3RD ANNUAL
CANNAEAST
COMPLIANCE SUMMIT

January 17 - 19, 2018 | B Resort & Spa | Orlando, FL

Main Summit

Thursday January 18, 2018

7:00–7:55 *Registration and Networking Breakfast*

7:55–8:00 *Opening Remarks by the Summit Chair*

Reggie Gaudino, Ph.D., *Chief Science Officer,* STEEP HILL LABS, INC.

Federal and State Legislature Compliance Series

8:00–9:15 *Keynote Regulatory Panel I:* **Creating the Best Regulatory Frameworks for Cannabis Compliance**

- Creation and development of a compliance program for the cannabis industry in your state
- State models and structures set-up in your state, challenges of implementations, and lessons learned from those
- Risk assessment process
- Cannabis diversion prevention
- Best practices for inspections

Moderator:
Alexander Spelman, *Vice President - Business Development*, SICPA PRODUCT SECURITY LLC

Panelists:
Christian Bax, *Director, Office of Medical Marijuana Use*, FLORIDA DEPARTMENT OF HEALTH
Norman Birenbaum, *Principal Policy and Economic Analyst, Medical Marijuana Program*, RHODE ISLAND DEPARTMENT OF BUSINESS REGULATION
Lori Dodson, *Deputy Director/Director of Laboratory Compliance,* MARYLAND MEDICAL CANNABIS COMMISSION

For Speaking Opportunities, Contact:
Erin Dolleris | *Event Producer* | ErinD@infocastevents.com | (818) 888-4445 ext. 48

Shelly Edgerton, *Director,* MICHIGAN DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
Arian R. Gibson, *Program Manager, Division of Medical Marijuana and Integrative Therapy (MMIT), Health Regulation and Licensing Administration*, DISTRICT OF COLUMBIA DEPARTMENT OF HEALTH (DOH)
Michelle Larson, PhD, MPA, *Director, Office of Medical Cannabis***,** MINNESOTA DEPARTMENT OF HEALTH
Nicole Quackenbush, PharmaCann.D, *Director, Medical Marijuana Program***,** NEW YORK STATE DEPARTMENT OF HEALTH

9:15–10:00 *Keynote Regulatory Panel II:* **Lessons Learned from Implementing Statewide Cannabis Programs**

Moderator:
Moe Afaneh, *COO*, BIOTRACKTHC

Panelists:
Bridget Degnen, *Former Deputy Director,* STATE OF ILLINOIS
Ken Groggel, *Former Manager,* NEW MEXICO MEDICAL CANNABIS PROGRAM

10:00–10:30 *Networking Break*

Cannabis Product Safety

10:30–11:00 *Presentation:* **How Cannabis-Derived Medications Go Through the FDA Approval Process: Development and Regulation**

Securing approval from the Food and Drug Administration (FDA) is difficult for any investigational medication, but the challenges are even greater for products derived from botanical materials. In addition, there are additional hurdles and requirements for products containing substances that may affect the central nervous system (CNS). Strict control of the conditions of cultivation and harvest of the botanical starting material is the essential first step. Multiple quality control steps, specifications (agreed to by FDA), and batch-to-batch consistency are required at each point along the way as the botanical raw material moves through various stages into a finished drug product. FDA must inspect and approve all manufacturing sites and processes before marketing

approval and no major changes can be made to any of these without FDA agreement. Extensive toxicology and other safety testing (in animals and humans) is necessary. Phase I-IV clinical trials will assess safety, efficacy, and the effects of different doses. The dosage form must deliver a reproducible dose each time and the characteristics of cannabinoids may make it challenging to develop a precise and stable dosage form. Since cannabis is classified in Schedule I of the Controlled Substances Act, researchers studying an investigational cannabis product must obtain Schedule I research licenses from the Drug Enforcement Administration and from many state controlled substances authorities. Because cannabinoids have CNS activity, a full battery of abuse potential studies must be conducted. Upon FDA approval, a new cannabinoid product must be rescheduled under both state and federal law before it can be dispensed by pharmacies.

Alice Mead, *Vice President, U.S. Public Policy and Public Affairs,* GW PHARMACEUTICALS

11:00–12:00 *Panel Discussion:* **Food Safety Regulations of Cannabis-Infused Products Panel**

Cannabis is a rapidly evolving industry that is creating a lot of confusion due to always changing regulations that differ from state to state. Presenters of this session will provide a high-level overview and summary of findings from the Developing Guidance for Food Safety Regulations of Cannabis-Infused Products workshop, discuss key issues and model practices identified, and other themes that emerged from the workshop, as well as define next steps towards the development of a guidance document based on the needs of the regulator community.

