Dealing with the various submission formats- CTD vs. eCTD vs ACTD
- Certificate of Pharmaceutical Product (CPP) requirements and how to overcome time-challenges
- Outlining varying submission strategies and dossier requirements across regions and countries
 - ~ Streamlined global submission processes
 - ~ Globally integrated operation model to increase efficiencies for global regulatory submissions

Ikhsan Rambia, Head of International Regulatory Affairs, Sanbe Farma, Indonesia

Post Market Surveillance Essentials & Compliance

4:40 CMC Variation Essentials in Lifecycle Management

- New manufacturing site registration (Vaccines)
- Comparability protocol for new manufacturing site registration
- Lifecycle of drug product with multiple drug substances
- Best practices in regulatory submission

Tong-Lay Crystal Lau, Senior Technical Regulatory Specialist (Global), GSK, Singapore

5:20 Chairperson's Summary and End of Conference Day Two

Pre-Conference Workshop: 3 August 2015 | 9am - 5pm

Registration in the ASEAN Region: Overview of Dossier Requirements, Time-Frames and Registration Procedures

This interactive workshop is aimed at all professionals with an interest in regulatory affairs in the ASEAN region. The interaction will feature exchange of practical insights and experience with colleagues. The level of detail in this workshop and interactions will provide a useful extension to the main conference.

By attending this full day workshop, participants will share experience and gain:

- A greater understanding of ASEAN harmonization initiatives and level of implementation across the region
- An overview of particular requirements for country-specific submissions: the do's and don'ts
- Insights for planning approval timelines into your regulatory strategy
- Details about country-specific requirements essential for dossier approval



About Your Workshop Leader

Michel Mikhail, *Expert in International Global Regulatory Affairs, Germany*

Dr. Michel Mikhail has more than 25 years Pharmaceutical Industry experience in Senior roles, with a track record of achievement in R & D and International Regulatory Affairs in large multinational Research-based pharmaceutical companies as well as in the Generic & Biosimilars industry. Dr Mikhail served the DIA as a volunteer contributor since more than 2 decades, as speaker & session chair. Dr Mikhail served on the Safety working group and Efficacy working Group of the European Federation of Pharmaceutical Industry associations (EFPIA) also as a Topic leader. He served on the Regulatory Group of the European branch of the Pharmaceutical Research and Manufacturers of America (PhRMA Europe), on the Regulatory and Scientific Affairs Group of the European Generic medicines Association (EGA), as well as on different associations and organisations. He is member of the organisation for Professionals in Regulatory Affairs (TOPRA). Dr. Mikhail is an Expert in Regulatory Affairs, Regulatory Science and Expert in Biosimilars.

Post-Conference Special Focus Day: 6 August 2015 | 9am - 5pm

Regulatory Strategies for Clinical Trials

9:00 **Welcome from IBC Asia & Speed Networking**

9:10 **Chairperson's Opening Address**

Yuko Kikuchi, *Senior Director Asia Regulatory Affairs, Eisai, Japan*

Clinical Regulatory Pathways: Timelines, Submissions and Regulatory Challenges of Conducting Local Clinical Trials in Key Regions

9:15 **Japan** – **Yuko Kikuchi**, *Senior Director Asia Regulatory Affairs, Eisai, Japan*

10:00 **Thailand** – **Noppadon Adjimatera**, *SEA Regional Regulatory and Medical Affairs Director, Reckitt Benckiser, Thailand*

10:45 **Morning Refreshments**

11:15 **Philippines** – **Julie Anne Odarbe**, *Regulatory Affairs Manager, Allergan Healthcare Philippines*

11:55 **Vietnam** – **Thao Nguyen**, *Regulatory and Government Affairs Director, Roche, Vietnam*

12:45 **Networking Lunch**

2:00 **India** – **Premnath Shenoy**, *Regulatory Affairs Director, AstraZeneca, India*

