

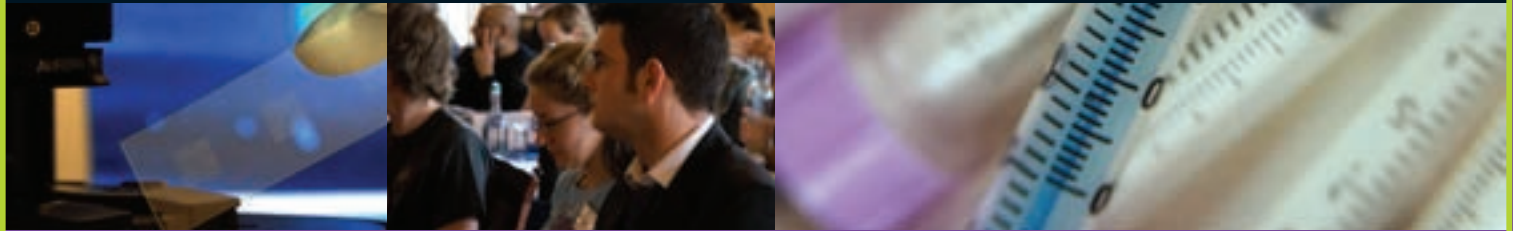
# Vaccines Workshop

AT THE PAUL-EHRLICH-INSTITUT, GERMANY



TOPRA – The Organisation for Professionals in Regulatory Affairs

Reference: CA4



## Will vaccinology recover from the flu? A new paradigm in vaccines regulation

### Aim

This workshop will explore the regulatory aspects of vaccines and how regulation is impacted by the many external factors surrounding vaccination programmes. It will also debate possible ways forward to improve vaccine availability in a global environment.

### Course content includes

#### How to profile a new vaccine –

##### Part I Pre-registration, safety and efficacy

The management of benefit-risk during Pre-licensing i.e. strategies in real time to manage such risk by taking into account preclinical, clinical, theoretical, meta-analytical, epidemiological and other viewpoints. Acceptable benefit-risk ratios for novel vaccines may change when given together with established vaccines. How should concomitant use studies be designed? What is the limit of acceptable risks in a concomitant use setting? How to conduct efficacy studies for second generation (expanded) combination vaccines e.g. HPV and pneumococcal conjugates. Are non validated surrogate markers for efficacy acceptable?

#### How to monitor a new vaccine –

##### Part II Post-registration, safety and efficacy

Post-marketing requirements set by Regulatory Authorities, feasibility of vaccine evaluation studies in post-marketing, infrastructures needed to perform huge post-marketing studies as well as roles of industry versus public health institutions. It will also discuss Risk Management Plans – translating theory into practice, the H1N1 example.

#### Moving into new regulatory provisions

A focus on upcoming and established regulatory provisions with a strong impact on the manufacture and clinical investigation of vaccines: The paediatric regulation and the implementation of the new Variations regulation.

#### Moving into a global regulatory environment

This will take the form of a round table discussion and will debate: The role of European and FDA approval in a developing world setting e.g. Africa. How can flexible dosing schedules be registered e.g. to accommodate missed doses? How can safety be monitored in a developing world setting? If a safety signal is identified in Europe how should it impact the use of the product in the developing world e.g. the shift in B:R may be different in different settings e.g. Rotavirus vaccines.

### Who should attend

This important meeting is essential for anyone involved in vaccines from a regulatory viewpoint and also those involved in preclinical and clinical research, those involved in data analysis, epidemiology and pharmacovigilance etc. Persons from both the regulatory agencies and industry and other related public health institutions are welcome to join the debate. If you wish to influence the future of vaccines regulation then you must attend!

### Speakers include

- Michael Pfeleiderer, Chair, EMA vaccines working party, Paul-Ehrlich-Institut, Germany
- Pieter Neels, Co-Chair, EMA vaccines working party, CHMP member for Federal Agency for Medicinal and Health Products, Belgium
- Daniel Bresseur, member vaccines working party, Chair, EMA Paediatric Committee, Federal Agency for Medicinal and Health Products, Belgium
- Andrew Deavin, Director, Worldwide Vaccines Registration, GSK Biologicals, Belgium
- Elizabeth Miller, Head, Immunisation Department, Health Protection Agency, UK
- Brigitte Keller-Stanislawski, Head, Pharmacovigilance, Paul-Ehrlich-Institut, Germany
- Thomas Breuer, Senior Vice President, Global Clinical R&D Vaccines & Chief Medical Officer, GSK Biologicals, Brussels, Belgium
- Klaus Cichutek, Chair, EMA CHMP GTWP, Paul-Ehrlich-Institut, Germany
- Johannes Löwer, former director of the PEI, Director of Federal Institute for Medicinal Products and Medical Devices, Germany
- Ingrid Uhnoo, Senior Expert, Department of Preclinical and Clinical Assessment Medical Products Agency, Sweden
- Ralf Clemens, Global Head, Development Novartis Vaccines and Diagnostics, Italy

For more information or to obtain a booking form, please contact TOPRA via email: [meetings@topra.org](mailto:meetings@topra.org) or tel: +44 (0) 207 510 2560 or go to the website: [www.topra.org/vaccines](http://www.topra.org/vaccines)

One-day  
Conference

### Date:

Thursday  
27 May, 2010

### Venue:

The Paul-Ehrlich-  
Institut, Langen,  
Germany



Lifelong learning

\*For more information please visit  
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# BOOKING FORM 2010 Vaccines Workshop



One-day Conference Date: Thursday 27 May 2010 Venue: The Paul-Ehrlich-Institut, Langen, Germany Ref: CA4

## Will vaccinology recover from the flu? A new paradigm in vaccines regulation

### Ways to book

Please complete in block capital letters and return this form with payment to TOPRA using one of the following methods:

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#### Please note:

Fee excludes accommodation and travel. The delegate ticket includes refreshments at coffee breaks, buffet lunches and drinks reception.

#### Discounted fees:

Personnel in full-time education, working in academia (full-time) or working for a statutory regulatory body may be entitled to a discount on the above fees. Please contact the TOPRA office for details.

#### Cancellations:

All cancellations must be received in writing 28 calendar days before the start of the course and will be subject to an administration fee of €150 + GB VAT. Payment can be in Euro or Sterling.

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