Join Authorities, Global Regulators, Industry Representatives, and Marketing Application Holders for an Interactive Discussion of RMPS.

This conference will teach you how to identify and organize essential components of an RMPs as they apply to medicinal products, therapeutic biologics, and vaccines. Experts speakers will focus on well-described risks, poorly understood risks, and certain potential risks of products, which may be made available to patients and healthcare providers in different regions of the world.

Featured Topics

- Why risk management plans (RMPs) are important to your organization from a global regulatory perspective
- Pros and cons of a global vs. local approach to developing RMPs
- How an harmonized RMP can promote efficient, evidence-based decision-making to support the best use of marketed products and thereby enhance public health
- How to develop an harmonized approach to creating an RMP

Who Should Attend

Professionals with a basic to intermediate experience in pharmacovigilance and risk management and who are responsible for:

- Developing and evaluating RMPs
- Generating and assessing drug safety signals
- Organizing post-authorization safety studies
5:00-7:00 PM GENERAL SESSION REGISTRATION

DAY 1 | THURSDAY, DECEMBER 10

7:00-8:00 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:00-8:05 AM WELCOME AND OPENING REMARKS

**William W. Gregory**
Director, Safety and Risk Management
Pfizer Inc

8:05 AM-12:00 PM SESSION 1

**Risk Management Plans: What Do They Mean and What Are the Requirements for Each Region?**

**CHAIRPERSON:**

**William W. Gregory**
Director, Safety and Risk Management
Pfizer Inc

Regulatory agencies from around the globe present Risk Management Plans from the perspective of the Pharmaceuticals and Medical Devices Agency in Japan, US Food and Drug Administration, Health Canada, and regulatory authorities in the EEA.

8:10-8:50 AM Risk Management Plans from the Perspective of Regulatory Authorities in the EEA

**Jan Petracek, MD**
Risk Management Team, Sector Pharmacovigilance and Risk Management
European Medicines Agency (EMEA), EU

As part of the European Risk Management Strategy for medicinal products, risk management systems are required for all new medicinal products in the EU since November 2005. Risk management plans (RMPs) that describe the system have become standard parts of dossiers in Europe. The EU-RMPs mandate hundreds of post-authorization studies and about 10-20% of them also include some

8:50-9:30 AM Risk Management Plans from the Perspective of the Pharmaceuticals and Medical Devices Agency (Japan)

**Junko Sato, PhD**
Director for Risk Management
Office of Safety, Office of International Program
Pharmaceuticals and Medical Devices Agency (PMDA), Japan

In addition to international-accepted approaches to risk management for medicinal products, there are several specific activities that are unique to Japan. These include Early Phase Postmarketing Vigilance (EPPV) Surveillance for the first six months following product launch, “Zenreichosa” observational studies for all approved indications for new products, initial restrictions on product use, and direction of medical representatives who provide product information to healthcare professionals. In this session, attendees will be introduced to Risk Management Plans as implemented in Japan, including an overview of those components that are unique to the situation in Japan.

9:30-10:00 AM REFRESHMENT BREAK

10:00-10:40 AM Risk Management Plans Post-FDAAA – An FDA Perspective

**Claudia B. Karwoski, PharmD**
Director, Division of Risk Management
Office of Surveillance and Epidemiology
CDER, Food and Drug Administration (FDA)
FDAAA has given the FDA enhanced authorities regarding post-market safety of drugs. Under FDAAA, the FDA may determine if a REMS is needed to ensure that the benefits of the drug outweigh the risks of the drug prior to approval or post-approval if the FDA becomes aware of new safety information. This presentation will address how the FDA is managing the REMS provisions under FDAAA.

10:40-11:20 AM  Risk Management Plans in Canada: Current Regulatory Approaches and Future Perspectives
Marc Berthiaume, MD
Director, Marketed Pharmaceuticals and Medical Devices Bureau
Marketed Health Products Directorate
Health Canada

This presentation will review the current processes in place in Canada for requesting and reviewing Risk Management Plans, and will also present potential future developments in the regulatory Canadian framework to better integrate this new piece of information within the data review processes, both before and after market authorization.

11:20 AM-12:00 PM  QUESTION & ANSWER PERIOD

12:00-1:00 PM  LUNCHEON

1:00-3:30 PM  SESSION 2
Risk Management Plans: What Have We Learned from RMPs About Managing Product Risks?
Chairperson: Junko Sato

This session will focus on RMPs that have been in place for several years. Speakers will discuss the challenges in implementing RMPs from a practical perspective, as well as lessons learned. Emphasis will be placed on metrics that have been adopted to evaluate the success of specific RMPs and triggers for RMP modification.