2:45 **Bridging Studies and Waivers in Asia**

- Clinical data sharing
- Use of harmonized clinical trials data
- Is there any trend towards single dossier requirements in North Asia for Korea, Taiwan, Japan and China with harmonization of ethnic sensitivity assessment?
- Overview of the different routes and possibilities of bridging studies and waivers in Asia
- Strategies in seeking bridging studies and waivers approvals
- Difficulties faced and how they were tackled when seeking bridging waivers in Asia

Shun Jin, *Regulatory Policy & Intelligence Director, JAPAC, AbbVie Singapore*

3:30 **Afternoon Refreshments**

4:00 **Challenges in Drug Safety and Efficacy Reporting**

- Linking PV essentials to Risk Management Plans (RMP)
- Regulatory reporting essentials for drug safety and efficacy
- Dealing with variations in post market approvals across the region
- Crisis management and product recalls

Pai Raghavendra, *Regional Pharmacovigilance Manager, Lundbeck Singapore*

4:45 **Chairperson's Closing Remarks**

4:55 **End of Post-Conference Special Focus Day**

Post-Conference Forum

6 AUGUST 2015 | 9am - 5pm

Join us at IBC Asia's **4th Medical Affairs Forum 2015** – the region's longest running strategy forum where leading medical affairs professionals share best practices, discuss common issues and learn from industry experts to enhance scientific reputation, sustain collaboration, build their brand names and achieve success.

Key areas of focus for this year will be on finding the balance between commercial and clinical functions in medical affairs, with discussions on cross function team collaborations, sustained KOL engagement strategies and developing competent Medical Science Liaison teams to achieve success.

For more information, visit www.medicalaffairsasia.com

MEDICAL AFFAIRS FORUM ASIA 2015



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PharmaCon
Pharmaceutical Congress Asia

3-6 August 2015

Grand Copthorne
Waterfront Hotel,
Singapore

Accelerating Regulatory Approvals to Fast Track your Drugs to the Market

The challenge in Asia is the frequency of changing regulations and increasing time-lags for regulatory approval – Factors which can significantly impact the time to get your products to the market, and in turn adversely affect commercial success.

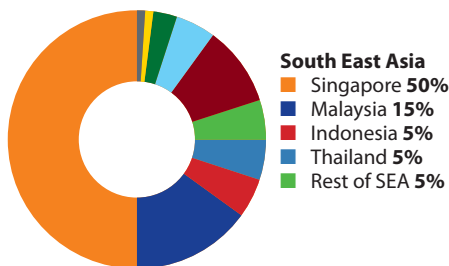
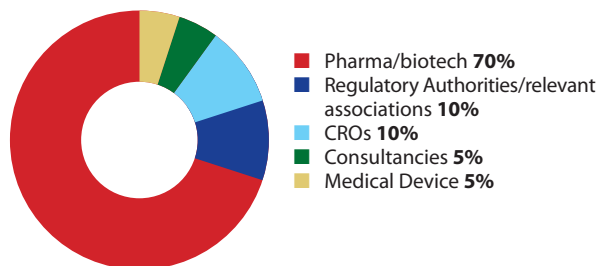
Being up-to-date with current requirements and understanding individual authority interpretation of guidelines is critical for successful product registration.

The 8th annual event will address these concerns with an increased focus on crafting regulatory strategies for efficient drug approvals in each jurisdiction, as well as identifying regulatory pathways for key products across Asia.

