Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

GMP/GDP CONSULTATIVE COMMITTEE MEETING
2nd May 2018, 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** • Welcome • New Committee Members	Mark Birse
2.	**Minutes of the last meeting and Matters Arising**	Mark Birse
3.	**Brexit** • Agency update • Members update	Mark Birse/Adrian Bartlett Committee members
4.	**Agency Update** • Changes within MHRA • Accommodation move • Trawl of new senior posts • Operational Transformation.	Mark Birse John Quinn/Rob Knowles
5.	**Inspectorate Update**	
	Operational	
	• GMP staff changes & recruitment	Tracy Moore
	• Stakeholder engagement	Sara Berry
	• GDP team update and changes	Claire Glenister
	• GDP Working with enforcement	Bernadette Wilson
	• Specials manufacturers, short notice inspection programme	Ian Harwood
	• Specials Q&A	Ian Harwood
	Providing Authoritative Information	
	• Agency Symposia ▪ The GMP Symposium agenda ▪ The GDP Symposium agenda ▪ Labs team Symposium	Graham Carroll Bernadette Wilson Christine Gray
	• Data Integrity Guidance – Update	Tracy Moore
	• Inspectorate Blog	Mark Birse
	• Proposal for industry-MHRA collaboration to refine and evolve compliance guidance – JPAG update.	Mark Birse
	• GDP transport issues	Peter Coombs

6. **British Pharmacopoeia Update.** Peter Crowley

7. **DMRC Section** Catherine Pitt

- Staff changes
- Feedback from members/stakeholders about DMRC Guide to defective medicines and reports received.
- Feedback on harmonisation on EMA

8. **Support for Innovation** Ian Rees/ABPI

9. **Diversion of CDs Update on Z drugs** Bruce Figg

10. **Feedback from the EMA**

- GMP-GDP Inspectors Working Group David Churchward
- Work on continuous supply of medicines Bernadette Sinclair-Jenkins

11. **Qualified Persons update** Ian Harwood

12. **Falsified Medicines Directive**

- Safety Features Adrian Bartlett

13. **International Interactions** Mark Birse

- EU-USA Mutual Recognition Agreement
- International Coalition of Medicines Regulatory Authorities (ICMRA)
- Pharmaceutical Inspection Co-operation Scheme (PIC/S)

14. **Any Other Business**

15. **Date of Next Meeting**

To be advised