PharmaED RESOURCES, Inc.

Canna Pharma 2021

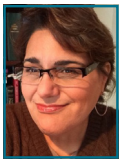
Advancing the Science of Medicinal Cannabis Through GMP, Quality Control, and Emerging Therapeutic Applications. November 9–10, 2021, San Diego, CA

Featuring Lessons Learned and Case Studies from Industry Experts

Amber Wise
Medicine Creek Analytics

Ethan Russo
CReDO Science

Nandakumara Sarma
US Pharmacopeia



Susan Audino
A2LA

Reginald Gaudino
Front Range Biosciences

Donald Abrams
UCSF

Hope Jones
Emergent Cannabis Sciences & Superior Phenos

Jeffrey Raber
The Werc Shop

Dale Hunt
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Ralph Paroli
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Randall Murphy
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Robert Morgan
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Bruce Mackler
Ethicann Pharmaceuticals

Anthony Macherone
Agilent

Beth Kroeger
Steris

Tara Lin Couch
EAS Consulting

Dan Dobrez
Dober

Len May
Endocanna Health

With Comprehensive Coverage On:

- Can Cannabis Cure Cancer: Cannabis in Cancer Care
- Qualifying Cannabis Substances as Suitable for Clinical Trials
- Bringing Cannabis Products to Market in a Fractured Regulatory Landscape
- Harmonizing Quality Control Standards of Cannabis-derived Products
- New Frontiers & Methods in Cannabis Safety & Quality Testing
- Cannabis Extraction: What We're Doing Wrong & Possible Solutions
- Best Practices in Cannabis & Hemp Cultivation
- Delta-8 THC: Chemistry, Loopholes, and Risks
- CB1 & CB2 Cannabinoid/Cannabis Signaling: Pharmacology and Potential Downstream Effects
- Cannabinoid Lipid-based Formulations for Oral & Topical Delivery

And Don't Miss our Exclusive Pre-conference Workshop on November 8th!
How to Win Regulatory Approval and Bring New Cannabinoid-based Drugs to Market
See Inside for Details!

With Representation From:

Breeder's Best · Gattefossé · Front Range Biosciences · Agilent Trusted Answers · USP · The Werc Shop · Alterola Biotech · California Cannabis Industry Association · A2LA · ASTM International · Temple University · UCSF Health · CReDO Science · Orion GMP Solutions · Steris · ecs Emergent Cannabis Sciences · EAS Consulting Group · NRC-CNRC Canada · Ethicann Pharmaceuticals · Endo-Canna Health · green Scientific Labs · Dober · Medicine Creek Analytics

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Tuesday, November 9

7:30 *Check-in & Complimentary Breakfast*

8:00

Charperson Len May's Welcome and Opening Remarks

Spotlight on Regulatory Compliance—Challenges & Opportunities in a Fragmented Landscape

8:05

Multi-State Medical Cannabis Compositions

Dr. Jeffrey Raber, CEO & CVO, The Werc Shop

The complexity of the cannabis plant, coupled with physical chemical changes that are inevitable when performing any type of extraction, lends toward exceptional manufacturing and production challenges for any specific cannabis medicinal product. While building a brand is based on delivering a consistent experience around an expectation of performance, delivering a medicine is based on providing a uniform, high-purity, exceptionally consistent expected physiological response via a specific mode of administration.

The common theme between these two markets is consistency, and the differential is determined by the respective definitions of uniformity and purity which is often set by local regulations. Different states have unique regulatory requirements pertaining to purity and uniformity. Furthermore, an effective cannabis medicine may require anywhere between 1 and 50 specific active ingredients to be effective at the desired levels.

Medical precision and purity drive the degree of sophistication required to produce quality medical cannabis products. Adult-use brands more often than not fail to reach the levels of sophistication and infrastructure investment necessary to produce true medical products. The unfortunate disparity of these two product streams tends to cause confusion over the product quality and consistency differences present across the wide range of products currently available. This is further confounded by the regulatory inconsistencies across multiple geographies. This talk will highlight some of the challenges in producing quality medicinal cannabis products in multiple states while being confined via today's patchwork of laws and regulations.

