

PHARMA ANTI-COUNTERFEITING 2014

"COMPETENCES TO COMBAT COUNTERFEITS IN EU & U.S."

23RD & 24TH SEPTEMBER 2014, MARRIOTT HOTEL MAIDA VALE, LONDON, UK

KEY SPEAKERS:-

Wendy Greenall, Head of Anti-Counterfeiting Laboratory for Europe, Middle East & Africa, **Pfizer**

Sumit Munjal, Medical Director, **Takeda**

Maarten Van Baelen, Medical Affairs Manager, **EGA - European Generic Medicines Association**

Gregory Mandoli, Special Agent, **Homeland Security Investigations (HSI) - US Embassy London**

Matthias Heck, Head of Brussels Office, **German Pharmaceutical Industry Association**

Mike Isles, Executive Director of the EAASM, **European Alliance for Access to Safe Medicines (EAASM)**

Chris Doyle, Head of Healthcare Sector, **GS1**

Andrew O'Neil, NIR & RAMAN Product Manager, **SciMed**

Michael Gallagher, Global Applications Manager, **Thermo Scientific**

Jose Henrique Vasi Werner, Partner, **Dannemann Siemsen Advogados (Brazil)**

Pipasha Biswas, Director, **Symogen**

Sophie Molle, IPM Senior Manager, **WCO (World Customs Organization)**

Sandy Eisen, Chief Medical Officer, **Frontline Pharma Consulting**

Franklin Apfel, Managing Director, **World Health Communication Associates**

Phil Lewis, International Cooperation & Legal Affairs Department, Cooperation Programmes Service, **Office for Harmonization in the Internal Market (OHIM)**

Mark Davison, CEO, **Blue Sphere Health**

David Franklin, Director - Brand Protection, **NetNames**

Ashvin Patel, Director of Regulatory Affair (CMC Biologics), **European Regulatory Solutions**

Ruth Hoy, Partner - Intellectual Property & Technology Group, **DLA Piper**

Stephen Wilkins, Secretary General, **Child-Safe Packaging Group**

Plus Many More...

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CONFERENCE INTRODUCTION:-

Growing cases of counterfeiting have resulted in execution of anti counterfeiting technologies. Anti counterfeiting technologies are of two types namely authentication packaging and track and trace packaging technologies. North America currently holds a major share of the global anti counterfeiting market. Asia is said to be the one who has the highest growth rate due to untapped market and significant level of counterfeiting. Europe has a lower growth rate due to a relatively lower number of cases of counterfeiting.

The global anti counterfeiting packaging market is predictable to be worth US\$79.3 billion by 2014, growing at an predictable CAGR of 8.6% from 2009 to 2014. Bar code forms the largest market segment; and is expected to reach US\$26 billion by 2014. However, as the bar code market is attaining development it is growing at a very low CAGR of 0.4% for the same period. RFID market has the highest growth likely and is expected to grow with a CAGR of 20.2% for the same period. North America is the largest segment in the anti counterfeiting market and is predictable to reach US\$49 billion by 2014, accounting for nearly 62% of the revenues rising at a CAGR of 6.8%. Asia is the second largest market and is expected to range US\$14 billion by 2014 with a highest CAGR of 19.7%

Overall world revenue for pharmaceutical anti-counterfeiting technologies will reach \$1.11bn in 2014. Rising concerns about counterfeit drugs worldwide will stimulate demand for drug security, authentication and verification solutions. According to a research company, a market intelligence company specializing in global connectivity and emerging technology, drug counterfeiting is a worldwide criminal enterprise, costing drug manufacturers \$30 billion a year in lost revenue and brand deterioration. The Federal Drug Administration (FDA) and World Health Organization (WHO) estimate that 10% of all drugs worldwide are counterfeit. It is also predicted that 'Pharmaceutical Anti-counterfeiting Technologies Market Will Reach \$1.2bn in 2015'. The worldwide prescription drug market is worth approximately \$800 or \$900 billion. The global market in counterfeit prescription drugs is approximately \$75 billion per year. 80% of counterfeit drugs originate overseas

The wake-up call is that counterfeits REMAIN a SERIOUS THREAT AND GETTING BIGGER while the industry and various stake-holders are mobilizing on their sides for a serious battle. This conference will gather government bodies, pharmaceutical companies and solution and technology providers to discuss the in-depth insights into the strategies and cutting edge technologies for pharmaceutical anti-counterfeiting.

