Meet with ZWIERS!

2dayRA PROGRAM

Day 1	
9.00-9.15	**Meet with Zwiers!** And each other…
9.15-10.30	**RA: All through drug development** Refresher drug development and RA involvement
10.30-11.00	Coffee break
11.00-12.30	**Dossier: content in a common format** Electronic Common Technical Document
12.30-13.15	Lunch
13.15-15.00	**Procedures: obligations or opportunities?** EU marketing authorisations applications and the US New Drug Application
15.00-15.45	Coffee break Quiz **"What's new?"** EU pharmaceutical legislation, MDR
15.45 -17.00	**DIY!** Cases, tasks, discussion
Day 2	
9.00-9.30	**Welcome back** addressing DIY/outstanding/new questions
9.30-11.00	**What's next?** Post approval regulatory requirements and activities
11.00-11.15	Coffee break
11.15-12.30	**DIY – do it right** Cases, tasks, discussion
12.30-13.30	Lunch
13.30-15.00	**Pharmacovigilance: detect, assess, understand and prevent** Explanation on PV activities closely related to RA
15.00-16.30	**Pave the path: regulatory strategy** Interactive session on legal basis, abridged dossiers, exclusivity, special products/procedures

ZWIERS
Regulatory Consultancy
A ProductLifeGroup Company