8:40

Hemp Cannabinoids in Food: The Three Regulatory Pathways

Brad Douglass, VP of Intellectual Property & Regulatory Affairs, EAS Consulting & The Werc Shop

Language in the Agricultural Improvement Act of 2018 (the "2018 Farm Bill") has opened the door to the use of a wide range of hemp preparations and components in food, beverage, and dietary supplement products.

In some quarters of the nascent hemp industry, there is an unrealistic expectation that companies will immediately begin using minor cannabinoids, such as cannabigerol (CBG) and cannabichromene (CBC), to create new products. Yet, there currently is a missing link. Without checking the necessary regulatory and compliance boxes, companies are loath to even consider the possibility of working with an ingredient.

This presentation will delve into the three regulatory pathways available to hemp-derived ingredients that will enable such ingredients to be used in food, beverage, and dietary supplement products: the food additive petition pathway; the generally-recognized as safe (GRAS) pathways; and the new dietary ingredient notification approach. The exciting advantages and disadvantages of each will be discussed.

Critical Issues—Harmonizing Quality Control and Analytical Testing Standards for the Medicinal Cannabis Industry

9:15

Normative Standards in the Service of the Cannabis Sector

Robert J. Morgan, Director, Technical Committee Operations, ASTM International & Dr. Ralph M. Paroli, Director, R&D, Chem. NRC-Metrology

The global cannabis sector is growing at a rapid pace. Standards that help build confidence in this field help this industry blossom. Since 2017, a diverse group of globally recognized industry leaders from 30 countries joined together to help develop standards that promote safety and quality in various branches of the industry under the ASTM umbrella (ASTM Committee D37). The committee takes into account diversity, equality and inclusion as well as sustainability when developing standards in the area of horticulture, quality management, laboratory analysis, processing/packaging, security/transportation, credentialing, hemp and devices. An update will be given on where ASTM D37 is with respect to the development of standards and how ASTM is helping the sector via the astmcannabis.org website.

9:45 *Morning Networking Break*

10:10

When is "Good Science" Good Enough in the Cannabis Industry?

Susan Audino, PhD, Instructor/Lead Assessor & Team Leader, American Association for Laboratory Accreditation (A2LA)

All hopeful and new laboratory owners have the same platform: To Offer The Best Science! The expectation is that "good science" will drive a successful and respectful business however reality tells a different story. It seems "good science" has limitations, compromising the good intentions of laboratory owners and scientists' education and training, while simultaneously increasing business opportunities. When a simple matrix is used to

validate an analytical method, regulatory requirements are achieved however the method may never be challenged when more complex matrices are introduced. Laboratory scientists would (hopefully) agree that hempseed oil would not be the best matrix for quality control in a batch of chocolates or flower, however it is a fairly straight-forward matrix that will likely 'pass' these sample batches. This session will unveil some of the cloaked and otherwise non-transparent business decisions that are designed to consciously limit scientific integrity, such as using a simple matrix to serve as quality control or choosing a quality control that is known to yield notably high (or low) concentrations of a given analyte to accommodate customer need.

Panel Discussion

10:40

Harmonizing Product Testing, Quality Control, & Regulatory Compliance—What Next? A Roundtable Discussion

Moderator:
Len May, Endocanna Health

Panelists:





- Susan Audino, A2LA
- Ralph Paroli, NRC-Canada
- Jeff Raber, The Werc Shop
- Lindsay Robinson, CCIA
- Nandakumara Sarma, US Pharmacopeia

Participants: The Audience

Critical Issues—Delta-8 THC & Its Implications for the Industry

11:20

Delta-8 THC: Chemistry, Loopholes, and Risks

Kristofer Marsh, PhD, Director of Integrated Sciences, Green Scientific Labs

The sudden rise of products containing delta-8 THC over the past year has come with it a wave of controversy. An analogue of delta-9 THC (or just "THC"), delta-8 THC is a naturally occurring cannabinoid that can be produced synthetically. However, the synthesis of delta-8 THC from CBD, how the majority of delta-8 THC is produced, raises many questions including risks to consumer health and its status as a legal, hemp-derived compound. Here we will review the chemistry of delta-8 THC synthesis and discuss its implications for the legal cannabis and hemp markets.

