Nov | 1st – 2nd | 2024 Gaithersburg Marriott Washingtonian Center



# **2024 8th KAPAL ANNUAL CONFERENCE** with KIC-DC, KSEA-DC, and KLAM " Drug Development A to Z "











KLAM Korean Life scientist Association of Maryland 메릴랜드 한인 생명과학자 협회

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## Al-Driven **Oncology Target Discovery**

Gradiant Bioconvergence has built Asia's largest repository of patient derived cancer organoids with next-generation sequencing (NGS). Through our unique Al-driven platform utilizing cancer organoids, we are opening a new chapter in target discovery and drug development for the global pharmaceutical industry.



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Ladies and Gentlemen,

Welcome to the 8th KAPAL Annual Conference (KAC) 2024!

As we gather here today, we are filled with gratitude and excitement. Over the past several years, KAC has continued to thrive, attracting over 190 participants and achieving significant success despite various challenges.

KAC has become a valuable platform that promotes innovation and collaboration between Korean and American life science organizations, including both industry and academia. Our mission is to share and expand knowledge in drug development and life sciences. This year, we are honored to host a diverse group of experts across the biopharmaceutical field, covering everything from drug discovery to bringing new medicines to market.

Over the next two days, I am confident that each participant will find ample opportunities for collaboration, build valuable professional relationships, and expand their networks. The success of this conference is a testament to the tireless efforts of our dedicated organizers and the exceptional speakers they have brought together. We also extend our deepest gratitude to the Embassy of the Republic of Korea and the Korea Health Industry Development Institute (KHIDI) for their steadfast support in making this event possible.

The 8th KAC 2024 is co-organized in partnership with the Korea Innovation Center DC (KIC-DC), the Korean-American Scientists and Engineers Association Washington DC Metro Chapter (KSEA-DC), and the Korean Life Scientist Association of Maryland (KLAM). This collaborative effort enriches the event by bringing together multidisciplinary experts from diverse fields, offering even greater value to our community. I hope this conference serves as a catalyst for global collaboration in the life sciences.

We extend our deepest gratitude to all the sponsors who have generously supported these events. Your contributions are vital to the ongoing success of our gatherings, year after year.

In conclusion, I would like to extend my heartfelt gratitude to our esteemed speakers, dedicated organizing committee members, and each participant. Together, let us embark on a journey to make the 8th KAC 2024 both successful and truly memorable.

Thank you for your participation!

Best regards, Jihoon Park, PhD

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President of KAPAL



#### JOINT ORGANIZING COMMITTEE

#### KAPAL



Jihoon Park President





Admin Dir.



Byung Ha Lee Exec. Dir.



Sang Tae Park Exec. Dir.



Suntae Kim IT Dir.



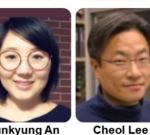
#### **KIC-DC**

BD Dir.





#### **KSEA-DC**



**Eunkyung An** Scientific Dir. Exec. Dir.



Woosub Lee General Dir.

