15th EGA Regulatory and Scientific Affairs Conference

Meeting the Future Challenges and Opportunities in the Regulatory Environment

28 - 29 January 2016

Radisson Blu Portman Hotel
22 Portman Square, London W1H 7BG, UK

Thursday 28 January 2016 | **15th EGA Regulatory and Scientific Affairs Conference**

08:00 Registration and networking coffee

09:00 **Opening Session - Looking to the future - Strategy 2020 for pharmaceuticals**
Chair | ***Adrian van den Hoven**, Director General, European Generic and Biosimilar medicines Association*

This session will set the scene for a political discussion on the future direction of the pharmaceutical sector, focusing on turning a high level political objective into a work plan.

Strategy 2020 for pharmaceuticals - how to translate high level objectives into concrete deliverables

- **EMA/HMA Strategy 2020 and Work Plan** | ***Noel Wathion**, Chief Policy Adviser, European Medicines Agency (EMA), **Ian Hudson**, Chief Executive, MHRA on behalf of the Heads of Medicines Agencies (HMA) and **Christer Backman**, MPA (SE) on behalf of the CMDh*
  - What can we expect in the next 4 years?
  - How will it impact the regulatory environment and pharmaceutical policy for generic and biosimilar medicines?

How can the generic medicines industry actively contribute to the process? | ***Beata Stepniewska**, Deputy Director General and Head of Regulatory Affairs, European Generic and Biosimilar medicines Association*

Panel Discussion composed of session speakers *and **Caroline Kleinjan**, Chair EGA Regulatory and Scientific Committee, Sandoz*

10:30 Networking coffee break

11:00 **Session 2 - Maintenance of medicinal products: is there a better way of handling this in practice?**
Chairs | ***Caroline Kleinjan**, Chair EGA Regulatory and Scientific Committee, Sandoz and **Beata Stepniewska**, Deputy Director General and Head of Regulatory Affairs, European Generic and Biosimilar medicines Association*

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- **Challenges of the current variations system: consequences of inefficiency, the main findings from the EGA Regulatory Efficiency Report and proposed solutions** | ***Susana Pereira**, TEVA*

Open debate on proposed solutions

- **How can we reduce the workload for industry and authorities in handling variations?**
- **How to ensure longer term sustainability of the variations system**
- **How can telematics support the regulatory processes, especially variations, to make them more efficient?**
- **Is on-going ICH Q12 work bringing any solutions?**
- **Is the e-leaflet a way forward to disseminate the latest Patient Information?**

Panellists: ***Christa Wirthumer-Hoche**, AGES - MEA (AT), **Alexis Nolte**, Head of Information Management Division, EMA, **Remco Munnik**, Asphalion, **Graham Powell**, Mylan, **Constant van Belkum**, MEB (NL) and **Susanne Winterscheid**, BfArM (DE)*

Q&A Session with a panel composed of session speakers

12:45 Networking buffet lunch

14:00 **Session 3 - Tackling the effects of the globalisation of pharmaceutical operations - challenges, opportunities and priorities**

This session covers the broad implications of globalisation on development and international filing strategy compliance and highlights the benefits of more dialogue with regulators from key

Chair | ***Andreas Potthoff**, Mylan and **Julie Maréchal-Jamil**, European Generic and Biosimilar medicines Association*

- **Towards global submission - what would make a real difference?** | ***Susanne Braunhofer**, Acino Pharma AG*
  - **Industry's product development and international filing strategy**
    - **Case study on transdermal patches**
- **How can various international initiatives support convergence?** | ***Petra Dörr**, Swissmedic (CH)*
  - **State of play, latest developments and achievements**
  - **Can some European practices be promoted internationally?**
- **Challenges and opportunities of globalisation - strategic priorities for the EU network** | ***Emer Cooke**, EMA*

Q&A Session with a panel composed of session speakers, ***Peter Bachmann**, BfArM (DE) on behalf of the CMDh and **Sébastien Goux**, Unit Medicinal Products - Authorisations, EMA (D5) - DG SANTE, European Commission*

15:30 Networking coffee break

16:00 **Session 4 - Watch this space in 2016 - are you ready to implement?**
Chair | ***Beata Stepniewska**, Deputy Director General and Head of Regulatory Affairs, European Generic and Biosimilar medicines Association*

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This session covers several stand-alone topics to raise awareness in the industry of the upcoming implementation process.

- ***EMA policy on publication of the clinical data and transparency requirements of the Clinical Trial Regulation - how does it affect your applications?*** | ***Fergus Sweeney**, EMA*
- ***Borderline medicinal products - Do on-going changes to medical devices, food supplement legislation impact your products?*** | ***Elizabeth Baker**, MHRA*
- ***How does the ICH Q3d guideline on elemental impurities affect your products?*** | ***Mechthild Sander**, AET*
- ***Falsified Medicines Directive** - regulatory consequences of the implementation of safety features* | ***Paul Fleming**, BGMA*

Q&A Session with a panel composed of session speakers

17:30 Closure of the day

19:30 Conference dinner | Informal Attire

Friday 29 January 2016 **15th EGA Regulatory and Scientific Affairs Conference**

08:00 Welcome coffee

TWO parallel technical tracks (please advise choice when registering)

TRACK ONE – THE REGULATORY IMPLICATIONS OF DEVELOPMENTS IN THE LEGAL AND OPERATIONAL ENVIRONMENT - IMPACT ON SUPPLY CHAIN

09:00 **Session 5A - Management of the active substance regulatory dossier - Finding the right balance to allow compliance, transparency and operability**
Chairs | ***Keith Pugh**, QWP, MHRA and **Koen Nauwelaerts**, European Generic and Biosimilar medicines Association*

This session will address the interplay between GMP and regulatory obligations related to APIs and will set the scene for a discussion on a more independent assessment and management of the API regulatory dossier.

