Driving Cannabis Science & Therapeutics Forward
October 12–13, 2022, San Diego, CA

Featuring Lessons Learned and Case Studies from Industry Experts

With Comprehensive Coverage On:

- Decentralizing Clinical Trials for Rapid Development of Cannabinoid-derived Pharmaceuticals
- Overcoming Formulation & Bioavailability Challenges of Cannabinoids
- CBD & PEA for the Treatment of Diabetic Neuropathic Pain
- Clinical Considerations for Medical Cannabis and Harm Reduction—What Patients and Providers Can Teach Us
- CBG and THCV: Sources of Novel Cannabis Therapeutics
- Navigating IP Opportunities and Risks in Cannabis—What Everyone in the R&D Business Should Know
- Function of the Endocannabinoid System in the Regulation of Endometriosis
- Managing Consumer Protection While Growing a Robust Inclusive Cannabis Space
- Hear from US Pharmacopeia & Health Canada on Cannabis Quality and Safety Testing
- Tissue Culture Techniques in Cannabis & Hemp Cultivation
- Northern Exposure: A Risk-based Approach to Human Subject Non-Therapeutic Cannabis Research—How Canada is Doing It
- Harmonizing Quality Control Standards of Cannabis-derived Products
- Critical Cleaning—the Key to your Product’s Quality & Safety

And Don’t Miss our Exclusive Pre-conference Workshop on October 11th!
Good Manufacturing Practices for the Cannabis Industry—Details Inside!

With Representation From:
Wednesday, October 12

7:00 Check-in & Complimentary Breakfast
7:55 Chairperson Monica Taing’s Welcome & Opening Remarks

Quality Control and Analytical Testing Standards: Current Problems & Potential Solutions

8:00 The Triangulation (Or Strangulation) Consuming Cannabis-Testing Laboratories
Susan Audino, PhD, Instructor/Lead Assessor & Team leader, American Association for Laboratory Accreditation

With the proliferation of legalized cannabis and hemp, there is no shortage of regulations and specifications. Laboratories have been struggling to keep up with specifications to meet regulatory requirements while balancing customer requirements and scientific integrity. Given the lack of a straightforward path or expectation, laboratory owners must juggle all these needs while retaining experienced laboratory personnel. This session will provide insight into the origin of several regulations, insight into the business decisions to compromise science to maintain customer-base, and discuss ways in which technical methods are marginalized to provide greater uncertainty. Further, the nascent industry attracts young and inexperienced scientists who strong-arm lab management for rapid promotion or resign for more ‘impressive’ job titles. The convergence of these elements threatens the legitimacy of the cannabis industry and undermines the consumer-safety base upon which the industry is built. Finally, this session will provide an update on the gains/progress standard test methods may offer testing labs.

8:35 Why Are We Using Non-Selective UV Detectors for Regulatory Cannabinoid Profiling and PotencyTesting?
Anthony Macherone, PhD, Senior Scientist, Cannabis Technical Lead, Agilent Technologies

Cannabinoid quantitation is a regulated test where medicinal and recreational cannabis usage by adults has been legalized. Generally, this test is performed to determine total \( \Delta 9 \)-tetrahydrocannabinol (THC) content of a plant or cannabinoid product. The testing is usually performed with HPLC systems using UV detection. Why is this the case? Given the fact that cannabis products and matrices are extremely complex, why are labs providing critical product safety and quality information using non-selective UV detectors? Given the complexity of cannabis matrices and the increasing occurrences of novel cannabinoids like THC-acetate, \( \Delta 10 \)-THC, cannabinoid diastereomers and enantiomers, etc., we suggest mass spectrometry (MS) is a superior methodology for regulatory potency testing. This presentation will discuss the pros and cons of MS with liquid and gas chromatography and compare these to UV detectors. We will highlight the power of MS and contrast this with potential pitfalls to consider before switching to MS.

