

# INDUSTRY

INDUSTRY UPDATE ON CANNABIDIOL RESEARCH,  
MEDICINAL USES AND HOW IT TRANSLATES TO  
THE PHARMACEUTICAL INDUSTRY

# UPDATE

Thursday, August 22, 2019

LA JOLLA PHARMACEUTICAL COMPANY

4:30-6:00 PM | REGISTRATION, NETWORKING

6:00-7:30 PM | SPEAKER PANEL

## SPEAKER PANEL DISCUSSION

- *CHALLENGES WITH SAFETY, EFFICACY, & QUALITY CONTROL*
- *CLINICAL RESEARCH & POTENTIAL USES*
- *FACILITY REQUIREMENTS, CGMP, & VALIDATION*
- *BARRIERS WITH CURRENT LEGISLATION*
- *OVERCOMING ANALYTICAL TESTING INCONSISTENCY*

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*Please Join Us For An Evening Event*

## Industry Update on Cannabidiol Research, Medicinal Uses and How it Translates to the Pharmaceutical Industry

Join ISPE San Diego as we dive into discussion with four subject matter experts that are leading the way in the Industry for the safe use of Medicinal Cannabis for patient health

Thursday, August 22, 2019  
4:30-7:30pm

### Sponsored by:



### Location:

La Jolla Pharmaceutical Company  
4550 Towne Centre Court, San Diego, CA 92121

### Program Managers:

Shena Weeks, VP of Healthcare and Life Sciences Solutions & Services Segment, ISO Med Inc  
Deborah Neatherlin, Senior Account Executive Life Sciences, Siemens

### Speakers:

Vered Gigi, PhD, VP of Strategy and Business Development, CURE Pharmaceutical  
David Grelotti, MD, Medical Director, University of California Center for Medicinal Cannabis Research  
Pritesh Kumar, PhD, Senior Managing Director, PhytoSciences AG  
Michael Rochlin RN, MN- President, Confidential Therapeutics, LLC

### Schedule:

4:30-6:00pm Registration, Networking, Happy Hour and Appetizers  
6:00-7:30pm Panel

### Synopsis:

With the growing search for new drug therapies, Cannabis sativa L has shown promise in delivering a therapeutic effect for epilepsy, and yet 80 more biological active chemical compounds including the best-known compounds, 9-tetrahydrocannabinol, or THC, and cannabidiol, or CBD are still under research for therapeutic discovery.

With the first ever plant-based cannabinoid to receive FDA approval in 2018, the FDA is advancing sound development programs that properly evaluate and provide scientific evidence that the active ingredients contained in cannabis can safely reach the maximum therapeutic response achievable in a research setting for a beneficial medical discovery. These discoveries have forced regulatory and the life science community to provide more focus on the future involvement of cannabinoids for medicinal use in healthcare. The FDA will continue to support rigorous scientific research on the potential medical uses of cannabis-derived products and is working with product developers and manufacturers who are interested in bringing patients safe and effective, high quality products.

### Topics to be discussed:

- \* CGMP Upstream and Downstream Processing (From Seed to Extraction to Final Packaging)
- \* Designing, Implementing and Managing Cleanrooms and Laboratories for Processing
- \* Clinical Research and Requirements
- \* Challenges w/ Safety and Efficacy without regulatory oversight and standardization
- \* Current Legislation Movement

## Industry Update on Cannabidiol Research

### Thursday, August 22, 2019

**Who Should Attend:**

CMOs, CROs, chemists, microbiologists, those working in laboratory analytic processing, regulatory, quality professionals, legal staff and those who are curious about the cannabis industry and the medical use of CBD.

### About the Speakers

**Vered Gigi PhD, Vice Preseident of Strategy and Business Development, CURE Pharmaceutical**

As VP of strategy and BD, Dr. Gigi is responsible for the corporate development by identifying and shaping CURE's strategy both organically and inorganically to deliver sustained growth and diversified revenue. She is also responsible for building and maintaining relationships with the pharmaceutical companies, academia and other collaborators. Together with the office of the COO, her charter is to drive operational excellence and competitiveness. Prior to joining CURE, Dr. Gigi was a Project Leader with the Boston Consulting Group. During her tenure, she led and supported a variety of projects at global biopharma and MedTech companies with a focus on corporate and network strategy, operations, marketing and post-merger integration initiatives. Dr. Gigi holds a PhD in Immunology from the University of Pennsylvania and a BSc. in Bio-Medical sciences from Tel-Aviv University in Israel. During her years in academia she investigated immunotherapy, stem cell and DNA repair mechanisms.



