11th Annual

WDM SUMMIT 2012

Swissötel Düsseldorf, Germany

26TH - 28TH NOVEMBER 2012

WWW.WDMSUMMIT.COM

INCREASING INNOVATION AND REDUCING COSTS ACROSS GLOBAL OPERATIONS

PROGRAMME

Researched and Produced by:
wtg | pharma

The increasing competition from generics has only added to the immense pressure the industry is under. Companies are responding to the pressure by focussing more than ever on achieving excellence in manufacturing. This will be a central focus to this year's summit. Based on industry case studies, the programme will analyse how each stage of the manufacturing process can be improved to overcome.

Previous speakers include:

- **Dr Olivia Darmuzey,**
  QbD Leader PharmOps, **Novartis Pharma Stein AG**
- **Marc-Antoine Perrissin-Fabert,**
  Head of Knowledge Management & Innovation, **Abbott Healthcare SAS**
- **Ralf Garczorz,**
  VP, Value Chain OTC/CHC, **Johnson & Johnson Consumer Europe**
- **Victor Torres,**
  Master Blackbelt Lean Deployment Global Leader, **Baxter Bioscience**
- **Marcel De Grutter,**
  Manager Automation and MES Expert Group, **Abbott Laboratories**
- **Christian Houborg,**
  Divisional Director, Service and Technical Operations, **H. Lundbeck A/S**
- **Michael Schousboe,**
  Principal Scientist and Project Manager, Manufacturing Science & Quality, **Novo Nordisk**
- **Silvia Alvarez,**
  Black Belt - Process Improvement Coordinator, **Merck Serono**
- **Georg Strieder,**
  Head Pharmaceutical Development, **AOP Orphan Pharmaceuticals A**G
- **Mario Roggero,**
  Director Product and Technology Support, **Ferring Pharmaceuticals**
- **Philippe Heitz,** Head of Engineering, **Novarti**s
- **Leif Osterling,**
  VP Global ERP Programme Management, **Ferring Pharmaceuticals**
- **Dr. Jyrki Syväri**,
  Global Integration Program Lead, Supply Chain Integrity, **Boehringer Ingelheim GmbH**
- **Phil Warner,**
  Director, Lean & Supply Chain, **GKN Driveline**
- **Dr. Dirk Schrader,**
  VP Lean, Global Operations, **AstraZeneca**
- **Mayo Pujols,**
  Director, Manufacturing, **MedImmune**
- **Tobias Massa,**
  VP, Global Regulatory Sciences, Chemistry Manufacturing & Control (CMC), **Bristol Myers Squibb**

Multi-streamed sessions on:

Operational Excellence

Aligning manufacturing with other functions, achieving a sustainable cultural change and technology transfer efficiency

QBD

Risk based quality management approach, real-time release in pharma manufacturing

Globalisation

Developing manufacturing in emerging markets, overcoming the cultural and regulatory barriers

COGS reduction

Cost-effective processes, impact of cost of drug development and Cost of Goods Sold

Facility management and engineering

Flexible, multi-product manufacturing facilities, efficient energy and water management, integrating the latest technologies and continuous manufacturing

Manufacturing IT

Effective data management to improve control and decision making, implementing MES, PAT and automation

For full details download the programme at www.wdmsummit.com.

What are other people saying about World Drug Manufacturing?

"Great networking opportunities and knowledge transfer"
Abbott, Senior Program Manager, Global Engineering Services

"Excellent opportunity to benchmark business excellence strategies with both small and large companies"
Head Production, Biopharmaceutical Operations Huningue, Novartis

"A great opportunity to discuss indsustry issues and share some best practices"
Associate Director Operational Excellence, Genentech

08:00 **Delegate Registration**

09:05 **Chairman's Introductory Remarks**

09:10 **Overcoming the Manufacturing Implications of Emerging Legislation - Remarks from the Regulator**

How can the manufacturer prepare to meet the ever more stringent regulations being published?

- The Falsified Medicines Directive - Ensuring harmonised, pan-European safety and control measures are met
- Developments in Pharmacovigilance - Modernizing existing systems to meet the quality control and patient safety parameters
- What measures are in place by the Regulators to boost the harmonisation of legislative action across the continent?

