



DSRU

Drug Safety Research Unit

REALISE YOUR
POTENTIAL

DEVELOP
YOUR SKILLS

IMPROVE
YOUR CAREER

EXPAND YOUR
KNOWLEDGE

Pharmacovigilance in Products Subject to Licensing Agreements

Hybrid Event: Novotel London West Hotel, London and Online | 27 - 28 November 2024

Wednesday 27 November 2024

0845 - 0900 (GMT) Registration / Meeting room open for delegates to join

0900 - 0915 Introduction to the meeting

0915 - 1000 The nature and types of relationships from a pharma company perspective

◇ *Common types of commercial partnerships* ◇ *Pre and post licensing*
◇ *Common terminologies* ◇ *Safety involvement*

Learning objectives:

- To understand the type of commercial partnerships that exist, why and when these are set up, and what implications they have for safety

1000 - 1005 Comfort break

1005 - 1050 Safety language in other agreements

◇ *Wholesaler agreements* ◇ *Compassionate Use Programmes* ◇ *Patient Support Programmes*
◇ *Investigator Sponsored Studies etc.*

Learning objectives:

- To learn about the contracts, other than those mentioned above, which need safety input and the kinds of topics which need to be covered.

1050 - 1105 Coffee/Tea break

1105 - 1220 Content of Safety Agreements

1220 - 1225 Comfort break

Book your place here: www.dsrु.org/education-training

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1225 - 1300	Due diligence activities: Models and process
1300 - 1345	Lunch break
1345 - 1430	<p>Challenges in managing PV Agreements from a smaller company's perspective</p> <p>◇ <i>When small companies need PV Agreements</i> ◇ <i>Type of PV Agreements</i> ◇ <i>Challenges in establishing and maintaining PV Agreements</i> ◇ <i>Compliance</i></p> <p>Learning objectives:</p> <ul style="list-style-type: none"> • To appreciate the challenges faced by small companies in establishing PV Agreements.
1430 - 1435	Comfort break
1435 - 1520	Compliance measures and audit of partners
1520 - 1535	Comfort break
1535 - 1635	A legal perspective on safety agreements
1635 - 1650	Question & Answer session
1650	End of day one
1650 - 1730	Postgraduate Students only are requested to meet the Assessor to discuss their pre-course assignment for this course.

0845 - 0900 (GMT)	Registration / Meeting room open
0900	Start of day 2
0900 - 1000	Challenges for generics safety agreements
1000 - 1005	Comfort break
1005 - 1050	The challenges to consider in using a CRO
1050 - 1105	Comfort break
1105 - 1150	The challenges to consider in acquisition and divestment
1150 - 1155	Comfort break
1155 - 1245	Pharmacovigilance and Commercial Departments (Presentation & Interactive workshop)
1245 - 1330	Lunch break
1330 - 1430	Approaches in managing PVA relationships/responsibilities
1430 - 1435	Comfort break
1435 - 1520	An inspector's expectation of safety agreement content and measures
	Learning objectives: <ul style="list-style-type: none">• To understand why robust contracts are essential for pharmacovigilance and to highlight 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
1520 - 1535	Comfort break
1535 - 1605	Termination of agreements
1605 - 1630	Question and answer session, final comments

1630

Close of meeting

1630 - 1645

Postgraduate Students only

Student Voice meeting to discuss any questions regarding the post-course assignment or postgraduate programme

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