9:10 An Overview of Chemical and Microbial Contaminant Requirements for Cannabis Products in Canada
Andrew Waye, PhD, Acting Manager, Office of Cannabis Science and Surveillance, Health Canada

In line with its public health approach of creating a strict legal framework for cannabis, one of the means by which the Canadian Cannabis Act and its Regulations aims to protect public health is through strict safety and quality regulations. Under the Cannabis Act, the Cannabis Regulations require the application of Good Production Practices and leverage existing standards such as the United States Pharmacopeia to ensure the quality of cannabis products and to mitigate against cannabis products from being contaminated. Regulatory requirements for chemical and microbial contaminant testing and tolerance limits are meant to address not only current, but also emerging issues as they relate to the quality control of cannabis. As the cannabis landscape in Canada continues to evolve, guidance and standards on the quality aspects of cannabis are important resources that license holders can use to help further protect consumers and demonstrate how they are meeting their regulatory obligations.

9:45 Morning Networking Break

10:15 Panel Forum—Ask the Regulators
Moderator: Monica Taing, Holistic Industries

Panelists:
- Lori Dodson, Maryland Medical Cannabis Commission
- Heather Krug, Colorado Department of Public Health & Environment
- Lindsay Robinson, California Cannabis Industry Association

Discussants:
The Audience
just a plain challenge to remove. Strong solvents and harsh chemicals might be a quick answer, for sure. But the wise answer, the innovative answer, are detergents that are not only effective, but end-user safe, aqueous, free-rinsing, interfering residue-free, biodegradable, and without any added dyes, fragrances, brighteners, or softeners. In other words, maintaining the whole reason why cannabis and its “natural” state is sought after. Critical cleaning is defined as when the level of cleaning directly impacts the value of the final product. The cannabis and related industries certainly apply, and mastery of both the right detergents, for the right applications, right procedures, and right guidance documentation, ensures the end product is at its highest efficacy possible.

**Northern Exposure—A Framework for Human-subject Research**

**A Risk-based Framework to Facilitate Non-therapeutic Research on Cannabis in Humans in Canada**

Sophie-Anne Lamour, PhD, Senior Scientific Evaluator, Health Canada

The existing framework for clinical trials in Canada presents challenges that have led to missed opportunities to advance knowledge about the use and effects of legal, regulated cannabis products available to adult consumers. To address this issue, Health Canada is proposing to amend the Cannabis Regulations to facilitate non-therapeutic research on cannabis (NTRC) in humans. The purposes of NTRC are to increase knowledge on cannabis and its non-therapeutic effects to inform public health and public safety measures, public education and policy as well as further research and development of cannabis products. NTRC studies would be categorized into one of three risk-based categories based on various elements of the study design and characteristics of participants. Specific application requirements proportional to the risk category would be required to obtain an NTRC research license. This new framework should help increase the available body of evidence on the non-therapeutic effects of cannabis in humans.

**Afternoon Networking Break**

**Calling All Breeders—What You Need to Know to Maximize Yield, Avoid Unwanted Epigenetic Change, and Ensure Your IP Rights are Solidly Protected**

Hope Jones, PhD, Founder & CEO, Emergent Cannabis Sciences

How tissue culture can be used to eliminate pests and disease (including virus and viroids) and to “reboot” epigenetic changes that cause the loss of desirable traits.
Navigating IP Opportunities and Risks in Cannabis—What Everyone in the R&D Business Should Know

Dale Hunt, Esq/PhD, Founder & CEO, Breeder’s Best

There are many misconceptions about intellectual property, including some that are unique to the Cannabis industry. This presentation addresses those and will explain some key IP principles and make actionable recommendations that any company with an R&D component can adopt.