Gerald Heddell, *Director, Inspection, Enforcement and Standards Division*, **MHRA** UK

09:45 **Achieving Operational Excellence to Leverage Operations & Grow your Business**

Breaking the mould to promote a paradigm shift in how operations can grow your business

- Leveraging operational excellence initiatives in driving business growth
- Analysing the true technical principles behind a shift in excellence
- Understanding how the technicalities of OpEx influence business productivity
- Calculating integral analysis of your operations
- Creating the 'Walls of the Innovation Funnel' in driving new products to market
- **Interactive Exercise:** Addressing the nine tough questions that enable Operational Excellence

Kevin Duggan, *Founder & Author*, **Institute of Operational Excellence**

10:45 **Pre-arranged 1-to-1 Meetings**

12:25

Cultural Shaping & Engagement

Striking a Balance between People Engagement & the Lean Toolkit

Case Study

- Abandoning the 'top to bottom'-type model - Evaluating what level of understanding is needed throughout the hierarchy
- Assuring buy-in from those deploying the programme & deep understanding from those executing it concurrently
- Managing the complexity of lean to streamline its sustainability whilst maintaining technical detail
- Flexibility in Lean - Assessing the natural inclinations of your personnel & adapting the model accordingly, taking mentality into consideration

Jurgen Polak, *Director, Industrial Engineering*, **Astrazeneca** Sweden

Advancing QbD

Adopting an Holistic & Integrated approach to QbD Implementation

- Involving manufacturing input in product and process design in early phase development
- Patient-centric QbD - Designing the manufacturing process according to the needs of both the product and patient
- Generating site-specific risk assessments
- Deploying an effective quality control and monitoring strategy
- Integrating QbD with existing quality management systems

Tech Transfer

Clarifying the Industry's Definition of Tech Transfer in Strengthening Standardisation

Understanding the industry's expectations of tech transfer

- Realising the difference between tangible technology transfer and human knowledge tech transfer
- Best practices in translating intangible technology to transferable data
- Engaging key discussions in knowledge management & sharing
- Ensuring human 'technology' is titrated between levels - Facts, knowledge & experience
- Tackling an ageing workforce - Why does Grandad always know more?

13:00

Interactive Workshop

Formulating a Winning Strategy in Reaching Operational Excellence

- Supporting all levels of the organisation during a lean transformation
- Best practices in implementing and sustaining vital cultural change
- Incorporating existing core principles and systems with lean values and culture
- Determining key challenges areas and resolving them efficiently

Interactive Workshop

Reducing Risk Throughout your Supply Chain

Utilizing a Process Intelligence Platform that spans organizations and geographies

- Realizing supply chain benefits of QbD tech transfer to reduce risk within & between organizations
- Utilizing process intelligence platforms to provide self-service data access, aggregation, contextualization & analytics
- Reporting capabilities to span local and geographically remote process development, quality assurance and manufacturing operations

Justin O. Neway, PhD., *Vice President & Chief Science Officer*, **Aegis Analytical Corporation**

Interactive Workshop

The Need for Lean Models in Optimising the Tech Transfer Process

- Effectively incorporating lean principles into new & existing tech transfer protocols
- Facilitating the flow of scientific knowledge
- Reducing costs, risks and time related to tech transfer
- Sustaining quality in a more effective and productive manner with lean

13:35 **Networking Luncheon**

14:35

Interactive Workshop

Led by Eukerdruck GmbH & Co KG

Interactive Workshop - *Quality Intelligence*

Benchmarking & Continuous Improvement of Quality Systems

Measuring and optimizing compliance and performance of quality systems in an intelligent way

- Exploring the fundamentals, methodology & concept of Quality Intelligence
  Presenting the diagnostic tool (Q- MoD)
- that captures regulatory requirements and industry guidelines
  Considering best practices in risk
- management, lean, agile practices, World Class Manufacturing & other best-in-class sources
- Client case study - Illustrating the QI-methodology on a quality operations topic
- Demonstrating assessment performance & a real deployed diagnostic

Dieter Unseld, Ph.D., *Senior Practice Manager, Quality Intelligence*, **Altran**

