



European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

WORKSHOP
IN VITRO CYTOKINE RELEASE ASSAYS TO PREDICT
CYTOKINE RELEASE SYNDROME:
THE CURRENT STATE-OF-THE-SCIENCE

To be held at the European Medicine Agency, London
November 19, 2009

8:15	Registration and coffee	
9:00	Introductions and Welcome	<u>Beatriz Silva Lima</u> , Chairperson SWP EMEA (10')
9:10	Key Note Speaker Clinical Features of Infusion Reactions / Cytokine Release Syndrome	<u>Hermann Einsele</u> , University of Würzburg, Germany (30')
9:40	Key Note Speaker Mechanism of Infusion Reactions / Cytokine Release Syndrome	<u>Andrew George</u> , Imperial College London, England (30')
10:10	Optimisation of cytokine release assays for unwanted intrinsic activities of medicines	<u>Stephen Poole</u> , NIBSC, England (20')
10:30	Coffee Break	
10:50	Use of flow cytometry for investigating immunomodulatory effects of medicines	<u>Richard Stebbings</u> , NIBSC, England (20')
11:10	Separation from Self explains failure of circulating T-cells to respond to the CD28 Superagonist TGN1412	<u>Thomas Hünig</u> , University of Würzburg, Germany (20')
11:30	Evaluation of the Soluble and Solid Phase Cytokine Release Assay	<u>Jing Min</u> , Pfizer, St. Louis, MO (20')
11:50	A Novel In Vitro System to Assess Reactogenic Effects of Biologic Agents	<u>Padma Narayanan</u> , Amgen, Seattle, WA (20')
12:10	Whole blood assay; a novel in vitro test for cytokine release	<u>Heather Hinton</u> F. Hoffmann – La Roche AG, Switzerland (20')

12:30	Lunch and Poster Review	(60')
13:30	Development, validation and regulatory approval of a cytokine release test for contaminants	<u>Peter Bruegger</u> , Novartis, Switzerland (20')
13:50	Questions for speakers	(10')
14:00	Challenges with using in vitro assays to predict Cytokine Release Syndrome	<u>Jan Mueller-Berghaus</u> , Paul-Ehrlich-Institut, Germany (15')
14:15	Open Discussion Session Challenges, Future Research Needs	Moderator: <u>Robin Thorpe</u> – NIBSC, England (90')
15:45	Coffee Break and Poster Review Development of Meeting conclusions and list of recommendations by the Planning Committee	(45')
16:30	Summary of the meeting conclusions and recommendation	<u>Jan-Willem van der Laan</u> EMA (30')
17:00	Close	

Planning Committee

Jan-Willem van der Laan
 Marc Pallardy
 Jan Mueller-Berghaus
 Stephen Poole
 Robin Thorpe
 Huub Schellekens
 Karin Cederbrant
 Thomas Kawabata
 Jean-Marc Vidal