2018 IPEC EUROPE ANNUAL EXCIPIENTS FORUM - BORDEAUX

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**
Dr Susanne Keitel, EDQM

- Co-processed excipients – where does the Ph. Eur. stand?
- Implementation of ICH Q3D in the Ph. Eur. – an update
- General Methods' Modernisation Program

Session Chair – Dr Frank Milek, IPEC Europe Vice-Chair

9:45 **Co-processed Excipients**
Mr Brian Carlin, Excipient Expert

10:30 **COFEE BREAK**

11:00 **Updating USP-NF Excipient Monographs: Strategies and Challenges**
Ms Catherine Sheehan, USP

- 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**

Session Chair – Adrian Bone, IPEC Europe Senior Advisor

14:00 **Update on Chinese Regulations Related to Excipients**
Mr Colin Li, Merck, IPEC China Chair

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Session Chair – Dr Amina Faham, IPEC Europe Board Member

14:45 **Risk Assessment for GMP excipients**
Ms Kate Coleman, McGee Pharma International

15:15 **COFFEE BREAK**

15:45 **Quality by Design (QbD) Through Collaboration Between Suppliers & Users**
Dr Yvonne Rosiaux, Gattefossé & Dr Brian Carlin, Excipient Expert

- 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
    - o USP range and batch-to-batch variability
    - o Potential CMAs
    - o Effects of CMAs on final drug product

16:30 **Excipient Attributes Required for Parenteral Preparations**
Ms Elham Blouet, Roquette Frères

17:00 **Afternoon Q & A**

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

18:45 **Transfer to Château Smith Haut Lafitte – Grand Cru Classé**

19:30 **COCKTAIL RECEPTION**
with a wine cellar tour

20:00 **FORUM DINNER**

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

Programme subject to change