11:55 *Lunch Break*

GMP for a Regulated Industry: What You Need to Know

1:05

Good Manufacturing Practices (GMPs) and Cannabis

Dr. Tara Lin Couch, Senior Advisor EAS Consulting

As States have legalized and regulated the Cannabis industry, and more and more cannabis products come on the market, important considerations must be addressed. One of these is the development and implementation of Good Manufacturing Practices (GMPs) and a quality system. This will ensure that your cannabis products are consistently manufactured to prescribed quality standards, and go a long way in meeting the various State regulations. While not all State regulations are the same—indeed, some are similar to the food industry and others more like dietary supplement and pharmaceutical GMPs—the expectation across the board is that facilities throughout the supply chain will have these systems and be closely monitored. Learn the basic tenets of any GMP and quality system and how implementing such a GMP system in your facility will not only ensure compliance but also streamline your business.

This talk will cover:

1. What are the basic tenets of a GMP system.
2. What are the primary differences between a food and a dietary supplement GMP system.
3. What is a finished product specification.
4. What is a master manufacturing record.
5. When to conduct a material review.

Ensuring Critical Quality Attributes through Environmental Controls and GMP—What Labs and Cultivators Need to Know

1:40

Best Practices for Ensuring Patient & Consumer Safety in Cannabis and Hemp Manufacturing—A Novel Approach for Cleaning and Disinfection

Beth Kroeger, Technical Services Senior Manager, Contamination Control Solutions, STERIS Life Sciences

Part I: Designing Quality into your product

- How to build Quality into Cannabis production and manufacture of extracts to reproducibly deliver therapeutic benefit and the role of Cleaning Validation
- Identify critical attributes (CQAs) of final product to control to meet target product Quality profile
- Design process to produce the product having these attributes and identify critical process parameters (CPPs) to control for CQAs
- Best practices adapted from pharma to control your tissue culture, cultivation, and cGMP manufacturing process environments resulting in fewer lost batches and reduced costs.

Part II: Contamination Control – Environmental and equipment

- Understanding what "clean" means so you can better defend your process to inspectors, auditors, and investors.
- Time-kill data for common disinfectants
- Pesticide removal
- Understand the cleaning parameters which impact cleaning processes
- Best practices and a novel approach for equipment cleaning to optimize your cleaning process to ensure your extraction equipment is efficiently cleaned to produce Quality product that is safe for Consumers and more importantly, patients.
- Improving contamination control in cannabis cultivation and extraction processes and meeting regulatory requirements at each of these stages.

2:15 *Afternoon Networking Break*

Critical Issues—How Safe is That Vape Pen? The Need for More Robust Testing Protocols for Cannabis Vape Devices and Their Aerosols

2:40 **Method Optimization and Analysis of Cannabis Cartridge Aerosols for 10 Heavy Metals**

Amber R. Wise, PhD, Scientific Director, Medicine Creek Analytics (Co-authors Charlie McDaniel & Srinivasa R. Mallampati)

Cannabis vaporizer cartridges have increased in popularity and availability, and there are concerns regarding exposure to heavy metal compounds from their use. The hardware components of the cartridge devices themselves have been implicated as a potential source of metals exposure, but it is not known if these metals migrate into the inhalable vapor. This study has two parts; the first is optimizing the sample collection, preparation, and analysis of the nonpolar cannabis aerosol mixtures and the second part analyzes the hardware components and aerosol mixtures of vaporizer cartridges for 10 different metals (As, Cd, Co, Cr, Cu, Hg, Mn, Ni, Pb and Sn) using ICP-MS. We investigate various model systems as well as 13 randomly purchased commercially-available cannabis cartridges to compare the elemental profiles. Results indicate Chromium, Copper, Nickel, and Lead migrate both into the cannabis oil and the inhaled vapor phase. Non-cartridge heating methods of cannabis flower and concentrate were compared and results indicate the heating device hardware is a source of metals contamination. As safety and compliance testing regulations evolve, it will be important to update analytical methods as well as include more than the standard As, Cd, Hg, and Pb elements to the list of regulated metals.