Opportunities & Challenges in Cannabinoid-derived Pharmaceutical Development—Targeting Novel API’s & Therapeutic Ensembles

Cannabigerol (CBG) and Tetrahydrocannabivarin (THCV): Sources of Novel Cannabis Therapeutics

Ethan Russo, MD, Founder & CEO, CReDO Science

Cannabis produces upwards of 150 distinct phytocannabinoids, but to date, the pharmacology of only about a dozen has been investigated to any degree, with the industry concentrating merely on THC and CBD with speculative and potentially dangerous tangents into synthetics. Two of the most promising “minor cannabinoids” are finally attracting the interest that they deserve. Cannabigerol (CBG) can be considered the “mother of all cannabinoids,” as it is the precursor for the entire panoply of pentyl (five-carbon sidechain) derivatives, while tetrahydrocannabivarin (THCV) is the archetype of the propyl (three-carbon sidechain) molecules. We will explore the genetics and therapeutic potential of CBG for treatment of anxiety, pain, primary cancer treatment and antibiotic-resistant bacterial infections, and THCV for obesity, metabolic syndrome, Type II diabetes mellitus and drug addiction.

Happy Hour Mixer

Join us in the lounge for informal networking. Complimentary appetizers provided.

Wednesday, October 13

Complimentary Breakfast

Research Spotlight—Toward National Standards for Clinical Research

Quality Considerations for Cannabis Clinical Research

Nandu Sarma, PhD, Director, Dietary Supplements & Herbal Medicines, US Pharmacopeia

The understanding of how cannabis constituents modulate the endogenous receptors to elicit biologic activities continues to be a developing area of science. Due to active and growing interest in cannabis for medical purposes, definition of quality attributes can help support sound and reproducible basic and clinical research. In July 2020, FDA published a Draft Guidance on Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research. Information on the quality attributes for evaluation of these materials in terms of identity, composition, and purity, and the scientific resources to test for these, can help improve the quality of clinical research results based on an understanding of the composition of the product(s) tested and the ability to develop consistent material for clinical research. Information regarding appropriate quality specifications for the investigational article includes validated analytical procedures, acceptance criteria, and reference standards. Quality considerations include: (1) appropriate nomenclature for cannabis and cannabis-derived compounds, (2) laboratory verification of identity as cannabis and the specific cannabis chemotypes, and (3) quantitative composition of cannabinoids and terpenes, including the calculation of the percentage of delta-9 THC. Tests are needed to help ensure the risk of exposure to contaminants such as pathogenic microorganisms, toxic elemental contaminants, mycotoxins, and pesticide residues is appropriately controlled. This presentation will share USP perspectives on the standards that set forth specifications for quality attributes which are fundamental to the characterization of the materials for cannabis clinical research.

Case Studies: Identification of Minimum Essential Therapeutic Mixtures from Cannabis Plant Extracts by Screening in Cell and Animal Models

Andrea Small-Howard, PhD, President & CSO, GB Sciences, Inc.

Medicinal Cannabis has shown promise for the symptomatic treatment of a variety of human disorders, but patient exposure to whole plant extracts may be undesirable due to concerns around safety, consistency, legality, psychoactivity, and standard routes of delivery (i.e., smoking and vaping). We hypothesized that within Cannabis plant extracts there would be a minimal essential compound set that could safely and consistently reproduce the positive therapeutic effects of Cannabis without the need to use whole plant extracts. Using sequential in silico, in vitro, and in vivo screens, unique and patentable subsets of Cannabis components with therapeutic potential have been identified and validated in cell and animal models. Cell-based screening has revealed promising complex therapeutic mixtures for the treatment of Parkinson’s disease, chronic pain, and inflammation. Using animal-based screening, we have validated the therapeutic potential of simplified disease-specific, minimum essential mixtures (MEM), each containing 3 to 5 cannabinoids and terpenes. The case studies presented herein highlight the potential for the development of disease-specific, cannabinoid-based therapeutics for the prescription drug market to treat Parkinson’s disease, chronic pain, or inflammation, among others.
These disease-specific MEM are produced for clinical evaluation using synthetic homologs of cannabis-based ingredients incorporated into sophisticated oral delivery modalities including Oral Dissolving Tablets (ODT), Oral Thin Films (OTF), time-released oral nanoparticles, and gel capsules to increase the stability, bioavailability, and ease-of-use of the ingredients relative to Cannabis plant extracts. Minimum Essential Mixtures are designed to retain increased therapeutic effectiveness from molecular synergies within the original plant extracts, but with the manufacturing efficiencies, quality assurances, and regulatory advantages of single ingredient drugs.

