



GMP/GDP CONSULTATIVE COMMITTEE MEETING
10th October 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
	<ul style="list-style-type: none"> • Welcome • New Committee Members 	
2.	Minutes of the last meeting and Matters Arising	Mark Birse
3.	Brexit	
	<ul style="list-style-type: none"> • Agency update • Members update 	Mark Birse/ Adrian Bartlett Committee members
4.	Agency Update	
	<ul style="list-style-type: none"> • Changes within MHRA • Reappointment of MHRA chairman • Move and operational transformation 	Mark Birse Mark Birse Sam Atkinson
5.	Inspectorate Update	
	<u>Operational</u>	
	<ul style="list-style-type: none"> • GMP staff changes & recruitment • Stakeholder engagement • GDP team update and changes • Inspections in high risk third countries • Periodic update meeting with VMD 	Christine Gray Phil Neale Christine Gray / Richard Andrews Richard Andrews
	<u>Providing Authoritative Information</u>	
	<ul style="list-style-type: none"> • Agency Symposia W/c 20 November <ul style="list-style-type: none"> ▪ GMP Symposium agenda ▪ The GDP Symposium agenda • Data Integrity Guidance – Update • Inspectorate Blog • Behavioural Insight • Proposal for industry-MHRA collaboration to refine and evolve compliance guidance – JPAG update. 	Michelle Rowson Phil Neale Christine Gray Mark Birse Rose Geeson Mark Birse

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| 6. | British Pharmacopoeia Update. | Helen Corns |
| 7. | Support for Innovation | Ian Rees |
| 8. | Diversion of CDs Update on Z drugs | Phil Neale |
| 9. | Feedback from the EMA <ul style="list-style-type: none">• GMP-GDP Inspectors Working Group | David Churchward |
| 10. | Qualified Persons update | Ian Harwood |
| 11. | Falsified Medicines Directive <ul style="list-style-type: none">• Safety Features | Adrian Bartlett |
| 12. | International Interactions <ul style="list-style-type: none">• EU-USA Mutual Recognition Agreement (formerly MRI)• International Coalition of Medicines Regulatory Authorities (ICMRA)• Pharmaceutical Inspection Co-operation Scheme (PIC/S) | Mark Birse |
| 13. | Any Other Business | |
| 14. | Date of Next Meeting
19 April 2018 | |