1:00-1:30 pm  RMP for a Medicinal Product
Speaker Invited

Rosuvastatin Calcium (Crestor) is indicated for the treatment of hypercholesterolemia. In Japan, Crestor was approved based on a strategy to bridge Western clinical trial data with Japanese data. Considering the situation in the EU, US, and Japan at authorization, the company and PMDA agreed that an RMP should be initiated in Japan. The local RMP was based on the global RMP, but with a specific EPPV and various adjunctive programs. The content, implementation challenges, metrics, and evolution of the Crestor RMP will be presented.

1:30-2:00 pm  RMP for a Therapeutic Biologic
Speaker Invited

Pegaptanib sodium (Macugen) is indicated for the treatment of exudative (wet) AMD. First in class, this is a selective vascular endothelial growth factor (VEGF) antagonist administered via intravitreous (IVT) injection. An RMP was required at the time of EU marketing authorization to further characterize known risks associated with its route of administration. As data from actual use were collected and analysed the RMP was modified to reflect the evolving safety profile. Despite pre-authorisation agreement on the original RMP by the CHMP, customisation of the RMP was requested by individual NCAs to meet post-authorisation requirements of individual countries in the EEA. The content, metrics, and triggers for evolution of the Macugen RMP will be presented.

2:00-2:30 PM  REFRESHMENT BREAK

2:30-3:00 PM  RMP for a Vaccine: US Perspective
Speaker Invited

Preventive vaccines are administered to healthy persons, and this condition of use underlies vaccine benefit-risk assessments. Labeling plays a crucial role in risk management, but in special cases, a RMP may be needed.

3:00-3:30 PM  RMP for a Vaccine: EU Perspective
Thomas Nisslein, DVM, PhD
Safety Evaluations Manager
Solvay Pharmaceuticals GmbH

The development of a vaccine for the 2009 H1N1 Pandemic Influenza strain required urgent deployment of resources once the pandemic strain was characterized. Development and implementation of a plan to evaluate safety and efficacy of a protective vaccine required a collaborative effort between health authorities, manufacturers, the public health sector, and other stakeholders. This presentation will discuss the special challenges for RMPs that address a pandemic situation, including safety responsibilities of manufacturers as outlined in the guidance for the Core RMP, special tools such as the Abbreviated PSUR, and implications for various stakeholders.

3:30-4:00 PM  PANEL DISCUSSION
Regulator’s Perspective

What did the regulators think about how each process was handled. Suggestions and tips for improvement.

4:00-5:00 PM  SESSION 3
Create Your Own RMP: Introduction to Practical Exercise
Chairperson: Marc Berthiaume, MD

Characteristics of a fictitious product will be presented and working groups will be identified.

5:00-6:00 PM  NETWORKING RECEPTION

DAY 2  FRIDAY, DECEMBER 11

7:00-8:00 AM  REGISTRATION AND CONTINENTAL BREAKFAST

8:00-8:15 AM  WELCOME AND OPENING REMARKS
8:15-8:30 AM  SESSION 3 – CONTINUED
Create Your Own RMP: Introduction to Practical Exercise – Review
CHAIRPERSON:
Marc Berthiaume, MD
Director, Marketed Pharmaceuticals and Medical Devices Bureau
Marketed Health Products Directorate
Health Canada

Characteristics of a fictitious product will be presented and working groups will be identified.

8:30-10:30 AM  SESSION 4
Develop Harmonized Risk Management Plan – BREAKOUT SESSIONS
CHAIRPERSONS:
Marc Berthiaume, MD
Director, Marketed Pharmaceuticals and Medical Devices Bureau
Marketed Health Products Directorate
Health Canada
Claudia B. Karowski, PharmD
Team Leader, Risk Management Team
Office of Surveillance and Epidemiology
CDER, Food and Drug Administration (FDA)

Meeting participants will break out into groups to create a global RMP for a fictitious product. The breakout groups will be led by regulators from the various regions, accompanied by experienced representatives of marketing authorization holders. Participants will have the opportunity to interact with regulators from various regions during this hands-on dynamic session.

10:30-11:00 AM  REFRESHMENT BREAK

11:00 AM-12:30 PM  SESSION 5
Successes and Opportunities for Harmonized Risk Management Plans – GROUP REPORTS
CHAIRPERSON:
Jan Petracek, MD
Risk Management Team, Sector Pharmacovigilance and Risk Management
European Medicines Agency (EMEA), EU

A volunteer from each breakout group will briefly share their group’s experience in developing an RMP for use in multiple regulatory jurisdictions. Discussion will include exploration of challenges encountered, solutions identified, and outstanding questions. Regulators and industry will be available to offer feedback, respond to questions, and provide examples of additional opportunities when an RMP might apply in multiple regulatory jurisdictions.

