

# Module 11: The US Regulatory Environment

Date: 24<sup>th</sup> – 26<sup>th</sup> March 2026



**Location:** TOPRA Office: 3rd Floor, City Reach 5, Greenwich View Place, London, E14 9NN

**Module Leader:** Manfred Kurz

**Day 1:** Tuesday 24<sup>th</sup> March 2026

<b>Time</b>	<b>Activity</b>	<b>Speaker</b>
<b>13:30 – 14:00</b>	<b>Registration</b> <b>Welcome &amp; Introduction to the Module</b>	<b>Manfred Kurz</b> Independent Consultant
<b>14:00 – 15:00</b>	<b>Lecture 1: History and Basis of Drug Regulation in the USA</b> <ul style="list-style-type: none"><li>• US legislative process</li><li>• Role and structure of the FDA</li><li>• FDA jurisdiction and statutory powers</li></ul> Relevant legislation, policy and guidance documents	<b>Paul T Kim</b> Principal Kendall Square Policy Strategies
<b>15:00 – 15:30</b>	<b>Refreshment Break</b>	
<b>15:30 – 17:00</b>	<b>Lecture 2: IND Process and How to Manage it</b> <b>IND Process: submission, review, approval and 30-day notification period</b> <ul style="list-style-type: none"><li>• Types of IND (sponsor, investigator, compassionate use)</li><li>• Components of the IND: technical sections, financial disclosure, commitments undertaken, Form FDA 1571 and 1572</li><li>• Issues: clinical hold, how to manage inactive INDs, GCP compliance and enforcement</li><li>• Maintenance of INDs: updates and annual reports</li><li>• Electronic Submissions</li></ul>	<b>Miriam Meyer</b> Vice President, Global Head of Regulatory Affairs Immatics
<b>17:00</b>	<b>Close</b>	

**Day 2: Wednesday 25<sup>th</sup> March 2026**

<b>Time</b>	<b>Activity</b>	<b>Speaker</b>
<b>09:15 – 09:30</b>	<b>Introduction to Day 2</b>	<b>Manfred Kurz</b> Independent Consultant
<b>09:30 – 10:45</b>	<b>Lecture 3: Adverse Event Reporting: FDA regulations and reporting procedures</b> <ul style="list-style-type: none"> <li>• Pre-marketed and marketed products</li> <li>• Domestic and international activities</li> <li>• CIOMS and ICH</li> </ul> Workshop/Activity	<b>Chauneen Wood</b> Director of Regulatory Affairs Verathon
<b>10:45 – 11:00</b>	<b>Refreshment Break</b>	
<b>11:00 – 12:30</b>	<b>Lecture 4: Emerging Technologies</b> <ul style="list-style-type: none"> <li>• Stem Cell Therapies</li> <li>• Biosimilars</li> <li>• Combination Products</li> </ul>	<b>Christopher Bravery</b> <b>Manfred Kurz</b>
<b>12:30 – 13:30</b>	<b>Lunch</b>	
<b>13:30 – 15:15</b>	<b>Lecture 5: Communicating with the FDA</b> <ul style="list-style-type: none"> <li>• Product assigned- Division and therapeutic group</li> <li>• Division structured and organisation, Role of regulatory project manager</li> <li>• Initiating and maintaining contact (formal and informal). What is FDA's expectation</li> <li>• Types of meetings (A, B, C) with their respective timetables and package requirements, including "the program" for NMEs/NCEs.</li> <li>• Advisory committee meetings: structure, format, preparation, working examples of meetings and their outcomes, insight into the public influence on approvals</li> <li>• Communicating with field officers</li> <li>• FDA Communication Activity</li> </ul>	<b>Daniela Drago</b> Partner NDA Partners
<b>15:15 – 15:30</b>	<b>Refreshment Break</b>	
<b>15:30 – 16:30</b>	<b>Lecture 6: Breakthrough Therapy Designation Fast Track Approvals and Orphan Drugs</b> <ul style="list-style-type: none"> <li>• Eligibility and Practical Issues</li> <li>• Post approval obligations</li> <li>• Orphan drug definition</li> </ul> <b>Provisions and Consequences of Orphan Drug Act</b>	<b>Daniela Drago</b> Partner NDA Partners
<b>16:30 – 18:30</b>	<b>Case Study: Applying FDA Rules to Drug Cases</b>	<b>Manfred Kurz</b> Independent Consultant

**Day 3: Thursday 26<sup>th</sup> March 2026**

<b>Time</b>	<b>Activity</b>	<b>Speaker</b>
<b>09:00 – 09:15</b>	<b>Introduction to Day 3</b>	<b>Manfred Kurz</b> Independent Consultant
<b>09:15 – 10:45</b>	<b>Lecture 7: The NDA and BLA</b> <ul style="list-style-type: none"><li>• Definition of drugs, biologics and devices</li><li>• Types of NDAs: 505(b)(1) and (b)(2)</li><li>• Pre-NDA/BLA meetings and pre-submission issues</li><li>• NDA/BLA application structure and components. Also paediatric requirements and waivers, financial disclosure, debarment certification, drug listing /NDC codes, and user fees</li><li>• FDA review process and Advisory Committee meetings</li><li>• Supplemental NDA (sNDA) and NDA maintenance</li><li>• Post approval obligations and annual reports</li><li>• Electronic submissions</li></ul>	<b>Manfred Kurz</b> <b>Paul T Kim</b> <b>Chauneen Wood</b>
<b>10:45 – 11:00</b>	<b>Refreshment Break</b>	
<b>11:00 – 11:45</b>	<b>Lecture 8: Generics and OTC Products:</b> <ul style="list-style-type: none"><li>• Drug Competition and Patent Term Restoration Act</li><li>• Abbreviated New Drug Applications (ANDAs): Content, Data requirements and FDA Review</li><li>• GDUFA</li><li>• Legal basis for OTC</li><li>• Registration of new OTC formulations</li><li>• Switching from prescription to OTC</li></ul>	<b>Kalpana Vanam</b> Senior Vice President (Generics, Specialty and Biosimilar) Lupin Pharmaceuticals
<b>11:45 – 12:30</b>	<b>Lunch</b>	
<b>12:30 – 13:45</b>	<b>Lecture 9: Labelling and Advertising Controls</b> <ul style="list-style-type: none"><li>• Definitions</li><li>• Controls and meaning of the legislation</li><li>• Role and practises of the FDA</li><li>• Influences on industry and academia</li><li>• Direct-to-consumer advertising</li></ul> <p>OPDP Interactions and Submissions</p>	<b>Bob Dean</b> Head of Global Labelling Strategy & Ad/Promo EMD Serono, Inc.
<b>13:45 – 14:15</b>	<b>Course Evaluation and Close</b>	<b>Manfred Kurz</b>