#### KLAM



**Bumrae Cho** Program Dir.



Hyungjin Yun Sr. Manager



President

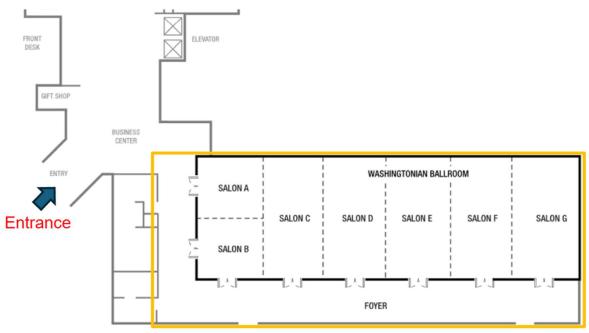


Seong-Beom Park President



Su-Jeong Kim Co-Vice President

### Venue (Washingtonian Ballroom)



### **Program-at-a-Glance**

#### Day 1. | Friday | November 01, 2024 (Salon C-E)

| Time           | Session  |
|----------------|--|
| 1:00 – 2:00 pm | <b>Registration &amp; Networking</b><br>(with light snacks and drinks)   |
| 2:00 – 2:30 pm | Johns Hopkins Global Biotechnology Innovation Center: Pioneering<br>Biotechnology and Healthcare Through Academic-Industry Partnerships<br>Across US-Korea Borders |
|                | Moderator: Seong-Beom Park, President, KLAM  |
|                | Hyeon-Cheol Park, PhD,<br>Program Manager & Director of Research and Translation,<br>Johns Hopkins Global Biotechnology Innovation Center                          |
| 2:30 – 3:00 pm | Innovative Gene Therapy Approaches for Neurodevelopmental Disorders:<br>ASO and AAV Strategies Targeting SYNGAP1 Syndrome  |
|                | Moderator: Seong-Beom Park, President, KLAM  |
|                | Ingie Hong, PhD, Instructor, Department of Neuroscience,<br>Johns Hopkins University School of Medicine  |
| 3:00 – 5:00 pm | KIC Startup Pitch  |
|                | (Please refer to the separate program book by KIC-DC)  |
| 5:00 – 5:30 pm | Key U.S. Issues to Watch for the Bio-Health Industry   |
|                | Seog-II Chang, Deputy Director, KOTRA Washington   |
| 5:30 – 6:30 pm | Registration, Dinner, and Networking   |
| 6:30 – 7:00 pm | Opening Remarks<br>KAPAL   |
|                | Jihoon Park, PhD, President, KAPAL   |
|                | Korea Health Industry Development Institute USA  |
|                | Soonmahn Park, PhD, President, KHIDI USA   |
|                | Montgomery County<br>Marc Elrich, County Executive   |
|                |  |
|                | <b>The State of Maryland</b><br>Susan Lee, Secretary of State of Maryland  |

| 7:00 – 7:15 pm  | Group Photo   |
|-----------------|---|
| 7:15 – 7:45 pm  | Sponsor Talk- SK Biopharmaceuticals   |
|                 | SK Life Science's Success Story: From Clinical Research to<br>Commercialization in the U.S. |
|                 | Josh McLaughlin, J.D., LL.M., General Counsel<br>SK Life Science, Inc.                      |
| 7:45 – 8:15 pm  | Sponsor Talk- Gradiant Bioconvergence   |
|                 | Cancer Patient-derived Organoid Banking & AI - driven Target Discovery                      |
|                 | Jinguen Rheey, PhD, CEO<br>Gradiant Bioconvergence  |
| 8:15 – 8:25 PM  | Sponsor Talk- Huons USA   |
|                 | The Next Leap in Anesthetic Products and Beyond   |
|                 | Taehyung (Edward) Kim   |
|                 | Sales & Business Development Team Leader, Huons USA   |
| 8:25 – 8:35 PM  | Sponsor Talk- Yuhan USA Corporation   |
|                 | Yuhan's Innovative Drug Development   |
|                 | Taewon Yoon, PhD, CEO   |
|                 | Yuhan USA Corporation   |
| 8:35 – 8:45 PM  | Sponsor Talk- CorestemChemon  |
|                 | Pioneering Comprehensive Nonclinical Solutions for Global Success                           |
|                 | Yoonseon Kim, Project Manager   |
|                 | CorestemChemon  |
| 8:45 – 10:00 PM | Networking  |
|                 | (with light snacks and beer)  |

#### Day 2. | Saturday | November 02, 2024 (Salon B, C-E, F-G)

| MAIN SESSION hosted by KAPAL (Salon C-E) |  |  |
|--|--|--|
| Time                                     | Session  |  |
| 8:30 – 9:00 am                           | <b>Networking</b><br>(with light snacks and drinks)  |  |
| 9:00 – 9:10 am                           | Opening Remarks  |  |
|  | KAPAL<br>Jihoon Park, PhD, President, KAPAL  |  |
| 9:10 – 10:10 am                          | An overview of drug development process: principles, practice and case studies   |  |
|  | Moderator: Jihoon Park, President, KAPAL   |  |
|  | Shahin Gharakhanian, MD, CEO, Shahin Gharakhanian Consulting, LLC.<br>Silvia Helou, MD, Executive Consultant, Helou Consulting, LLC.   |  |
| 10:10 – 10:40 am                         | Introduction to FDA's Investigational New Drug Application (IND)   |  |
|  | Moderator: Jihoon Park, President, KAPAL   |  |
|  | Marci Aderiye, MS, RAC, Senior Director, Regulatory Affairs, PPD   |  |
| 10:40 – 11:00 am                         | Coffee Break and Networking  |  |
| 11:00 – 11:30 am                         | Artificial intelligence (AI) in drug development: present status and prospects   |  |
|  | Moderator: Byung Ha Lee, PhD, Executive Director, KAPAL  |  |
|  | Jinguen Rheey, PhD, CEO, Gradiant Bioconvergence   |  |
| 11:30 – 12:00 pm                         | Considerations and steps to operationalize a clinical trial  |  |
|  | Moderator: Byung Ha Lee, Executive Director, KAPAL   |  |
|  | May Litt. MBA, CCRA, RAC, CEO, Litt Consulting Group, LLC.   |  |
| 12:00 – 1:10 pm                          | Lunch and Networking   |  |
| 1:10 – 1:40 pm                           | Strategic US IP Protection<br>Subtopic 1: IP Protection for Companies Conducting Business in the US<br>Subtopic 2: Utilizing Freedom-to-Operate Analysis to Avoid Patent<br>Infringement |  |