**David Grelotti, Medical Director, University of California Center for Medicinal Cannabis Research**

Dr. Grelotti is an Associate Professor of Psychiatry at the University of California San Diego and the Medical Director of the University of California Center for Medicinal Cannabis Research (CMCR). An adult and child psychiatrist, he graduated from medical school at the Johns Hopkins University School of Medicine and completed residency training in the Harvard Medical School Combined Pediatrics, Adult Psychiatry, and Child Psychiatry Residency Training Program at Massachusetts General Hospital and McLean Hospital. With colleagues at the CMCR, he is currently conducting a study of cannabis-related driving impairment, a randomized, placebo-controlled clinical trial of cannabis for low back pain, and investigations of the impact of cannabinoids on the endocannabinoid system in bipolar disorder, HIV, and healthy persons. His research is funded by the National Institutes of Health and the State of California.

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## Industry Update on Cannabidiol Research

### Thursday, August 22, 2019

#### About the Speakers

##### **Pritesh Kumar, PhD, Senior Managing Director, PhytoSciences AG**

Dr. Pritesh Kumar earned his PhD in Pharmacology and Toxicology, with a focus in cannabinoid (cannabis) pharmacology, from the University of Louisville, Kentucky. Previously, Dr. Kumar conducted pharmacological testing of FDA- approved drugs as potential ligands for the cannabinoid receptor 2 (CB2) and investigated the pharmacology of cannabinoids.

He is the Senior Managing Director of PhytoSciences AG, a swiss-based consulting firm comprised of 100+ scientists & analysts across the EU, India, Canada, Africa, and USA. The

firm advises stakeholders in the areas of clinical trial solutions, novel drug delivery technology development, industrial scale manufacturing, analytical testing, and commercial bioprocessing.

Dr. Kumar is also the Scientific Advisor for Addis Ababa University, School of Pharmacy (SoP) in Ethiopia. In this role, Dr. Kumar facilitates advancements in graduate student education, promotes the interest of the SoP, and develops relationships between the SoP and the private sector.

He previously served as an Advisor to the WHO (World Health Organization) based in Geneva, Switzerland. In this role, Dr. Kumar provided consultation services to the 40th Meeting of the Expert Committee on Drug Dependence regarding Cannabis Toxicology. He was also the Chief Scientific Officer for PharmaCielo Ltd., a Canadian company with operations in Colombia, South America. In this role, he was responsible for the company's R&D, global business product development strategy, and Phase I development of a state- of-the-art GMP pharmaceutical bioprocessing plant. He was previously the Chair of PharmaCielo's Research Advisory Board and worked closely with the Medical Advisory Board, headquartered in Geneva, Switzerland, to coordinate clinical programs for cannabinoid-based therapeutics.

He has received numerous honors and awards including Best Oral Presentation from the International Cannabinoid Research Society (ICRS) Conference in Vancouver and fellowships from Drug Discovery and Target in Boston and Integrated Programs in Biomedical Sciences (IPIBS) as well as travel awards from the National Institute on Drug Abuse and University of Louisville School of Medicine for his presentations in the U.S., Canada, Italy, and Germany.

Dr. Kumar has been published in numerous scientific journals including the European Journal of Pharmacology, Pharmacology and Physiology, Journal of Medicinal Chemistry, Investigative Ophthalmology & Visual Science and Biochemical and Biophysical Research Communications.



##### **Michael Rochlin RN, MN- President, Confidential Therapeutics, LLC**

Hailing from the San Francisco Bay area, Michael brings a bit of western hospitality to all his clients. He moved to Seattle over thirty years ago after graduating with his undergraduate degree in Nursing from Pennsylvania State University.

He practiced at various Eastern and Western US hospitals and became Charge Nurse at the Cardiac Intensive Care Unit (CICU) of University Washington Medical Center (UWMC). Later he was offered a CDC NIOSH grant and completed a Master's degree in Nursing, Business Administration and Public Health at UW.

Mike relocated to Oregon in 2010, to lead Environmental Health & Safety for the Intel D1X Site Construction project. After that project was completed, he helped OHSU Healthcare remedy their FMLA/ADAAA processes. Mike is a Past-President and Professional member of the Puget Sound Chapter of the American Society of Safety Professionals, member of PNS-American Industrial Hygiene Association, and active research & education committee member of the American Cannabis Nurses Association, as well as Founding Member of the Cannabis Nurses Network. Mike was recently appointed to the Oregon Cannabis Commission Clinical Practice and Training Subcommittee. Michael stays up-to-date on the latest endoCannabinoid Therapeutic scientific discoveries. When not striving to keep his clients happy and healthy, he enjoys exploring scenic wonders of Oregon.



