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Drug Safety Research Unit

## Pharmacovigilance in Products Subject to Licensing Agreements

Novotel London West Hotel, Hammersmith, London

27 – 28 November 2019

Chairperson: Elspeth McIntosh

Wednesday 27 November

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<b>0830 - 0900</b>	<b>Registration for delegates</b>
<b>0900 - 0915</b>	<b>Introduction to the course</b> Elspeth McIntosh, Castle Pharmacovigilance Ltd
<b>0915 - 1000</b>	<b>The nature and types of relationships from a pharma company perspective</b> Rachel Pleeth, AstraZeneca  <i>◇ Common types of commercial partnerships ◇ Pre and post licensing ◇ Common terminologies ◇ Safety involvement</i>  <b>Learning objectives:</b> <ul style="list-style-type: none"><li>To understand the type of commercial partnerships that exist, why and when these are set up, and what implications they have for safety</li></ul>
<b>1000 - 1045</b>	<b>Safety language in other agreements</b> Elspeth McIntosh, Castle Pharmacovigilance Ltd  <i>◇ Wholesaler agreements ◇ Compassionate Use Programmes ◇ Patient Support Programmes ◇ Investigator Sponsored Studies etc.</i>  <b>Learning objectives:</b> <ul style="list-style-type: none"><li>To learn about the contracts, other than those mentioned above, which need safety input and the kinds of topics which need to be covered.</li></ul>
<b>1045 - 1100</b>	<b>Coffee</b>
<b>1100 - 1215</b>	<b>Content of Safety Agreements</b> Dagmar Mickler, Gilead Sciences International
<b>1215 - 1300</b>	<b>Due diligence activities: Models and process (Presentation &amp; Interactive workshop)</b> Dagmar Mickler, Gilead Sciences International
<b>1300 - 1400</b>	<b>Lunch</b> <b>1300 - 1400 Pharmacovigilance Clinic – delegates are welcome to discuss their problems / challenges individually with speakers</b>

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**1400 - 1430**    **Challenges in managing PV Agreements from a smaller company's perspective**  
Elspeth McIntosh, Castle Pharmacovigilance Ltd

◇ *When small companies need PV Agreements* ◇ *Type of PV Agreements* ◇ *Challenges in establishing and maintaining PV Agreements* ◇ *Compliance*

**Learning objectives:**

- To appreciate the challenges faced by small companies in establishing PV Agreements.

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**1430 - 1515**    **Pharmacovigilance and Sales and Marketing Departments (Presentation & Interactive workshop)**  
Speaker invited

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**1515 - 1530**    **Tea**

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**1530 - 1630**    **Approaches in managing relationships/responsibilities**  
Elspeth McIntosh and Dagmar Mickler

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**1630 - 1700**    **Question and answer session**  
Led by Elspeth McIntosh

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**1700**    **Close of day one**

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**1700 - 1745**    **Postgraduate in Pharmacovigilance programme students only (pre-course assignment presentations)**

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**0845 - 0900**    **Registration**

**0845 - 0900**    **Postgraduate in Pharmacovigilance students only**  
Student meeting

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**0900**    **Start of day 2**

**0900 - 0945**    **Compliance measures and audit of partners**  
Noha Kassem, Lilly UK

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**0945 - 1045**    **Challenges for generics safety agreements**  
John Barber, Plain Pharma Consultancy Ltd

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**1045 - 1100**    **Coffee**  
**Postgraduate programme information session (optional)**

**1100 - 1145**    **The challenges to consider in using a CRO**  
Barry Mulchrone, IQVIA

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**1145 - 1230**    **The challenges to consider in acquisition and divestment**  
Barry Mulchrone, IQVIA

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**1230 - 1330**    **Lunch**  
**1245 - 1315 Pharmacovigilance Clinic – delegates are welcome to discuss their problems/challenges individually with speakers**

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**1330 - 1430**    **A legal perspective on safety agreements**  
Yuung Yuung Yap, Pfizer

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**1430 - 1515**    **An inspector's expectation of safety agreement content and measures**  
Speaker invited

**Learning objectives:**

- To understand why robust contracts are essential for pharmacovigilance and to highlight the legal references
- To learn about the types of contracts requested during an audit or inspection and an auditor/inspectors expectation with regards to the management and maintenance of contracts

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**1515 - 1530**    **Tea**

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**1530 - 1600**    **Termination of agreements**  
Elspeth McIntosh, Castle Pharmacovigilance Ltd

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**1600 - 1630**    **Question and answer session, final comments**  
Led by Elspeth McIntosh

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**1630**            **Close of meeting**

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