

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 9th May 2023

Time (BST)	Activity	Speaker
13.30 – 13.45	Welcome & Introduction to Module	Chairperson: Eva Kopecna, Acino International
13.45 – 14.45	Lecture 1: Role and Strategic Importance of Regulatory Affairs	Eva Kopecna, Acino International
14.45 – 15.00	Afternoon Break	
15.00 – 15.45	Lecture 2: Regulatory Competency Model and its Application for Development of RA Professionals	Daniela Drago, NDA Partners
15.45 – 16.45	Lecture 3: Management in Regulatory Affairs	Angela Stokes, Sharp Regulatory Consulting
16.45 – 17.00	Questions & Answers	All

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Date: Wednesday 10th May 2023

Time (BST)	Activity	Speaker
09.00 – 09.05	Introduction to Day 2	Chairperson: Angela Stokes, Sharp Regulatory Consulting
09.05 – 10.05	Lecture 4: Leadership and Management of Regulatory Affairs during Mergers and Acquisitions	Eva Kopecna, Acino International
10.05 – 11.05	Lecture 5: External Communication and Regulatory Intelligence	Angela Stokes, Sharp Regulatory Consulting
11.05 - 11.20	Morning Break	
11.20 – 12.30	Lecture 6: Communication with Regulatory Affairs – An Agency Perspective	Janine Jolly, MHRA
12.30 – 13.15	Lunch Break	
13.15 – 14.15	Lecture 7: Cross-functional Communication	John Faulkes, Consultant
14.15 – 17.00	Case Study 1 (Includes afternoon refreshment break)	Angela Stokes, Sharp Regulatory Consulting
17.00 – 17.30	Case Study 1 Feedback	Eva Kopecna, Acino International

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Time (BST)	Activity	Speaker
09.20 – 09.25	Introduction	Chairperson: Eva Kopecna, Acino International
09.25 – 10.25	Lecture 8: Search, Selection, Recruitment, Job description and Career Progression	Natalie Jones Regulatory Affairs Recruitment Linkfield Life Sciences Ltd.
10.25 - 10.40	Morning Break	
10.40 – 11.40	Lecture 9: Outsourcing of RA to External Service Provider – What are the Challenges and Benefits?	Stephan Hütter, PharmaLex
11.40 – 12.40	Lecture 10: Project Development Planning: “Projects & Portfolio”	Helen Easter, TEVA Pharmaceuticals
12.40 – 13.15	Lunch Break	
13.15 – 14.15	Lecture 11: Organisational Leadership & Governance	Steve Hayes, Regulatory Alchemist
14.15 – 15.45	Case Study 2	Eva Kopecna, Acino International
15.45 – 16.00	Closure of the Module	Eva Kopecna, Acino International