The 7th Workshop on the Characterisation of Heparin Products

Symposium organized by the National Institute for Biological Standards and Control and United States Pharmacopeial Convention

Sponsored by Institute of Pharmaceutical Science, King's College London

12 - 13 December 2017, Coin Street Neighbourhood Centre, London

~ Agenda ~

Day 1, Tuesday, 12 December 2017	
08:45 – 09:45	**Registration** with Coffee
09:45 – 09:50	**Welcome Address** *Clive Page, Professor of Pharmacology and Therapeutics, Director of Sackler Institute of Pulmonary Pharmacology, Institute of Pharmaceutical Sciences, King's College London.*
09:50 – 10:20	**Key note presentation** *Heparin, past, present and future. - H Coen Hemker, Emeritus Professor of Biochemistry, University of Maastricht, Netherlands*
10:20 – 11:45	**Session 1: Regulatory and Pharmacopoeia perspectives** Chair – Wes Workman, Pfizer.
10:20 – 10:40	*FDA Perspectives and recommendations for heparin applications – Ali Al-Hakim, CDER/FDA, USA*
10:40 – 10:55	*LMM Heparin Characterisation: SEC calibration method(s) and reference standards – Eriko Terao, EDQM*
10:55 – 11:10	*Heparin monographs in the European Pharmacopoeia – Olga Kolaj-Robin, EDQM*
11:10 – 11:30	*Brazilian Pharmacopoeia: distinct monographies for bovine and porcine heparins – Paulo Mourao, University of Rio de Janeiro, Brazil*
11:30 – 11:45	Q&A
11:45 – 12:30	**Session 2: Bovine Heparin, part I** Chairs – David Keire, CDER/FDA and Kevin Carrick, USP
11:45 – 12:05	*USP Bovine Heparin Round Robin Presentation: 1D and 2D-HSQC NMR: two methods to distinguish and characterise heparin from different animal and tissue sources – Marco Guerrini, Ronzoni Institute, Italy*
12:05 – 12:20	*USP Bovine Heparin Round Robin Presentation: Impurities – Wes Workman, Pfizer Inc, USA*
12:20 – 12:30	*Q&A*
12:30 – 13:30	**Lunch Break**

13:30 – 14:40	**Session 2: Bovine heparin, Part II**
13:30 – 13:40	*<u>USP Bovine Heparin Round Robin Presentation:</u> Molecular weights – Barbara Mulloy, King's College London, UK*
13:40 – 13:55	*<u>USP Bovine Heparin Round Robin Presentation:</u> Potency – Elaine Gray, NIBSC, UK*
13:55 – 14:10	*A bovine intestinal heparin preparation with high anticoagulant activity – Paulo Mourao, University of Rio de Janeiro, Brazil*
14:10 – 14:30	*FDA Proposals for reintroduction of bovine heparin to the US market – Ali Al-Hakim, CDER/FDA, USA*
14:30 – 14:40	Q&A
14:40 – 14:50	**Interlude**
14:50 – 16:10	**Session 3 – Heparin Safety Considerations** Chair – Ali Al-Hakim, FDA
14:50 – 15:05	*Prion removal during the heparin manufacturing process – David Keire, CBER/FDA, USA*
15:05 – 15:25	*Linking physicochemical characteristics of heparin-protein complexes with immune activation - Cynthia Sommers, CBER/FDA, USA*
15:25 – 15:45	*Immunogenicity studies of bovine heparin – Gow Arepally, Duke University, USA*
15:45 – 16:00	*Structural process impurities in heparin due to the use of basic conditions in the heparin process – Pascal Anger, Sanofi, France*
16:00 – 16:10	Q&A
16:10 – 16:35	**Coffee Break**
16:35 – 18:00	**Session 4 – Heparin Characterisation** Chair – Tim Rudd, NIBSC
16:35 – 16:50	*Determination of heparin activity by HSQC NMR – Bulent Ustun, Apsen Oss, Netherlands*
16:50 – 17:05	*A new process to produce high purity heparin sodium – Richard Yin, Yino Pharma, China*
17:05 – 17:20	*SAX-HPLC and HSQC NMR spectroscopy: orthogonal methods for characterising heparin batch composition – Franco Spelta, Opocrin SpA, Italy*
17:20 – 17:35	*Breakthrough in heparin analysis: holistic control by NMR spectrometry – Bernd Diehl, Spectral Services AG, Germany*
17:35 – 17:50	*USP potency adjusted bovine mucosal heparins are comparable to porcine mucosal heparin at equivalent level – Walter Jeske, Loyola University, USA*
17:50 – 18:00	*Q&A*
18:00 – 19:00	**Networking Drinks Reception**

Day 2, Wednesday, 13 December 2017	
09:00 – 10:25	**Session 5 - Low Molecular Weight heparin** Chair – Elaine Gray, NIBSC
09:00 – 09:15	*The single crystal X ray structure of the synthetic anticoagulant pentasaccharide fondaparinux sodium – Edwin Kellenbach, Aspen Oss, Netherlands*
09:15 – 09:30	*A highly integrated heparin supply chain and characterisation of a LMWH – Zhenyu Wang, Celsus Laboratories, USA*
09:30 – 09:45	*Sheep heparin and enoxaparin as an alternate for porcine heparin and porcine enoxaparin – Yiming Yao, Ronnsi Pharma, China*
09:45 – 10:10	*Scientific considerations in the approval of generic low-molecular weight heparins (LMWHs) in the United States. Andre Raw, CDER/FDA, USA*
10:10 – 10:25	Q&A
10:25 – 10:45	**Coffee Break**
10:45 – 12:00	**Session 6 – Heparin into the future** Chairs – Barbara Mulloy and Clive Page, King's College London
10:45 – 11:00	*Recombinant heparin: new opportunities – Charles Glass, Tega Therapeutics, USA*
11:00 – 11:15	*Novel biomedical applications of modified heparins and heparin by products – Jerry Turnbull, University of Liverpool, UK*
11:15 – 11:30	*New low-anticoagulant heparin analog from mollusc as potential antimetastatic drug - Rafael Aquino, Glicotech, Brazil*
11:30 – 11:50	*Beyond anticoagulation – new uses for heparin 100 years on – Clive Page, King's College London, UK*
11:50 – 12:00	*Q&A*
12:00 – 12:30	**Rapporteur Feedback** Wes Workman, Pfizer, USA
12:30 – 13:00	**General Discussion**
13:00	**Close of Workshop**