UDIs & Traceability

for Medical Devices Forum

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Main Conference:
25th-26th May 2016

Location:
Munich, Germany

The UDI-Dedicated Networking and Learning Meeting for Device Manufacturers and Healthcare Providers

Expert speakers include:

Ulrike Kreysa,
Vice President, Healthcare,
GS1 Global Office

Ton Van Zijl,
Chairman,
EHIBCC

Andy Crosbie,
Head of Biosciences and Implants, Devices Division,
MHRA

Mark Wasmuth,
CEO,
GMDN Agency

Jackie Pomroy,
Head of Supply Chain,
NHS South of England Procurement Services

Indira Konduri,
GUDID Program Manager,
FDA

The Only Meeting That Allows You to:

- Ensure you are ready for the **new 2016 European UDI guidelines** with **GS1**, **GMDN** and **HIBC**
- Stay up-to-date on **GUDID** and **how it will align with EUDAMED** with the **FDA**
- Network with and hear from **device manufacturers**, **healthcare providers** and **standards bodies**, all in the same room
- Work on the **practical aspects of UDI integration**, from labels and scanners to printing and packaging, and **improve your project efficiency**
- Ensure your **Master Data Management** is set up for GUDID, EUDAMED and supporting your organisation optimally
- Overcome the **challenges of awkward packaging** for labels and discuss Direct Marking
- Look **beyond the immediate compliance necessities** of UDIs to the **wider benefits** – both for businesses and for patients

Exciting for 2016!

- **Focus on the manufacturer-provider relationship** – how device manufacturers can support healthcare providers and vice versa, for the benefit of the patient
- **UK NHS case study** – the challenges of implementation and clear ROI of UDIs
- **Master Data Management** – compliance with GUDID and EUDAMED, but more than that – gaining benefits through MDM for the wider business

"Good variety of speakers from various organisations and extremely valuable to learn from the experiences of others"

– MERCK MILLIPORE

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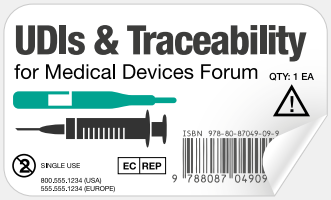

Dear Colleagues,

As the European healthcare regulatory landscape stands on the brink of change, the FDA Class II deadline in September fast approaches, the UK NHS complete the first couple of UDI integrations following their new supply chain mandates, and some countries make their own regulations on UDI known – it's been a very busy year for UDIs!

2016 looks set to be the most important year yet.

That's why we've brought together the most varied speaker panel yet, reflecting the maturing UDI landscape. Device manufacturers stand alongside healthcare providers and standards bodies. UDIs are not simply a single project in a single organisation; they are a multi-stakeholder, ongoing process with patient safety as the end goal and involving everyone in the supply chain along the way.

This year contains many important compliance milestones, but it's really about working together as stakeholders, across a domestic and global landscape. It is through meetings such as this that key relationships can be forged and strengthened, valuable lessons can be learned, and common pitfalls can be avoided.

I very much look forward to the high level of discussion that will take place at this year's forum – see you in Munich!

Best regards,

Arran Oakes
Director,
UDIs & Traceability for Medical Devices Europe

2016 Speaker List:

Andy Crosbie,
Head of Biosciences and Implants, Devices Division,
MHRA

Indira Konduri,
GUDID Program Manager,
FDA

Ulrike Kreysa,
Vice President, Healthcare,
GS1 Global Office

Ton Van Zijl,
Chairman,
EHIBCC

Dawn Fowler,
Sr. Manager, Labeling & Documentation,
Endologix

Mark Wasmuth,
CEO,
GMDN Agency

Jackie Pomroy,
Head of Supply Chain,
NHS South of England Procurement Services

Dr Hajo Reißmann,
Head of Medical Supply Controlling,
University Medical Center Schleswig-Holstein

Michaela Berlich,
Deputy Head of Purchasing,
University Medical Center Schleswig-Holstein

