REDUCE COMPLEXITY ENSURE SAFETY

PCI invites you to join us at our European Clinical Trial Seminar
taking place in partnership with Medicon Valley Alliance.

10 November, 2015 Copenhagen

12 November, 2015 Lund

Pharmaceutical manufacturers are facing a new challenge. The recent "Patent cliffs" and the exponential growth in the development of high value pharmaceutical products, biologically developed therapies (Biologics) and live vaccines has increased the importance of robust and carefully managed global clinical supply chains, from molecule to patient.

The latest industry technological breakthroughs are resulting in more effective treatments by virtue of more effective mechanisms of action, which is further complicated by growing size and complexity of clinical trials and greater regulatory demands for safety and efficacy data prior to drug approval.

At PCI we recognise that biologically derived therapeutic products are the new frontier, heralding revolutionary treatments of a number of diseases and injuries.

Join us for our latest seminar where we will address the complexities of working with more challenging therapies and demonstrate how to reduce the complexity whilst constantly ensuring the safety of your drug product.

AGENDA

8:30 AM	Registration and Breakfast	
8:50 AM	Welcome	Bob Misher
9:00 AM	Annex VI: Labelling challenges and the impact on patient safety	Shawn Murtough
9:30 AM	Cold Chain: Packaging techniques (Dry ice/Cold plate technology)	Rachel Griffiths
10:00 AM	Fast Track Packing: Handling adaptive clinical trial designs and minimising efficiencies	Rhys Evans
10:30 AM	Close and Networking	

SPEAKERS AND TOPICS

Changes and Challenges with the EU Trial Regulation

Dr. Shawn Murtough, Lead QP

The EU Clinical Trial Regulation (EU-CTR) was approved in April 2014 and published in the Official Journal of the European Union on 27 May 2014. It entered into force on 16 June 2014 and will come into application no earlier than 28 May 2016. The regulation will bring a number of changes to the way in which clinical trials are run within the EU, this talk seeks to highlight some of those changes and their impact on both sponsors and manufacturers.

In particular we will examine the anticipated impact of;

The single assessment procedure
Subtle but significant changes to label text requirements
The future of Interactive Response Technology (IRT) in conduct of clinical trials

Consideration will be given as to how the regulation will affect clinical trial costs, GMP and compliance.

The Stable Cold Chain: Innovative Packaging Techniques

Rachel Griffiths, Technical Services Manager

The demonstrated exponential growth and the predicted future growth of Biologics has increased the need for cold chain packaging. During this seminar we will consider the current methods of packaging these materials and examine innovative and improved ways of addressing the complexities that traditional methods demonstrate. By attending this presentation delegates will gain a greater understanding of the logistical challenges associated with packaging and low temperatures and the options available to safe guard the cold chain custoday of thier drug product.

Fast Track Packing: Handling adaptive clinical trial designs and maximising efficiencies

Dr Rhys Evans, Project Manager

Traditionally the end to end clinical trials packaging process touches a number of different departments and people with the standard for the turnaround of such projects being anything between 4 to 8 weeks. However, there is an increasing need for rapid packing, labelling and distribution in clinical trials coupled with the need to maintain flexibility of the drug product. The session will address how Fast Track can be beneficial during smaller trials where data is needed as quickly as possible and there will be a review into JiT and how it can reduce cost when running two parallel studies with one or more of the same drugs and look at the innovative and unique methods FastTrack employs to deliver compliant Clinical Trial supplies, for time-critical studies, in the shortest possible time, without compromising on quality.

Registration info here