

Module 10: Leadership and Strategic Management Regulatory Affairs  
30<sup>th</sup> January – 1<sup>st</sup> February 2019



De Vere Latimer Estate, Church Lane, HP5 1UG Chesham, UK

**Module Leader(s):** Eva Kopecna and Angela Stokes

**Date:** Wednesday 30<sup>th</sup> January 2019

<b>Time</b>	<b>Activity</b>	<b>Speaker</b>
<b>16.00</b>	Registration	
<b>16.30 – 17.45</b>	Welcome & Introduction To Module 10 Lecture 1: Role and strategic importance of Regulatory Affairs	Dr Eva Kopecna Teva
<b><i>Management in Regulatory Affairs</i></b>		
<b>17.45 – 18.30</b>	Lecture 2: Management in Regulatory Affairs	Angela Stokes Syneoshealth
<b>18.30 – 19.00</b>	New Student Tutorial	Dr Laura Brown Course Director
<b>19.30</b>	<b>Dinner</b>	



**Date:** Thursday 31<sup>st</sup> January 2019

<b>Time</b>	<b>Activity</b>	<b>Speaker</b>
<b>08.30 – 08.35</b>	Introduction	Chairperson: Angela Stokes
<b>08.35 – 09.45</b>	Lecture 3: Management of Regulatory Affairs during mergers and acquisitions	Jonathan Rousell TEVA Pharmaceuticals
<b>09.45 – 10.30</b>	Lecture 4: Life in a Regulatory Agency – From Managed to Manager	Sue Harris MHRA
<b>10.30 – 11.00</b>	Refreshment Break	
<b>Regulatory Operations</b>		
<b>11.00 – 12.30</b>	Lecture 5: Regulatory Submissions and Information Management Regulatory Operations	Ashley Burt Regulatory Submissions and Information
<b>12.30 – 13.30</b>	<b>LUNCH</b>	
<b>Training, Recruitment and Outsourcing in Regulatory Affairs</b>		
<b>13.30 – 14.30</b>	Lecture 6: Search, selection, recruitment, job description and career progression	Paul Foster The RSA Group
<b>14.30 – 15.30</b>	Lecture 7: Outsourcing of RA to CRO – what are the challenges and benefits	Nick Littlebury Diamond Pharma Services
<b>15.30 – 16.00</b>	<b>Refreshment Break</b>	
<b>16.00 – 17.30</b>	Case Study 1	Angela Stokes&Sue Harris
<b>19.00</b>	Dinner	



**Date:** Friday 1<sup>st</sup> February 2019

<b>08.30 – 08.35</b>	Introduction	Chairperson: Eva Kopečna
<b>Communication in Regulatory Affairs</b>		
<b>08.35 – 09.30</b>	Lecture 8: External Communication and regulatory intelligence	Angela Stokes
<b>09.30 – 10.30</b>	Lecture 9: Communication with Regulatory Affairs – Agency perspective	Melanie Pires MHRA
<b>10:30 – 11.00</b>	<b>Refreshment Break and Check Out</b>	
<b>11.00 – 12.00</b>	Lecture 10: Cross-functional communication	John Faulkes Consultant
<b>Project/development planning – Contribution of Regulatory Affairs</b>		
<b>12.00 – 13.00</b>	Lunch	
<b>13.00 – 14.15</b>	Lecture 11: Project/development planning: "Projects & Portfolio"	Helen Easter Teva
<b>14.15 – 14.30</b>	<b>Refreshment Break</b>	
<b>14.30 – 16.15</b>	Case Study 2	Eva Kopečna