Chris Parr,
UDI Program Manager,
Merck KGaA

Fabien Roy,
Senior Associate,
Hogan Lovells International LLP

Nada Savatic,
Senior Program Manager,
Abbott Laboratories

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Become a member here: www.pharma-iq.com/join.cfm

Day One: Wednesday, 25th May 2016

08.15 **Registration & Networking Coffee**

09.00 **Chairman's Opening Remarks**

09.10 **UDI – What's in the Legislation?**
- IMDRF guidance on UDI
- US UDI system; Timelines and GUDID
- Europe; what's in the proposed regulations

Andy Crosbie, Head of Biosciences and Implants, Devices Division, **MHRA**

09.50 **The UDI Requirements Imposed by the Draft Regulation On Medical Devices: A Stakeholder Perspective**
- Overview of the UDI requirements proposed in the draft regulation on medical devices
- Challenges raised by the proposed UDI requirements
- Benefits of a UDI system for:
  - Medical devices companies
  - The competent authorities
  - Patients and healthcare professionals

Fabien Roy, Senior Associate, **Hogan Lovells International LLP**

10.30 **Networking Coffee Break**

11.00 **GMDN – A Requirement for UDI**
- How to use the new GMDN website to comply with the UDI Rule
- What have we learned from the FDA, half-way through the compliance timetable?
- What to do when you can't find a GMDN Term for your product
- Where are the new markets now using the GMDN?

Mark Wasmuth, CEO, **GMDN Agency**

11.40 **The European UDI & Regulatory Landscape: Staying Ahead!**
- Expected timeframe for adoption and implementation of the EU UDI system (update on the EU decision-making process)
- The EU UDI system in the European landscape (EU/UK, Netherlands etc and how these systems will be working together once the EU UDI system will be implemented)
- The EU UDI system in the global landscape (EU/US, China, Saudi Arabia etc and how to ensure a globally harmonised implementation)
- Get ready for the EU UDI system using GS1 global standards

Ulrike Kreysa, Vice President, Healthcare, **GS1 Global Office**

12.20 **Networking Lunch**

13.30 **UDIs with HIBC**
- Where you see HIBC, UDI is incorporated
- Identical REF and coded UDI, capacities and limits
- Brand new HIBC 2.4 standard features HIBC UDI and internet link with same code symbol

Ton Van Zijl, Chairman, **EHIBCC**

14.10 **FDA GUDID Overview**
- Submissions best practice
- Troubleshooting problems
- Pitfalls to avoid

Indira Konduri, GUDID Program Manager, **FDA** (remote presentation)

14.50 **Networking Coffee Break**

15.20 **Interactive Roundtable Discussions**

Roundtable A
Working Successfully in a Cross-Departmental Project Team

Roundtable B
Handling Unusual Packaging and Labelling Variants – Interactive Session

Roundtable C
Getting Internal Buy-In from Senior Stakeholders
- UDIs as an Ongoing Project, not a One-Time Thing!

16.20 **Panel Discussion:**
UDIs in the European and Global Regulatory Landscape
- How can manufacturers and healthcare providers best prepare for the EU guidelines?
- What key lessons have we learned from the FDA deadlines that are transferrable?
- Developing a global, flexible compliance strategy that accounts for the existing FDA regulations, the upcoming EU guidelines and individual unique requirements (e.g. Turkey, China and Taiwan)

Ton Van Zijl, Chairman, **EHIBCC**
Ulrike Kreysa, Vice President, Healthcare, **GS1 Global Office**
Mark Wasmuth, CEO, **GMDN Agency**
Andy Crosbie, Head of Biosciences and Implants, Devices Division, **MHRA**

17.00 **Chairman's Summary and Close of Day One**

"Very valuable insight into the struggles manufacturers are having."
- GS1

Day Two: Thursday, 26th May 2016

08.30 **Registration**

09.00 **Chairman's Recap on Day 1**

THE HEALTHCARE PROVIDER'S PERSPECTIVE

09.10 **Medical Device Master Data: the Good, the Bad, and the Ugly**

- Streamlining processes to enable the provision of high end medicine for an increasing number of patients at the lowest cost possible without jeopardising patient safety
- Identifying devices by means of reliable data carriers on all devices or their packages - essential for both patient safety and processes!
- Highlighting the additional benefits that can be gained from enhanced master data attributes
- Discussing how manufacturers can leverage the UDI requirements as an opportunity to also optimise their master data for the benefit of their customers and their own business