- **API Variations - Findings and Recommendations from the EGA regulatory efficiency project** | ***Joseph Bondin**, Actavis*
- **Towards more independent management and assessment of API regulatory dossiers - An APIC perspective** | ***Marieke van Dalen**, Aspen Oss B.V.*
- **API supply chain - EU MS regulatory perspective on the interplay between the description in the regulatory dossier and GMP/GDP oversight** | ***Kristofer Olofsson**, MPA*
- **EDQM approach and latest policy for CEP** | ***Hélène Bruguera**, EDQM*

Q&A Session with a panel composed of session speakers and ***Andreas Sundgren**, NOMA (NO)*

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11:00 Networking coffee break

11:30 **Session 6A** – **Risk-Based Approaches – Towards more EU convergence in the implementation of the concept**
Chair | ***Brendan Cuddy**, EMA*

This session will focus on the implementation of the risk- based concept in the GMP and GCP. The main goal is to illustrate variability in approaches and the consequences for operations/businesses as well as highlight potential mitigation strategies.

- **A Member State inspectorate approach to risk-based GMP/ GCP inspections** | ***Mark Birse**, MHRA and **Stephen Vinter**, MHRA*
- **Industry experience with risk-based approaches and outlook** | ***Désirée Vendrig**, TEVA and **Susana Almeida**, Inflamax Research*

Q&A Session with a panel composed of session speakers and ***Mechthild Sander**, AET*

13:00 Networking buffet lunch

TRACK TWO – THE LATEST DEVELOPMENTS IN THE ELECTRONIC SUBMISSION ENVIRONMENT

09:00 **Session 5B - ISO IDMP is around the corner: how are we going to handle the implementation?**
Chair | ***Kelly Hnat**, Senior Director, Regulatory Information Management, TEVA*

This session will focus on preparatory work towards ISO IDMP implementation and on recommending how to be prepared internally to provide data.

Update on the submission of information on medicinal products in the EVPRM format | ***Francisco Peñaranda Fernandez**, EMA and **Nora Weitbrecht**, Salutas/Sandoz*

- Overview of the submission process and dealing with pending issues
- Maintenance of data
- What is planned for 2016?

The implementation of international standards for identification of medicinal products | ***Francisco Peñaranda Fernandez**, EMA, **Thomas Balzer**, BfArM and **Kelly Hnat**, TEVA*

- Roadmap towards ISO IDMP
  - Migration of data in EVPRM format into ISO IDMP
- What are the consequequences for the industry and authorities?
- How to be prepared internally to provide data?

Q&A Session with a panel composed of session speakers

11:00 Networking coffee break

11:30 **Session 6B – EU telematics environment- what's new?**
Chair | ***Remco Munnik**, Asphalion, Chair of the EGA Telematics WG*

This session will focus on progress and the next steps in some telematics projects affecting the industry.

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Road map on eCTD- how to handle the conversion from NeeS to eCTD? | ***Karin Gröndahl**, MPA (SE) and **Remco Munnik**, Asphalion*

- **Case study** | ***Elke Schydlo**, Sandoz*

Brief look to the future - Interoperability of systems and various projects - how to connect dots and to create synergy | ***Karin Gröndahl**, MPA (SE), **Radhouane Cherif**, EMA, **Constant van Belkum**, MEB (NL) and **Kevin Horan**, HPRA (IE)*

- CESP/Gateway - evolution into a Single Submission Platform
- Future plans to extend functionalities of existing tools: eAF, SSP, eCTD, CTS, digital signature
- Open panel discussion between Industry and Authorities how shape the telematics future and to create the synergy

13:00 Networking buffet lunch

Common session

14:30 **Session 7** – **Put your questions to the Regulators**
Chairs | ***Peter Bachmann**, BfArM (DE) and **Caroline Kleinjan**, Sandoz*

An opportunity to address questions to the European Regulators on various regulatory issues. Questions should be formulated generally, without reference to a given product/procedure and should be sent 2 weeks in advance to beata@egagenerics.com

Q&A Session with representatives from the EU authorities: ***Susanne Winterscheid**, BfArM (DE)* | ***Sonia Ribeiro**, EMA* | ***Christer Backman**, MPA (SE)* | ***Marta Marcelino**, INFARMED (PT)* | ***Kora Doorduyn-van der Stoep**, MEB (NL)* | ***Keith McDonald**, MHRA (UK)* | ***Christa Wirthumer-Hoche**, AGES-MEA (AT)*

16:00 End of conference and networking coffee

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SEE YOU NEXT YEAR AT THE 16th EGA REGULATORY AND SCIENTIFIC AFFAIRS CONFERENCE 26-27 JANUARY 2017!

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