Moderator:
Cindy Rice, *Food Safety Specialist & President*, EASTERN FOOD SAFETY

Co-Moderator:
Elizabeth Landeen, *Associate Director, Program and Partnership Development,* NATIONAL ENVIRONMENTAL HEALTH ASSOCIATION (NEHA)

Panelists:
Camille K. Gourdet, JD, MA, *Research Public Health Analyst,* RTI INTERNATIONAL
Kara Lavaux, *Food Safety and Marijuana Program Supervisor, CP-FS, Public Health Inspections Division, Department of Environmental Health*, CITY AND COUNTY OF DENVER, CO

Joe Lillis, CP-FS, *Managing Partner, Regulatory Specialist*, CANNWELL ADVISORS
Peggy Moore, *CEO/Partner*, LOVE'S OVEN, LLC

12:00-12:25 *Presentation:* **State Regulations and Their Cooperation with Accreditation Bodies**

Bill Hirt, Ph.D., ANSI-ASQ NATIONAL ACCREDITATION BOARD

12:25–1:30 *Group Luncheon*

1:30–1:45 *Presentation:* **State of the Industry: The National Perspective**

Aaron Smith, *Executive Director*, NATIONAL CANNABIS INDUSTRY ASSOCIATION (NCIA)

1:45–2:00 *State Legislative Keynote Address*

Senator Tom Davis, SOUTH CAROLINA

Cannabis Product Safety Cont.

2:00–2:30 *Presentation:* **Consumer Safety**

- Product ingredients like flavoring agents in edibles and smoking/vaping products
- Product contamination (mold, pests, pesticides)
- Approved source issues for hemp products.

Kara Lavaux, *Food Safety and Marijuana Program Supervisor, CP-FS, Public Health Inspections Division, Department of Environmental Health*, CITY AND COUNTY OF DENVER, CO

2:30–3:30 *Operators' Panel Discussion:*
Cultivating and Producing Safe Cannabis Products
This panel of various cultivators and producers will discuss their perspectives on following best manufacturing practices, following cannabis compliance cultivation requirements in different states, ensuring product quality and safety by using different cultivation techniques to differentiate from competition, and overcoming common

pitfalls and sharing lessons learned in their daily operations.

Moderator:
Lydia Abernethy, *Director of Cultivation Science*, STEEP HILL LABS, INC.

Panelists:
Jonathan Gilbert, *Director,* COLUMBIA CARE LLC
Mitchell P. Kahn, *Principal and CEO,* GREENHOUSE GROUP, LLC*;* GRASSROOTS CANNABIS, LLC; FRONTLINE REAL ESTATE PARTNERS, LLC
Tim Keogh, *CEO*, AMERICANN, INC.
Gabe Perlow, *CEO,* PUREPENN, LLC
Jeremy Unruh, *General Counsel*, PHARMACANN LLC

3:30–4:00 *Networking Break*

4:00–5:00 *Retailers' Panel Discussion:*
Running a Compliant Retail Business and Sourcing Safe Cannabis Products
Retailer business can get highly competitive in certain areas and dispensaries have to be creative to figure out ways how to differentiate from others. Retailers have nowadays many choices of products to put on their shelves. Therefore, well branded products that are safe for consumers are in high demand. But it's difficult for retailers to know all of their products and if their ingredients are safe and if the labels on them can be trusted to secure safety of their customers. This panel will discuss best practices how to source safe cannabis and cannabis-infused products and establish good and trusted relationships with cultivators and producers, how to manage retail facility to be compliant with local and state laws, and how to manage risk, daily retail operations and deal with security.

Moderator:
Doug Fischer, *Chief Legal Officer and Head of National Standards*, NATIONAL ASSOCIATION CANNABIS BUSINESSES (NACB)

Panelists:
Scottie Gordon, Esq., *COO*, ERMONT INC.
Kim Napoli, Esq., *Marketing Specialist*, NEW ENGLAND TREATMENT ACCESS, INC.
Hillary Peckham, *COO,* ETAIN, LLC

Dr. Richard Tempel, LIBERTY HEALTH SCIENCES
Brad Zerman, *CEO*, SEVEN POINT

5:00-5:05 Welcome Remarks by the Reception Sponsor

Arby Barroso, *Co-Founder*, GREEN ROADS

5:05-5:30 *Day 1 Wrap-Up Session:* **Cannabis Regulation in the Trump Administration: Lessons Learned and What Lies Ahead**

This insightful and interactive session will explore what impact the Trump administration has had and will continue to have on the cannabis industry. In addition, Jonathan Havens will offer insights into both the changing federal and state cannabis regulatory landscapes, including offering predictions on what's to come, and how these changes could affect industry members, consumers, patients, and the research community.