|                | Moderator: Kwan-Ho (Alex) Chung, PhD, JD, General Director, KAPAL  |
|----------------|--|
|                | Yong Ha Kim, Director, KOIPA U.S. Capital IP Center  |
|                | Kwangho Jang Attorney, Bookoff McAndrews, PLLC.  |
|                | Sangwoo Ahn Partner, Bookoff McAndrews, PLLC.  |
| 1:40 – 2:10 pm | Due Diligence Considerations in Transactions   |
|                | Moderator: Kwan-Ho (Alex) Chung, PhD, JD, General Director, KAPAL  |
|                | Allison Cho, Associate, Morrison Foerster  |
|                | Sophia Han, Partner, Kirkland&Ellis  |
| 2:10 – 2:40 pm | FDA medical device clearance and approval process  |
|                | Moderator: Kwan-Ho (Alex) Chung, PhD, JD, General Director, KAPAL  |
|                | Philip Won, PhD, JD, Associate, Alston & Bird, LLP.  |
| 2:40 – 3:00 pm | Coffee Break and Networking  |
| 3:00 – 3:20 pm | The PIE Act: What device companies can say prior to product approval   |
|                | Moderator: Sung Park, Counsel, Reed Smith LLP  |
|                | Sung Park, JD Counsel, Reed Smith LLP  |
|                | Taber Rueter, JD Senior Associate, Reed Smith LLP  |
| 3:20 – 3:40 pm | What's left for broad, functional claims?  |
|                | Moderator: Sung Park, Counsel, Reed Smith LLP  |
|                | Kwanho Chung, JD, PhD, Partner, Sheppard Mullin  |
| 3:40 – 4:00 pm | Coffee Break and Networking  |
| 4:00 – 4:30 pm | Trend in Early-Stage Innovation Ecosystem in the US  |
|                | Moderator: Woosub Lee, MBA, General Director, KAPAL  |
|                | Ian Ryu, PhD, Mentor-in-Residence, Korea Innovation Center DC  |
| 4:30 – 5:00 pm | Investing at the Intersection of Medicine, Regulation, and Innovation  |
|                |  |
|                | Moderator: Woosub Lee, MBA, General Director, KAPAL  |
|                | <u>Moderator</u> : Woosub Lee, MBA, General Director, KAPAL<br>Tae Heum Jeong, PhD, Managing Partner, Adelphi Ventures   |
|                |  |
| 5:00 – 5:30 pm | Tae Heum Jeong, PhD, Managing Partner, Adelphi Ventures  |
| 5:00 – 5:30 pm | Tae Heum Jeong, PhD, Managing Partner, Adelphi VenturesLuciana Borio, MD, Venture Partner, ARCH Venture PartnersStrategic Med-Tech Partnerships: Key Success Factors in Developing |

### MAIN SESSION hosted by KSEA-DC (Salon B, F-G)

| Time             | Salon F-G<br>Moderator: Kyowon Kim (President, KSEA-DC)   | Salon B                                       |
|------------------|---|---|
| 09:10 – 10:00 am | Networking  |   |
| 10:00 – 10:30 am | High-Fidelity CNOT Gate on Fluxonium Qubits:<br>Verifying Analogies with Transversely Coupled Spin-<br>1/2 Systems for 24-Day Stability |   |
|                  | Hyunheung Cho, Dept. of Physics, Univ. of Maryland  |   |
| 10:30 – 11:00 am | Large Scale Stochastic Modelling of Heterogeneous<br>Cell Populations   |   |
|                  | Hyeon Jin Cho, Biological Sciences, Univ. of Maryland   |   |
| 11:00 – 11:15 am | Effect of dietary Intervention on hypertensive patients:<br>a cross-sectional analysis of the PREMIER Trial                             |   |
|                  | Yu Jin Lim, Dept. of Exercise and Nutrition Science,<br>The George Washington Univ.   |   |
| 11:15 – 11:30 pm | Mobile application intervention to reduce sodium intake on stroke survivors   |   |
|                  | Yu Jin Lim, Dept. of Exercise and Nutrition Science,<br>The George Washington Univ.   |   |
| 11:30 – 1:10 pm  | Coffee Break, Lunch, and Networking   |   |
| 1:10 – 1:30 pm   | How Climate Shapes Wildfire Impacts on Soil Organic<br>Carbon: Insights from Maui, Hawaii   |   |
|                  | Yewon Lee, Dept. of Geology, Univ. of Maryland  |   |
| 1:30 – 1:45 pm   | The Influence of Heat on Animal Fiber Transformation<br>in a Microscopy Approach  |   |
|                  | Hwan Hee Lee, Dept. of Forensic Science, The George<br>Washington Univ.   |   |
| 1:45 – 2:00 pm   | BREAK   |   |
| 2:00 – 2:20 pm   | (Moving to Salon B for the following KSEA-DC sessions)  | Drone team<br>competition and<br>presentation |
| 3:00 – 5:00 pm   | (Salon B)   | Poster<br>presentation                        |