Interactive Workshop

Led by Horvath & Partners

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Christian Daxböck, *Principal, Head of Business Segment, Supply Chain Management*, **Horváth & Partner Management Consulting GmbH** Germany
Christoph Ebensperger, *Principal, Head of Business Segment Life Sciences*, **Horváth & Partner Management Consulting GmbH** Germany

15:10

Lean Titration

Titrating Excellence throughout the Organisation

Case Study - Finding the right level of lean at each level of the organisation

- IT & analytical testing to gather concrete data of lean benefits at each level
  Ensuring that, at the start of each lean
- journey, a specific process or division will truly benefit
  Truly understanding the psyche of each
- level and pinpointing what the barriers to change are
- Establishing models to forecast long-term success
- Deploying the most effective training schedules and content for each level

Markus Mattern, *Head, Production*, **Roche** Germany

Quality Function Deployment (QFD)

Structuring Quality System Improvements using QFD Strategies

- Realising the true potential of QFD as a functional precursor to QbD implementation
- Prioritising the reduction of process complexity in highlighting discrepancies
- Simplifying to the root cause vs additional process instalment
  Characterizing key processes and
- business outcomes for comparison with predetermined benchmarks
  Evaluating what areas should be targeted
- as a matter of priority in rolling out the most promising outcomes
- Generating key implementation & improvement strategies moving forward

Contract Manufacturing Facilities

Best Practices in Converting an Inhouse Facility into a Successful CM Venture

- Exploring the benefits & challenges of insourcing
- Efficiently utilizing facility capacity & equipment
- Process design & development
- Regulatory considerations in design space and insourcing
- Implications of insourcing on existing inhouse manufacturing

15:45 **Pre-arranged 1-to-1 Meetings**

17:05

Case Study – Defence

Pitching your Existing Operational Excellence Programme against that of the US army

Promoting strategic alignment, performance improvement, and innovation throughout global operations

- The US Army at a Glance – Key facts & figures of size, people, facilities & global presence
  Generating a deployment plan for
- transformational change – 'As is' vs 'To be'
  Facilitating lasting change in governance,
- business process mapping & shop floor culture using CPI/LSS initiatives
  Deploying the CPI/LSS programme
- throughout the strategic, operational & tactical levels
  Selecting the extent of lean & recognising
- the main areas of focus at each subsequent level to promote lasting change
  Ensuring enduring Army competency
- through the maturity model via CPI/LSS performance & end-to-end process management

Kirk Nicholas, *Director, Lean Six Sigma Programme, Office of Process Improvement, Office of Business Transformation*, **US Army** USA

Case Study - Food Industry

Product Quality & Safety – Preparing your Organisation for Product Recall & Outbreaks

Protecting consumer health & product image through effective generation of recall and worst case scenario strategies

- Exploring clear processes & decision-making plans to limit delays in targeting the problem
  Identifying the extent of an issue rapidly
- and ensuring effective solutions are to hand
  Generating & deploying pre-determined
- recall plans and incident teams in limiting production downtime
- Effectively notifying regulatory authorities, retailers & consumers
- Mitigating product safety & quality incidents from going viral in a digital age
  Promoting the exchange of relevant
- information in a timely manner to the right audience in maintaining brand integrity

Idwin Bouman, *Director SHEQA & Food Safety*, **FrieslandCampina** The Netherlands

Cross Industry Case Study 3

The Best IT Systems in Supporting a Productive Manufacturing Framework

17:40 **Establishing the Next Level of Industrial Excellence**

Case Study

- Diagnostic evaluation of facility excellence - Highlighting gaps in manufacturing productivity
- Establishing what areas are challenged and within what order they need to be remedied
- Structuring similar faulted sites into networks and ensuring that the challenges are tackled, under control and solutions made as effective as possible
- Releasing lean into these faulty areas slowly and in a controlled manner to prevent short-term issues and ensure long-term success

Jean-Paul Kaczmarczyk, *Head, Lean Six Sigma & Transformation*, **Eli Lilly** France

18:15 **Chairman's Closing Remarks**

18:20 **Drink's Reception**

08:30 **Delegate Re-registration**

09:05 **Chairman's Opening Remarks**

09:10 **Panel Discussion - Harmonisation of Regulations & Requirements**

Finding a Common Language between Regulators across the Continent

Gerald Heddell, *Director, Inspection, Enforcement and Standards Division*, **MHRA** UK
Gorm Herlev Jørgensen , *Head of Department PharmaBiotech*, **Danish Medicines Agency** Denmark
Maria Arfwedson, *Director and Head, Pharmaceutics & Biotechnology*, **Medical Products Agency (MPA)** Sweden