It gives us immense pleasure in welcoming you to **"Pharma Anti-Counterfeiting 2014 - Competences to Combat Counterfeits in EU & USA"**

KEY THEMES DISCUSSED AT THIS CONFERENCE:-

- What issues decide the future of this industry and market?
- Anti-Counterfeiting and Product Security in EU and USA: government policies & strategies
- Discovering successful business models - Opportunities & Challenges
- Develop strategies for using the latest technology throughout your supply chain
- International partnerships and EU & U.S. regulations to combat counterfeit medicines
- US law is changing – Keep yourself updated
- Practical Tips - Strategies for securing the supply chains of the 21st century - authentication, digital serialization, track and trace technologies and government enforcement
- Improve consumer trust by utilizing authentication technologies and educate the public
- Protect your products - Learn how to use the right packaging identification systems effectively
- Plan for your most pressing security concerns
- Effective drug packaging design & technologies enhancing product efficiency, patient and health personnel security, compliance, ease of use
- Establish robust pharmaceutical anti-counterfeiting and brand protection strategy to protect product and brand revenue
- Involve the latest cutting edge serialisation & track & trace technologies for anti-counterfeiting
- Monitor the internet effectively to combat cybercrime and illegal online pharmacies
- Include anti-counterfeiting in your business plan in order to secure product and supply chain safety in your company
- Lead successful diversion and gray market investigations by overcoming investigative barriers
- How the FBI is currently addressing intellectual property crime and partnering with U.S. government agencies?
- Network in our combined exhibition and catering area
- Evening networking reception for all attendees

WHO SHOULD ATTEND:-

- Pharmaceutical manufacturers and distributors
- Healthcare professionals
- Pharmacists
- Brand – protection, enforcement, security, integrity and management companies
- Drug regulatory agencies, customs and police
- Intergovernmental organizations (IGOs) involved in healthcare and IPR protection
- Non-governmental organizations (NGOs) active in healthcare
- Patients' representatives
- Healthcare research organizations
- Pharmaceutical associations
- Anti-counterfeiting organizations
- Packaging, labelling and converting companies
- Authentication technology suppliers
- Anti-counterfeiting service suppliers – IP specialists, investigators, lawyers

WHY SHOULD YOU ATTEND:-

Pharma Anti-Counterfeiting 2014 - Competences to Combat Counterfeits"

Get more from the event, with a broader scope bringing the whole communications value chain together. Enjoy and make the best out of our dedicated networking drinks time, meet the leading companies showcasing the products of tomorrow in the co-located exhibition. Expand your knowledge of the latest business models and strategies in the high-level conference.

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DAY ONE - 23rd SEPTEMBER 2014

08:30 – Coffee and registration

09:30 – Morning Chair's opening remarks

Mark Davison, CEO, Blue Sphere Health
(<http://www.linkedin.com/in/markdavison100>)

MARKET ANALYSIS & CURRENT OVERVIEW

09:40 – **Morning Keynote Address 1: Trade and the Dark Net**

- Discussion of the Intellectual Property Rights Center and Homeland Security Investigations (HSI)
- Overview of black market, online market places and crypto-currency
- HSI investigative efforts

Gregory Mandoli, Special Agent, Homeland Security Investigations (HSI) - US Embassy London

10:20 – **Morning Keynote Address 2: Risk management plan – Protecting your product**

- Risk Management Regulations as per GVP modules
- Challenges of conducting Pharmacovigilance Risk Management for Counterfeit products
- Introducing a system to combine risk and signal tracking actions, whilst conducting quality control activities for counterfeit products
- Improving and adjusting the risk management processes by measuring them correctly
- Assessing different tools in context to counterfeit products in drug risk minimisation strategies

