



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

Featuring Lessons Learned and Case Studies from Industry Experts



Sophie-Anne Lamour
Health Canada



Nandu Sarma
USP



Susan Audino
A2LA



Karolina Urban
Avicanna



Stephen Goldner
PG Pharmaceuticals



Hunter Land
Alterola Biotech



Monica Taing
Holistic Industries



Anthony Macherone
Agilent



Marilyn Barrett
Pharmacognosy Consulting



Scheril Murray Powell
JUSTUS Foundation



Ethan Russo
CreDO Science



Lori Dodson
MMCC



Dale Hunt
Breeder's Best



Heather Krug
CDPHE



Lindsay Robinson
CCIA



Hope Jones
Emergent Cannabis Sciences



Zev Barnett
Maven Hemp



Inayet Ellis
Gattefossé



Andreas Pappas
Antares Health Products



Andrew Wayne
Health Canada



Andrea Small-Howard
GB Sciences



Rob Davidson
Cure Pharmaceutical



Michael Moussourakis
Alconox

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:



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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 Potency Testing?***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 Δ^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, Δ^{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.

Panel Forum—Ask the Regulators**9:10****Industry Regulation in Practice—A Panel Discussion & Audience Q&A***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

9:45*Morning Networking Break***10:15****An Overview of Chemical and Microbial Contaminant Requirements for Cannabis Products in Canada***Andrew Wayne, 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.

Critical Issues—Balancing Safety and Equitable Access in a Just Industry

10:50 Managing Consumer Protection while Growing a Robust Inclusive Cannabis Space



Scheril Murray Powell, Esq., The JUSTÜS Foundation

In this presentation, I will highlight the importance of quality standards in the evolving industry that balances barriers to entry with the need for industry standards that protect the consumer. We will explore the role of State and Federal agencies in producing a safe consumer product across the entire chain of custody from seed to sale. We will also look at international models for cannabis and quality standards.

11:25 Hemp Derived Medicine: The Need for Fast Global Adoption



S. Zev Barnett, Founder & CEO, Maven Hemp

As hemp has reappeared in the Americas and re-emerged as a healthy alternative to traditional medicine in Europe, the governments and the cannabis/hemp industry have now created mass confusion amongst consumers. We know that here are over two hundred compounds available in the Cannabis Sativa L plant. With a multitude of singular molecules that are beneficial for human and animal use, Cannabidiol or CBD is the most well-known after THC. This however, is just the proverbial tip of the iceberg. With vastly different regulatory environments in the United States, the EU, the Middle East, and Latin America, innovation is slowed at best or almost stifled. As leaders in medicine and industry, we can do better for patients. Attendees will learn:

- How we can take regional practices and create global change
- How we can set standards to ensure safety and reliability
- Taking a look at cannabinoid trial data, how we can ascertain clinically meaningful results
- Innovative cannabis-based therapies being used by doctors around the world

12:00 Lunch Break

Northern Exposure—A Framework for Human-subject Research

1:15 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.

1:50 Critical Cleaning: The Key to Quality & Safety



Michael Moussourakis, Senior Director, Strategic Affairs, Alconox

Critically clean processing equipment, whether it be labware, glassware, instrumentation, or processing and extraction equipment, is vital. The potency, purity, and quality, essential characteristics of any drug, rely on critically clean surfaces. Cannabis is no different, and in fact, likely more difficult than traditional drug manufacturing. Waxy, resinous, oily, and sticky residues abound which can be highly adherent, difficult to emulsify, and 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.

2:25 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

2:55 Tissue Culture Techniques



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.

3:35

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.

4:15

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.

4:55

Happy Hour Mixer

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

Thursday, October 13

7:30

Complimentary Breakfast

Research Spotlight—Toward National Standards for Clinical Research

8:05

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.

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

8:45

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.

9:25

Active Pharmaceutical Ingredients: Strategic Considerations for Cannabinoid Development

Hunter Land, VP, Translational Research and Board Member, Alterola Biotech



Treating unmet medical needs with various forms of cannabis has been documented throughout millennia. Technological developments in recent decades have allowed scientists to further characterize cannabis and cannabinoid-like compounds, determine potential mechanisms of action, while identifying conditions where these compounds may be efficacious. In recent years, advanced cannabinoid manufacturing techniques have set the stage to produce potential cannabinoid medicines synthetically, biosynthetically, and through advanced botanical extraction and standardization methodologies. This presentation will explore strategies for the development of cannabinoids and cannabinoid derivatives as medicines while outlining benefits of synthetic and biosynthetic production vs extraction and standardization under the FDA Botanical Drug Guidance.

10:05

Morning Networking Break

Our Plenary Keynote—Decentralizing Clinical Trials

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.

KEY NOTE

Cannabinoid Product Development—Getting Down to Cases

11:15

Avicanna Presentation

Karolina Urban, PhD, VP of Scientific & Medical Affairs, Avicanna, Inc.



Abstract Coming Soon

CASE STUDY

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.

CASE STUDY

1:50

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

CASE STUDY

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.

Critical Issues—In the View of Patients & Clinicians

2:30

Clinical Considerations for Medical Cannabis and Harm Reduction



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

Abstract Coming Soon

3:10

Afternoon Break

Technology Spotlight—Improving Bioavailability & Meeting Formulation Challenges

3:25

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

4:05

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.

4:45

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.

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 1/2 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:



***Charlotte Peyton, Independent Consultant,
EAS Consulting Group***

Charlotte Peyton supports EAS dietary supplement and pharmaceutical clients from startup and growth through manufacturing and manufacturing support. Her expertise includes quality, regulatory and management, method development and method validation for FDA regulated drug, dietary supplement, and bioanalytical samples. She has extensive experience in writing validation protocols, reports and SOPs and assists with implementation of stability programs and report writing for drug and dietary supplement finished products.



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Dates: **October 11–13, 2022**
 Venue: **Marriott San Diego Mission Valley**
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