

PERIODIC SAFETY UPDATE REPORTS

13 - 14 JUNE 2012

Solent Hotel, Whiteley, near Fareham

PROGRAMME – WEDNESDAY 13 JUNE

- 0845 – 0915** **Registration for delegates**
- 0915 - 0930** **Welcome and introduction to the course**
- 0930 - 1030** **History and rationale for writing PSURs**
Michael Richardson, Bristol-Myers Squibb Pharmaceuticals Ltd
Teaching objective: To introduce course participants to the history of PSURs and rationale for writing PSURs.
▪ Evolution of PSURs from CIOMS II to ICH, to the new EU PV legislation
▪ ICH E2C R1 and R2 ▪ CIOMS V ▪ Importance during early post-marketing years
- 1030 – 1045** **Coffee**
- 1045 – 1145** **Regulatory aspects of PSURs**
Kristina Strutt, Merck Serono SA
Teaching objective: To provide course participants with an understanding of the regulatory aspects of PSURs.
Guidance and regulations ▪ Reporting requirements ▪ Renewals ▪ Assessment process ▪ PSUR outcomes ▪ Compliance
- 1145 – 1215** **Round table discussion**
Facilitators: Kristina Strutt, Michael Richardson and Anne Kehely
- 1215 - 1300** **Core Safety Information and local datasheets**
Anne Kehely, Eli Lilly & Co
Teaching objective: To enable course participants to understand the concepts of the company core datasheet, the company core safety information and local datasheets.
Development core safety information ▪ Company core safety information ▪ Listed (PSUR) vs labelled (expedited reporting) ▪ Safety sections in the SPC
- 1300 – 1400** **Lunch**
- 1400 – 1445** **PSURs: Signal and risk evaluation**
Anne Mariathas, GlaxoSmithKline
Teaching objective: To discuss the guidance given for the Signal and risk Evaluation section of the PSUR
▪ Links to the Risk Management Plan
- 1445 - 1450** **Introduction to workshop: Signal and risk evaluation**
Dr Kristina Strutt, Merck Serono SA
Teaching objective: To give course participants practical experience in reviewing data to evaluate signals and risks and writing this section of the PSUR
- 1450 – 1600** **Workshop: Signal and risk evaluation (group work)**
Facilitators: Kristina Strutt and Anne Mariathas

1600 - 1615	Tea
1615 - 1700	Benefit evaluation Integrated benefit-risk analysis Kristina Strutt, Merck Serono SA Teaching objective: To provide course participants with an understanding of the scope of benefit-risk evaluation required in the new EU PSURs, and outline the principles involved to achieve this <ul style="list-style-type: none">▪ Benefit information to include▪ Characterisation of benefits▪ Benefit-risk context and evaluation
1700	End of day one
1900	Complimentary course dinner

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PROGRAMME – THURSDAY 14 JUNE

0845 – 0900	Registration for delegates
0900	Start of day 2
0900 – 1000	PSURs: Clinical studies David Lewis, Novartis Pharma AG Teaching objective: To illustrate the types of studies and published literature which may be suitable for inclusion in a PSUR. <ul style="list-style-type: none">▪ How to find information on studies▪ Who to consult over study methodology and findings▪ What to report from studies and published literature?
1000 – 1045	Patient exposure for PSURs Ian Douglas, London School of Hygiene & tropical Medicine Teaching objective: To discuss sources of exposure data for a PSUR <ul style="list-style-type: none">▪ Exposure data from clinical trials▪ Postmarketing exposure data▪ Practicalities in obtaining exposure data
1045 – 1100	Coffee
1100 – 1145	Published literature David Lewis, Novartis Pharma AG Teaching objective: To provide course participants with an understanding of how to handle published literature in PSURs. <ul style="list-style-type: none">▪ Search strategies▪ Obtaining search results▪ Presentation of literature in PSURs
1145 - 1230	Planning, writing and reviewing a PSUR Catherine de Whalley, AstraZeneca Teaching objective: To discuss the planning, writing and reviewing of a PSUR <ul style="list-style-type: none">▪ The PSUR process▪ Factors to consider in estimating time and resources needed to complete PSUR▪ Use of contributors from other parts of company▪ The writing process▪ Reaching a conclusion▪ Reviewing PSURs
1230 – 1330	Lunch
1330 - 1335	Introduction to workshop: Reviewing a PSUR Dr Kristina Strutt, Merck Serono SA Teaching objective: To give course participants practical experience in reviewing sections of a PSUR
1335 - 1435	Workshop: Reviewing a PSUR (group work) Facilitators: Kristina Strutt, David Lewis and Catherine de Whalley
1435 - 1500	Final discussion
1500	End of course