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3rd Annual **PHARMA PACKAGING & LABELING**

19-20 MARCH 2013
BERLIN | GERMANY



MEMBERS OF THE JURY:

TASSILO KORAB
Healthcare Compliance Packaging Council, Austria
Executive Director

PHILL MARLEY
AstraZeneca, UK, Packaging Intelligence Manager

JOHN GILL
John Gill Technology Ltd, UK

ANDREW LOVE
Be4ward Ltd., UK, VP, Capability Development

JAN GEISSLER
Patvocates, Germany
CEO - Cancer Policy, Patient Advocacy and Social Media

THOMAS B. DRIES
Honeywell, Germany, Market Development Manager

YOUR PRESTIGIOUS SPEAKER PANEL

TASSILO KORAB
Healthcare Compliance
Packaging Council,
Austria | Executive Director

RAJESH MISHRA
Abbott, India
GM - Packaging Development

MICHAEL NIEUWESTEEG
NVC Netherlands
Packaging Centre |
Managing Director

KAREL VAN DER WAARDE
Avans, University of
Applied Sciences, Breda,
The Netherlands | Professor

DAVID HOWARD
J&J, USA | Global Director
of Product Protection

JIM THOMSON
European Alliance for Safe
Medicines, UK | Chair

JOHN MCKEON
Portalis Limited, Ireland
Technical Director

RUXANDRA ROGOSCA
Former - regulatory affairs
and medical manager
Balkans by Reckitt
Benckiser, Romania

ULRIKE KREYSA
GS1 Global Office, Belgium
Vice - President Healthcare

STEPHEN WILKINS
Child-Safe Packaging
Group, UK | Secretary General

HINRIK PETURSSON
Actavis, Switzerland
Global Artwork Director

FEARGAL MC GROARTY
St. James' s Hospital,
Ireland | Project Manager,
National Haemophilia System

HANS-WALTER HOEHL
Bayer Healthcare Product
Supply, Germany
VP Strategy & Projects, Global
Pharmaceutical Production

PILAR PEÑA
Nekicesa Packaging, Spain
Quality Assurance Manager

**CAROLINA
SANCHEZ CESPEDES**
Eli Lilly, Spain, Manager of
Packaging Operations

ANDREW LOVE
Be4ward Ltd., UK
VP, Capability Development

SUZANNE IVORY
The Perigord Group,
Ireland | Quality Manager

ENDORISING PARTNERS:



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FIND YOUR REASONS TO ATTEND

More recently, there has been a considerable shift in focus towards the role of packaging and labeling. Regulatory compliance is a constant challenge, therefore staying up to date and learning the best practice approaches is crucial for pharmaceutical companies that desire to run with efficient capacity. Fleming Europe's Pharma Packaging and Labeling conference intends to **debate and discover the latest changes and innovations from top industry professionals**. The 3rd year will be featuring the hottest topics that are currently affecting the industry today, such as product recalls, anti-counterfeiting, the most relevant regulations and more. Join us at this exclusive two day "Pharma Packaging and Labeling" conference which will explore innovative packaging design and development, artwork compliance, serialization and labeling strategies, all of which will lead your company to achieve cost effectiveness and sustainability.

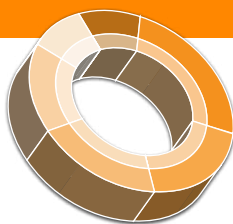
JOIN THE MOST EXTENSIVE
PHARMA PACKAGING & LABELING FORUM OF 2013!