9:25  API’s for Cannabinoid-derived Pharmaceutical Development
Hunter Land, VP, Translational Research and Board Member, Alterola Biotech
Abstract coming soon

10:05  Morning Networking Break

10:35  Decentralizing Clinical Trials for Rapid Development of Cannabinoid-derived Pharmaceuticals and Other Need-to-Know Items
Stephen Goldner, Esq., CEO & Chair, Board of Directors, Pure Green Pharmaceuticals
Seventy-plus years of illegality halted legitimate medical science cannabis discovery. But the 2016 United Nations General Assembly Special Session was devoted to a wholesale reconsideration of the War on Drugs. This created a watershed moment to recognize medicinal cannabis as a legitimate field of scientific inquiry and commercial opportunity. Several speakers at the 2016 special session, including Mr. Goldner himself (who at the time was Regulatory Advisor to the National Institute of Health), helped restart legal cannabis medical research and brought perspective to important global drug policy issues. In this Keynote talk, Steve will describe and demonstrate the best-in-class clinical, scientific, business and legal approaches being implemented to make cannabis-derived medicine a highly recognized STEM profession and a top business opportunity for investors. Application of these approaches is yielding rapid, cost-effective translational cannabis medical research, enhanced investor ROI, and additional professional opportunities.

11:15  Avicanna Presentation
Karolina Urban, PhD, VP of Scientific & Medical Affairs, Avicanna, Inc.
Abstract Coming Soon

11:55  Lunch

1:10  Diabetic Neuropathic Pain Decreased Upon Coadministration of CBD and PEA
Marilyn Barrett, PhD, Founder & Principal, Pharmacognosy Consulting
PG Pharma has developed a significant therapy for diabetic neuropathy, a discovery that is expected to bring relief to a population without a safe and effective treatment for pain. First in a proof-of-concept study and later in a small randomized placebo-controlled study, a mixture of cannabidiol (CBD) and palmitoylethanolamide (PEA) demonstrated the ability to relieve pain and to improve lifestyle for patients by relieving anxiety and improving sleep. Now the company is in conversations with the FDA for entry into a larger Phase II study. This talk will discuss overcoming a myriad of obstacles and taking advantage of opportunities on the path of pharmaceutical development.

1:50  Function of the Endocannabinoid System in the Regulation of Endometriosis
John Taenzler, PhD, Senior Vice President, Healogix, & Rahim Dhalla, Co-founder, Peak Pharm Labs
Endometriosis impacts 1 in 10 women across the globe, and current therapies involving pain medications and hormone therapies have been found to be inadequate for a large portion of these women. We will examine the current science showing the role of the endocannabinoid system (ECS) in the female reproductive system, show how the ECS plays a vital role in the regulation and dysregulation of the menstrual cycle, and present case studies showing the impact of topical cannabinoids on treating the underlying causes, drivers and symptoms of endometriosis.
Critical Issues—In the View of Patients & Clinicians

2:25
Clinical Considerations for Medical Cannabis and Harm Reduction

Monica B. Taing, PharmD, RPh, MS, Medical Science Liaison, Holistic Industries

Abstract Coming Soon

3:00
Afternoon Break

Technology Spotlight—Improving Bioavailability & Meeting Formulation Challenges

3:15
Overcoming Formulation Challenges of Cannabinoids

Inayet Dumanli-Ellis, PhD, Scientific Director, Gattefossé

Due to their lipophilic properties, cannabinoids present formulation challenges across many conventional drug delivery modalities. This presentation will cover the following areas:

- Improving stability of cannabinoids in lipid vehicles
- Development of oral THC and CBD Self-emulsifying formulations
- Selection of vehicles in fine-tuning of skin penetration, transdermal delivery and topical formulations of cannabinoids

3:50
Emerging Formulation Technologies for Pharmaceutical Applications of Cannabinoids

Andreas Pappas, PhD, CEO, Antares Health Products, Inc.

