

DEVELOP  
YOUR SKILLS

IMPROVE YOUR  
CAREER

REALISE YOUR  
POTENTIAL

EXPAND YOUR  
KNOWLEDGE



Drug Safety Research Unit

## Pharmacovigilance in Products Subject to Licensing Agreements

Hybrid event: Novotel London West Hotel, Hammersmith, London and Online

15 - 16 November 2023

Wednesday 15 November

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<b>0845 - 0900 (GMT)</b>	<b>Meeting room open for delegates to join</b>
<b>0900 - 0915</b>	<b>Introduction to the course</b>
<b>0915 - 1000</b>	<b>The nature and types of relationships from a pharma company perspective</b>  <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 - 1005</b>	<b>Comfort break</b>
<b>1005 - 1050</b>	<b>Safety language in other agreements</b>  <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>1050 - 1100</b>	<b>Coffee break</b>
<b>1100 - 1215</b>	<b>Content of Safety Agreements</b>
<b>1215 - 1255</b>	<b>Lunch break</b>
<b>1255 - 1325</b>	<b>Due diligence activities: Models and process</b>
<b>1325 - 1330</b>	<b>Comfort break</b>

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**1330 - 1415**    **Compliance measures and audit of partners**

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**1415 - 1425**    **Comfort break**

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**1425 - 1525**    **A legal perspective on safety agreements**

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**1525 - 1530**    **Comfort break**

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**1530 - 1615**    **Challenges in managing PV Agreements from a smaller company's perspective**

◇ *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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**1615 - 1645**    **Question and answer session**

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**1645**            **Close of day one**

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**1645 - 1715**    **Postgraduate in Pharmacovigilance programme students only (pre-course assignment presentations)**

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Thursday 16 November

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<b>0845 - 0900 (GMT)</b>	<b>Meeting room open</b>
<b>0900</b>	<b>Start of day 2</b>
<b>0900 - 1000</b>	<b>Challenges for generics safety agreements</b>
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<b>1000 - 1005</b>	<b>Comfort break</b>
<b>1005 - 1050</b>	<b>The challenges to consider in using a CRO</b>
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<b>1050 - 1100</b>	<b>Comfort break</b>
<b>1100 - 1145</b>	<b>The challenges to consider in acquisition and divestment</b>
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<b>1145 - 1150</b>	<b>Comfort break</b>
<b>1150 - 1240</b>	<b>Pharmacovigilance and Commercial Departments (Presentation &amp; Interactive workshop)</b>
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<b>1240 - 1330</b>	<b>Lunch break</b>
<b>1330 - 1430</b>	<b>Approaches in managing PVA relationships/responsibilities</b>
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<b>1430 - 1435</b>	<b>Comfort break</b>
<b>1435 - 1520</b>	<b>An inspector's expectation of safety agreement content and measures</b>

### Learning objectives:

- To understand why robust contracts are essential for pharmacovigilance and to highlight

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the legal references

- To understand the types of contracts requested during an inspection and an inspector's expectation with regards to the management and maintenance of contracts

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**1520 - 1530**    **Comfort break**

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**1530 - 1600**    **Termination of agreements**

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**1600 - 1630**    **Question and answer session, final comments**

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

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**1630 - 1645**    **Postgraduate in Pharmacovigilance students only**  
Student meeting to discuss any questions regarding the post-course assignment

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