

Module 10: Leadership and Strategic Management in Regulatory Affairs

Date: 10-12 November 2025



LOCATION: TOPRA OFFICE, LONDON, UK / ONLINE

Module Leader(s):

Date:

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

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	Introduction to Day 2	Chairperson: Angela Stokes, Sharp Regulatory Consulting
	Lecture 4: Leadership and Management of Regulatory Affairs during Mergers and Acquisitions	Eva Kopečna, Acino International
	Lecture 5: Communication with Regulatory Affairs – An Agency Perspective	Janine Jolly, MHRA
	Morning Break	
	Lecture 6: External Communication and Regulatory Intelligence	Angela Stokes, Sharp Regulatory Consulting
	Lunch Break	
	Lecture 7: Cross-functional Communication	John Faulkes, Consultant
	Case Study 1 (Includes afternoon refreshment break)	Angela Stokes, Sharp Regulatory Consulting
	Case Study 1 Feedback	Eva Kopečna, Acino International

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Introduction

Chairperson:
Eva Kopecna, Acino
International

Lecture 8: Search, Selection,
Recruitment, Job description and Career
Progression

Natalie Jones
Regulatory Affairs
Recruitment Linkfield
Life Sciences Ltd.

Morning Break

Lecture 9: Outsourcing of RA to External
Service Provider – What are the
Challenges and Benefits?

Stephan Hütter,
PharmaLex

Lecture 10: Project Development
Planning: “Projects & Portfolio”

Helen Easter, TEVA
Pharmaceuticals

Lunch Break

Lecture 11: Organisational Leadership &
Governance

Steve Hayes,
Regulatory Alchemist

Case Study 2

Eva Kopecna, Acino
International

Closure of the Module

Eva Kopecna, Acino
International