KEY TOPICS

- Explore the latest **regulatory trends** and **industry standards**
- Reveal **innovative case studies** on serialization
- Gain insight into the **strategies used against counterfeiting**
- Learn how to **develop and sustain** excellent packaging, labelling and artwork capabilities
- Obtain information on **multilingual packaging and labeling**
- Plan further progress on **efficiency of drug information**
- Discover effective methods to **ensure patient compliance and adherence**

BREAKDOWN BY DEPARTMENT

PATIENT COMPLIANCE	25%
PRODUCT IDENTIFICATION AND SECURITY	20%
REGULATORY AFFAIRS	19%
PRODUCT DEVELOPMENT	16%
BUSINESS DEVELOPMENT	10%
GLOBAL LABELING	10%



GEOGRAPHICAL BREAKDOWN

WESTERN EUROPE & OTHER	81%
CENTRAL & EASTERN EUROPE (CEE)	12%
SOUTH EAST EUROPE (SEE)	7%



JOB TITLES BREAKDOWN

VPS, HEADS OF DEPARTMENTS, DIRECTORS	57%
C-LEVEL, GENERAL MANAGEMENT, BOARD MEMBERS	29%
SENIOR MANAGERS	14%



TESTIMONIALS

"Outstanding networking opportunities!"

HEAD OF PACKAGING LABORATORY, **BAYER**

"HCPC Alliance' s Award was a unique feature and an enriching benchmark experience"

SOLID PACKAGING CHIEF, **SANOVEL PHARMACEUTICALS**

"Organization was very good."

PPM SITE COORDINATOR, **LILLY SA**

"Interactive sessions with useful real-life business practice, delivered by a great selection of high-level Speakers!"

ASSOCIATE DIRECTOR, PRODUCT AND SUPPLY DEVELOPMENT, **ASTELLAS**

"Choice of location and selection of participants were perfect!"

HEAD OF ANTEAM, **ZENTIVA GROUP**

"Interaction with voting, networking roundtables and panel discussions! Great added value!"

HEAD OF FINAL PRODUCT, **CSL BEHRING**

"Professional organization and handling of all situations!"

PROJECT MANAGER, **NYCOMED**

"Very supportive staff!"

GENERAL MANAGER FOR PACKAGING DEVELOPMENT, **ABBOTT HEALTHCARE**

WHO WILL YOU MEET?

Senior Vice Presidents, Vice Presidents, Senior Executives, Heads, Directors, Managers, Advisors, Strategists and Analysts of Pharmaceutical companies, Biotech companies, HTAs, Governments, Payers, Insurance companies, responsible for Packaging Design/ Labelling, Packaging Technology, Artwork, Quality Assurance, Quality Control and Assurance, Good Manufacturing Practice, Regulatory Affairs and compliance, Product Information, Product development, Operations, Licensing, Marketing and Sales, Patient Compliance, Purchase/Facilities, Manufacturing Technology, International Labeling Liaison, Global Labeling, Project Management, Materials handling/ management, Supply chain and logistics, across Europe.

Following up on the previous two successful conferences, we will reveal the most notable strategic policies at the **3rd Annual Pharma Packaging and Labeling**

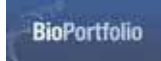
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MEDIA PARTNERS:



Berlin

: THE CITY THAT DESERVES YOUR UNDIVIDED ATTENTION



EUROSTARS BERLIN
HOTEL LUXURY CLASS BERLIN

The Eurostars Berlin Luxury Class is a spectacular business hotel located right on Friedrichstrasse, the most important retail artery right in the heart of Berlin. Its April 2011 opening marked the debut of the Eurostars chain in one of the cities with the busiest trade fair calendar in Europe.

The building stands out for its imposing glass facade and amazing tall atrium, which brings natural light into the entire establishment. The 221 rooms in the hotel, all of them spacious and elegantly appointed, are spread over eight floors.

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DAY 1 | MARCH 19, 2013

9:00 Welcoming note from Fleming Europe

9:10 Opening remarks from the Event Chair - MICHAEL NIEUWESTEEG | NVC Netherlands Packaging Centre | Managing Director

ENSURING COMPLIANCE WITH THE NEW WAVE OF REGULATORY TRENDS AND INDUSTRY STANDARDS

9:15 KEYNOTE ADDRESS: **The Role of Packaging in the War Against Counterfeiting**

- The functions of packaging in the past
- The evaluation of product protection through packaging innovation
- Typical overt, covert, temper evident thinking
- A new approach to forensic packaging analysis & deployment
- Assessing risks, detecting counterfeiting, best practice development, and more

DAVID HOWARD | J&J, USA | Global Director of Product Protection

9:50 **The implementation of anticounterfeiting features in Pharma Packaging Material**

