

Informa Life Sciences' 4th Annual

# Labelling and Packaging Compliance for Medical Devices & IVDs

*Uncover the latest regulatory requirements and practical solutions to ensure your current practices are cost efficient and compliant*

20-21 October 2010 • Holiday Inn London Regent's Park, London, UK

[www.informa-ls.com/labelling](http://www.informa-ls.com/labelling)

## Expert Speaker Panel

Joachim Wilke, **Medtronic**, Germany

Scott Mathis, **Siemens Healthcare Diagnostics Inc.**, USA

Virginia G. Serra, Ph.D., **Johnson & Johnson**, Germany

Auke Poutsma, **Medtronic Europe**, The Netherlands

Janice Kite, **GS1 Global Office**, UK

Bianca Gravenhorst Greve, **Coloplast A/S**, Denmark

Holger Most, **Kimberly-Clark Healthcare**, Belgium

Michael Grimm, **Synthes**, USA

Philippe Auclair, Pharmacist, PhD, **Abbott Vascular International**, Belgium

Thierry Wagner, **DuPont Medical and Pharmaceutical Protection**, Luxembourg

Lucie Mattera, **European Diagnostic Manufacturers Association (EDMA)**, Belgium

Anne Van Nerom, **Belgian Competent Authority for In Vitro Diagnostic Medical Devices**, Belgium

## Benefits of attending in 2010

- ✓ Benchmark your current procedures: Gain vital advice from leading **medical device** and **IVD** companies
- ✓ Explore the current proposals for e-labelling for medical devices. Plus benefit from first hand feedback on designing and rolling out a pilot program for electronic labelling
- ✓ Discover the latest initiatives for **Unique Device Identification (UDI)** and **bar coding**. Uncover practical insights for implementation using **GS1 Standards** and how to manage the transition
- ✓ Take away practical solutions for **overcoming language requirements** by establishing an effective translation process for Europe and the Rest of World
- ✓ Examine the importance of the **use of symbols** for overcoming labelling and translation issues
- ✓ **New quickfire panel and question and answer session** looking at labelling and IFU requirements in emerging markets including China & Japan
- ✓ Understand the key regulatory requirements and discuss best practices for operating in a global marketplace

### PRE-CONFERENCE WORKSHOP

Tuesday 19 October 2010

### Written Information Provision Beyond the EU: Spotlight on the Americas

Led by Mark Gibson, **Consumer Information Specialist**, UK

### EVENING SEMINAR & DINNER

Wednesday 20 October 2010

### Practical Solutions to Label Design

Led by: Salma Michor PhD, **CEO & Principal Consultant**, **Michor Consulting EU**, Austria

Media partners:

CLINICA

JOURNAL of  
MEDICAL  
DEVICE  
REGULATION

EDMA

RAJ DEVICES

Medical  
Device

pharmaphorum  
bringing healthcare together

PACKAGING-GATEWAY.COM

CPD  
CERTIFIED  
The CPD Certification  
Service

The course is CPD  
accredited, gaining you  
formal recognition for  
your attendance

Sponsor:

PRISYM<sup>ID</sup>

## PRE-CONFERENCE WORKSHOP Tuesday 19 October 2010

### Written Information Provision Beyond the EU: Spotlight on the Americas

09:30 Registration 10:00 Start 16:00 End of Workshop  
Lunch, morning and afternoon refreshments provided

This workshop is aimed at discussing topics relating to written information provision outside of the EU, with a specific focus on the USA, Canada and emerging markets in South America.

#### Topics to be covered:

- The changing face of written information in the USA
- Colliding cultures: Will there be future convergence or divergence between the USA and the EU?
- Product information in emerging markets: Focus on Argentina and Brazil

#### What attendees will gain:

- The opportunity to share information and learn from emerging trends outside the EU
- Knowledge that may affect attendees directly, relating to global product launches and licensing maintenance in the Americas

Workshop Leader: **Mark Gibson, Consumer Information Specialist, UK**

## Day One: Wednesday 20 October 2010

08:30 Registration

09:00 Opening remarks by the Chairperson

### Initiatives for Labelling by Alternative Means and Electronic IFUs

#### 09:10 E-labelling and Labelling by Alternative Means for Medical Devices: Current Regulatory Status

- Status of legislation
- Issues
- Outlook

**Joachim Wilke, Director Regulatory Affairs & Policy Europe, Medtronic, Germany**

#### 09:45 Designing a Pilot Program for E-labelling for Medical Devices

- To develop or not develop a website for e-labelling?
- What are the roadblocks?
- Implementation issues
- Validation and updates of your site
- Protection measures and risk assessment

