



Controlled Release Society

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ANNUAL MTGS & EXPOS

- 2010 Annual Mtg & Expo

CALENDAR

- CRS/AAPS Workshop
Nov 7-8, 2009
Los Angeles, CA

Past Meetings

- 2009 Annual Mtg & Expo
- 2008 Annual Mtg & Expo
· Highlights of the Mtg
- 2007 Annual Mtg & Expo
- 2006 Annual Mtg & Expo

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DEVELOPMENT AND REGULATORY CHALLENGES FOR CONTROLLED RELEASE

FORMULATIONS

CRS/AAPS WORKSHOP

LOS ANGELES CONVENTION CENTER

NOVEMBER 7-8, 2009

LOS ANGELES, CALIFORNIA



Chaired by the CRS Young Scientist Committee:

Dody Reimer, Northern Lipids, Inc., Canada; Avinash Thombre, Pfizer, Inc., U.S.A.; Ron Ortiz, Upsher Smith, U.S.A.; and Louise Rosenmayr-Templeton, Tower Pharma Consulting, Austria

Who Should Attend?

Industrial, government, and academic professionals from research and development, quality assurance, and regulatory affairs who have responsibility for the design, development, and registration of controlled/modified release dosage forms should attend this two-day joint CRS/AAPS workshop.

Educational Objectives:

- To provide an understanding of the developmental and regulatory challenges for controlled release formulations utilizing mature and evolving new technologies in Europe and North America.
- To provide a venue for Young and/or established scientists to informally meet with other scientists and regulatory authorities.
- To share and discuss fundamental science and experiences that may be of value to individuals dealing with various CR technologies.
- To gain an understanding of the differences between the regulatory bodies of EU and the FDA.
- To increase an individual's knowledge about a variety of controlled release technologies that may not be found in the literature through shared experiences and panel discussions.
- To apply newly acquired knowledge and a suitable approach to the potential design of the attendees own pharmaceutical products.

How to Register**?

CRS members can register at the AAPS member rates. Register with AAPS by September 11, 2009, for the best rates.

[Registration Form](#) * [Online Registration](#)

[AAPS Annual Meeting & Exposition Website](#)

*Registration rates include two days of programming, with coffee breaks and two lunches. The registration fee does not include breakfast.

How to Sponsor?

This workshop offers a unique and targeted audience. To support the workshop and gain visibility with a sponsorship, please contact CRS staff [Deborah Woodard](#) (phone: +1.651.994.3817).

Saturday, November 7: Day 1



07:30 – 08:30	Registration
08:30 – 08:45	Welcome and Workshop Objectives - Introduction to Day 1 Session 1: MATURE TECHNOLOGIES
08:45 – 09:30	<i>The Regulatory Challenges During the Development of Risperdal Consta – A Long Acting Injectable</i> , Michael Palmieri, Alkermes, Inc., U.S.A.
09:30 – 10:15	<i>Development of Orally Disintegrating Tablets</i> , Richard Green, Pfizer, U.K.
10:15 – 10:45	Networking Coffee Break
10:45 – 11:30	<i>The Development History of NanoCrystal® Products: A Ten-Year Perspective</i> , Elaine Liversidge, Elan Drug Technologies, U.S.A.
11:30 – 12:00	Panel Discussion
12:00 – 13:30	Networking Lunch Provided by CRS
13:30 – 14:15	<i>Developmental and Regulatory Challenges with Liposomes</i> , Tom Redelmeier, Northern Lipids, Inc., Canada
14:15 – 15:00	<i>Development and Regulatory Challenges Associated with the Transdermal Delivery of Small Molecules</i> , Michael Horstmann, LTS Lohmann Therapie Systeme AG, Germany
15:00 – 15:30	Networking Coffee Break
15:30 – 16:15	<i>Carrying out Early Phase Clinical Trials in the European Union on Non EU Produced Investigational Medicinal Products: Importation and Qualified Person Certification Challenges</i> , Aidan Madden, FivePharma, Ireland
16:15 – 17:00	Panel Discussion
Sunday, November 8: Day 2	
08:00 – 08:30	Registration
08:30 – 08:45	Summary of Day 1 and Introduction to Day 2 Session 2: EMERGING TECHNOLOGIES
08:45 – 09:30	<i>Developmental and Regulatory Challenges with Interferon Microparticles - Locteron</i> , Laurens van Pinxteren, OctoPlus NV, The Netherlands
09:30 – 10:15	<i>Technical and Regulatory Challenges associated with Diffucaps Drug Delivery Systems</i> , Gopi Venkatesh, Ph.D, Eurand, U.S.A.
10:15 – 10:45	Networking Coffee Break
10:45 – 11:30	<i>Controlled Release and Immunogenicity - A Vaccine Perspective</i> , Kevin Harper, Sanofi-Pasteur, Canada
11:30 – 12:00	Panel Discussion
12:00 – 13:30	Networking Lunch Provided by CRS
13:30 – 14:15	<i>Developmental and Regulatory Challenges with RNAi Therapeutics</i> , Sara Nochur, Anylam, U.S.A.
14:15 – 14:45	Networking Coffee Break
14:45 – 15:30	<i>The Science and Regulatory Perspectives of Controlled Release Products with Emerging Technologies</i> , Patrick Marroum, FDA, U.S.A.
15:30 – 16:00	Panel Discussion