Dr. Hajo Reißmann, Head of Medical Supply Controlling, **University Medical Center Schleswig-Holstein**
Michaela Berlich, Deputy Head of Purchasing, **University Medical Center Schleswig-Holstein**

09.50 **UDI in the NHS - Challenges and Benefits**

- Practicalities of implementation
- Challenges we came across
- Benefits delivered to date

Jackie Pomroy, Head of Supply Chain, **NHS South of England Procurement Services**

10.30 **Networking Coffee Break**

11.00 **We've Got UDI – Now What Are We Going to Do With It?**

- UDI and patient safety
- Medical device recalls
- Vigilance reporting
- How UDI will improve post-market surveillance

Andy Crosbie, Head of Biosciences and Implants, Devices Division, **MHRA**

11.40 **Case Study:**
Implementation of UDI – Data and GUDID

- Our journey into GDSN
- Leveraging GDSN to satisfy US UDI rule
- Progress to date
- Leveraging current solution to additional UDI requests as they come up (Europe, China, etc.)
- Lessons learned

Nada Savatic, Senior Program Manager, **Abbott Laboratories**

12.20 **Networking Lunch**

13.30 **Case Study:**
UDI Implementation – Opportunities and Challenges for a Global Organisation

- Issuing agency and AIDC selection
- Label design, GMP and logistics
- GUDID account setup and submission
- Maintenance of GUDID master data
- Readiness for UDI in other regions

Chris Parr, UDI Program Manager, **Merck KGaA**

14.10 **Taking Stock: Evaluating Where You Are Now and What You Need to Do Next**

- Which areas of your business will be affected?
- Critical analysis of these areas to identify gaps
- Developing a thorough yet flexible plan to bring these gaps up to compliance

Dawn Fowler, Senior Manager, Labeling & Documentation, **Masimo** (remote presentation)

14.50 **Networking Coffee Break**

15.20 **Interactive Roundtable Discussions**

Roundtable A
Working Successfully in a Cross-Departmental Project Team

Roundtable B
Handling Unusual Packaging Variants

Roundtable C
Getting Internal Buy-In from Senior Stakeholders – UDIs as an Ongoing Project, not a One-Time Thing!

16.00 **Chairman's Summary and Close of Conference**

"The mix of speakers from the industry on one hand and from authorities on the other is great"
- COLOPLAST

Maximise Your Involvement: Sponsorship and Exhibition Opportunities

The European UDI Forum is attended by senior officials and decision-makers from industry, bringing together buyers and suppliers in one location.

Focused and high-level, the event will be an excellent platform to initiate new business relationships. With tailored networking, sponsors can achieve the face-to-face contact that overcrowded trade shows cannot deliver.

Exhibiting and Sponsorship options are extensive, and packages can be tailor-made to suit your individual company's needs. Most packages include complimentary entry passes, targeted marketing to industry officials and executives, and bespoke networking opportunities.

Other features of sponsorship include:

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Who should Attend:

- UDI Project Managers
- Regulatory Affairs Directors & Managers
- Labelling Directors & Managers
- Packaging Directors & Managers
- IT Directors
- Supply Chain Directors
- Healthcare providers & hospitals
- Non-profit healthcare organisations

Past attendees include:

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CareFusion Finland 320 Oy
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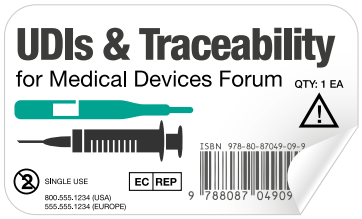

Main Conference:
25th-26th May 2016

Venue:
Munich, Germany

My registration code **PDFW**

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2-Day Conference (25th - 26th May)	✔
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VENUE & ACCOMMODATION

Venue: Munich, Germany
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