#### MAIN SESSION hosted by KIC-DC (Salon F-G)

| Time           | Session  |
|----------------|--|
| 2:00 – 2:30 pm | Navigating the US Market: A strategic Blueprint for Korean Startups      |
|                | Jim Chung  |
|                | Former Associate VP for Research, Innovation & Entrepreneurship          |
|                | George Washington University   |
| 2:30 – 3:00 pm | Access to Capital and Building Strong Banking Relationships for Startups |
|                | Ruth Kim, Relationship Manager, VP, M&T Bank                             |
|                | Fred Seo, Relationship Manager, M&T Bank                                 |
| 3:00 – 3:20 pm | Softlanding Program- Maryland  |
|                | Jessica Reynolds, Senior Director  |
|                | Office of International Investment and Trade                             |
|                | Maryland Department of Commerce  |
| 3:20 – 3:40 pm | Softlanding Program- Virginia  |
|                | John Hoeveler, Manager   |
|                | National Business Investment- Capital Attraction                         |
|                | Life Sciences and Quantum Technology                                     |
|                | Fairfax County Economic Development Authority (FCEDA)                    |

| FINAL SESSION (Salon C-E) |  |  |
|---------------------------|--|--|
| 5:30 – 6:00 pm            | Raffle - Awards<br>Closing Remarks<br>(KAPAL, KIC-DC, KSEA-DC, and KLAM) |  |
| 6:00 – 9:00 pm            | Dinner & Networking<br>(with beer and wine)                              |  |





# SPEAKERS



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#### Day 1. Speakers

#### Title: Johns Hopkins Global Biotechnology Innovation Center: Pioneering Biotechnology and Healthcare Through Academic-Industry Partnerships Across US-Korea Borders



#### Hyeon-Cheol Park, PhD

Program Manager & Director of Research and Translation Johns Hopkins Global Biotechnology Innovation Center Research Associate, Department of Biomedical Engineering The Johns Hopkins University School of Medicine

**Biographical Information:** Dr. Hyeon-Cheol Park received a Ph.D. from KAIST. He is currently a program Manager & Director of Research and Translation at Johns Hopkins Global Biotechnology Innovation Center. He leads research and translation at the Johns Hopkins Global Biotechnology Innovation Center (JBIC). He bridges academia and industry, translating research into commercial products. His expertise drives innovation and fosters collaborations between Johns Hopkins and Korean companies, contributing to the global biotechnology landscape.

**Summary of Presentation:** Dr. Park will showcase the Johns Hopkins Global Biotechnology Innovation Center (JBIC), which accelerates biotechnology and healthcare innovation through R&D support, technology incubation, and strategic consulting. JBIC fosters collaboration between Johns Hopkins University and Korean companies, leveraging expertise in biomedical engineering and Al/digital healthcare. With access to state-of-the-art facilities and a strategic location near U.S. regulatory institutions, JBIC helps Korean companies enter the U.S. market and promotes global biotechnology innovation and commercialization.

**Original abstract:** The Johns Hopkins Global Biotechnology Innovation Center (JBIC) is a pioneering hub dedicated to advancing biotechnology and healthcare research and development, with a focus on technology commercialization. JBIC's mission is to accelerate innovation in biotechnology and drug discovery by providing tailored R&D support, technology incubation, and strategic consulting services. Designed to foster collaboration between Johns Hopkins University (JHU) and Korean companies, JBIC leverages JHU's renowned expertise in biomedical engineering, pharmaceuticals, and Al/digital healthcare to offer a versatile platform for joint research, technology transfer, and commercialization. The Center provides Korean partners access to state-of-the-art laboratories, core facilities, and dedicated incubation spaces. Strategically located near key U.S. regulatory and research institutions, JBIC is uniquely positioned to support Korean companies in entering the U.S. market. By promoting cross-border collaboration, JBIC aims to catalyze groundbreaking research and create an ecosystem for global biotechnology innovation and commercialization.

