Excipients - selection, control, application and suitability

Monday 23rd and Tuesday 24th May 2016

Speakers from MHRA, ExciPact, IPEC and suppliers

A great opportunity for effective networking with multiple registration discounts available

This two day residential meeting focusses on pharmaceutical excipients and the current regulatory environment. The meeting will be held on **Monday 23rd and Tuesday 24th May 2016** at **Burleigh Court, Loughborough, Leicestershire (http://www.burleigh-court.co.uk/)** organised by the Academy of Pharmaceutical Sciences Material Science and Regulatory focus groups.

Background to the Meeting:

Excipients are fundamentally important to the success of new pharmaceutical products. The design of new medicinal products is a risky and lengthy process and excipients play an essential role in delivering the active ingredient to the patient in the most effective way. Excipient use has always been regulated, but recently important new regulations have been introduced on the sourcing of excipients. This meeting has been designed to bring experts in the area together to discuss the implications of these essential changes and share best practice.

This event brings together formulation scientists, material scientists, industry regulatory affairs professionals, assessors and inspectors from the MHRA, excipient suppliers and experts from the International Pharmaceutical Excipients Council (IPEC) to discuss the changing regulatory environment and opportunities relating to excipients. With multiple registration discount this also offers a fantastic opportunity for all researchers to meet the key opinion leaders in the field.

The meeting will also enable discussion of topics where there is an unmet need for information and identify areas that can be progressed further within the APS focus groups and for interested parties to generate funding opportunities.

Meeting Format:

We are very pleased to offer a stimulating two day programme of presentations from high profile speakers who are leading experts in their particular areas and to provide the opportunity to participate in workshop discussion sessions on:

- GMP and regulatory aspects
- Excipient specifications
- Novel excipients

There will also be the opportunity to hear case studies from FMC, BASF and Grace.

With 20% discount for joint registrations this is the ideal way to facilitate learning and generate new ideas within the whole team.

For more information and registrations, please visit us online at:

http://www.apsgb.co.uk/events/default.asp

Excipients - selection, control, application and suitability - Programme

Monday 23rd May 2016	
0900	**Registration and coffee**
0930	***Introduction*** Chairs: Elaine H. Stone, Merlin-PC, Materials Science FG Chair and Malcolm Dash, MHRA, Regulatory FG Chair
0945	***Regulatory expectations regarding GMP of excipients*** Speaker: Richard Andrews, Unit Manager, Inspection Operations, MHRA
1030	***Using the User/Supplier partnership to complete risk assessments for the Falsified Medicines Directive*** Speaker: Kevin Hughes, Regulatory Affairs Manager, Colorcon Limited, UK
1100	**Tea & coffee**
1120	***The use of independent certification to demonstrate appropriate excipient GMP*** Speaker: Kevin McGlue, IPEC
1155	***The role of pharmacopoeial monographs for excipients*** Speaker: Liz Meehan, AstraZeneca
1230	**Lunch**
1330	***Group Discussion #1: GMP and regulatory aspects.*** • What would your ideal excipient be? • What would you want? • Appropriate level of control? • Is there a risk of going too far with excipient GMP? • Should an excipient that has an effect on the patient be more tightly regulated? • What GMP do we need to apply for continuously processed excipients?
1430	***Is Excipient variability an issue?*** Speaker: Mike Tobyn, BMS
1505	***QbD of excipients – an excipient suppliers view*** Speaker: Bastiaan Dickhoff, DFE
1540	***Practical Challenges of Implementation of ICH Q3D – an IPEC EU Q3D Taskforce perspective*** Speaker: Andrew Teasdale, IPEC working party/ AstraZeneca, UK
1610	**Tea & coffee**
1630	***Group discussion #2 :*** • Can we define functionality tests for excipients? • What's an empirical analytical approach? • What's expected in an excipient monograph? • Should we be concerned about the effects of processing on excipients?
1730	**Close**
1900	**Networking dinner**

Tuesday 24th May 2016	
0900	***Setting the scene: Novel Excipients – who needs them?*** Speaker & Chair: Michael Leane, BMS, Ireland
0915	***Toxicologist's interaction with Quality: A Regulatory Toxicologist's view of Excipients*** Speaker: Henry Stemplewski, Expert Non-clinical Assessor, MHRA
0950	***The Regulator's perspective: MHRA support & experience*** Speaker: Dr Elspeth Gray, Senior Pharmaceutical Assessor, MHRA
1020	**Tea & coffee**
1040	***Novel excipients case study: Co-Processed excipients - Prosolv and beyond*** Speaker: Brian Carlin, FMC
1115	***Novel excipients case study: Development of new excipients for better medicines*** Speaker & Chair: Philipp Hebestreit, BASF
1150	***Novel excipients case study: Mesoporous Silicon dioxide : From excipient to drug delivery strategy*** Speaker: Fred Monsuur, Grace
1230	**Lunch**
1330	***Group Discussion #3: Novel Excipients*** • Do we need new excipients at all? • How do we speed up innovation in excipients / formulation or both? • Do new modes of manufacture require or new excipients or merely better understanding? • What variability do we need to track for continuous manufacture?
1500	**Tea & coffee**
1515	***Summary Discussion:*** • Overall summary of what was discussed. • What is best to do with the output from our discussion sessions? • Prioritise hot topics (for adoption by APS focus groups for future action).
1630	**Close**