

**GMP/GDP CONSULTATIVE COMMITTEE**  
**18<sup>th</sup> April 2016, 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
<b>1.</b>	<b>Introduction</b>	Mark Birse
	<ul style="list-style-type: none"> <li>• Welcome</li> <li>• New Committee Members</li> </ul>	
<b>2.</b>	<b>Minutes of the last meeting and Matters Arising</b>	Mark Birse
<b>3.</b>	<b>Agency Update</b>	
	<ul style="list-style-type: none"> <li>• Changes within MHRA</li> <li>• Changes within IE&amp;S               <ul style="list-style-type: none"> <li>○ Quality Strategy</li> </ul> </li> <li>• HMA Multi Annual Work Plan</li> <li>• MHRA annual lecture</li> </ul>	Mark Birse  Nikki Thomas  Mark Birse Mark Birse
<b>4.</b>	<b>Inspectorate Update</b>	
	<u>Operational</u>	
	<ul style="list-style-type: none"> <li>• Inspectorate staff changes &amp; recruitment</li> </ul>	Mark Birse
	<u>Providing Authoritative Information</u>	
	<ul style="list-style-type: none"> <li>• Inspectorate Blog</li> <li>• Agency Symposia</li> <li>• Publications               <ul style="list-style-type: none"> <li>○ The Orange/Green Guide</li> </ul> </li> <li>• Office-Based Assessments</li> </ul>	Mark Birse  Michelle Rowson  David Olszowka  Phil Neale
<b>5.</b>	<b>Bioequivalence issues</b>	Andy Gray
<b>6.</b>	<b>Support for Innovation</b>	ABPI/Ian Rees/Stephen Fawbert
<b>7.</b>	<b>International Interactions</b>	Mark Birse
	<ul style="list-style-type: none"> <li>• MRI</li> <li>• ICMRA</li> <li>• India</li> <li>• PIC/S</li> <li>• BEMA</li> </ul>	
<b>8.</b>	<b>Qualified Persons</b>	Mark Birse/ABPI/ Joint Professional Bodies

- Transitional QPs for MIA(IMP) licences

Michelle Rowson/Bernadette  
Sinclair-Jenkins

**9. Falsified Medicines Directive**

- Safety Features
- Excipients guidance

Andrew Gregory  
Richard Andrews

**10. Feedback from the EMA**

- GMP-GDP Inspectors Working Group

David Churchward

**11. Any Other Business**

- Meeting format

Mark Birse

**12. Date of Next Meeting**

October 2016