**Auke Poutsma, Regulatory Affairs Manager, Medtronic Europe, The Netherlands**

#### 10:20 Requirements and Planning for IVD Labeling Delivery by Alternative Means

- Methods of delivery available to IVD manufacturers
- Regulatory requirements for content and delivery
- Product classification and limitations of use
- Insuring usability and customer satisfaction

**Scott Mathis, Senior Director, Global Product Labeling, Siemens Healthcare Diagnostics Inc., USA**

10:55 Morning coffee and exhibition viewing

### Unique Device Identification (UDI) and Bar Coding

#### 11:25 Unique Device Identification (UDI): Regulation Update and What Will This Mean in Practical Terms?

- Current status and what they expect ideal standards to be
- What will this mean in practical terms?
- Developing the Unique Device Identification System
- Advice to manufacturers on ideal approaches for implementation
- Impact on manufacturing: What will be required to be put on the labels to meet the FDA requirements?
- Timelines: What is the deadline and transition period for compliance?
- Exemptions: Will there be any exemptions?
- Attempts to harmonise regulations between FDA and EU and strategies for global compliance

**David R. Dills, Industry Regulatory & Compliance Consultant, Jacksonville, Florida U.S.A.**

#### 12:00 How Manufacturers Can Implement Standards-Based AIDC and Traceability: Update on GS1 Standards

- Important regulatory and industry developments affecting AIDC and standardisation
- AIDC application standards for healthcare
- How global standards will enable UDI
- Specific marking requirements for different packaging levels
- Standardising traceability processes

**Janice Kite, Director Healthcare Traceability, GS1 Global Office, UK**

#### 12:35 Effectively Utilising Technology Solutions for UDI Implementation Without Derailing Production

- Review options such as web based technology to meet the challenges of global label management across disparate locations
- Discover how to implement UDI with minimal impact on your organisation
- Evaluate the role that smart design and labelling systems can play in meeting all required regulatory elements
- Learn how these systems can also help in meeting 21 CFR Part 11 for security and electronic signatures
- Assess how technology can reduce manual processes and paper trails

**Dave Taylor, Product Manager Life Sciences, PRISYM ID, UK**

13:10 Lunch and exhibition viewing

### Labelling Solutions

#### 14:30 Industry Perspective: Designing a Label and Instruction for Use in Accordance to the Medical Device Directive

- MDD requirements for labelling
- How to fulfil labelling requirements
- Use of symbols
- At what level should the information be included: On the product, primary packaging, retail box or shipper box?
- Country specific requirements for labelling
- Information to be included in Instructions for Use

**Bianca Gravenhorst Greve, Regulatory Affairs Manager, Coloplast A/S, Denmark**

#### 15:05 Classification and Labelling Requirements for Combination Products

- Recent developments in the regulatory framework of medical devices and their impact
- Impact of adjacent regulations and their impact on the labelling of medical devices
- Combination products: Which directives do you need to comply with?
  - Medical Devices - Personal Protective Equipment
  - Medical Devices - Medicinal Products (Drugs)
  - Medical Devices - Biocides
- Borderline issues

**Holger Most, Regulatory Affairs EMEA, Kimberly-Clark Healthcare, Belgium**

15:40 Afternoon tea and exhibition viewing

### Regulations Impacting on Packaging and Labelling for Medical Devices and IVDs

#### 16:10 Environmental Regulations Affecting the Labelling of Devices: REACH and the CLP Regulations

- REACH communication requirements and consequences for labelling - Safety Data Sheets (SDS)
- Labelling of devices containing Substances of Very High Concern (SVHC)
- Effects of the GHS / CLP regulation on the labelling regime applicable to devices
- Other EU environmental legislations affecting the labelling of devices

**Lucie Mattera, Regulatory Affairs Officer, European Diagnostic Manufacturers Association (EDMA), Belgium**

#### 16:45 RECAST of the Medical Devices Directives

The presentation will review the European Commission RECAST project initiated in 2008. The various steps are described and commented on, as well as the industry position. The presentation reviews the possible impact of the EU commission reorganisation which followed the European elections and will give an update on the latest developments.