Pipasha Biswas, Director, Symogen
(<https://www.linkedin.com/pub/pipasha-biswas/0/b93/859>)

11:00 – Morning Coffee & Networking

CHALLENGES & OPPORTUNITIES

11:20 – **Morning Keynote Panel Discussion: Challenges and Opportunities**

- Ensuring effective post-marketing surveillance systems to detect and mitigate counterfeits
- How should organizations work together to combat the problem of counterfeiting
- Combating the illegal sale or supply of medicines over the internet sales
- Predicting and dealing with common pitfalls and challenges
- Case study: learning from recent real-world examples

Moderator –

Mike Isles, Executive Director of the EAASM, European Alliance for Access to Safe Medicines (EAASM)

Panelists –

Wendy Greenall, Head of Anti-Counterfeiting Laboratory for Europe, Middle East & Africa, Pfizer
(<http://www.linkedin.com/pub/wendy-greenall/15/5a3/619>)

David Franklin, Director - Brand Protection, NetNames
(<http://www.linkedin.com/pub/david-franklin/0/489/101>)

Franklin Apfel, Managing Director, World Health Communication Associates (<http://www.linkedin.com/pub/franklin-apfel/7/603/942>)

Sandy Eisen, Chief Medical Officer, Frontline Pharma Consulting

BUSINESS MODELS

12:10 – **Fighting Fakes**

- Framing for (re)action- making the case for action
- Crafting policies that can make a difference- "fighting fakes" as a health diplomacy issue
- Using whole-of-government and whole-of-society approaches- "fighting fakes" as a governance issue.
- Applying technology to protect health and well being for all - "fighting fakes" as a human rights issue

Franklin Apfel, Managing Director, World Health Communication Associates (<http://www.linkedin.com/pub/franklin-apfel/7/603/942>)

12:50 - Networking luncheon - Take your discussions further & build new relationships in a relaxed & informal setting...

14:00 – **The NHS mandate for GS1 Coding**

- How the NHS has mandated the use of GS1 Coding across its estate and in private providers.
- The impact of this mandate on the choice of a coding standard for serialisation.
- How the NHS will use GS1 Coding beyond the supply chain for patient safety, product verification and Electronic Health Records.
- How GDSN (Global Data Synchronisation Network) will be used by the NHS and how this can offer competitive advantage to manufacturers

Chris Doyle, Head of Healthcare Sector, GS1
(<http://www.linkedin.com/pub/chris-doyle/4/771/641>)

ANTICOUNTERFEIT - PACKAGING & LABELLING TECHNIQUES

14:40 – **Packaging & Labelling, beyond – staying a step ahead of counterfeiters**

- Using packaging materials and technologies to stay one step ahead of counterfeiters
- Emerging product and packaging trends and technologies
- Track and traceability in pharmaceutical industry
- Package designs and information inserts as copyright works
- Shifting targets - how regulatory and legal responses to counterfeiting creating their own challenges

15:20 – **Afternoon coffee & Networking**

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15:40 – Packaging – Staying a step ahead of counterfeiters

- What factors to take into account for packaging
- Primary and secondary packaging: what solutions are most effective
- Using packaging materials and technologies to stay one step ahead of counterfeiters
- Interactions of drug product with primary packaging and processing equipment
- Strategies for handling changes in packaging materials

Stephen Wilkins, Secretary General, Child-Safe Packaging Group

ENSURING COPYRIGHT & BRAND PROTECTION

16:20 – Copyright as a means for combatting counterfeiting and parallel importation of Pharmaceutical Products

- Successful brand protection procedures
- What should a brand owner be knowing about launching brand protection efforts
- World-wide copyright in literary and artistic works
- Dealing with infringing copies of works
- Enforcement of copyright in pharmaceutical works
- Updates on legal protection

17:00 – Chairperson's closing remarks and end of conference

Mark Davison, CEO, Blue Sphere Health
(<http://www.linkedin.com/in/markdavison100>)

17:10 - 18:10 - Networking Drinks - Take your discussions further & build new relationships in a relaxed & informal setting...