#### Title: Innovative Gene Therapy Approaches for Neurodevelopmental Disorders: ASO and AAV Strategies Targeting SYNGAP1 Syndrome



#### Ingie Hong, PhD

Instructor, Department of Neuroscience, Johns Hopkins University School of Medicine

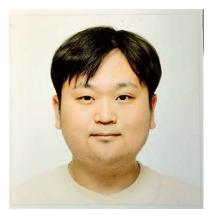
**Biographical Information:** Dr. Ingie Hong holds a Ph.D. from Seoul National University. He is currently an instructor in the Department of Neuroscience at Johns Hopkins University School of Medicine. He is an exceptionally multitalented expert, with expertise in molecular biology, computational analysis, and machine learning. Dr. Hong has made outstanding contributions to synapse research in neuroscience, and has achieved significant translational breakthroughs that enable clinical applications based on these contributions.

**Summary of Presentation:** This presentation introduces two advanced therapeutic approaches for SYNGAP1-related neurodevelopmental disorders, which cause intellectual disability and epilepsy. The first approach uses antisense oligonucleotide (ASO) therapy to restore SYNGAP1 gene function by modulating splicing. The second approach employs adeno-associated virus (AAV)-mediated gene therapy to correct synaptic dysfunction. These innovative strategies, grounded in preclinical studies, have the potential to revolutionize treatments for patients with neurodevelopmental disorders, advancing gene therapy closer to clinical application.

#### **Original abstract:**

Neurodevelopmental disorders (NDDs), including intellectual disability, epilepsy, and autism spectrum disorders, are frequently caused by monogenic mutations that disrupt synaptic function. Among these, mutations in the SYNGAP1 gene are a leading cause, resulting in severe intellectual disability and highly penetrant epilepsy. Like many other rare genetic brain disorders, current therapeutic strategies for SYNGAP1 syndrome are limited to symptom management, underscoring the urgent need for disease-modifying treatments. This talk will present two cutting-edge therapeutic approaches: antisense oligonucleotide (ASO) therapy and adeno-associated virus (AAV)-mediated gene therapy. We will focus on SYNGAP1 as a therapeutic target, exploring how ASO therapy can modulate SYNGAP1 splicing to restore gene function, and how AAV-mediated SYNGAP1 delivery can potentially correct synaptic dysfunction. Integrating findings from basic science and implementing best practices in preclinical studies, we demonstrate how these precision medicine approaches may transform the treatment landscape for patients with neurodevelopmental disorders, advancing gene therapy toward clinical application.

#### Title: Recent Biopharmaceutical Trends to Watch For – From Obesity Drug to 2024 Elections



#### Seog-II Chang

Deputy Director, KOTRA Washington

**Biographical Information:** Seog II Chang is currently working for research and analysis department of KOTRA Washington. His main focus area is economic and trade policies, and its impact on Korean industries. Previously, he has served for KOTRA's Mumbai office, fostering cooperation between Korean and Indian industries. He graduated from Korea University with B.A. in Economics and Business Administration.

**Overview:** AI, GLP-1, ADC; those were the few selected keywords to watch for the biopharmaceutical industry. House of Representative has passed BIO SECURE Act, and it is highly likely to pass the Senate during the lame duck session. Both presidential candidates want to bring the drug price down, but their pathways for the same goal are quite different from each other.

In this session, we will review the recent biopharmaceutical trends KOTRA has observed nationwide -- from the innovations of BIO USA to the desks of policymakers at Washington, D.C. -- and share its implications to the Korean Industry.

#### **Opening Remarks**



at the R&D Center.

#### Soonmahn Park, PhD

President, KHIDI (Korea Health Industry Development Institute) US Office.

**Biographical Information:** I am currently the president of KHIDI USA in Cambridge, USA. I have worked for KHIDI (Korea Health Industry Development Institute, a South Korean government affiliated agency) for 21 years. My prior roles with KHIDI have included research, policy development, market analysis and business planning to promote the South Korean medical devices industry.

Since March 2021, I've been helping Korean pharmaceutical, biotech, and medical device companies enter the U.S. market. My institution provides insightful and reliable information about the Korean health industry, and in our role as mediator, we can help U.S partners collaborate with South Korean companies.

Prior to KHIDI, I worked as a Software Engineer at Mediface (now INFINITT), a PACS spin-off company of the Medison Group, from 2000 to 2004. My main duties were DICOM Image Acquisition, Compression, Backup Server Development, and I led the Server Development Team

My undergraduate major was Biomedical Engineering, and my PhD was in Medical Imaging Software.



Marc Elrich Montgomery County Executive

**Biographical Information:** Marc Elrich was elected as Montgomery County Executive on Nov. 6, 2018. He had previously served three terms (12 years) on the Montgomery County Council as an at-large member, being first elected in 2006. He served as a Councilmember on the Takoma Park City Council from 1987-2006. For 17 years, he was a teacher at Rolling Terrace Elementary School in Takoma Park.

