Triclinic Labs
Physical and Analytical Chemistry Expertise

ELDICO SCIENTIFIC
THE ELECTRON DIFFRACTION COMPANY

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

2024 Summit on Drug Development

Discover new methods and techniques to improve your drug development program

DATES:

Tuesday, October 15th, 2024
San Francisco, CA at Hilton San Francisco Airport Bayfront
Address: 600 Airport Blvd, Burlingame, CA 94010

Thursday, October 17th, 2024
San Diego, CA at Marriott La Jolla,
4240 La Jolla Village Dr, La Jolla, CA 92037

Tuesday, October 22nd, 2024
Newark, NJ at Liberty International Airport Marriott
1 Hotel Rd.
Newark, NJ 07114

Thursday, October 24th, 2024
Boston, MA at Courtyard by Marriott Cambridge
777 Memorial Drive,
Cambridge, Massachusetts, USA, 02139

Please RSVP before 10/10/2024 (see link below)

Schedule and Abstracts:

Time	Scientific Topic	Speaker
8:30-9:00	**Coffee, Continental Breakfast** **Introductions and Welcome**	Deena Conrad-Vlasak
9:00-9:45	**Introducing electron diffraction, a dedicated electron diffractometer, and the benefits for the Pharma industry** Electron diffraction (3D ED, also known as microED) has emerged as a powerful technique for structural analysis on particles smaller than 1000 nm, offering unique advantages in studying crystalline materials. This presentation introduces the fundamental principles of electron diffraction and highlights the capabilities of the ELDICO ED-1, a state-of-the-art electron diffractometer designed specifically for sub-microcrystalline samples. The ELDICO ED-1, engineered with Swiss precision and innovation, features a unique, optimized design that is tailored for the structure elucidation of nano-sized particles, ensuring the highest quality results. With utmost flexibility in mind, the ELDICO ED-1 has a cutting-edge goniometer, zero distortion by objective lenses, fixed sample-to-detector distance, and advanced automation capabilities. This not only enhances performance but also ensures that the system is ready for the future of electron diffraction as it opens new applications like the so-called Electron Diffraction Crystal Mapping, which can help, for instance, to identify unknown new phases or micro crystallinity in amorphous samples. Other applications interesting for people working in the pharmaceutical industry in the areas of drug discovery, solid state research, chemistry, process development, formulation and IP regulations will also be addressed.	Dr. Gustavo Santiso-Quiñones Ph.D.
9:45-10:30	**Case studies: Using a dedicated electron diffractometer for pharmaceutical applications** The application of electron diffraction in the pharmaceutical industry is rapidly transforming how researchers analyze and characterize microcrystalline materials. This presentation delves into real-world case studies demonstrating the use of a dedicated electron diffractometer, the ELDICO ED-1, in pharmaceutical research and development. The case studies illustrate how electron diffraction can assist even when traditional methods fall short. Some example case studies which will be presented are: - accurately identify polymorphs, cocrystals, or salts - determine the absolute configuration of a molecule - detect unknown impurities in a formulation - crystallization and molecular structure using very low amounts of sample (< 100 µg)	Dr. Gustavo Santiso-Quiñones Ph.D.

	By showcasing successful implementations of the ELDICO ED-1 in overcoming specific challenges in drug development, this talk highlights the instrument's impact on accelerating innovation, improving efficiency, and ensuring the reliability of pharmaceutical processes. Attendees will gain practical insights into the advantages of incorporating electron diffraction into their workflows, positioning them at the forefront of cutting-edge pharmaceutical research.	
10:30-10:45	**Break**	
10:45-11:45	**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 create a process to manufacture the desired solid form in a high yield and with sufficient target purity. To succeed in such endeavors, “inventing the wheel” is sometimes required, involving nontraditional multi-disciplinary efforts. However, protecting the invention requires more than just handing 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, we will discuss three things chemists need to know to protect intellectual property. we will also discuss several crystalline form and process patent examples to learn from the failures and successes of other patent applications.	Aeri Park, Ph.D and David E. Bugay, Ph.D.
11:45-12:30	**Rapid Screening and Development of Amorphous Solid Dispersions (ASD)** Amorphous solid dispersions (ASD) have long been used to increase the solubility and bioavailability of poorly soluble compounds. A considerable amount of research has been carried out and knowledge of the amorphous state and ASD has significantly advanced over the last decade. Surprisingly, the number of examples that combine the different stages of ASD development has been meager. Herein, case studies are presented where ASD candidates were rapidly determined within 2-3 weeks by utilizing a compilation of these techniques. Examples of crystallization onset detection with various analytical techniques, including microED will be presented.	Nico Setiawan, Ph.D. and David E. Bugay, Ph.D.
12:30-1:30	**Lunch, Networking & Discussions**	

