Module 10: Leadership and Strategic Management in Regulatory Affairs

Date: 10th of November 2025 to 12th of November 2025

LOCATION: TOPRA THIRD FLOOR, CITY REACH
5 GREENWICH VIEW PLACE, E14 9NN

Module Leader(s): Alenka Dražumerič / Leah Heathman

Date: Monday, 10th November 2025

Time (BST)	Activity	Speaker
09.00 – 09.15	**Welcome & Introduction to Module**	Chairperson: Alenka Dražumerič Introduction to Module 10 by Leah Heathman
09.15 – 10.15	Lecture 1: Project Development Planning: "Projects & Portfolio"	Helen Easter *TEVA Pharmaceuticals*
10.15 – 11.15	Lecture 2: Role and Strategic Importance of Regulatory Affairs	Leah Heathman *Fusion Pharma*
11.15 – 11.30	**Morning Break**	
11.30 – 12.30	Lecture 3: Management in Regulatory Affairs	Gabriel Micallef *Astra Zeneca*
12.30 – 13.30	**Lunch Break**	
13.30 – 14.30	Lecture 4: Regulatory Intelligence and the AI Advantage	Natasha Long *Fusion Pharma*
14:30 – 14.45	**Afternoon Break**	
14.45 – 16.45	Case Study 1	
16.45 – 17.15	Case Study 1 Feedback	
	Questions & Answers	

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Date: Tuesday, 11th November 2025

Time (BST)	Activity	Speaker
09.00 – 09.15	**Introduction to Day 2**	Chairperson: Leah Heathman
09.15 – 10.15	Lecture 5: Search, Selection, Recruitment, Job description and Career Progression	Sue Allen *Mundipharma*
10.15 – 11.15	Lecture 6: Regulatory Competency Model and Its Application for Development of RA Professionals	Vincenzo Cannizzaro, PhD *Global Regulatory Affairs Expert*
11.15 – 11.30	**Morning Break**	
11.30 – 12.30	Lecture 7: Cross-functional Communication	John Faulkes *Phetairos Ltd.*
12.30 – 13.30	**Lunch Break**	
13.30 – 14.30	Lecture 8: Communication with Regulatory Affairs – An Agency Perspective	Thao Huynh *MHRA*
14.30 – 14.45	**Afternoon Break**	
14.45 – 16.45	Case Study 2	
16.45 – 17.15	Case Study 2 Feedback	
	Questions & Answers	

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Date: Wednesday 12th November 2025

Time (BST)	Activity	Speaker
09.00 – 09.05	**Introduction to Day 3**	Chairpersons: Alenka Dražumerič / Leah Heathman
09.05 – 10.05	Lecture 9: Outsourcing of RA to External Service Provider	Stephen Huetter *Pharmalex*
10.05 – 11.05	Lecture 10: Leadership and Management of Regulatory Affairs during Mergers and Acquisitions	Eva Kopecna *Acino International*
11.05 – 11.15	**Morning Break**	
11.15 – 12.15	Lecture 11: Organisational Leadership & Governance	Rade Injac, PhD, MBA *Senior Research Fellow, University of Ljubljana*
12.15 – 12.30	**Closure of the Module**	