Bio
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Preclinical Regulatory Science Symposium
September 9, 2010

Mark Rogge, Ph.D.
Chair, BioSafe

Agenda

- **Introduction**

- **Study Design Considerations For Biopharmaceuticals**
  Maggie Dempster - Glaxo Smith Kline
  Theresa Reynolds – Genentech

- **Unique PK/PD Properties of Biotechnology-Based Therapeutics and FIH Considerations**
  Peter Lloyd – Novartis
  Mark Rogge – Biogen Idec

- **Options to address reproductive toxicity with biotechnology-derived products: appropriate study design and data interpretation**
  Jenny Sims - Novartis
  Pauline Martin - Centocor (Johnson & Johnson)

- **Immunogenicity (Anti-Drug Antibody) Testing Strategies for Nonclinical Toxicity Studies and Results Interpretation**
  Marque Todd - Pfizer
  Danuta Herzyk – Merck

- **Carcinogenicity Assessment of Biopharmaceuticals: A Review of Recent Practices with Case Studies**
  Shawn Heidel - Eli Lilly
  John Vahle - Eli Lilly

- **Open Discussion – All Attendees and Speakers**

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Participants

Mark Rogge, Ph.D.
Biogen Idec

Marque Todd, DVM, PhD
Pfizer

Maggie Dempster, PhD
Glaxo Smith Kline

Pauline Martin, PhD
Centocor

Theresa Reynolds, PhD
Genentech

Katie McCarthy
BIO

Shawn Heidel, DVM, PhD
Eli Lilly

Peter Lloyd, PhD
Novartis

Jenny Sims, PhD
Novartis

Danuta Herzyk, PhD
Merck

Kelly Lai
BIO

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BioSafe

- The mission of BioSafe is to serve as a resource for BIO members and BIO staff by identifying and responding to key scientific and regulatory issues related to the preclinical safety evaluation of biopharmaceutical products.
  - *Outreach & Education*
  - *Regulatory Authority Dialog*
  - *ICH Participation*

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Bio
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

- Created in 1993
- Headquarters – Washington, DC USA
- Largest Biotechnology Organization
  > 1000 Companies Represented
- Encompasses Healthcare, Agricultural & Industrial Biotechnology Industries

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BIO Health Section Governing Board

BIO Regulatory Affairs Committee

BioSafe

Executive Committee
Leadership Committee
Expert Working Groups
Task Forces
General Membership

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BioSafe Leadership Committee

Mark Rogge (Biogen Idec)	*Chair*	2013
Jenny Sims (Novartis)	*Vice Chair*	2012
George Treacy (Centocor)	*Sec'y*	2013
Laura Andrews (Genzyme)		2010
Jeanine Bussiere (Amgen)		2011
Joy Cavagnaro (Access BIO)		2012
Maggie Dempster (GSK)		2012
Jim Green (Biogen Idec)		2013
Shawn Heidel (Lilly)		2011
Christopher Horvath (Taligen)		2012
Marque Todd (Pfizer)		2013
Randy Soltys (Genentech)		2010
Ken Hastings (Sanofi-Aventis)		2010
Stan Roberts (SARSafety)		2011
Diann Blanset (Consultant)		2012

Katie McCarthy (*BIO)*

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BioSafe Expert Working Groups

CBER EWG

Tim MacLachlan, Chair

Blood Products

Inge Ivens – Bayer *
Birgid Reipert – Baxter
Jenny Melquist – Hematech
Mehrshid Alai – Baxter
Monica Richardson – Baxter
Linda Zuckerman – ProFibrix

Vaccines

Deborah Novicki – Novartis *
Sarah Gould – Sanofi-Pasteur
Danuta Herzyk – Merck
Peter Thomas – Covance
Frank Brennan – Novartis
Martha Leibbrandt – Novartis
Leigh Ann Burns-Naas – Pfizer
Michaela Sharpe – Pfizer
Martin Finkelstein – Pfizer
Ken Draper – LAB

Gene Therapies

Tim MacLachlan – Genzyme *
Laura Dill-Morton – Novartis

Cell Therapies

Lauren Black – Charles River *
Jane Lebkowski – Geron
Sicco Popma – Centocor
Clifford Sachs – Centocor
Peter Bugelski – Centocor
Vladimir Vexler – Roche

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BioSafe Expert Working Groups

PKD EWG

Peter Lloyd, Chair

Peter Lloyd	Novartis
Ivan Nestorov	Biogen Idec, Inc.
Honghui Zhou	Johnson & Johnson Pharma
Hua Yang	Millennium Pharmaceuticals, Inc.
Kerry Culm-Merdek	Genzyme Corporation
Tarundeep Kakkar	Amgen
Frank-Peter Theil	Genentech, Inc.
Vic Wroblewski	Lilly Researh Laboratories
Volker Fischer	Abbott
Andreas Baumann	Bayer Schering Pharma
Xin Xu	Pfizer
Stan Roberts	SarSafety, Inc
Mark Rogge	Biogen Idec, Inc.

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BioSafe Task Force Groups

Juvenile Toxicity Assessments
Tim Coogan, Chair

Comparability Assessments
Joy Cavagnaro, Chair

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Key Ongoing Activities

ICH Participation

- S6 R1 (Shawn Heidel)
- S9 (Jim Green)
- S12 (TBD)

White Papers

- Carcinogenicity (Published)
- Immunogenicity (Published)
- Chronic Toxicity Studies (Published)
- TCR (Published)
- FIH (Published)
- ADC (Submitted for publication)
- Comparability (In Draft)

Annual Scientific Symposium

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New Initiatives

Expand Regulatory Agency Interactions

- FDA (2010)
- **PMDA (2010)**
- EMEA (2011)
- SFDA (2011)

Expand Educational Activities

- Internet Lecture Series (Webinars)

Increase Expert Working Group & Task Force Activities

- Juvenile Tox Task Force (Tim Coogan)
- Biosimilar Task Force (Joy Cavagnaro)
- Benchmarking Surveys (Volker Fischer, TBD)

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Questions?

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