09:45 **Evaluating True Risk to Product Quality when Reducing Costs**

Overcoming the challenges of surviving in a generics environment - Lessons to be learnt

- Realising governmental pressures of utilising only the cheapest manufacturing processes
- Evaluating every potential risk to quality when turning to cheaper processes
- Determining what is negotiable in product quality so costs can be reduced in the short-term
- Generating a longer-term strategy to ensure quality parameters continue to be met whilst maintaining cheaper operations

10:20

The Shingo Prize - Achieving Operational Excellence In Drug Manufacturing

The Shingo Model in Driving & Assessing Transformational Change

- Understanding the difference between lean tools, lean management systems, and lean principals
- How striving to understand lean principals can transform your corporate culture
- Implementing lean manufacturing practices into the organisation
- Improving core business processes
- Using the Shingo Prize Model as a benchmark for success

Robert Miller, *Executive Director*, **Shingo Prize Initiative** USA

Quality - Anti-counterfeiting & Serialisation

Understanding the Serialisation Legislation - Where are we Now and What is to be Expected?

Case Study: Preparing your Manufacturing Operations for Emerging Legislation

- Understanding the discussion strategy between the industry and the EU commission - Input & response
- Clarifying the technical details of the legislation to date and filing industry data, concerns and queries
- Generating a strategy without full legislative information & requirements - Preparing for the unknown
- Concerning China - Realising the additional requirements of the East & preparing your global suppliers
- Case Study USA - E-pedigree pilot strategy
- Case Study Germany - E-pedigree pilot strategy

Dr Hans-Walter Hoehl , *VP Global Strategy & Projects, Pharmaceutical Production*, **Bayer HealthCare** Germany

Advancing Facility Technologies

Introducing New Technologies to Accommodate the Personalised Therapy Trend

Case Study

- Utilizing strict process engineering strategies to generate a process plan to efficiently manufacture personalised products
- Incorporating these strategies into start up plants to reach a production baseline
- Introducing process improvements in existing sites to reduce exceptions and streamline process flow
- Advancing automation in facility design and process development
- Overcoming the challenges linked with complex personalised scheduling

Timothy Largen, *Sr Director, Industrial Operations*, **Dendreon Pharmaceuticals** USA

Delegate Roundtable Discussions

10:55

Discussion 1

What is the Next Level of Operational Excellence?

Discussion 2

Defining Concrete ROI on your Lean Projects

Tim Schwarting, *Master Black Belt* , **Novo Nordisk** Denmark

Discussion 3

What are the Engineering Realities of Lean Start-up & Maintenance?

Discussion 4

Determining Key Considerations of Greenfield & Existing Facility Design & Upgrade

Discussion 5

IT & Automation in Strategic Planning

Discussion 6

Managing your CMO Relationships

11:55

Interactive Workshop

Successfully Combining Opex and Quality Management Systems

- Moving Opex initiatives into a new direction
- Realising the true potential of Opex as more than a waste-eliminating initiative
- Integrating Opex into daily business as opposed to have it function as a separate entity
- Taking a more quality-based view on lean by implementing a good Quality Management System
- How we can make Opex the mindset of everything we start to build in pharma and a truly integrated part of the quality

Interactive Workshop

Supply Chain Quality & Integrity

Drug Anti–counterfeiting and Pharmaceutical Supply Chain Integrity

- Verification, Authentication, ePedigree and Tracking & Tracing
- Implementing an integrated mass-serialisation and pedigree application
- Sharing serialised product data across the supply chain
- Overcoming the risks of counterfeit and diverted drugs entering the drug distribution supply chain
- Improving supply chain and brand integrity

Interactive Workshop

Facility Design and Upgrades

Transforming How the Pharma Industry Approaches Drug Manufacturing

- Delivering speed and capital efficiency with control and long-term solutions
- Integrating and simplifying facility operations and systems
- Designing sustainability into the facility to reduce water and energy usage
- Eliminating the need for CIP/SIP rooms and infrastructure
- Flexible solutions in promoting multi-product manufacturing

management system?

