

Outline of the day

- 08.30 – 09.00 Registration with coffee
- 09.00 – 09.15 Brief introduction of the speakers and outline of the day
- 09.15 – 10.15 A comprehensive overview of the EU-eCTD structure
- 10.15 – 10.30 Questions
- 10.30 – 10.45 Coffee break
- 10.45 – 11.45 Applying for a Marketing Authorization in the EU
- 11.45 – 12.00 Questions
- 12.00 – 13.00 Lunch
- 13.00 – 14.00 Maintenance of your Marketing Authorization in the EU
- 14.00 – 14.15 Questions
- 14.15 – 15.45 Workshop – Submitting a variation in the EU
- 15.45 – 16.00 Coffee break
- 16.00 – 17.00 Tips and tricks for your MAA from a Regulator's perspective
- 17.00 – 17.30 Wrap up and closing by the chairman
- 17.30 – 18.30 Networking drinks