2018 IPEC EUROPE ANNUAL EXCIPIENTS FORUM - BORDEAUX

Provisional Programme
1 February 2018, Bordeaux, France

8:45 Opening remarks
Mr Frithjof Holtz, IPEC Europe Chair

9:00 The draft General Monograph on Co-processed Excipients and other current developments in the Ph. Eur.
Dr Susanne Keitel, EDQM Director
• Co-processed excipients – where does the Ph. Eur. stand?
• Implementation of ICH Q3D in the Ph. Eur. – an update
• General Methods' Modernisation Program

9:45 Co-processed excipients
Mr Brian Carlin, IPEC-Americas Consultant

10:30 Coffee break

11:00 Updating USP-NF Excipient Monographs: Strategies and Challenges
Ms Catherine Sheehan, USP Senior Director Science – Excipients
• Update on USP's Excipients program unit in terms of monograph and general chapter up to date initiative (modernisation)
• Current work carried out in the area of harmonization that relates to excipients at the PDG level and at the global collaboration /harmonization level, such as bilateral harmonization efforts currently underway through MOUs such as CHP and JP, as well as other opportunities of collaboration

11:45 WHO: Good Pharmacopoeial Practices and future convergence
Dr Sabine Kopp, WHO Group Lead Medicines Quality Assurance
• WHO convenes together with a host pharmacopoeia the series of international meeting of world pharmacopoeias. Usually attendance is 40-60 representatives from world pharmacopoeias, representing about 50 pharmacopoeias and pharmacopoeial authorities.
• The focus of these meetings lies in the collaboration towards convergence among the world pharmacopoeias and includes the drafting of good pharmacopoeial practices (GPhP) (as a baseline towards convergence).
• The outcome of these meetings should ultimately benefit patients through collaboration among world pharmacopoeias. The new synergies resulting from the GPhP will reduce potential duplication and foremost will enhance international efforts, to enable patients to be treated with safe quality medicines, all around the world.

12:30 Morning Q&A

12:45 Lunch

14:00 **Latest update on Chinese regulation related to excipients**
Mr Colin Li, Merck, IPEC China Chair

14:45 Quality by Design (QbD) through collaboration between suppliers & users

Dr Yvonne Rosiaux, Gattefossé
- General introduction to QbD and the role of excipients
- User-supplier collaborations – theory vs practice
- Short introduction to Gattefossé and internal QbD approach
- Case study with Compritol 888 ATO
    - USP range and batch-to-batch variability
    - Potential CMAs
    - Effects of CMAs on final drug product

15:30 **Coffee break**

16:00 Excipient attributes required for parenteral formulations
Ms Elham Blouet, Roquette Frères Global Market Manager

16:30 Risk assessment for GMP excipients
Ms Kate Coleman

17:00 Afternoon Q & A

17:15 Closing remarks
Mr Frithjof Holtz, IPEC Europe Chair

18:45 **Transfer to 'Château Smith Haut Lafitte'** (33650 Bordeaux Martillac, France)

19:30 **Cocktail reception and guided wine cellar visit**

20:00 **Forum Dinner**

23:00 **Transfer to Grand Hotel of Bordeaux**