12:30

Deploying Operational Excellence as a Strategic Weapon

Moving beyond Conceptual Thinking in Getting the Most from your OpEx Programme

Case Study

- Prioritising leadership engagement in supporting OpEx success
- Applying a focussed approach to train company leaders – Identifying how best to strengthen your staff, facility & overall operations
- Adopting a fully integrated strategy – Building shop floor initiatives into OpEx at the leadership level
- Highlighting what the shop floor really needs from you as a leader
- Generating a broader OpEx map for the shop floor roll-out

Rufus Schuuring, *Global Lead, Operational Excellence*, **Synthon Pharmaceuticals** The Netherlands

Real Time Release Testing (RTRT)

Understanding the RTRT 2012 Guidelines & its Implications on API & Finished Product Manufacturing

- What are the benefits of RTR over a traditional end-product testing strategy?
- What are the production specifications of RTRT?
- Winning strategies in applying RTRT to existing processes
- Extending RTRT to the production of biologicals
- Following documentation guidelines in remaining compliant

Maria Arfwedson, *Director and Head, Pharmaceutics & Biotechnology*, **Medical Products Agency (MPA)** Sweden

- Combining serialisation and pedigree management in a single, integrated application delivering regulatory compliance and business value

Continuous Manufacturing

Establishing Continuous Manufacturing in Pharmaceuticals

Exploring the "ultra-lean" way of manufacturing – Considerations from development and production

- Continuous manufacturing technologies and engineering efforts
- Overcoming the task of implementation
- Efficient process development within the continuous manufacturing paradigm
- Understanding the benefits of continuous manufacturing within R&D and commercial manufacturing
- Process control, QC- and Release concepts
- Understanding the regulatory aspects

Norbert Rasenack, *Team Leader CM-Downstream Solid*, **Novartis Pharma AG** Switzerland

13:05 **Themed Luncheon Discussions**

14:05

Holistic vs Agnostic Deployment

Do Holistic Lean Models Really Work in a Globalised Arena?

Holistic vs Agnostic deployment

- Post-holistic lean deployment - Has a 'big picture' strategy generated the desired results?
- Highlighting the key differences between global facilities that generate challenges to holism
- Evaluating key requirements and adapting lean models down to a facility basis
- Recognising where holistic measures can be afforded and where a more agnostic approach must be adopted

PAT & RTRt

Deploying PAT Systems to Support RTR Testing Pre-approval

Case Study: Reducing manufacturing timelines, whilst boosting product quality & validation

- Installing & maintaining PAT systems throughout manufacturing
- Utilizing near-infrared spectroscopy (NIRS) to rapidly penetrate batches & collect product data for analysis & validation
- Analysing overall time & resource savings vs traditional high-performance liquid chromatography (HPLC) technologies
- Submitting & justifying market applications to global regulators and overcoming key hurdles in approval
- Improving QbD deployment & maintenance
- Massively reducing down-time post-approval in cases of product recall

Amarish Singh, *Director, Global Regulatory Sciences-CMC*, **Bristol-Myers Squibb**

Information Security & Reliability

How is Technology being used to Deliver on Manufacturing Strategies?

Case Study

- Understanding past strategies of tackling data vulnerability – Application-based approaches
- Securing risk assessment, parallel to the move to a more automated system
- Evaluating how risk & security have changed following automation & integration
- What data is critical? Can it be corrupted between the shop floor and management?
- Generating global technology tools & applying them to boost business

Richard Williams, *Lead, Manufacturing IT*, **Eli Lilly** UK

14:40

Manufacturing Technologies

Technical Operations in Streamlining Vaccine Production

Case Study

- Re-defining what the customer-orientated focus of each manufacturing process should be
- Tackling the challenge of high discard and deviation rates in vaccine production
- Embedding technologies with operations in reducing error and waste
- Adapting the Toyota Six Sigma model to vaccine production
- Effectively utilising resources to reduce timelines, boost production and boost cost efficiency