About the Presenters

Dr. Gustavo Santiso-Quiñones Ph.D.
Founder of ELDICO Scientific AG

Dr. Gustavo Santiso-Quiñones was born in Guatemala City where he obtained his university degree in Chemistry (1997). He went to Germany to the Free University of Berlin where he obtained a Master degree in Chemistry (04/2000) and later his Ph. D degree (01/2005) in fluorine chemistry in the group of Prof. Dr. K. Seppelt. He has done Post-doctoral research activities in the University of Freiburg and RWTH-Aachen, Germany, and at the EPF-Lausanne, and ETH-Zürich, Switzerland. With more than 20 years of experience in the field of synthesis, crystallization and handling of sensitive or reactive materials and as many years of experience in the field of crystallography, he became independent in 09-2014 founded in Switzerland his own company Crystallise! AG. Since 2014 he offers to the Pharma-, Agro-, and Chemical industries crystallographic services, including the crystallization of the compounds.

Gustavo is also a founder of ELDICO Scientific AG, company which has been established in Switzerland since 2019. In collaboration with Dr. T. Grüne and others, their ideas and crystallographic approach to use Electron Diffraction (microED) for organic compounds, got a Science nomination for “Breakthrough of the year 2018”. The realization of an Electron Diffractometer dedicated to the Pharmaceutical industry, is now a reality where industry is profiting from this technology and device. At the present time Gustavo is Founder and CTO of Crystallise! AG and Founder and Senior Scientist of ELDICO Scientific AG. (https://www.eldico-scientific.com/)

David E. Bugay, Ph.D.
Chief Scientific Officer, Triclinic Labs, Inc.

Dr. Bugay, an AAPS Fellow, has over 35 years of experience in pharmaceutical development and associated intellectual property. Since receiving a Ph.D. in Physical Chemistry, he held advancing positions in the Analytical R&D Department of Bristol-Myers Squibb, was Senior VP of Analytical Chemistry at SSCI, Inc., and was Managing Director of the Legal Services group of Aptuit Consulting. His expertise includes vibrational and NMR spectroscopy, thermal analysis, X-ray diffraction, microscopy, chemometrics, and scientific/expert witness aspects of Paragraph IV patent litigation. Dr. Bugay has been an invited speaker at dozens of conferences and has taught numerous courses worldwide. In addition, he has published many peer-reviewed scientific papers, written book chapters, authored his own book, and served on the USP General Chapters Expert Committee from 2005 to 2010.

Aeri Park, Ph.D.
Chief Operating Officer, Triclinic Labs, Inc.

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 will lead Triclinic's efforts in physical and analytical chemistry services as well as contribute to its patent prosecution and litigation expert services practice. Dr. Aeri Park, was formerly Director of US

Operations for The 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.

Nico Setiawan, Ph.D.
Analytical Chemistry Group Leader, Triclinic Labs, Inc.

Dr. Nico Setiawan received his Ph.D. in Pharmaceutical Science from the University of Kentucky. Nico is an expert in the preformulation space of API development, including solid form screen and selection, solid-state and physicochemical characterization, crystallization process development, development of enabling formulation for poorly soluble compounds, and biorelevant dissolution method development for orally administered compounds. His research focuses on integrating properties of API and physiological barriers to deliver efficacious drug products. Dr. Setiawan has published papers in peer-reviewed journals and presented at national conferences. He is also an active reviewer of several peer-reviewed journals.

References for more information on Electron Diffraction and its capabilities for drug development

1) T. Gruene, et. al., Angew. Chem. Int. Ed., 2018, 57, 16313-16317. (link to paper)
2) T. Gruene, E. Mugnaioli, Chem. Rev. 2021, 121, 11823-11834. (link to paper)
3) J. Bruhn, et. al., Front. Mol. Biosci. 2021, 8, 648603. (link to paper)
4) Simoncic, et. al., Acta Cryst. E., 2023, 79, 410-422. (link to paper)
5) Merkelbach, et. al., Imaging and Microscopy, 2023, 3, 31. (link to paper)
6) D. T. Ungur, et. al., CrystEngComm, 2024. DOI: 10.1039/D4CE00518J (link to paper)
7) I. Rietveld, et. al., Crystal Growth & Design, 2024, 24, 5893-5897. (link to paper)
8) M. Lang, et. al., Molbank, 2024, 2024, M1851. (link to paper)
9) Absolute configuration confirmation using ED

Registration is required for this event

(click the link or scan the QR code)

Please RSVP before 10/10/2024 at

https://tricliniclabs.com/company-information/register-for-upcoming-events.html

Spaces fill up very quickly.

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

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