

EU Product Launch Workshop: Key timeline milestones from PhIII to launch

San Francisco: Monday 16th September 2019 **San Diego:** Tuesday 17th September 2019
Seattle: Thursday 19th September 2019

Agenda

09:00 - 09:15 Registration & Breakfast

09:15 - 09:30 Welcome and introductions

Frederick Cosby, Director of Business Development, Almac

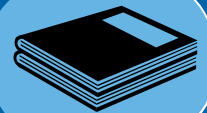
09:30 - 10:15 Introduction to the EU regulatory submission timeline

David McCoubrey, Regulatory Affairs Lead, Almac



10:15 - 10:45 Key quality milestones during product launch

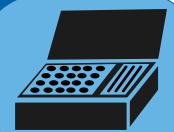
Dawn Douglas, Qualified Person, Almac



10:45 - 11:15 Tea/coffee break

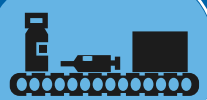
11:15 - 11:45 Pack design and artwork challenges

Stuart Hunter, Packaging Design Manager, Almac



11:45 - 12:15 Key operational considerations for validation & packaging in support of a product launch

Rebecca Tumelty, Client Team Leader, Almac



12:15 - 12:45 EU serialisation compliance

Gary Baird, Business Project Manager, Almac



12:45 - 13:15 Supply Chain Considerations for Product Launch
Emma Jordan, Logistics Manager, Almac



13:15 - 14:00 Lunch & Networking

14:00 - 15:00 Round table sessions: Regulatory, Quality, Pack Design,
Serialisation, Operational & Supply Chain

15:00 - 15:15 Wrap up, prize draw and closing remarks
Frederick Cosby, Director of Business Development, Almac