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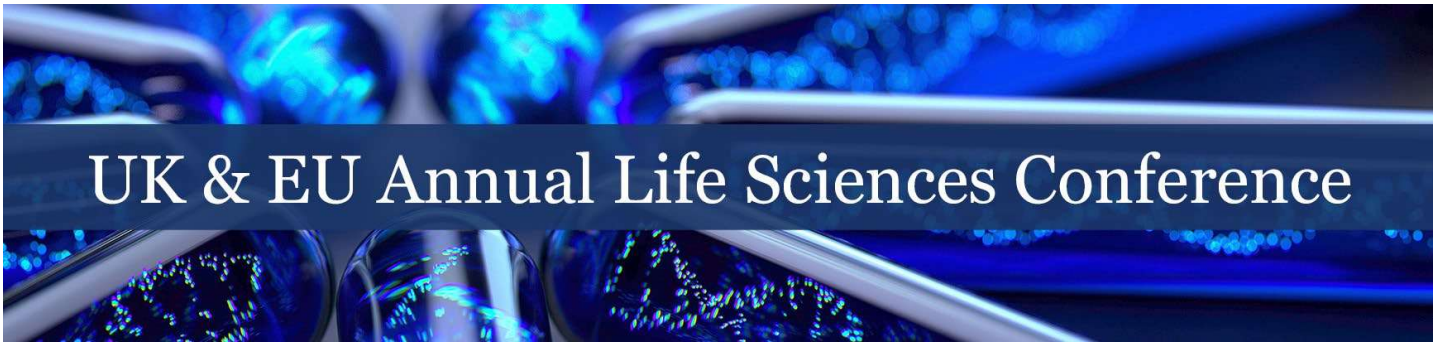

Thursday, 18 September 2025

Time	Seminar	Speakers
9.00-9.30 a.m.	**Registration and Welcome**	
9.30-10.30 a.m.	**How to plan for generic launch:** • Regulatory considerations, such as expiry of RDP, monitoring, engaging with authorities • Competition issues, including product denigration, internal communications, patent settlements, product strategies. • Managing IP expiry, including cross-border enforcement, forum shopping and strategy	**Jackie Mulryne** **Dr. Beatriz San Martin** **John Schmidt**
10.30-11.15 a.m.	**External speaker**	**Dr. Royth von Hahn, TÜV SÜD**
11.15-11.30 a.m.	**Coffee Break**	
11.30 a.m.-1.00 p.m.	**Quick fire regulatory update:** • Current status of EU Pharma Package • Tariffs and supply chains • Competition Points in Pharma Deals: notification requirements (merger control and FDI) and call ins in small transactions and licensing deals. • Critical Medicines Act and Biotech Act • Shortages and restrictions on products originating from China • New UK offence of “failure to prevent fraud” and impact on relationships with HCPs • Changes to GDPR, position in the UK	**Alexander Roussanov** **Ewan Townsend** **James Castro Edwards** **Libby Amos-Stone** **Ludovica Pizzetti** **Eftychia Sideri**
1.00-2.00 p.m.	**Lunch**	

2.00-2.55 p.m.	**Global trends in market access:** U.S. proposals on “most favoured nations” pricing for medicines and implications for UK/EU companies; international reference pricing, examples of developments in EU;, competition considerations including FoC supplies, distribution arrangements and joint ventures	**Adela Williams** **Pari Mody** **Zeno Frediani**
2.55-3.50 p.m.	**Use of AI and the medicines lifecycle:** Current implementation of the EU AI Act, interaction with MDR and the link to EHDS, impact of the Data Act and the Digital Services Act	**Jackie Mulryne** **Alexander Roussanov** **Dr. Beatriz San Martin** **Chris Bates**
3.50-4.05 p.m.	**Afternoon Break**	
4.05-5.00 p.m.	**Developments in the manufacture of advanced therapy medicinal products (ATMPs):** Changes to the hospital exemption in the EU Pharma Package, current trends (and controversies) with compounding, UK legislation on “Point of Care” manufacture and impact on cell therapy and ATMP manufacturing	**Adela William** **Eleri Abreo**
5.00-5.30 p.m.	**Product liability:** New EU Directive, impact in UK, growth in use of third party litigation funders	**Tom Fox** **Libby Amos-Stone**
5.30 p.m.	**Drinks, Canapés and Networking**	

Please be aware that this agenda is subject to change and updates.