



ALMAC EU PRODUCT LAUNCH WORKSHOP

Tuesday 13th November 2018

Hilton San Francisco Airport Bayfront

Time	Topic	Presenter(s)
08:00 - 08:30	Registration & Breakfast	
08:30 - 08:45	Welcome & Introductions	Adam Schroeder Director of Business Development, Almac
08:45 - 09:30	Considerations for Setting up an EU Entity and planning for Brexit	Victor Cowper Client Services Manager, PharmaLex
09:30 - 10:00	Preparing for a product launch and the importance of project management	David Finlay Client Team Leader, Almac
10:00 - 10:45	Introduction to the EU Regulatory Framework	David McCoubrey Regulatory Affairs Lead, Almac
10:45 - 11:00	Tea / Coffee Break	
11:00 - 11:30	The Role of the Qualified Person	Donna McKenna Product Quality Operations Manager, Qualified Person, Almac
11:30 - 12:00	Key Considerations for Product Launch & Packaging Design - The Differences between US & EU	Rory Davidson Business Support Manager, Almac
12:00 - 12:30	Panel Discussion	Almac & PharmaLex
12:30 - 13:15	Lunch & Networking	
13:15 - 14:00	EU Supply Chain Requirements & Considerations for a Temperature Sensitive Product & Seattle Genetics Case Study	Randall Sittner Associate Director, Global Logistics & Materials Management, Seattle Genetics & Emma Jordan, Logistics Manager, Almac
14:00 - 14:45	Challenges & Keys to Success for an Orphan Drug Product Launch	Evelyn Kelly Managing Director, Orphan Drug Consulting
14:45 - 15:15	Almac's Seamless Brexit Solution	Adam Schroeder Director of Business Development, Almac
15:15 - 15:45	Panel Discussion	Almac & Orphan Drug Consulting
15:45	Closing Remarks	Adam Schroeder Director of Business Development, Almac
	Drinks Networking Reception	