Mayo Pujols, *Director, Technical Operations*, **Merck & Co** USA

Quality Management

Developing a Risk Based Approach to Quality Management

- Adapting quality management systems in avoiding & responding to product recalls
- Reviewing quality, safety and regulatory procedures across the product portfolio
- Implementing failure mode & effects analysis (FMEA) to develop an integrated risk management programme
- Meeting the changing ICH Q guidelines
-

End-to-End Supply Chain Integration

Developing a Matrix-based Supply Chain Organisation

- Enhancing productivity, quality and throughput
- Shifting supply chain paradigms: from bottom and service level focus to holistic business contribution and partnering
- Integrating the supply chain with R&D and commercial functions to improve decision making and quality
- Expanding into new territories via extended distribution models
- Enabling growth through sourcing in external innovation

15:15

Lean in R&D

Translating Lean Principles from Manufacturing to Innovative & more Technical Development Stages

Energy Efficiency & Resource Management

Uncovering and Correcting Lost Green Opportunities in Manufacturing

Fully understanding operational inefficiencies

- Best practices in integrating operational excellence into the highly technical R&D environment
- Bringing standardization methodologies into R&D - A short-term hindrance with long-term benefits
- Reducing timelines & inefficiencies in boosting development success
- Enhancing manufacturing efficiencies with a leaner product from the start
- Ensuring cultural buy-in and principle maintenance

- 'Green' personnel visits to the facility floor to monitor operations and processes first hand
- Enhancing product and process knowledge amongst all personnel to increase waste awareness
- Collating data to improve processes and cut operation costs across the facility
- Further collation of facility data in the generation of a global sustainability strategy

15:50 **Panel Discussion: Reducing Cost of Goods Throughout Manufacturing**

Saving on capital spending whilst improving process efficiency and productivity

- Adopting a holistic approach to investing in existing facility enhancements
- Combating rising costs of manufacturing with COG reduction
- Building COG reduction into the development of the 'facility of the future'

16:25 **Chairman's Closing Remarks**

DELEGATE REGISTRATION FORM

TO REGISTER – please select one of the following options:

- BOOK ONLINE at **www.wdmsummit.com**
  Select delegate booking and quote the booking code in the box below.
- Fill out this form, scan and email it to **martin.fewster@wtgevents.com**
- Fill out this form, scan and fax it to **+44 (0)20 7202 7600**
- Call the booking hotline on **+44 (0)20 7202 7690**

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Job Title: _____

Email: _____

Direct Tel: _____ Mobile: _____

Industry delegate package Fees:

☐ **Royal Society of Chemistry members get 15% off full price of £1995 - Fee: £1,695.75 + Tax (MWST) @19%** (full access to the focus day (26th November) as well as the full conference programme 27th - 28th November)

If you are interested in making a group booking please call us on +44 (0)207 017 7690 for details or reduced rates available.

PAYMENT DETAILS

No. of Delegates: ☐ Amount: £

A 10% service charge will be levied to cover all administration services completed per delegate prior to the event.

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For all enquiries contact:
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the booking hotline on
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VENUE DETAILS

Swissötel Düsseldorf

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YOUR DELEGATE PACKAGE INCLUDES

- Access to the full 3 days 26th - 28th November
- Various networking opportunities including the drinks reception
- On-line Summit catalogue with detailed information on all attendees

Hotel accommodation is not included in the registration fee. Information on suitable hotels will be sent out on receipt of the registration form.

PRE-ARRANGED ONE-TO-ONE MEETING

World Trade Group reserves the right to refuse delegate participation in the one-to-one meeting sessions if entry criteria is not met. Contact us for more details.

wtg ON DEMAND

There's no substitute for being there, but if you cannot attend, purchase the On-Demand package which allows you to relive all the sessions at the summit.
This entitles you to:

- An easy to navigate password protected web site
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☐ Please send me my login for the World Drug Manufacturing Summit 2012 On-Demand package at GBP **£495** + UK VAT (Payment must be received before login details are granted)

TERMS AND CONDITIONS

Participation at event
Organiser will prepare a schedule of meetings and individual delegates will attend the business meeting appointments as detailed on the final itinerary presented to them at the venue.

Cancellation policy
Delegate bookings are transferable but cannot be cancelled. World Trade Group reserve the right to reject delegate applications.

Payment terms
14 days from date of invoice. All bookings are made in accordance with World Trade Group's terms of business. Details available on request.