DAY TWO - 24TH SEPTEMBER 2014

08:30 – Coffee and registration

09:30 – Morning Chair's opening remarks

Mark Davison, CEO, Blue Sphere Health
(<http://www.linkedin.com/in/markdavison100>)

SERIALISATION

09:40 – Morning Keynote Address 1: Serialisation – is coming to the global pharmaceutical supply chain

- How serialisation works and which countries are now having traceability laws
- Scoping out your strategy, tactics and implementation for serialisation
- Find out how to avoid investing in wrong places
- Adherence promotion, case management and follow up
- Profiting from serialisation - grey market diversion monitoring and detection; patient communications; controlled substance abuse and misuse; patient adherence and outcomes monitoring.
- Developing a cost-effective approach to implementing serialisation globally

Mark Davison, CEO, Blue Sphere Health
(<http://www.linkedin.com/in/markdavison100>)

IMPACT OF TECHNOLOGY

10:20 – Using molecular spectroscopy (NIR and RAMAN) as reliable tools for counterfeit product detection

- Spectroscopy can detect differences that the eye can't see
- Raman provides accurate material signature
- 1064nm provides greater information than usual 785nm
- Small portable NIR ideal for mobile detection

Andrew O'Neil, NIR & RAMAN Product Manager, SciMed

11:00 – Morning Coffee & Networking

11:20 – Portable Spectroscopy: Screening for Fake Drugs

- Fake Drugs screening
- Counterfeit medicine identification
- Sub-Standard medicine identification
- Chemical fingerprint screening

Michael Gallagher, Global Applications Manager, Thermo Scientific (<https://www.linkedin.com/pub/michael-gallagher/12/572/191>)

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INTELLECTUAL PROPERTY

12:00 – Online brand protection and IP infringement

- How to have a secure and adaptable online strategy to protect your brand
- How to control your brand in an expanding online market
- How to protect against IP infringement with a concrete detection, prevention and response strategy.
- How to leverage the relationship between trademark/IP professionals and the brand protection programme managers for successful results
- Discussing what trademarks brand owners are now registering, what criteria to use and how to protect them thoroughly
- Update on EU policy and legislation update in enforcing brand protection and combating counterfeiting

David Franklin, Director - Brand Protection, NetNames
(<http://www.linkedin.com/pub/david-franklin/0/489/101>)

12:40 - Networking luncheon - Take your discussions further & build new relationships in a relaxed & informal setting...

13:50 – Challenges facing enforcement of IP rights

- Scope and scale and impact of counterfeiting
- Pressure on enforcement authorities
- Political will
- Legal frameworks and
- Consumer demand

Phil Lewis, International Cooperation & Legal Affairs Department, Cooperation Programmes Service, Office for Harmonization in the Internal Market (OHIM)

14:30 – New compliance rules in Brazil

- The new Law 12846/13;
- Positive and negative aspects of the Law;
- What to expect from enforcement authorities;
- "Go do"

Jose Henrique Vasi Werner, Partner, Dannemann Siemsen Advogados (Brazil)

15:10 – Afternoon coffee & Networking

15:30 – WCO IPR activities IPM: a global standard platform between stakeholders in the fight against counterfeiting

- WCO focus on health and safety issues
- IPM mobile application with scanning possibility
- Interception operations
- How can brand owners and security feature providers contribute to this battle?

Sophie Molle, IPM Senior Manager, WCO (World Customs Organization) (<https://www.linkedin.com/pub/sophie-molle/26/462/427>)

REGULATORY

16:10 – Panel Discussion: Recent legislative and regulatory developments

- Update yourself on the recent legal enforcements in EU and US towards Anti-counterfeiting
- Insight into initiatives to promote a global anti-counterfeiting law
- What governments expect from brand holders when addressing IP cases
- Legal aspects of anti-counterfeiting measures for EU & US pharmaceutical stakeholders
- Collaboration & Interaction between stakeholders & law enforcement - Building an interactive network with government & police for investigating & to monitor, track, trace counterfeiting drugs
- Practical legal advice on anti-counterfeiting and brand protection