3:15 **New Frontiers in Cannabis Testing: Comprehensive Testing of Cannabis and Hemp**

Anthony Macherone, PhD, Senior Scientist, Agilent Technologies & Visiting Professor, Johns Hopkins University School of Medicine

The global movement for legalization of cannabis and hemp products and their export/import has led to the need to ensure the products are safe prior to retail distribution. Unfortunately, there is very little harmonization between nations or regions that defines the testing needs and action (not to exceed) levels of the various chemicals and microbes deemed necessary for testing. To ensure safety and regulatory compliance, a suite of chemical and biological analysis systems is required ranging from standard HPLC systems to liquid and gas phase triple quadrupole mass spectrometers, and quantitative polymerase chain reaction systems. However, in the U.S., Canada, and other regions around the globe, the regulations define targeted analysis of a limited number of endogenous or exogenous chemical classes. The question is: are these tests and their various target lists enough? For example, there are hundreds of commercially available pesticides but only a small subset has been regulated in the cannabis industry, and the target lists and action levels vary from state to state in the U.S. and country to country elsewhere. This presentation will discuss strategies for comprehensive and semi-targeted profiling of cannabis products using high-resolution accurate mass spectrometry in both the liquid and gas phases. These approaches will allow quantitative identification of cannabinoids, terpenoids, flavonoids, and putative identification of pesticides and other potential contaminates like mycotoxins.

Research Spotlight—Terpene Stability & Shelf-Life of Cannabis Flower

3:50 **Qualifying Cannabis Substance as Suitable for Clinical Trials**

Andrew Samann, CEO, Orion GMP Solutions

Universally, the most common dose form of cannabis sativa is dried flower that is smoked or vaporized. While respiration of cannabis flower provides an efficient and effective route of administration for cannabinoids and terpenes, problems associated with this method of consumption are inherent within the plant itself. Lack of homogeneity between batches, leading to inconsistent therapeutic effect, along with concern for the preservation of organic materials in finished packaging present a quandary for supply chain participants accountable to pharmaceutical-grade quality standards. Cultivators of other herbal medicinal substances must provide quality assurances for traceability, identity, and shelf life. Therefore, considering the production of cannabis flower as a botanical drug substance, cultivators and their vendors would benefit to understand how Good Agricultural and Collection Practice (GACP), and the application of Good

Manufacturing Practice (GMP) lead to safe, predictable materials and products. This presentation describes the application of appropriate quality systems for phases of production, and what steps should be taken to successfully produce cannabis flowers to the point of making shelf life claims suitable for clinical trials.

4:25 **Selecting The Safe Solution to Cannabis Cleaning**

Dan Dobrez, Executive Vice President, Dober

As the cannabis industry continues to gain in popularity, its crucial for manufacturers to meet customer demand through safe, effective cleaning processes. Producing these products can leave greasy, oily residues that do not mix well with water and dry to a sticky consistency. Traditional cleaning of oil and resins uses Isopropyl alcohol which can be expensive and poses concerns for safety handling and disposal. It's important to select a cleaning agent that can effectively and safely clean the most challenging residues, while adhering to regulated industry standards.

4:55 ***Happy Hour Mixer***

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

Wednesday, November 10

7:30 ***Complimentary Breakfast***

Spotlight on TIssue Culture

8:05 **Best Practices in Cannabis & Hemp Cultivation**

Hope Jones, PhD, CEO, Emergent Cannabis Sciences & President, Superior Phenos

Plant diseases in your grow? Some of your favorite strains not yielding as they used to? Can't seem to find good clean stock material anymore? Now what? Tissue culture MAY be a solution and it is becoming foundational to the cannabis industry. This presentation will focus on essential concepts behind tissue culture, virus/viroid & pathogen elimination and the importance of a good IPM regime once you have clean stock again.

