

GMP/GDP CONSULTATIVE COMMITTEE 31stth March 2017, 10:30am – 1:00pm Room G-1, Ground Floor, 151 Buckingham Palace Road.

AGENDA

Tea and coffee available from 10am in Room G-2; a buffet lunch will be provided after the meeting

Item	Title	Speaker
1.	Introduction	Mark Birse
	WelcomeNew Committee Members	
	New Committee Members	
2.	Minutes of the last meeting and Matters Arising	Mark Birse
3.	Brexit	
	Agency update	Mark Birse/Andy Gregory
	Members update	Committee members
4.	Agency Update	
	Changes within MHRA	Mark Birse
5.	Inspectorate Update	
	Operational	
	Inspectorate staff changes &	Tracy Moore
	recruitment	5
	Providing Authoritative Information	
	Agency Symposia	Peter Coombs
	Publications	David Olszowka
	• The Orange/Green Guide	Duvid Olszowka
	• Data Integrity Guidance	Tracy Moore
	Inspectorate Blog	Mark Birse
	Behavioural Insight	Mark Birse
	Proposal for industry-MHRA	JPAG
	collaboration to refine and evolve	
	compliance guidance	
6.	British Pharmacopoeia Update	Helen Corns
7.	Support for Innovation	Ian Rees
8.	Diversion of CDs	Peter Coombs

9. Feedback from the EMA

• GMP-GDP Inspectors Working Group

David Churchward

10. Qualified Persons

11. Falsified Medicines Directive

• Safety Features

12. International Interactions

- EU-USA Mutual Recognition Agreement (formerly MRI)
- International Coalition of Medicines Regulatory Authorities (ICMRA)
- Pharmaceutical Inspection Co-operation Scheme (PIC/S)
- Benchmarking of European Medicines Agencies (BEMA)

13. Any Other Business

14. Date of Next Meeting October 2017

Andy Gregory

Mark Birse

Ian Harwood