**Philippe Auclair, Pharmacist, PhD, Senior Director, Regulatory Strategy and Advocacy, Abbott Quality & Regulatory EMEA, Abbott Vascular International, Belgium**

17:20 Closing remarks by the Chairperson and end of day 1

## EVENING SEMINAR: Wednesday 20 October 2010

### Practical Solutions to Label Design

Registration 18:15 – Start 18:30 – End no later than 20:30, Dinner, wine and refreshments will be included

This will be a highly interactive practical seminar in order to establish solutions and best practices to designing a label for medical devices and IVDs. The seminar will highlight regulatory and compliance issues related to designing correct and compliant labels taking into consideration, the updated regulations, label size, single use devices, multi-language labels, use of symbols and much more. Participants will work on selected case studies based on real life examples which will help them gain an understanding of how to design legible and user friendly labels while ensuring regulatory compliance.

Some of the issues being addressed will include:

- Designing a label for regulatory compliance
- Product size considerations for label design, designing a label for small, medium and large medical devices
- Labels for single use devices
- Managing multi-language labels and ensuring correct translation
- Correct use of symbols
- Case study examples of successfully designed labels for a series of product types

Seminar Leader: **Salma Michor PhD**, CEO & Principal Consultant, **Michor Consulting**, E.U. Austria

## Day Two: Thursday 21 October 2010

09:00 Opening remarks by the Chairperson

### Symbols and Language Translation

#### 09:10 Medical Devices Symbols

- What new symbols or changes to symbols are expected?
  - Latest recommendations for use of (negation) symbols
  - New to use symbols with text descriptions: How long are the descriptions required on the label and Instructions for Use?
  - Standards to describe symbols.
  - Use of symbols for phthalates and plastic containing products
  - Legalisation symbol development, selection and validation
  - EN\_980 and ISO\_15223: Clarification of possible merger and timelines to implement if merger will occur
  - Harmonisation approaches: Feedback on current status
- Marieke van't Root**, Consultant Medical Technology, **NEN**, The Netherlands

#### 09:45 IVD: Regulatory Obligation for Labelling and Use of Symbols for IVDs

- Labelling requirements
- Where does the information need to be placed? Can it just be placed on the transportation packages, or is it required on the labels or the device/kit?
- Own brand labelling and other labelling issues for IVDs
- Global harmonisation of symbols
- Specific symbols for IVD
- Clarification of when new symbols still require text translation
- Hazardous labelling: What new symbols are required?

**Anne Van Nerom**, Coordinator, **Belgian Competent Authority for In Vitro Diagnostic Medical Devices**, Belgium

10:20 End of session question and answers

10:30 Morning coffee and exhibition viewing

#### 11:00 Practical Solutions for Overcoming Language and Translation Challenges in Europe

- Language requirements in the EU
- National requirements within Europe
- Best practises of undertaking language translation for 23+ European countries
- How to manage translation processes

**Virginia G. Serra, Ph.D.**, Regulatory Affairs Specialist, **Johnson & Johnson**, Germany

11:35



#### Spotlight Presentation

Spotlight presentations are hosted by leading companies operating in the medical device and in vitro diagnostics field. These sessions offer an opportunity for delegates to learn about the latest products and services. For more information about hosting a spotlight presentation, please contact **Linda Cole**, tel: +44 (0) 20 7017 6631, email: [Linda.Cole@informa.com](mailto:Linda.Cole@informa.com)

12:10 Lunch and exhibition viewing

### Labelling and IFU Requirements in Emerging Markets

#### 13:30 Quick-Fire Panel Session: Labelling and IFU Requirements in Emerging Markets - Asia Pacific

Each speaker will have 20 minutes to give a brief update on the current regulatory status, packaging and labelling requirements for Medical Devices and IVDs and the global harmonisation task force approaches in these regions. This session will be followed by an interactive Q&A session with the speaker panel and the chance to discuss issues in more detail the practical approaches people are taking with these markets.

##### Key points of discussion:

- Regulatory and local labelling requirements for medical devices and IVDs
- Technical issues: Labels required for import and export in these regions
- Translation: How to physically reproduce characters on a label for these markets
- Clarification on instructions for use translations required
- Acceptance of symbols
- Acceptance of global packs and labels
- Developing your labelling strategies for the Asia-Pacific region
- UDI: Where do we stand in emerging markets

Panelists to include:

**Seiko Ohyama**, Lead Engineering Associate Health Science (PAL), **UL Japan**, Japan

Plus a selection of speakers from the conference

14:45 Afternoon tea and exhibition viewing

### Packaging Solutions

#### 15:15 Package Integrity Test Methods for ISO 11607 Compliance

- Package integrity test methods for equipment qualifications and package performance testing
- Comparison of test method sensitivity
- Qualitative and quantitative test methods
- Update on recent standards development
- Case study example