Innovations in Extraction

8:40 **Cannabis Extraction: What We're Doing Wrong and Possible Solutions**

Ethan Russo, MD, Founder/CEO, CReDO Science

Phytocannabinoids and cannabis terpenoids are the primary medicinal components for most cannabis-based medicines. Heretofore, cannabis extraction and processing has always operated under the assumption that the material would be smoked. In modern times, this approach of drying and curing is outmoded and counterproductive, adding unnecessary steps, costs, and squandering monoterpenoid content while retaining extraneous components. Phytocannabinoids and cannabis terpenoids are produced in greatest abundance in the capitate glandular trichomes of unfertilized female inflorescences. Most other material in the flowers, leaves and other plant parts are extraneous to the majority of cannabis medicine preparations. Their inclusion in extraction may be counterproductive via inclusion of chlorophyll, phytol, extraneous lipid components and many other pharmacologically unnecessary compounds. Phytocannabinoids and terpenoids are secreted into and contained within the trichome envelope. Properly speaking, these contents are the key "active pharmaceutical ingredients" (APIs) of most medicinal cannabis preparations. Cannabis is commonly dried and cured prior to use, either in the sun, or under controlled humidity conditions. The original intent of this process was to improve "smoke-ability" by oxidation of chlorophyll to phytol, and to reduce chances of mold formation. In the process, the "headspace volatiles" of cannabis, the lower molecular weight monoterpenoids, are lost during drying and "curing," ranging from 31-55.2% depending on the length of the process (Ross & ElSohly, 1996). If one assumes that entourage effect is a valid concept in cannabis therapeutics, this militates for novel processes to preserve the biochemical profile of fresh flowers. This presentation will focus on two techniques to mitigate these problems: 1) A novel solventless extraction technique (patent pending) that preserves the cannabinoid and terpenoid profiles of the fresh flower, and 2) An approach to preserve monoterpenoid content in secondary extraction.

Cannabis Genetics—Expanding the Range of Potential APIs

9:15 **Cannabis Genetics Continued: Moving beyond CBD and THC to Maximize API Value from the Right Cannabis/Hemp Genetics**

Reginald Gaudino, PhD, Vice President of Research & Development, Front Range Biosciences

At Canna Pharma 2019, the Cannabis Genetics segment gave an overview of the genes and gene networks involved in the production of metabolites like cannabinoids and terpenes. That presentation focused on the work elucidating important differences in expression of those gene networks in the trichome of cannabis flower. Further work has allowed identification of numerous specialized cannabis cultivars that produce a number of other novel compounds such as Cannflavins, and other highly used flavonoids such as Orientin, Luteolin, Vitexin, at levels potentially competitive with existing raw materials from which those compounds are normally derived. Further, in some cases, a single cultivar may provide elevated levels of one or more desired compounds, making the byproducts of purification potentially valuable API's themselves. The 2021 Cannabis Genetics presentation

will explore some of these novel compounds, expression levels of some of these compounds in various plant tissue, and how careful consideration of the cultivar genetics can help maximize revenue from the raw starting material, as the byproducts of purification of the main API can yield additional API's that may also have significant value. Where elucidated, gene networks and/or markers for various compounds also will be discussed.

9:55 *Morning Coffee & Networking Break*

Cannabis-based Therapeutics: Current & Future Prospects

10:20 **Conference Keynote—Cannabis in Cancer Care: Can Cannabis Cure Cancer?**

Donald I. Abrams, MD, Professor of Medicine, University of California San Francisco

People living with and beyond cancer frequently benefit from the use of cannabis for symptom management. The National Academies of Sciences, Engineering and Medicine's report on The Health Effects of Cannabis and Cannabinoids noted strong evidence in support of the use of oral cannabinoids for the treatment of chemotherapy-induced nausea and vomiting. Delta-9-tetrahydrocannabinol (THC) pharmaceuticals- dronabinol and nabilone- were approved in 1985 for this indication, making oncologists the medical subspecialty with the longest history of access to use of a cannabis-based medicine. Published data in the medical literature on the effectiveness of the botanical itself for chemotherapy-induced nausea and vomiting is limited due to the extensive barriers to conducting research with this Schedule I substance, but anecdotal evidence from patient self-reports abound. Cannabis is the only antiemetic that also increases appetite. In addition, cannabis may be useful for treatment of pain (with or without opioid analgesics), insomnia, anxiety and depression in cancer patients and survivors. Oncologists strongly support the use of medical cannabis but the majority feel that they lack the knowledge to best discuss its use with their patients. Concerns that oncologists have regarding the use of the botanical include the risk of pulmonary aspergillosis in immunocompromised patients; possible interaction, especially with highly concentrated cannabidiol-based products, with the enzyme system in the liver that metabolizes many cancer treatment pharmaceuticals; and a possible decrease in the effectiveness of new immunotherapy treatments based on observational data.