## REGISTRATION INSTRUCTIONS

# Industry Update on Cannabidiol Research

Thursday, August 22, 2019

### Sponsorships Available

To Register and Receive an immediate receipt, use our on-line registration: <http://atdevents.net/register.php>

#### **ISPE LA, SD, SF Members:**

If you are an ISPE Member in California, please do not set up a new account, you should already be in our system. Please email Rob Fleming for assistance with your username and/or password.

#### **ISPE Members of other Chapters:**

You will not be in our system unless you have previously set up an account. Please follow instructions for Non Members below. To update your account to a Member account, please forward your confirmation email from ISPE or ISPE Membership Card to Rob Fleming. We need your Chapter name, your ISPE Member number and expiration date. You can get your Membership card once logged onto the ISPE website (see bottom left side of the screen).

#### **Non ISPE Members:**

If you do not have an account on our system, you can set one up on the site using letters (not numbers) as your username.

#### **\*\*Students:**

The Student Rate is for individuals who are enrolled full time in a related academic program at an accredited institution. The Student Rate does not apply to working professionals taking one or two courses on the side. To verify your status as a student, we may ask you to supply your student ID and copy of current class schedule. Final eligibility determined by ISPE SD.

**Registrations can also be faxed.** Complete the form and fax to 949-266-8461.

If paying by check, please mail your check made payable to:

ISPE San Diego Chapter, 5319 University Dr., Suite 641, Irvine, CA 92612. Tel: 949-387-9046. Tax ID#33-0551783.

**Registration Fee includes light dinner and free parking**

**Note: If you are between jobs or your company does not support your registration fees, please contact Kimberly Syre ([ksyre@cox.net](mailto:ksyre@cox.net)) for reduced fee options or sponsorship opportunities.**

Registration or Online Questions? Contact Rob Fleming: [rob.fleming@yahoo.com](mailto:rob.fleming@yahoo.com)

Name Badges will be given at the event.

**Cancellations** must be received via email to: [rob.fleming@yahoo.com](mailto:rob.fleming@yahoo.com) by August 15, 2019 for refund. After the cancellation date if you have reserved a space but do not attend, your payment **MUST** be remitted, however, an alternate person may attend in your place. If the alternate is not a member, they will need to pay the additional amount for non-members. Name badges will be given at the on-site registration desk.



**ISPE**®

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**Registration Form**  
**Industry Update on Cannabidiol Research**  
**Thursday, August 22, 2019**

**REGISTRATION RATES**

- \_\_\_\_\_ \$60 **ISPE Members**
- \_\_\_\_\_ \$90 **Non-Members**
- \_\_\_\_\_ \$70 **CBD Industry**
- \_\_\_\_\_ Free **Free for La Jolla Pharmaceutical Employees (First 10 free)**
- \_\_\_\_\_ \$40 **La Jolla Pharmaceutical Employees (after first 10)**
- \_\_\_\_\_ \$40 **ISPE Student or YP (Young Professional) Members**
- \_\_\_\_\_ \$500 **Sponsors (includes a table top at the meeting and two attendees)  
Additional attendees can attend at the ISPE Member rate**
- \_\_\_\_\_ \$250 **Happy Hour Sponsor (includes one attendee, does not include a table)  
Additional attendees can attend at the ISPE Member rate**

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First and Last Name: \_\_\_\_\_

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## **DRIVING DIRECTIONS:**

# **La Jolla Pharmaceutical Company**

4550 Towne Centre Court, San Diego, CA 92121

### **From Downtown San Diego**

Take 5 Freeway North.

Take exit 29 for Genesee Ave,

Use the right 2 lanes to turn right onto Genesee Ave.

Use the left 2 lanes to turn left onto Eastgate Mall.

Use the left 2 lanes to turn left onto Towne Centre Dr.

Turn left onto Towne Centre Ct.

Destination will be on the right.

### **From Los Angeles Area**

Take 405 Freeway South to the 5 Freeway South to 805 Freeway South.

Take Exit 25 for Miramar Rd/La Jolla Village Dr.

Use the right 2 lanes to turn right onto La Jolla Village Dr.

Use the right 2 lanes to turn right onto Towne Centre Dr.

Continue straight to stay on Towne Centre Dr.

Turn left onto Towne Centre Ct.

Destination will be on the right.

**Please be sure to look up directions from your own starting point.**