

GMP/GDP CONSULTATIVE COMMITTEE

8th May 2015, 10:30am – 1:00pm

Room R-T-410, 4th Floor, 151 Buckingham Palace Road.

AGENDA

Tea and coffee available from 10am; a buffet lunch will be provided

| 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. | Agency Update | |
| | <ul style="list-style-type: none"> • Changes within MHRA <ul style="list-style-type: none"> ◦ GOV.UK | Mark Birse Anna Parley |
| | <ul style="list-style-type: none"> • Changes within IE&S | Mark Birse |
| 4. | Inspectorate Update | |
| | <u>Operational</u> | |
| | <ul style="list-style-type: none"> • Inspectorate staff changes & recruitment | Richard Andrews/Andrew Gray |
| | <ul style="list-style-type: none"> • GMDP Compliance Reports <ul style="list-style-type: none"> ◦ Broker Compliance Reports | Tracy Lovatt |
| | <ul style="list-style-type: none"> • Office-based Assessments | Peter Coombs/Andrew Gray |
| | <u>Providing Authoritative Information</u> | |
| | <ul style="list-style-type: none"> • Agency Symposia | Michelle Rowson |
| | <ul style="list-style-type: none"> • Publications <ul style="list-style-type: none"> ◦ The Orange/Green Guide | David Olszowka |
| | <ul style="list-style-type: none"> • GMP/GDP Deficiency Data • Data Integrity Guidance | David Churchward/Phil Neale David Churchward |
| 5. | Support for Innovation | Ian Rees |
| 6. | International Interactions | Mark Birse |
| | <ul style="list-style-type: none"> • TTIP • ICMRA • India • PIC/S | |
| 7. | Qualified Persons | Joint Professional Bodies/ABPI |
| 8. | Falsified Medicines Directive | |
| | <ul style="list-style-type: none"> • Safety Features • Common Logo • Publication of Guidance | Gian Marco Currado Gian Marco Currado Richard Andrews |

9. **Feedback from the EMA**
 - GMP-GDP Inspectors Working Group
 - Shortages
 - JAP audit

10. **Any Other Business**

11. **Date of Next Meeting**
October/November 2015