**Michael Grimm**, Senior Packaging Engineer, **Synthes**, USA

#### 15:50 Recent Developments Regarding the Standards for Packaging of Sterile Medical Devices

- The ISO 11607 standards: Current status and path forwards for the future
- Discover the latest developments in microbial barrier test methods
- Understand what regulators require you to prove during validation
- The new upcoming ISO guidance document for ISO11607: Development status

**Thierry Wagner**, Regulatory Affairs Manager EMEA, **DuPont Medical and Pharmaceutical Protection**, Luxembourg

16:25 Closing remarks by the Chairperson and end of conference

### PROMOTIONAL OPPORTUNITIES

- 1 Exhibition • 2 Conferences • 1 Location

Benefit from this exclusive opportunity to access key decision makers involved in **labelling and packaging** across the **pharmaceutical, medical devices and IVD** industries from 2 co-located conferences in one exhibition hall.

#### Labelling and Packaging Compliance for Medical Devices and IVDs

[www.informa-ls.com/labelling](http://www.informa-ls.com/labelling)

#### Pharmaceutical Labelling and Packaging Summit

[www.informa-ls.com/pharmalabelling](http://www.informa-ls.com/pharmalabelling)

Raise your corporate profile by sponsoring or exhibiting at this event. This is a great opportunity to reach a carefully targeted audience. Make use of our excellent promotional and exhibition opportunities which include:

- An exhibition stand
- A spotlight session
- Extensive branding opportunities
- Hosting a lunch or a social function
- Complimentary and discounted conference passes
- Access to the conference attendee list

For more information on the promotional opportunities please contact:

**Linda Cole**, Tel: +44 (0) 207 017 6631  
or Email [linda.cole@informa.com](mailto:linda.cole@informa.com)

Sponsor:



To Register

Tel: +44 (0) 20 7017 7481






Fax: +44 (0) 20 7017 7823

Please Quote:  
CQ7073

Book online: [www.informa-ls.com/labelling](http://www.informa-ls.com/labelling)

Email: [registrations@informa-ls.com](mailto:registrations@informa-ls.com)

## 6 Easy ways to Register

-  +44(0) 20 7017 7481
  -  +44 (0) 20 7017 7823
  -  [registrations@informa-ls.com](mailto:registrations@informa-ls.com)
  -  [www.informa-ls.com/labelling](http://www.informa-ls.com/labelling)
-  The Bookings Department  
Informa UK Ltd  
P O Box 406  
Byfleet  
KT14 6WL

**Group Bookings:** To take advantage of group bookings please contact Simon Lau, Tel: +44(0) 20 7017 7165 email [simon.lau@informa.com](mailto:simon.lau@informa.com)

**Are we mailing you correctly?** To update your contact details on our database please email [integrity@informa.com](mailto:integrity@informa.com)

Your VIP number is on the address label. If there is no label, please quote CQ7073

Type of Pass: Select your pass	Code	Book Before Friday 23 July 2010	SAVE	Book between 23 July & Friday 17 September 2010	SAVE	Book after 17 September 2010	SAVE
Full Pass: Conf + pre conf w/shop + eve seminar	CQ7073CX	<input type="checkbox"/> £2297 + 17.5% VAT = £2698.98	£300	<input type="checkbox"/> £2397 + 17.5% VAT = £2816.48	£200	<input type="checkbox"/> £2497 + 17.5% VAT = £2933.98	£100
3 Day Pass: Conf + pre conf w/shop	CQ7073CX	<input type="checkbox"/> £1998 + 17.5% VAT = £2347.65	£200	<input type="checkbox"/> £2098 + 17.5% VAT = £2465.15	£100	<input type="checkbox"/> £2198 + 17.5% VAT = £2582.65	
2 Day Pass: Conf + eve seminar	CQ7073CS	<input type="checkbox"/> £1698 + 17.5% VAT = £1995.15	£200	<input type="checkbox"/> £1798 + 17.5% VAT = £2112.65	£100	<input type="checkbox"/> £1898 + 17.5% VAT = £2230.15	
2 Day Pass: Conference only	CQ7073C	<input type="checkbox"/> £1299 + 17.5% VAT = £1526.33	£200	<input type="checkbox"/> £1399 + 17.5% VAT = £1643.83	£100	<input type="checkbox"/> £1499 + 17.5% VAT = £1761.33	

### DELEGATE DETAILS – Please photocopy form for multiple bookings!

(Mr/Mrs/Ms/Miss/Dr) Family Name \_\_\_\_\_

Forename \_\_\_\_\_

E-mail \_\_\_\_\_

Tel \_\_\_\_\_ Fax \_\_\_\_\_

Job Title \_\_\_\_\_

Any special requirements? .....