Cannabinoids, especially purified and highly concentrated extracts including cannabidiol (CBD) and tetrahydrocannabinol (THC), are actively evaluated in pharmaceutical, veterinary, nutraceutical, and personal care applications. Major challenges in their effective utilization include poor solubility in water, low absorption, and significant first-pass metabolism resulting in low bioavailability. The presentation will focus on formulation technologies based on science and proven record of safety and efficacy supported by conclusive clinical evidence. Of particular interest is the role of these technologies on solubility, stability and enhanced absorption and bioavailability of lipophilic extracts including cannabinoids. The presentation will include examples of commercial applications in important product formats, including liquids, solids, capsules, creams, sprays, and others.

4:25
Proprietary Delivery Technologies for Increasing Bioavailability of Cannabinoid Molecules

Rob Davidson, CEO, Cure Pharmaceutical

In recent times, given the greater societal acceptance of cannabis and countless studies proving its medicinal use for anything from pain relief to insomnia to cancer therapies, there's been more momentum for such cannabis medical grade products. There is an increased interest in creating and expanding pharmaceutical-grade cannabinoid products. With this heated discussion, there's more and more focus on improving the bioavailability of cannabinoid molecules through different delivery methods. With the increased number of competitors in this field, there's more focus on the most effective route of these active ingredients such as tetrahydrocannabinol (THC), cannabidiol (CBD) and a plethora of other cannabinoid molecules into the bloodstream and related systems of the human organism. Since both substances have such well documented ways of helping human beings achieve greater health and wellness and relieving suffering, determining the best route of delivery is crucial for the further development of this field.

5:00
End of program
**Poster Presentations**

**Targeting Glioblastoma Invasion and Survival with Cannabis-derived Flavonoids**

*Akeem Gardner, CEO & Founder, Canurta, Inc.*

Cannflavins A and B are cannabis-enriched flavonoids known to reduce inflammation via biosynthesis inhibition of pro-inflammatory mediators. Accumulating evidence also suggest that these prenylated flavones may have neuroprotective and anti-cancer properties, but the mechanisms responsible for these effects remain elusive. While screening for novel modulators of receptor tyrosine kinases in neurons, our group found that cannflavins can prevent TrkB receptor activation by the growth factor BDNF. Since signaling by TrkB can be a factor in the biology of various types of brain tumors, and that targeting this pathway may be an effective strategy to limit the growth of aggressive cells, we aimed to test whether cannflavins can be leveraged to affect the survival, proliferation, and migration of glioblastomas (GBMs). **Material & Methods:** We used U87 and A172 lines to conduct cell viability, migration, and invasion assays. **Results:** Cannflavins A and B produce significant effects at a minimal dose against the tested hallmarks of cancer. **Conclusion:** Our study represents an initial effort to complete a systematic preclinical characterization of cannflavins against GBMs. Our goal is to position cannflavins as candidate therapeutic molecules to attack brain tumors, as well as other cancer types that thrive on the aberrant activity of TrkB.

**Developing Hemp Derived Active Pharmaceutical Ingredients Through an Analytical Lens: Carriers and Barriers**

*Akeem Gardner, CEO & Founder, Canurta, Inc.*

The understanding of how various non-cannabinoid cannabis constituents modulate pharmacological activity in a concentration dependent manner requires robust methods of analysis. There remains a paucity of properly validated analytical methods available in the literature and in the industry for many hemp constituents. Development of extracts and single ingredient products requires biomarker standardization and identification and quantification. The foundation of this research requires validated analytical methods that follow International Harmonization and FDA bioanalysis criteria. Liquid Chromatography with tandem mass spectrometry (MS) is a superior methodology for carrying and enhancing development testing of hemp-derived pharmaceutical ingredients. Quality considerations include quantitative composition of major constituents and their stability. Often lack of commercially available reference standards is a barrier to identification and development. This presentation will share case perspectives on the standards that set forth specifications for quality attributes which are fundamental to the characterization of the materials for development of some specific hemp derived flavonoids and stilbenes carried in hemp extracts for topical and oral formulation and dissolution characterization. This presentation will emphasize the importance of robust analytical methods for successful product development of hemp derived products.

