The scientists at Triclinic Labs and NOVASEP cordially invite you to their complimentary half-day seminar series:

6th Annual Summits on Drug Development

Discover new methods and techniques to improve your drug development programs

(8:30AM-1:15PM)

Boston Marriott Cambridge
Two Cambridge Center, 50 Broadway
Cambridge, Massachusetts 02142 USA
Phone: (617) 515-3390

Time	Scientific Topic	Speaker
8:30-9:00	**Coffee, Continental Breakfast** **Introductions and Welcome**	
9:00-10:00	**Do Amorphous (Non-crystalline) Materials Always Have to be Unstable?** It has been generally accepted that amorphous (non-crystalline) materials are inherently unstable (or metastable at best) and subject to physical and chemical instability. However, working with a large number of amorphous active pharmaceutical ingredients and formulated drug products has taught us that the general assumption of instability is not always true. While freshly prepared amorphous materials do show some relaxation and loss of free volume, there is not always a viable thermodynamic pathway through relaxation towards a more ordered (crystalline or meso-phase) solid form. Relaxation, in these cases, helps to form a high density stable amorphous form. This presentation will share some of our research, experiences, and case studies with 'stable' amorphous forms, and in particular how to accurately characterize their stability and shelf life for scientific, stakeholder, and regulatory purposes.	**Simon Bates, Ph.D.** Research Fellow *And* **G. Patrick Stahly, Ph.D.** Chief Operating Officer
10:00-11:00	**Three Things You Need to Know About Protecting Your Pharmaceutical Intellectual Property** In pharmaceutical R&D, we are constantly pressured to develop a solid form of a drug that is reproducible, stable, and has optimal particle size distribution. In addition, process chemists are challenged to develop a process to manufacture the desired solid form in a high yield and with sufficient target purity. To succeed in such endeavors, "inventing a wheel" is sometimes required, involving non-traditional multi-disciplinary efforts. However, protecting the invention requires more	**Aeri Park, Ph.D.** Vice President

	than just handing over laboratory records to patent attorneys. Pharmaceutical patents can face several hurdles that can invalidate claims, with one of them being the aptly named “death squads”, intent on killing IP rights. In this presentation, I will discuss three things chemists need to know to protect intellectual property. A number of crystalline form and process patent examples will be discussed to learn from the failures and successes of other patent applications.	
11:00-11:15	**Break**	
11:15-12:15	**Smart Processes for Multi-Step Syntheses and Purification From Azides to Antibody Drug Conjugates …** Molecules reaching the pharmaceutical market in the recent years present an ever-growing complexity. In the meantime, purity criteria are more important than ever to ensure patients’ safety. The combination of these two facts represents a big challenge for the manufacturing industry where the right mix of state-of-the-art synthesis and purification is necessary to meet the demand in a cost-effective and time-efficient manner. This presentation focusses on innovative case studies and examples of Novasep’s expertise and capabilities in combining and scaling up a uniquely broad range of technologies from specialized organic reactions to advanced purification services using robust processes under a high-quality standard.	**Yann Bethuel, Ph.D.** Senior Technology Manager, Chemistry
12:15-1:15	**Lunch, Networking, & Discussions**	

Registration is required for this event

Spaces fill up very quickly. Please RSVP.

For more information please contact us at: (US) 765-588-6200 or rfi@tricliniclabs.com

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About the Speakers:

Aeri Park, Ph.D.
Vice President

Dr. Park received her Ph.D. from the University of Oklahoma and is a recognized industry expert in API solid form screening and selection, solid-state characterization of APIs, intermediates, and drug products, crystallization method development, patent prosecution support, and frequently acts as an expert witness in Paragraph IV litigation matters both domestically and internationally. Dr. Park leads Triclinic's efforts in physical and analytical chemistry services as well as contributes to its patent prosecution and litigation expert services practice.

Dr. Aeri Park, was formerly Director of US Operations for Almac Group and established and grew a US-based analytical laboratory for the firm. Prior to joining Almac, Dr. Park was instrumental in the growth and scientific success of SSCI, a solid-state development group.

Yann Bethuel, Ph.D.
Senior Technology Manager, Chemistry

Dr. Yann Bethuel holds a Ph.D. in Organic Chemistry from the ETH Zürich where he studied with Prof. Erick Carreira and Prof. Karl Gademann. He also completed post-doctoral studies at the University of Toronto working with Prof. Mark Lautens.

Since joining Novasep in 2007, Yann has been involved in various projects ranging from managing a cross-functional, multi-skilled project team involved in the validation of phase III cytotoxic Active Pharmaceutical ingredients to developing, scaling-up and supporting manufacturing activities for early phase polyheterocyclic. Yann has recently joined the US headquarters of the company in Philadelphia in July this year. His most recent efforts as Senior Technology Manager, Chemistry have been focused in overseeing the projects in their acquisition and execution phases towards Novasep's Customers. In this matter, he brings extensive technical background and commit into Novasep's technology excellence.

Simon Bates, Ph.D.
Research Fellow

Dr. Simon Bates has more than 30 years of experience working with X-ray and neutron diffraction characterization of the solid state. For the last 9 years, he has been working on characterization and molecular modeling of pharmaceutical materials including both API and drug product systems. Before moving to Triclinic Labs, Dr. Bates worked at SSCI as a Research Fellow and a Principal at Aptuit Consulting. His work on pharmaceutical systems at SSCI/Aptuit lead to 13 peer reviewed publications 10 patent applications.

Dr. Bates' expertise also includes computational modeling of molecular systems, computational methods for IR Spectroscopy and Thermal Analysis, and Chemometrics. His expertise has allowed Dr. Bates to work as a scientific expert in numerous patent litigation and patent prosecution cases. Dr. Bates has more than 40 peer reviewed international publications and has been an invited speaker at many scientific conferences.