As a County Councilmember, he was the chief sponsor of several landmark pieces of legislation and programs. He led the successful effort to increase the Montgomery County minimum wage in coordination with surrounding jurisdictions to \$11.50 an hour and subsequent legislation that will eventually increase the minimum wage to \$15 an hour. He was the first elected official to propose building a Bus Rapid Transit (BRT) system throughout the County to address Montgomery's transportation and environmental problems. Ground was broken in Fall 2018 for the first BRT line, which will run along Route 29. Throughout his political career, he has been a champion of improving tenants' rights and for making developers pay for a greater share of the infrastructure cost to build schools and transportation solutions. He was a leader in the fight to preserve Ten Mile Creek in the Clarksburg area by limiting the proposed development that would have threatened the health

of Montgomery County's last best stream which flows into the County's backup water reservoir.



#### Susan C. Lee Secretary of State, Maryland

**Biographical Information:** Susan Lee was appointed as Maryland's 72nd Secretary of State on January 18, 2023 by Governor Wes Moore. She previously served over 20 years in the Maryland General Assembly, having been elected to the Senate in 2014 and to the House of Delegates in 2002 representing District 16. Lee, an attorney, is the first Asian American to serve as Maryland's Secretary of State, first Asian American elected to the Senate, and first Chinese American elected to the General Assembly. During her time in the General Assembly, Lee was a leader the cutting-edge issues of cyber security, innovation, identity theft, online fraud, consumer protection, pay equity, gun safety, and championed laws to fight domestic violence, sexual assault, human trafficking, child abuse, senior abuse, and hate crimes. Lee also led efforts to promote bioscience, nanobiotechnology, telehealth, IT, and emerging technologies. Lee was the lead senate sponsor of the Maryland Equal Pay for Equal Work Act, True Freedom Act, and Anti-Exploitation Act and laws to ban ghost guns, require background checks on long gun sales, and to empower women, children, families, and all hardworking individuals.

Lee served as the Senate Majority Whip, Member of the Senate Judicial Proceedings Committee, Member of the Senate Executive Nominations Committee, Legislative Policy Committee, Joint Committee on Cybersecurity, Information Technology and Biotechnology, Governor's Council on Family Violence, Workgroup to Study Safe Harbor Policy for Youth Victims of Human Trafficking, and Workgroup to Study Child Custody Proceedings Involving Child Abuse or Domestic Violence Allegations. She also served as the Co-Chair of the Maryland Cybersecurity Council Law & Policy Subcommittee, Co-Chair of the Maryland Commission on Cyber Security, Innovation and Excellence, Co-Chair of the Maryland Identity Theft Task Force, and Co-Chair of the Nanobiotechnology Task Force, and Member of the Council on Open Data, Maryland Student Privacy Council, State Advisory Board for Juvenile Services, State Advisory Board on Administrative Hearings, Task Force to Study Bicycle Safety on Maryland Highways, and Task Force to Study Recording Deeds for Victims of Domestic Violence. Lee was the first and past Chairman of the Maryland Legislative Asian American and Pacific Islander Caucus and past President of the Women Legislators of Maryland (Women's Legislative Caucus). She also was a Member of the National Conference of State Legislatures Task Force on Immigration and Task Force on Cybersecurity and Member of the Communications, Technology & Interstate Commerce Committee, Member of the Maryland Council for New Americans, and a Presidential Elector.

Lee is the daughter of a World War II veteran of the US Navy and retired *Washington Post* artist. She is a product of the Montgomery County public school system, having attended Leland Junior High School, Herbert Hoover Junior High, and Winston Churchill High School. She graduated from the University of Maryland, College Park and the University of San Francisco School of Law. Having served in both the public and private sectors, Lee was an attorney with the U.S. Commission on Civil Rights, the U.S. Patent and Trademark Office, and Of Counsel with Gebhardt & Associates. She was appointed to serve on the United States Patent and Trademark Advisory Board during the Clinton Administration. Lee was a member of the Western Montgomery County Citizens Advisory Board, Jewish Foundation for Group Homes Board, Progressive Maryland, Co-Chair of the Montgomery County NAACP Multicultural Community Partnership, President of Asian Pacific American Bar Association of Greater Washington Area, and Board Member of the Asian Pacific American Institute for Congressional Studies.