The first preclinical evidence that cannabinoids may have anticancer activity was published nearly 50 years ago. Since that time, elegant in vitro studies have confirmed that cannabinoids, acting through the cannabinoid receptors, may have direct tumor killing activity, especially against the most aggressive brain tumor cells. In addition, cannabinoids have been demonstrated to decrease new blood vessel formation and inhibit an enzyme that allows cancer cells to become invasive and metastasize. Although these test tube and animal model findings are promising, convincing evidence that cannabis has any impact on cancer in people is currently unavailable. Despite frequent social media testimonials and even documentaries where individuals proclaim that cannabis cured their cancers, evidence in the medical literature is absent. A single small published trial of nabiximols—a plant-based cannabis extract with a 1:1 ratio of THC:CBD—in patients with recurrent glioblastoma brain tumors demonstrated that the 12 patients receiving the true drug in conjunction with conventional chemotherapy had better survival than the 9 who received placebo. Although encouraging, this small study needs to be duplicated and conducted in a larger patient population to confirm the perceived benefit. In the meantime, patients are best advised to continue to use cannabis as a useful adjunct for management of symptoms related to cancer or its treatment but not to forego conventional cancer therapy in hopes that cannabis alone will have significant antitumor activity.

11:00 **The Endocannabinoid System & Cannabis: An Introduction to How Your DNA Shapes Cannabis Pharmacology**

Len May, CEO & Co-Founder, Endocanna Health

Abstract Coming Soon

11:20 **Cannabinoid/Cannabis Signaling**

Mary Abood, Professor Emeritus, Department of Anatomy and Cell Biology, Center for Substance Abuse Research, Lewis Katz School of Medicine, Temple University

Over 30 years ago, the CB1 cannabinoid receptor was identified as a molecular target mediating the effects of Δ9-tetrahydrocannabinol (Δ9-THC), the principal psychoactive constituent of marijuana (cannabis). A second receptor was identified (CB2). CB1 and CB2 are members of the G protein coupled receptor (GPCR) family. Subsequent to the identification of CB1, endogenous cannabinoids (endocannabinoids) anandamide (AEA) and 2-arachidonoyl glycerol (2-AG) were discovered. A range of pharmacological and genetic tools have been developed and used to delineate "cannabinoid receptor"-mediated activity. CB1Rs and CB2Rs have both similarities and differences in their pharmacology. Both receptors recognize multiple classes of agonist and antagonist compounds and produce an array of distinct downstream effects. More recently, additional GPCRs that recognize cannabinoid ligands, GPR55 and GPR18, have been proposed as candidate cannabinoid receptors. This talk will introduce CB1 and CB2 signaling, and the emerging pharmacological profiles for GPR55 and GPR18.

12:00 *Lunch Break*

1:15 **Translational Drug Discovery & Cannabinoid Research: Lesson Learned & Future Trends**

Hunter Land, Board of Directors and VP of Translational Research, Alterola Biotech

Abstract coming soon

1:50 **Cannabinoid Lipid-Based Formulations for Oral and Topical Delivery**

Inayet Ellis, PhD, Scientific Affairs Director, Gattefossé USA

Cannabidiol (CBD) and Delta-9-Tetrahydrocannabinol (THC) as two highly lipophilic APIs possess challenges in their formulation's stability and efficacy. While trying to attempt improving bio-efficiency, the formulators must also give attention to their stability and manufacturing aspects of the cannabinoid formulations.

In this talk, formulation screening procedures for THC and CBD will be covered to optimize oxidative stability and bioavailability of cannabinoids for efficient oral and topical delivery. Results from solubility screening in commonly used lipid vehicles, and their penetration/permeation performance will be shared. Screening of SEDDS oral formulation will also be discussed.