12:30-2:00 PM  SESSION 6
LUNCH WILL BE PROVIDED DURING THIS SESSION.

Risk Management Plans Town Meeting
CHAIRPERSON:
William W. Gregory
Director, Safety and Risk Management
Pfizer Inc

The interactive session will allow audience members to submit questions to the panel which will be made up of regulators from all regions present at

the meeting as well as selected industry representatives. The primary focus of the interactive session will be to discuss opportunities for a harmonized approach to Risk Management Plans to promote the best use of products and ultimately enhance public health.

William W. Gregory
Director, Safety and Risk Management
Pfizer Inc
Marc Berthiaume, MD
Director, Marketed Pharmaceuticals and Medical Devices Bureau
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Junko Sato, PhD
Director for Risk Management
Office of Safety, Office of International Programs
Pharmaceuticals and Medical Devices Agency (PMDA) Japan

2:00-3:30 PM  SESSION 7
Future Developments of RMPs and REMs
CHAIRPERSON:
William W. Gregory
Director, Safety and Risk Management
Pfizer Inc

Proactive Approaches to RMPs and REMs: An FDA Perspective
Speaker Invited
Proactive Approaches to RMPs and REMs: An EMEA Perspective
Jan Petracek, MD
Risk Management Team, Sector Pharmacovigilance and Risk Management
European Medicines Agency (EMEA), EU
Proactive Approaches to RMPs and REMs: A PMDA Perspective
Junko Sato, PhD
Director for Risk Management
Office of Safety, Office of International Programs
Pharmaceuticals and Medical Devices Agency (PMDA) Japan

3:30 PM  CONFERENCE ADJOURNS
REGISTRATION FORM
Register online or fax this page to +1.215.442.6199

2nd DIA Conference Harmonization of Risk Management Plans
Event #09014 • December 10-11, 2009
Washington Marriott Hotel, Washington, DC, USA

Registration Fees If DIA cannot verify your membership, you will be charged the nonmember fee. Registration fee includes refreshment breaks, luncheons, and reception (if applicable), and will be accepted by mail, fax, or online.

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- US $1270 □
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GROUP DISCOUNTS* Register 3 individuals from the same company and receive complimentary registration for a 4th! All 4 individuals must register and prepay at the same time – no exceptions. DIA will apply the value of the lowest applicable fee to this complimentary registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred. Group registration is not available online and does not apply to the already-discounted fees for government or charitable nonprofit/academia. To take advantage of this offer, please make a copy of this registration form for EACH of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together to DIA.

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- CHECK drawn on a US bank payable to and mailed along with this form to: Drug Information Association Inc, PO. Box 95000-1240, Philadelphia, PA 19195-1240, USA. Please include a copy of this registration form to facilitate identification of attendee.

- BANK TRANSFER When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the Bank Transfer. Payment should be made in US dollars. Your name and company, as well as the Event I.D. # must be included on the transfer document to ensure payment to your account.

TRAVEL AND HOTEL
The most convenient airport is Ronald Reagan National Airport and attendees should make airline reservations as early as possible to ensure availability. The Washington Marriott Hotel is holding a block of rooms at the reduced rate below until November 18, 2009, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

- Single $189
- Double $189

Please contact the Washington Marriott Hotel by telephone at +1.202.872.1500 and mention the DIA event. The Washington Marriott Hotel is located at 1221 22nd Street, NW, Washington, DC 20037, USA.

CANCELLATION POLICY: On or before DECEMBER 3, 2009
Administrative fee that will be withheld from refund amount:
- Member or Nonmember = $200
- Government or Academia or Nonprofit (Member or Nonmember) = $100
- Tutorial (if applicable) = $50

Cancellations must be in writing and be received by the cancellation date above. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations. You may transfer your registration to a colleague at any time but membership is not transferable. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable.

DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.

Participants with Disabilities: DIA event facilities and overnight accommodations are accessible to persons with disabilities. Services will be made available to sensory-impaired persons attending the event if requested at least 15 days prior to event. Contact the DIA office to indicate your needs.

EVENT INFORMATION
Contact Ellen Diegel, Program Manager, Phone +1.215.442.6158
Fax +1.215.442.6199, email Ellen.Diegel@diahome.org

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