Moderator –

Ashvin Patel, Director of Regulatory Affairs (CMC Biologics), European Regulatory Solutions

Panelists –

Maarten Van Baelen, Medical Affairs Manager, EGA - European Generic Medicines Association

Sumit Munjal, Medical Director, Takeda
(<http://www.linkedin.com/pub/sumit-munjal/17/400/410>)

Matthias Heck, Head of Brussels Office, German Pharmaceutical Industry Association
(<http://www.linkedin.com/pub/matthias-heck/44/646/325>)

Ruth Hoy, Partner - Intellectual Property & Technology Group, DLA Piper (<http://www.linkedin.com/pub/ruth-hoy/14/73a/b8a>)

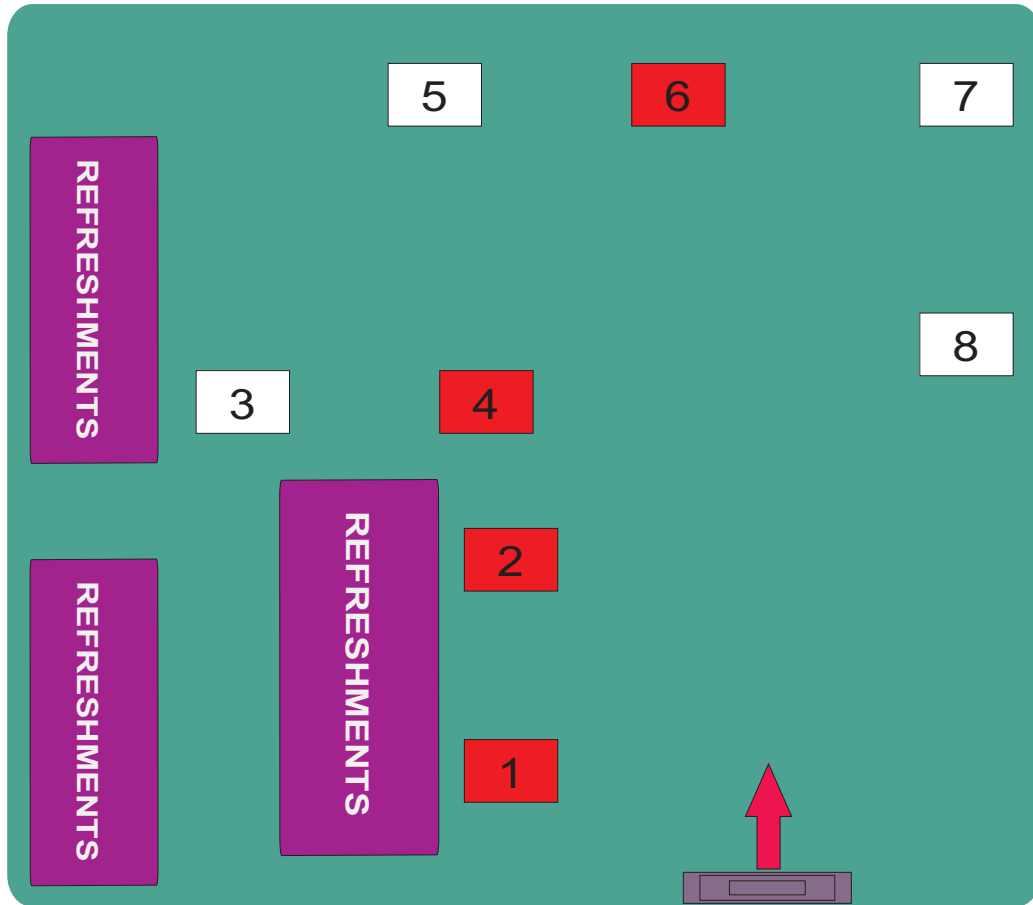
16:50 – Chairperson's closing remarks and end of conference

Mark Davison, CEO, Blue Sphere Health
(<http://www.linkedin.com/in/markdavison100>)

17:00 – End of Pharma Anti-Counterfeiting 2014

FLOOR PLAN - Pharma Anti-Counterfeiting 2014

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2 **AlpVision**

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