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Agenda

1.00 - 2.00pm	**Registration and lunch**
2.00 - 2.10pm	**Welcome and introduction**
2.10 - 2.30pm	**How to enhance biodisponibility?** **JULIEN LEROUDIER, HEAD OF SOLID STATE – SEQENS** It is a fact that around 40% of drugs fail during the preclinical trial process due to bioavailability issues, as such it is of the upmost importance to address bioavailability at the earliest stage of development as possible, allowing faster and greater success of your drug candidates. The Developability Classification System (DCS) has been created for early detection of potential bioavailability issues for oral drug candidates and solutions to be implemented mainly based on solubility and permeability parameters. There are several approaches available to improve drug performance, in this presentation we will review and discuss these methods in more detail
2.30 - 2.50pm	**The use of flow chemistry and biocatalytic steps to deliver an enhanced performance** **RONAN ROCLE, MARKETING MANAGER, INNOVATIVE TECHNOLOGIES – SEQENS** When synthesizing your APIs, implementing flow chemistry and biocatalytic steps will allow you to achieve higher performances compared to classical synthesis routes, but these methods are currently underused due to lack of awareness of the technoligies involved. Operating chemical processes in plug flow reactors has several advantages over batch processes: product quality, safety, competitiveness and sustainability. Enzymatic (or biocatalytic) processes are also of particular interest for chemical synthesis when enantioselectivity or regioselectivity is required, due to the large selective catalytic sites present within enzymes. Advances in protein engineering and bioinformatics allow to design customized enzymes for a wide range of chemical reactions on synthetic substrates. Redesigning API synthesis routes in order to incorporate these approaches is a clear opportunity of improvement. Hear how from our experts.
2.50 - 3.20pm	**Meet your tight timelines with innovative manufacturing solutions** **JEROME DETREILLE, SENIOR DIRECTOR NEW BUSINESS DEVELOPMENT – PCI PHARMA SERVICES** Meeting your first patient in deadline in an increasing complex supply chain environment is becoming more and more of a challenge. The complexities involved in the development of many of today's more complex drug candidates, coupled with increasing regulatory requirements means it is imperative to understand the challenges to successfully develop your products in the shortest yet safest time. In this presentation, Jerome will discuss the key considerations and innovative Engineering Solutions in the development and manufacture of your complex products which will enable you to start your clinical studies in the fastest, most efficient way.
3.20 - 4.00pm	**Networking break – Coffee and snacks**
4.00 - 4.30pm	**Australia as your introduction to clinical trials** **ROB JONES, EXECUTIVE DIRECTOR, BUSINESS DEVELOPMENT, MANUFACTURING EMEA/APAC – PCI PHARMA SERVICES** Australia over the last 20 years has grown to become a destination of choice for the conduct of early phase clinical trials. This presentation will provide an overview of the regulatory and investigational product management requirements in Australia. It will provide up to date information on the regulatory framework for clinical trials in Australia and compare and contrast this with the EU/US requirements. It will also describe the various options for investigational product management, including manufacturing as well as GMP requirements for Phase I packaging and labelling. Attendees should leave with a good understanding of the regulatory and investigational product requirements for Australia.
4.30 - 5.00pm	**Preparing to outsource & selecting the right vendor – access to skills and expertise which may be limited or lacking in-house** **CAROLYN TIMPANY, SENIOR CLINICAL SUPPLY MANAGER – PCI PHARMA SERVICES** In today's digital-first economy globalization is the new norm, with organizations outsourcing activities and augmenting their staff more rapidly than ever. During this session we will explore best practices and practical tips for planning and executing your outsourced clinical supplies activities. We will also review different approaches to outsourcing, and the planning pathway to avoid delays. For those new to the subject, we'll introduce core start up documents, optimal team structures and communication flows to power collaboration - the engine that drives your journey to study success.

5.00 - 5.30pm	**Importing your Clinical Trial Materials into challenging countries** **GAVIN MORGAN, SENIOR MANAGER, GLOBAL LOGISTICS – PCI PHARMA SERVICES** With the continued globalization of clinical trials many sponsors are expanding their research into new countries resulting in a shift in clinical trial sites to emerging regions such as Eastern Europe, Latin America, Asia, the Middle East, and Africa. The importation of IMP into such countries can often provide challenges. Defining a suitable supply chain method and identifying roles and responsibilities is crucial for your clinical trial success. PCI's Gavin Morgan will share some of his own experiences including what needs to be considered and how aligning with all key stakeholders can enable successful importation and study activation.
5.30 - 8.00pm	**Close out – Activity and finger food**

Register now: **pci.com/events/accelerating-your-journey-lyon**
For more information, please email:
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