Why You Must Attend This Year's Event

- ▶ The ONLY event that has both country and bioproduct focus
- ▶ Wide breadth & depth of pertinent topics covered
- ▶ Ideal networking opportunities with regulatory representatives and industry experts
- ▶ Develop strategies to gain market access into key Asian markets
- ▶ Develop cost-cutting strategies in getting drug approvals
- ▶ Multitude of interactive sessions for you to discuss on the various regulatory topics

Who You Will Meet:



Top 5 Reasons to Attend:

- ▶ Gain exclusive country updates and overview of regulatory environments from industry experts as well as tips to achieve efficient approvals in these key markets
- ▶ Understand regulatory pathways and crafting regulatory strategies for specific bioproducts such as biosimilars and vaccines in different key markets
- ▶ Gain insights on the latest trends towards regulatory convergence, adaptive licensing and formulating global regulatory strategies
- ▶ Breadth and depth of key topics in dealing with both clinical regulatory issues, as well as pharmacovigilance and compliance, will be addressed
- ▶ Extensive networking opportunities with pharmaceutical industry leaders and peers, with co-located events under PharmaCon

PharmaCon
Pharmaceutical Congress Asia

4 Events Under 1 Roof

Clinical Trials
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1. Would you like to raise your visibility in the pharma industry?
2. Could you benefit from showcasing your products & services before key industry players?
3. Are you seeking the lowest cost way of meeting a target audience of decision-makers from the following industries?
 - Big Pharma/Small biotech/large biotech
 - Medical Device/Diagnostics
 - CROs (Global and APAC)

If so, we can help you achieve your goals, perhaps what you need is a branding opportunity at this event! Increase your reach through our extensive marketing campaign, targeted at your qualified business audience.

For information about placing your brand & profile top-of-mind to key buyers, contact **Yvonne Leong**, Business Development Manager on Tel: + 65 6508 2489 or Email: yvonne.leong@ibcasia.com.sg

8th Annual Pharmaceutical Regulatory Affairs Asia

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 3 – 6 August 2015, Grand Copthorne Waterfront Hotel, Singapore
- ☐ I would like to purchase the conference presentations at SGD1000 + GST (SGD1070) per log in.

FEE PER DELEGATE	Early Bird Rate Register & pay on or before 29 May 2015	Special Rate Register & pay on or before 26 June 2015	Normal Rate Register & pay after 26 June 2015	Group Rate (3 or more delegates)
☐ 4 Day Package: 2 Day Conference + 2 Workshops	SGD 3,895	SGD 4,095	SGD 4,295	SGD 3,795
☐ 3 Day Package: 2 Day Conference + ☐ Pre-Conference Workshop OR ☐ Post-Conference Workshop OR ☐ Post-Conference Medical Affairs Forum	SGD 3,395	SGD 3,595	SGD 3,795	SGD 3,295
☐ 2 Day Conference only	SGD 2,695	SGD 2,895	SGD 3,095	SGD 2,595

- Multiple Bookings Discount pricing is applicable to groups of 3 or more delegates from the same organisation registering for the same event, at the same time. Fee stated is the discounted price PER DELEGATE. Only one discount applies; either the early bird rate OR special rate OR group rate.
- All fees stated include luncheons, refreshments and complete set of documentation. It does not include the cost of accommodation and travel.
- Registration fees are subject to the prevailing government tax

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Name: Dr/Mr/Ms _____
 Job Title: _____
 Department: _____
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Delegate 4 Details

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 Job Title: _____
 Department: _____
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Who is Head of Training?

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CANCELLATIONS / SUBSTITUTION

Should you be unable to attend, a substitute delegate is welcome at no extra charge. Cancellations must be received in writing at least 10 business days before the start of the event, to receive a refund less 10% processing fee per registration. The company regrets that no refund will be made available for cancellation notifications received less than 10 business days before the event.

IMPORTANT NOTE

Please quote the name of the delegate, event title and invoice number on the advice when remitting payment. Bank charges are to be deducted from participating organisations own accounts. Please fax your payment details (copy of remittance advice, cheque or draft to +65 6508 2407).

Attendance will only be permitted upon receipt of full payment. Participants wishing to register at the door are responsible to ensure all details are as published. IBC assumes no further liability or obligation, beyond the refund of the paid registration fee, in the event of postponement or cancellation by IBC.

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