

## Module 10: Leadership and Strategic Management in Regulatory Affairs

**Date:** 9 – 11 May 2023



---

**LOCATION:** TOPRA OFFICE, LONDON, UK / ONLINE

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

**Date: Tuesday 9<sup>th</sup> May 2023**

Time (GMT)	Activity	Speaker
14.30 – 14.45	Welcome & Introduction to Module	Eva Kopecna, Acino International
<b><i>Management in Regulatory Affairs</i></b>		
14.45 – 15.45	Lecture 1: Role and Strategic Importance of Regulatory Affairs	Eva Kopecna, Acino International
15.45 – 16.45	Lecture 2: Regulatory Competency Model and its application for development of RA professionals	Daniela Drago, Biogen Eva Kopecna, Acino International

## Module 10: Leadership and Strategic Management in Regulatory Affairs

**Date:** 9 – 11 May 2023



**LOCATION:** TOPRA OFFICE, LONDON, UK / ONLINE

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

**Date: Wednesday 10<sup>th</sup> May 2023**

Time (GMT)	Activity	Speake
09.30 – 09.35	Introduction	Chairperson: Angela Stokes
09.35 – 10.30	Lecture 3: Management in Regulatory Affairs	Angela Stokes, Sharp Regulatory Consulting
10.30 – 11.30	Lecture 4: Leadership and Management of Regulatory Affairs during mergers and acquisitions	Michael Banks, TEVA Pharmaceuticals
11.30 – 12.00	Morning break	
<b>Regulatory Operations</b>		
12.00 - 13.30	Lecture 5: Regulatory Submissions and Information Management Regulatory Operations	Ashley Burt, Seqirus
13.30 – 14.30	Lunch break	
<b>Training, Recruitment and Outsourcing in Regulatory Affairs</b>		
14.30 - 15.30	Lecture 6: Search, selection, recruitment, job description and career progression	Paul Foster, Rare Talent
15.30 – 16.30	Lecture 7: Outsourcing of RA to external service provider – what are the challenges and benefits	Stephan Hütter, PharmaLex
16.30 - 17.00	<b>Refreshment Break</b>	
17.00 – 17.30	Case Study 1	Angela Stokes

## Module 10: Leadership and Strategic Management in Regulatory Affairs

**Date:** 9 – 11 May 2023



**LOCATION:** TOPRA OFFICE, LONDON, UK / ONLINE

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

**Date:** Thursday 11<sup>th</sup> May 2023

Time (GMT)	Activity	Speake
09.00 – 09.30	Case Study Feedback	Angela Stokes
09.30 – 09.35	Introduction	Chairperson: Eva Kopečna
<b><i>Communication in Regulatory Affairs</i></b>		
09.35 – 10.45	Lecture 8: External Communication and regulatory intelligence	Angela Stokes
10.45 – 12.00	Lecture 9: Communication with Regulatory Affairs – Agency perspective	Melanie Pires, Nicole Small, MHRA
12.00 – 12.15	Morning break	
12.15 – 13.15	Lecture 10: Cross-functional communication	John Faulkes Consultant
<b><i>Project/development planning – Contribution of Regulatory Affairs</i></b>		
13.15 – 14.00	Lunch break	
14.00 – 15.15	Lecture 11: Project/development planning: “Projects& Portfolio”	Helen Easter, TEVA Pharmaceuticals
15.15 – 16.45	Case Study 2	Eva Kopečna
16.45 – 17.00	Closure of the module	Eva Kopečna & Angela Stokes