To assist us with future correspondence, please supply the following details:

Head of Department: \_\_\_\_\_

E-mail \_\_\_\_\_

Tel \_\_\_\_\_ Fax \_\_\_\_\_

Booking Contact: \_\_\_\_\_

E-mail \_\_\_\_\_

Tel \_\_\_\_\_ Fax \_\_\_\_\_

Name of Company \_\_\_\_\_

Department \_\_\_\_\_

Address \_\_\_\_\_

\_\_\_\_\_ City \_\_\_\_\_

Postcode \_\_\_\_\_ Country \_\_\_\_\_





Tel \_\_\_\_\_ Fax \_\_\_\_\_

Nature of Company Business \_\_\_\_\_

No. of employees on your site: 1) 0-49  2) 50-249  3) 250-499  4) 500-999  5) 1000+

### PAYMENT INFORMATION

Please invoice

Credit Card. Please debit my:        

Card No:

CVV Number  (this is the 3 digit code on the back of your credit card)

CVV Number Amex  (this is the 4 digits code on the front of your credit card)

Expiry Date: .....

Signature: .....

Credit card billing address: .....

.....

Contact Number for Card Holder: .....

.....

Please note that cards will be debited within 7 days of your registration on to the conference

Yes I agree to the terms and conditions as stated on this form.

Delegates who do not pay with their booking are requested to provide a copy of bank transfer / credit card / cheque details to help payment allocation. Staff at the event will request a credit card guarantee for delegates without proof of payment.

**Venue Details:**  
 Holiday Inn London Regent's Park, London, UK  
Carburton Street  
London  
W1W 5EE England  
Hotel Front Desk: 44-871-942 9111  
Hotel Fax: 44-207-387 2806

**Reduced Rate Accommodation:** The cost of accommodation is not included in the conference fee. Reduced rate accommodation can be booked by using the following link: <http://www.HotelMap.com/M82ZJ>. Alternatively if you would like to book your accommodation by phone, you can call Daniel Spinner on +44 20 7292 2335 quoting Special Reference Code M82ZJ. Please book early to avoid disappointment.

#### Conference Documentation: Cannot Attend?

For those busy executives who cannot take full advantage of this event, the papers give you a useful record of the presentations made at the event. The set of speakers papers and/or slides from the conference is available after the event for £399 + 17.5% VAT. Contact Customer Services on tel: +44(0) 20 7017 7481, fax: +44 (0) 20 7017 7823 or e-mail: [registrations@informa-ls.com](mailto:registrations@informa-ls.com)

#### Terms and Conditions

**FEE:** This includes all technical sessions, lunch and and documentation in electron format.

**CANCELLATIONS:** Cancellations received in writing before and on 5th October 2010 will be subject to a service charge of £99. The full conference fees will remain payable after 5th October 2010. Substitutions are welcome at any time. It may be necessary for reasons beyond the control of the organiser to alter the content and timing of the programme or the identity of the speakers. In the unfortunate event that an event is cancelled Informa are not liable for any costs incurred by delegates in connection with their attendance. This contract is subject to English Law.

**ARE YOU REGISTERED?:** You will always receive an acknowledgement of your booking. If you do not receive anything, please call us on +44(0) 20 7017 7481 to make sure we have received your booking.

**DATA PROTECTION:** The personal information shown on this form, and/or provided by you, will be held on a database and may be shared with other companies in the Informa Group in the UK and internationally. If you do not wish your details to be available to companies in the Informa Group please contact the Database Manager at the above address, Tel: +44 (0)20 7017 7077, Fax: +44 (0)20 7017 7828 or email: [integrity@informa.com](mailto:integrity@informa.com)

Occasionally your details may be obtained from, or made available to, external companies who wish to communicate with you offers related to your business activities. If you do not wish to receive these offers, please tick the box

**INCORRECT MAILING:** If you are receiving multiple mailings or you would like us to change any details or remove your name from our database, please contact the Database Manager at the above address, Tel: +44 (0)20 7017 7077, Fax: +44 (0)20 7017 7828 or email: [integrity@informa.com](mailto:integrity@informa.com) - quoting the reference number printed on the mailing label

**ANY SPECIAL REQUIREMENTS:** Please inform us if you have any special requirements by calling Customer Services on +44(0) 20 7017 7481.