- Types of anticounterfeiting features in Pharma Packaging
- Deciding the proper anticounterfeiting solution: goals, requirements, regulations, resources
- Case study: How to manage efficiently the implementation of AC features in packaging
- Confidentiality in processes: supply chain overview
- Directive 2011/62/EU: a packaging supplier approach

PILAR PEÑA | Nekicesa Packaging, Spain
Quality Assurance Manager

10:25 **Implementation of the European Medicines Verification System (EMVS)**

- Responding to the requirements of the EU Falsified Medicines Directive
- Building a stakeholder coalition for system governance
- Designing a flexible European verification system
- Establishing the operational structure with a service provider
- Preparing a pilot test in Q2/2013

HANS-WALTER HOEHL
Bayer Healthcare Product Supply, Germany
VP Strategy & Projects, Global Pharmaceutical Production

11:00 Morning coffee & networking

11:30 **Benefits of the implementation of GS1 standards – for patient safety and supply chain efficiency**

- Why are global standards needed
- The McKinsey report and its findings
- Global trends in the regulatory environment
- Traceability – why and how

ULRIKE KREYSA
GS1 Global Office, Belgium | Vice - President Healthcare

12:05 **Can we use barcodes on medication packaging to improve patient safety and increase supply chain efficiency? Yes, there's an App for that!**

- Help prevent counterfeit medication entering the supply chain using serialization and GS1 datamatrix barcodes
- Ensure medication is always available for patients
- Minimize medication wastage
- Ensure medication compliance
- Comply with GMP/GCP conditions such as expiry date management and accountability
- Comply with upcoming US and EU requirements
- Provide immediate real-time location of all medication (Track and Trace) in event of a recall

FEARGAL MC GROARTY | St. James' s Hospital, Ireland
Project Manager, National Haemophilia System

12:40 Luncheon

14:00 **Serialisation and Beyond**

- Corporate and site considerations
- How to implement a solution, options 1-4
- What are the benefits
- Next steps, future opportunities and partnerships

JOHN MCKEON | Portalis Limited, Ireland | Technical Director

14:35 SPECIAL FEATURE: **India 2013: Insights into Serialization**

- Indian Government Regulation on Serialization and its compliance by pharmaceutical industries in three phases – tertiary, secondary and primary packages
- Criteria for selecting the robust process and the solution provider for serialization
- Learn from lessons on the ground in India while implementation of serialization – problem faced by pharmaceutical industries to accommodate serialization in existing packing line and the way-out
- Advantages of Mass Serialization in India – its current status and future prospects

RAJESH MISHRA | Abbott, India | GM - Packaging Development

15:10 **Packaging designing with focus on patient adherence**

- The relationship between poor adherence and medical outcome
- The stakeholders that are effected by poor medical adherence
- How can packaging design contribute to improved medical adherence
- Setting up compliance packaging strategy
- The future of compliance packaging

HINRIK PETURSSON | Actavis, Switzerland | Global Artwork Director

15:45 WRAP - UP DISCUSSION **on achieving cost savings through standardization and optimization of packaging**

16:05 Afternoon tea & networking

16:35 INTERACTIVE WORKSHOP: **Applying Accessible and Inclusive Design Principles to Pharmaceutical Packaging**

- Trends in accessible and inclusive packaging design
- Turning ageing into an opportunity
- Business game

MICHAEL NIEUWESTEEG
NVC Netherlands Packaging Centre | Managing Director

17:30 "AWARD APETIZER" - **discussion on Patient Compliance Enhancing Packaging Design**

Short presentation (10-15 minutes) of the packs that the HCPC jury sent to the final three

18:05 Closing remarks from the Event Chair

19:00 Speakers and delegates are cordially invited to attend our
"COLUMBUS AWARD FOR COMPLIANCE ENHANCING PACKAGING DESIGN 2013"
GALA AWARD DINNER HOSTED BY THE HCPC-EUROPE



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DAY 2 | MARCH 20, 2013

8:30 Registration and Coffee

9:00 Opening remarks from the Event Chair

TASSILO KORAB | Healthcare Compliance Packaging Council, Austria, | Executive Director