Jonathan A. Havens, *Associate*, SAUL EWING ARNSTEIN & LEHR LLP

5:30-6:30 Networking Reception Sponsored by: GREEN ROADS™

Friday January 19, 2018

7:00–7:55 *Registration and Networking Breakfast*

7:55–8:00 *Opening Remarks by the Summit Chair*

Reggie Gaudino, Ph.D., *Chief Science Officer,* STEEP HILL LABS, INC.

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Focus on Testing

8:00–8:30 *Presentation:*
Microbial Contamination in Cannabis Cultivation: Important Tips to Avoid Regulatory Failure
The talk will center around the current testing regulations in legal states, going into detail about why each test type is or is not relevant for Cannabis and how certain cultivation practices lead to microbial contamination. Many cultivators and regulators do not understand where microbiological pathogens enter the production chain; this talk will illuminate the common pitfalls, behaviors to avoid, and appropriate remediation techniques. I will cover moisture analysis and water activity in the presentation and be sure to include relevant data.

Lydia Abernethy, *Director of Cultivation Science*, STEEP HILL LABS, INC.

8.30–9:00 *Presentation:*
Fast, Reproducible Extractions for Potency and Pesticide Analysis

Tom Hall, *Vice President of Sales and Marketing,* FLUID MANAGEMENT SYSTEMS (FMS, INC.)

9:00–9:30 *Presentation:*
Pesticide Thresholds, Microbials (PCR), Heavy Metals and Genetics

Stephen Goldman, *Head of Research and Development,* EVIO INC.

9:30–10:00 *Presentation:*
Colorado Pesticides Case Study
The discovery of non-registered pesticides contamination in Cannabis plant material in Colorado prompted the need to set mandatory reporting limits (MRLs) for these pesticides in Colorado to ensure public safety. Since then the Colorado Department of Public Health and Environment (CDPHE) undertook the responsibility for setting such MRLs. Colorado's novel approach to determine the proper levels for each pesticide involved forming a working group with its in-state laboratories and expert volunteers to agree on an analytical procedure to determine Method Detection Limits (MDLs) using an industry-standard approach. The authors will tell the story of how this approach formed

a collaborative public-private partnership where the state government worked side-by-side with labs to establish procedures and complete a multi-lab study to report MDLs for thirteen pesticides in Cannabis flowers using QuEChERS extraction with dSPE cleanup with analysis by LC-MS/MS. The author will share the procedures employed in this approach, an overview of the data generated by the participating labs and the outcome of the study which led to setting MRLs which became final rule in November, 2017 and are effective in Colorado as of January 1st, 2018.

Joe Konschnik, *Business Development Manager*, *Food & Agriculture Markets,* RESTEK CORPORATION

10:00–10:20 *Networking Break*

10:20–10:40 *Presentation:*
Lab Accreditation Highlights

- Third party accreditation's value
- Criteria for laboratories
- Overview of the various accreditation processes and its benefits

Michelle Bradac, *Senior Accreditation Officer,* A2LA

10:40–11:30 *Panel Discussion:*
Creating Reliability, Safety and Standardization in Cannabis Quality Testing

- Mandated testing based on science to provide consistent quantifiable data on the safety and quality of the medicine
- Safety testing vs. potency testing
- Developing best testing practices and methodologies for sampling and testing
- The future of cannabis lab testing and importance of safety testing
- The role of standards and good manufacturing practices in producing safe, quality, consistent products

Moderator:
Roger Brauninger, *Biosafety Program Manager*, A2LA

Panelists:
Susan Audino, Ph.D., *Chair, Cannabis Advisory Working Group*, AOAC INT. and *Principal*, S.A. AUDINO & ASSOCIATES, LLC
Joe Konschnik, *Business Development Manager*, *Food & Agriculture Markets,* RESTEK CORPORATION
Jahan Marcu, Ph.D., *Chief Science Officer*, AMERICANS FOR SAFE ACCESS
Robert J. Morgan, *Director, Technical Committee Operations*, ASTM INTERNATIONAL

11:30 *Summit Adjourns*