**Cannabinoids in Dermatology**

*Dr. Jeanette Jacknin, CBD Consultant & Brand Ambassador, Medterra CBD*

This presentation starts with a brief overview of what the endocannabinoid system is and how it is involved in the skin. Next, I will discuss the recent scientific studies behind cannabinoids and beauty, anti-aging, acne, itch, eczema, and psoriasis. If time allows, I will include examples of what products are already on the market, and where that market is projected to extend to.

**Hemp Synergistics Poster Presentation**

Abstract coming soon.
Pre-Conference Workshop
Tuesday, October 11, 2022, 1:00–5:00 PM,
Marriott San Diego Mission Valley, San Diego CA

Co-sponsored by Pharma Ed Resources & EAS Consulting Group

Good Manufacturing Practices (GMPs) for the Cannabis Industry

The Good Manufacturing Practices (GMP) dictated in FDA’s 21 CFR 111 require that “Each person engaged in manufacturing, packaging, labeling, or holding, or in performing any quality control operations, must have the education, training, or experience to perform the person’s assigned functions.” EAS Consulting Group is presenting a ½ day workshop covering a GMP overview for the cannabis industry, including expectations and compliance requirements to help your employees stay on top of critical quality and safety issues.

This workshop can be used as part of an annual GMP refresher training and will provide a deeper understanding of how to perform specific job responsibilities in a GMP compliant manner. This GMP workshop will benefit anyone involved in direct handling of cannabis products, especially product manufacturers and processors.

Workshop Leader:

Dr. Tara Lin Couch, PhD, Senior Director, Dietary Supplements, EAS Consulting Group

Dr. Tara Lin Couch is a PhD in analytical/organic chemistry with exceptional analytical abilities and over 25 years of diverse laboratory and regulatory experience in academic, field, contract, and manufacturing environments. She is a sought-after expert on issues pertaining to QC in pharmaceutical, dietary supplement and tobacco manufacturing facilities including the establishment of specifications and the development of well-organized, sophisticated laboratories. As a Senior Director for EAS Consulting Group, Dr. Couch has assisted numerous companies with the development, improvement, and implementation of strong quality systems that are scientifically sound, efficient, practical, and compliant with all FDA regulations. She also performs mock FDA inspections, gap-analyses, and contractor facility audits. In addition, Dr. Couch provides GMP and laboratory training via seminar, webinar, and on-site presentations. Tara serves on various industry committees for the Council for Responsible Nutrition (CRN), Consumer Healthcare Products Association (CHPA), and the Food, Drug Law Institute (FDLI). She is also active in the American Herbal Products Association (AHPA).
About your conference destination:
Located in Mission Valley, the Marriott San Diego Mission Valley is the ideal gateway to experience the best of San Diego. Enjoy easy access to San Diego State University, SDCCU Stadium (formerly Qualcomm), Old Town, or hop on the Rio Vista Trolley and explore Mission Bay, SeaWorld, and Downtown San Diego including PETCO and Gaslamp District. See our refreshed meeting spaces including our all-new event lawn ideal for memorable outdoor gatherings. Enjoy a host of amenities and services, from views and casual dining at DEN to our fully equipped fitness center and outdoor pool with a waterfall. Well-appointed guest rooms and spacious suites offer 55” SMART TV’s, high-speed Internet and balconies and are perfect for groups visiting San Diego. You will appreciate our Mission Valley hotel’s unmatched charm and sophistication.

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PLEASE NOTE:
PharmaEd Resources does not offer refunds. However, if you cannot attend after registering, we are happy to apply your registration fee to another PharmaEd Resources event, or transfer your registration to a colleague. Notice of cancellation must be received at least 5 days prior to the event.

VENUE INFORMATION:
Dates: October 11–13, 2022
Venue: Marriott San Diego Mission Valley
Venue Address: 8757 Rio San Diego Drive
San Diego, CA 92108
Venue Phone: (619) 692-3800