2:25 ***Afternoon Networking Break***

2:45 **Development of New Cannabinoid Drugs Utilizing Creative Regulatory & Clinical Strategies**

Bruce F. Mackler, PhD, JD, EVP of Regulatory & Clinical Affairs; Board Director; Co-Founder, Ethicann Pharmaceuticals

Ethicann Pharmaceuticals (USA/Canada) Inc. is developing THC:CBD combination new drugs using oral dissolving technology (ODT) to treat clinical diseases. The company has licensed the use of proprietary ODT (Zydis, Catalent Pharma Solutions, Ltd.), enabling patients to rapidly receive therapeutic effects without the First Pass Liver Effects, which typically removes up to 45% of ingested cannabinoid API's. Ethicann is committed to using expedited regulatory approaches in order to reach global markets in less than 5 years, avoiding the financial black hole of an 8- to 12-year traditional development timeframe. Ethicann has met with FDA and Health Canada regulatory authorities and continues to meet its commercialization value milestones. Ethicann has a robust pipeline, which includes CBD Zydis clinical formulations and is performing R&D to develop proprietary drug product formulations. This presentation will present regulatory strategies for winning FDA/Health Canada approval, through case studies and examples of products currently in the Ethicann pipeline.

3:20 **Innovation in Isolation and Purification of Natural Product-Derived Cannabinoids for Pharmaceutical APIs**

Randall B. Murphy, PhD, CSO, Metagreen Inc.

Natural products traditionally served as a direct source of pharmaceuticals in the past. However, over the last fifty years few actual finished APIs were directly isolated from plants, and the focus shifted to marine and bacterial sources as interesting potential lead compounds for the development of novel synthetic small-molecule scaffolds. With the present interest in cannabis, this has dramatically changed, and now there is substantial interest in producing pharmaceuticals directly from cannabis and hemp, including not only THC and CBD but minor cannabinoids and mixtures of terpenes from specific cannabis strains combined with such cannabinoids. But this is challenging for several reasons. First, the cannabis industry has traditionally not employed methodology which would be considered full GMP in the pharmaceutical industry. Second, because there is fairly good evidence that specific mixtures of terpenes and cannabinoids behave quite differently in vivo than their isolated constituents do, and that these differences are probably not due to simple pharmacokinetics and are poorly understood at a molecular pharmacological level. And third, because the costs of large, multicenter double-blinded regulatory-quality clinical studies are for the most part beyond those that investors can justify for cannabis since it is for the most part not (yet) marketed as an ethical, FDA-regulated pharmaceutical. Our principal focus at Metagreen has been on development of novel extraction and purification methodology to enable the cost-effective production of GMP isolated cannabinoids, including minor cannabinoids from strains in which those are abundant. Employment of this type of methodology will enable meaningful clinical studies to be performed, which will allow the deconvolution of the mechanisms underlying the plethora of effects attributed to complex and poorly defined cannabinoid mixtures and hopefully lead in due course to the regulatory approval of new pharmaceuticals with demonstrated safety and effectiveness.

Closing Discussion—Are Your Cultivars, Products & Technological Processes Protected?

3:55 **Recent Trends in Intellectual Property Rights Across the Medicinal Cannabis Supply Chain**

Moderator:
Len May, Endocanna Health

Panelists:



- **Brad Douglass, EAS Consulting & The Werc Shop**
- **Reginald Gaudino, Front Range Biosciences**
- **Dale Hunt, Esq., Breeder's Best, & Plant and Planet Law Firm, LLC**

Participants:

The Audience

4:35 ***Close of Program***

Pre-Conference Workshop

Monday, November 8, 2021, 1:00–5:00 PM, Marriott San Diego Mission Valley

Co-sponsored by Pharma Ed Resources & Ethicann Pharmaceuticals

The Trials and Tribulations of Developing Cannabinoid Drugs: How to Win Regulatory Approval and Bring New Products to Market

The development of cannabinoid-based pharmaceuticals presents a number of unique challenges to start-up companies seeking entry into this new and dynamic market. In this Workshop, two pharmaceutical executives who are currently addressing cannabinoid-based product formulation development, API supply, FDA regulatory approval, clinical strategies, and market positioning challenges on a daily basis, will share their knowledge and experiences. The development of high value new pharmaceutical drugs that must be approved by FDA as being safe and effective presents regulatory challenges, especially if they are first in class, or even copies of approved drugs. This Workshop will assist corporate management of cannabinoid-based companies, regulatory people, clinical investigators developing research programs and product pipelines, investors and financial analysts to formulate a winning strategy to bring a new product to market. Key topics for discussion will include:

- **How does a start-up choose a winning cannabinoid-based drug?**
- **What is the best formulation given the attributes of cannabinoid-based drugs?**
- **What are the scientific, manufacturing and regulatory challenges facing a startup?**
- **Does a startup follow the GW Pharma model or develop new models, formulations and claims?**
- **What are the most appropriate regulatory approval pathways?**
- **What have been the concerns of investors in supporting cannabinoid-based pharma companies?**

The Workshop is structured to enable the attendees to apply the information through a case study presentation, to integrate the information provided into a product development case study for discussion. Each workshop group will be given 5–7 minutes to present their business plan, followed by an analytic discussion time permitting.

Workshop Speakers:

Bruce F. Mackler, PhD, JD, EVP of Regulatory & Clinical Affairs; Board Director; Co-Founder, Ethicann Pharmaceuticals

Dr. Mackler is a renowned drug regulatory strategist with many years' experience, first as a regulatory attorney in private practice serving mainly large pharma on FDA, EMA and Health Canada matters and more recently as an advisor/investor in emerging pharma businesses. He has successfully prepared Investigational New Drug (IND) and New Drug (NDA) applications, involving meetings with global regulatory authorities. His PhD is in immunology and he has over 100 publications. He was a venture partner at TVM Capital & sits on several biopharma boards.

Brandon J. Price, PhD, EVP of Business Development & Board Director; Co-Founder, Ethicann Pharmaceuticals

Dr. Price has 35 years of experience in biopharma, and has been a co-founder and/or CEO of a number of bio- pharma start-ups. A PhD in biophysics, he teaches entrepreneurism at several universities, and sits on several biopharma and other high-tech boards. His pharma experience is broad, involving responsibilities for drug manufacturing, testing, quality assurance, marketing, sales and business development for small and large companies.

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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.

Registration Information

Register for the conference using one of three options:
Online: www.pharmaedresources.com
Phone: (217) 721-5774
Mail: 2810 Robeson Park Drive, Champaign, IL 61822

Please Complete the Following

FIRST NAME: _____

LAST NAME: _____

TITLE: _____

COMPANY: _____

ADDRESS: _____

ADDRESS: _____

CITY: _____ **STATE:** _____

ZIP: _____ **COUNTRY CODE:** _____

OFFICE PHONE: _____

MOBILE PHONE: _____

FAX: _____

E-MAIL: _____

VENUE INFORMATION:

Dates:	November 9–10, 2021
Venue:	Marriott San Diego Mission Valley
Venue Address:	8757 Rio San Diego Drive San Diego, CA 92108
Venue Phone:	(619) 692-3800

Please register me for:

Canna Pharma 2021

Standard Full – Workshop & Conference (*Cannabis Industry)	**$645**
Standard Full – Workshop & Conference (Pharmaceutical Industry)	**$845**
Standard Conference Only (*Cannabis Industry)	**$495**
Standard Conference Only (Pharma Industry)	**$695**
Pre-Conference Workshop Only	**$275**

Call for Academic, Student, Government, or Non-Profit Pricing

***CANNABIS INDUSTRY RATES APPLY TO ORGANIZATIONS THAT WORK MOSTLY OR EXCLUSIVELY IN THE CANNABIS OR HEMP SECTOR**

PAYMENT METHOD

CREDIT CARD REGISTRATION:

☐ **CREDIT CARD** ☐ **VISA** ☐ **MASTERCARD** ☐ **AMEX**

NAME: _____

CARD #: _____

EXPIRATION: ____ / ____

SIGNATURE: _____

BILLING ADDRESS: _____

CHECK REGISTRATION:

To pay by check, please provide a purchase order below. Please note that all payments must be received five (5) days prior to the conference to ensure space. Attendees will not be admitted to the conference without full payment.

PURCHASE ORDER #:

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.