Lee is an inductee of the Montgomery County Human Rights Hall of Fame and the Montgomery County Women's History Archives. She is the recipient of the Maryland Legislative Agenda for Women's Legislative Leadership Award; Women's Law Center Dorothy Beatty Memorial Award; Maryland NOW's Leadership Award; *Bethesda Magazine*'s Women Who Inspire Award; *Baltimore Sun*'s 25 Women to Watch Award; *The Daily Record*'s Maryland Top 100 Women; Equality Maryland's Out for Justice Award; National Center for Children and Families' Spirit Award for Humanitarian Leadership; Baltimore Child Abuse Center's Outstanding Community Hero Award; Maryland Health Information Management Systems Award, Village of Friendship Heights Community Service Award; Progressive Maryland's Progressive Leader Award; Charles E. Smith Communities Chairman's Award for Commitment and Support of the Elderly Community; Mothers Against Drunk Driving Merit Award; Chinese American Citizens Alliance's George Frisbie Hoar Award; Korean American Senior Citizens Association MD Outstanding Senior Citizens Advocate Award and many more.

As a former state Senator and House Delegate and now as Secretary of State, I have been honored to have worked with outstanding advocates and leaders of women's, people of color, LGBTQ+, disability, faith, immigrant, civil rights, and other organizations to pass and implement landmark laws and policies that have helped uplift and empower women, children, families, and people of all backgrounds. We still must continue to work to protect and build on the significant strides made by those whose shoulders we stand on to ensure we are moving forward together to fulfil the promise of America and make this a better world for all.

Biography courtesy of the Maryland Commission for Women, 2024.

#### **Sponsor Talks**

#### Title: SK Life Science's Success Story: From Clinical Research to Commercialization in the U.S.



Josh McLaughlin, J.D., LL.M.

General Counsel, SK Life Science, Inc.

Josh is the General Counsel of SK Life Science, Inc. (SKLSI) where he leads several functions, including Legal, Compliance, Corporate Communications, Procurement, Government Contracting and Privacy.

**Biographical Information:** Josh joined SKLSI in 2020 from Bristol-Myers Squibb where he held a number of senior executive legal and compliance roles supporting business development, global R&D, commercial and international markets. Josh has a B.S. in Animal Physiology and Neuroscience from UC San Diego, a J.D. from Thomas Jefferson School of Law and an LL.M. in Intellectual Property Law from University of San Diego School of Law.

**Overview:** Introduction of SK Life Science's clinical capabilities and commercial prowess which enabled ongoing success of Xcopri (cenobamate)

#### Title: Cancer Patient-derived Organoid Banking & Al-driven Target Discovery



#### Jinguen Rheey, PhD

CEO, Gradiant Bioconvergence

#### **Biographical Information:**

2020 Jun – Present: Gradiant Bioconvergence (CEO) & Gradiant (Head of Investment)
2019 Apr – 2020 May: Hugel (Head of Investment & BD)
2016 Aug – 2019 Mar: Dong-A ST (BD Leader)
2011 Jul – 2016 Jul: Samsung Electronics (BD & Corporate Strategy)

Jinguen currently serves as the CEO of Gradiant Bioconvergence and Head of Investment at Gradiant, roles he has held since June 2020. Prior to this, he directed Investment and Business Development at Hugel from April 2019 to May 2020. From August 2016 to March 2019, he led Business Development at Dong-A ST, and before that, he worked in Business Development and Corporate Strategy at Samsung Electronics from July 2011 to July 2016.

His academic credentials include a PhD from École Normale Supérieure in Paris, a Master's degree from The George Washington University in Washington DC, and a Bachelor's degree from POSTECH in Pohang, Korea. His educational journey began at Seoul Science High School in Seoul, Korea.

**Abstract:** Patient-derived cancer organoid (PDO) is the most advanced 3D culture system for recapitulating genetic heterogeneity of tumor tissue and microenvironment. We have successfully established over 700 PDOs from patients with lung, gastric, colorectal, prostate, and ovarian cancers and sequenced at the whole-exome and transcriptome level. Among these PDOs, approximately 200 PDOs are paired with autologous immune cells which allows for the establishment of co-culture systems between autologous cancer and immune cells for immuno-oncology perspective. Our PDOs retain cancer-specific mutations, transcriptomic profile, and drug-responsiveness of original tumor tissues and their characteristics can be maintained after 20 passages of culture. In line with the next-generation sequencing and drug-responsiveness data, we have also developed proprietary artificial intelligence algorithms uncovering novel oncology targets and identified a number of targets that have the potential to overcome drug resistance against EGFR inhibitors in non-small cell lung cancer. Those targets have been validated in PDOs using a gene-editing system, leading to initiation of first-in-class drug discovery programs. We hereby present the unique potential of PDOs as a platform for target discovery and drug screening.