STRATEGIC CONSIDERATIONS FOR MAXIMIZING THE EFFECTIVENESS OF DRUG INFORMATION

9:10 KEYNOTE ADDRESS: Seeking for effective methods to improve patient compliance and adherence

- Geriatric populations require specifically tailored formulations
- Ensuring the most effective patient compliance and improving safety – enrollment of older populations in trials
- Discovering ways pharmacists can aid in patient compliance and educating patients
- Physician, Pharmacist and Health care provider initiatives

TASSILO KORAB | Healthcare Compliance Packaging Council, Austria | Executive Director

9:45 CASE STUDY: Implementing new technologies and information management to achieve efficiency in packaging operations

- Rapidly changing environment: understand present and future needs
- Strategic approach
- Selection and implementation of the right infrastructure: equipment, systems, organization and processes
- The human factor and its integration in daily work – this is how we do it
- Q&A

CAROLINA SANCHEZ CESPEDES | Eli Lilly, Spain
Manager of Packaging Operations

10:20 Industry experiences with multilingual labeling and packaging

- Single or multilingual? Evaluating labeling needs of countries with more than one language
- Secure the delivery of accurate information in multiple languages - Efficiency and accuracy in proofreading
- Increasing requirements for more details on leaflets
- Limited space versus package size
- No relabelling, more flexibility, cost reduction
- What are the biggest economic concerns?

10:55 Morning coffee & networking

11:25 Enforcement of the Falsified Medicines Directive at European legislative level

- Essential regulatory provisions to be acquainted with
- Characteristics and technical specifications of the “unique identifier”
- Early warning anti-counterfeit platform
- Collaboration and interaction between stakeholders in order to reduce the risks of counterfeit

JIM THOMSON
European Alliance for Safe Medicines, UK | Chair

12:00 Developing and Sustaining Excellent Packaging Labelling and Artwork Capabilities

- To ensure patient safety and reduce recall risk
- What are the critical aspects to consider in your labeling and artwork process design?
- What underpinning capabilities are required to assure your process?
 - Business Processes, Organisation and IT
 - Supporting capabilities
- Making the change happen

ANDREW LOVE | Be4ward Ltd., UK | VP, Capability Development

12:35 INTERACTIVE Q & A SESSION on quality of drug information

12:55 Luncheon

14:10 Quality Management in an Artwork Studio

- Benefits of a QMS in a GMP artwork studio
- A GMP compliant artwork process
- Standards
- How Asset Management and Workflow Technologies improve effectiveness

SUZANNE IVORY | The Perigord Group, Ireland
Quality Manager

14:45 US CPSC: New regulation on child-resistant packaging for certain decongestants - implications for drug manufacturers

- The challenges of compliance
- Balancing an effective child-resistant solution with senior-friendly ease of opening
- The impact on cost & on the existing packaging assembly line
- Will this have a knock-on effect in Europe?

STEPHEN WILKINS | Child-Safe Packaging Group, UK
Secretary General

15:20 Better Information, Better Health! Reading and understanding information about medicines

- Do we really “enable the users to act appropriately”?
- Approaching visual design from the perspective of patients, pharmacists and other professionals
- Providing convincing arguments to support the actions of people
- Combining online and paper?

KAREL VAN DER WAARDE | Avans, University of Applied Sciences, Breda, The Netherlands | Professor

15:55 Increasing brand awareness while complying with European Regulations

- Effective communication of medical information while complying with European Standards
- Fast track to regulatory compliance while complying with regulatory needs, but with patient needs as well
- Status of the “GAP” and Regulatory compliance
- Patient is in the middle of the “whole story”
- Future expectations in regulatory compliance
- Case study from the Balkans

RUXANDRA ROGOSCA | Former - regulatory affairs and medical manager Balkans by Reckitt Benckiser, Romania

16:30 PANEL DISCUSSION: How to design effective end-to-end packaging labelling and artwork process

16:50 Closing remarks from the chair

17:00 Farewell Coffee and Networking