



# UK & EU Annual Life Sciences Conference

Day Two: U.S. Life Sciences Update for European Counsel

Friday, 19 September 2025

| Time             | Seminar                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Speakers                              |
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| 8.00-9.00 a.m.   | Breakfast, Registration, and Welcome                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                       |
| 9.00-9.40 a.m.   | <p><b>Trump 2.0: The U.S. Political, Policy, and Legal Environment for European Life Sciences Companies</b></p> <p>This session will address the impact of the second Trump Administration on the environment for European life sciences companies operating in the U.S. We will survey:</p> <ul style="list-style-type: none"><li>• Key players, objectives, and initiatives to date, including Executive Orders and other mandates and initiatives,</li><li>• Actions with respect to regulatory agencies, rulemakings, and guidance,</li><li>• The Department of Government Efficiency (DOGE)’s activities,</li><li>• The prospects for critical legislation in the current Congress, and</li><li>• The political outlook for the mid-term election in 2026.</li></ul>                                    | <p>Dan Kracov<br/>Eugenia Pierson</p> |
| 9.40-10.30 a.m.  | <p><b>Fundamental Changes at FDA: Impact on Product Development and Commercialization in the U.S.</b></p> <p>The second Trump Administration’s actions have had a huge impact on almost every aspect of FDA, including leadership, expertise, programs, and resources. Fundamental assumptions about how FDA has worked in the past are being called into question, with serious consequences for European companies seeking to develop and market products in the U.S. We will survey the range of critical changes currently underway in both internal FDA practices and regulatory policies with respect to</p> <ul style="list-style-type: none"><li>• Innovator drugs and generics/biosimilars,</li><li>• Vaccines,</li><li>• Gene and cell therapies, and</li><li>• Devices and diagnostics.</li></ul> | <p>Dan Kracov<br/>Eva Temkin</p>      |
| 10.30-10.45 a.m. | Coffee Break                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                       |

| Time                  | Seminar                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Speakers                         |
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| 10.45-11.40 a.m.      | <b>Navigating Changes to U.S. Government Health Care Programs and Drug Pricing</b> <p>The second Trump Administration and Congress have advanced policies that will significantly impact the future of U.S. federal healthcare programs and reset prior assumptions by European life sciences companies about pricing and the U.S. market. This session will:</p> <ul style="list-style-type: none"> <li>• Delve into proposed and enacted reforms to the Medicare, Medicaid, and the 340B programs.</li> <li>• Address the Administration's efforts to lower U.S. drug prices, including the Inflation Reduction Act and the resurrection of the Most-Favoured-Nation pricing approach, which has potentially significant implications for European domestic market pricing as well.</li> </ul>                                                                                                                                                                                        | Eva Temkin<br>Pari Mody          |
| 11.40 a.m.-12.30 p.m. | <b>The European Impact of Trump Administration Changes to Tariffs, Supply Chains, and Enforcement</b> <p>This session will examine the Trump Administration's use of trade policy and national security enforcement tools to reshape global pharmaceutical supply chains and expand oversight of the life sciences sector. We will survey:</p> <ul style="list-style-type: none"> <li>• Reshoring initiatives, tariff evasion concerns in the pharma industry, and scrutiny of distribution networks and dependencies on China and other "countries of concern,"</li> <li>• Expansion of export and data controls to genomic data, advanced research tools, and AI-enabled drug discovery platforms,</li> <li>• Compliance risks in joint research settings involving non-U.S. nationals,</li> <li>• Use of the False Claims Act as a trade enforcement mechanism, and</li> <li>• Other enforcement priorities, including DEI policies and healthcare fraud and abuse cases.</li> </ul> | Deborah Curtis<br>Benjamin Mizer |
| 12.30-1.15 p.m.       | <b>Lunch and Adjournment</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                  |

*\* Please note that this agenda may be revised or updated.*