#### Title: The Next Leap in Anesthetic Products and Beyond



#### Taehyung Kim

Team Leader of Sales and Business Development, Huons USA

**Biographical Information:** Taehyung Kim, with 15 years of dedicated service to Huons Group, he has a wealth of experience spanning international business development, regulatory affairs, production, and quality control. His journey began right after graduating from Hanyang University, and he has since become a seasoned professional in global healthcare. Taehyung's multicultural background, shaped by his early years in Middle East, has uniquely positioned him to take on diverse markets. His experience in production and quality control has given him a comprehensive grasp of the pharmaceutical industry. Now, as Team Leader of Sales and Business Development at Huons USA, Taehyung is focused on pioneering Huons Group's next leap forward in the US market.

Abstract: Since its founding in 1965, Huons has consistently achieved double-digit growth, establishing itself as a promising company in the pharmaceutical industry. Among South Korean pharmaceutical companies, Huons is particularly active in the US market, especially in the field of generic anethetic injectable drugs supplied to hospitals. Recently, Huons Group has developed a bio-product, Human Recombinant Hyaluronidase (HyDIFFUZE™), innovative drug delivery technology that converts intravenous (IV) drugs to subcutaneous (SC) administration. Huons USA's vision is to establish itself as one of the largest suppliers in the US anesthetic injectable market.

#### Title: Yuhan's Innovative Drug Development



**Taewon Yoon, PhD** CEO, Yuhan USA Corporation

**Biographical Information:** Dr. Taewon Yoon was trained as a molecular oncologist at The University of Ilinois in Chicago and did his postdoctoral training at the University of Chicago. He then continued his research at Dr. Andy Minn's lab at the University of Pennsylvania as a senior research investigator, Department of Radiation Oncology with particular interest in therapy resistance before joining Yuhan USA as a Sr BD manager. He's been leading the Yuhan USA as a CEO since 2021.

**Overview:** Yuhan Corporation is a South Korea-based pharmaceutical company founded in 1926 by Dr. II-han New, an independence activist, educator, and innovative entrepreneur. Yuhan has 30+

internal research and development programs, 35+ strategic partnerships, and completed five global out-licensing deals during the past five years, resulting in a total deal size of \$3.54 billion. Our most recent achievement is Lazertinib, a 3rd generation therapeutic candidate for NSCLC, which we successfully licensed out to Janssen in 2018 and was recently approved by FDA.

#### Title: CorestemChemon: Pioneering Comprehensive Nonclinical Solutions for Global Success



#### Yoonseon Kim,

Project Manager, Corestemchemon US.

**Biographical Information:** Yoonseon Kim is a Project Manager at Corestemchemon US. She previously worked as a General Toxicology Study Director for three years at Corestemchemon nonclinical CRO research center in Korea. Now based in McLean, Virginia, she manages nonclinical projects and supports clients with study designs and regulatory submissions.

**Overview:** CorestemChemon is a nonclinical CRO with over 25 years of experience, specializing in a comprehensive range of nonclinical studies to support IND/NDA submissions. CorestemChemon offers expertise in toxicology, pharmacology, and efficacy testing across small molecules, biologics, and cell therapies. With a commitment to high-quality, efficient services, CorestemChemon has expanded globally,

with a U.S. office in Virginia to better serve international clients.

#### Day 2. Speakers

#### Title: Overview of Drug Development Process: Principles, Practice and Case Studies



#### Shahin Gharakhanian, MD, DPH,

Shahin Gharakhanian MD Consulting LLC, Cambridge MA (Boston), USA. & Boston Biotechnology Summit<sup>™</sup> Co-Founder.

#### **Biographical Information:**

- Chief Medical Officer (CMO) or taking leadership roles and responsibilities in Clinical Development & Medical Affairs.
- Executive Medical Expertise and Collaboration with CEOs of biotechnology companies to assure overall Corporate Development.
- Expertise/member in Scientific Advisory Boards (SAB) or Boards of Directors (BOD) for biotechnology companies.
- Office bases in Cambridge MA, USA & Paris Region, France. Profile: linkedin.com/in/shahin-gharakhanian-md-35758112 Websites: http://sgmdconsultingllc.com (Company) Email: shahin.gharakhanian@gmail.com



#### Silvia Helou, MD, MMSc

Executive Consultant, Helou Consulting LLC, New York Metropolitan Area, USA.

**Biographical Information:** Silvia has extensive drug development experience in major therapeutic areas including anti-infectives, dermatology, oncology/hematology, and immunology/biologics. She previously held various senior positions at Novartis, Schering-Plough and Scynexis in clinical development. She was also responsible for several development programs in anti-infectives, non-malignant hematologic disease, oncology and dermatology. She obtained her medical degree at the University of Buenos Aires, Argentina, and her post-graduate degree in infectious disease with board certification (infectious disease & amp; Mycology). She served as staff faculty in infectious disease at the Muniz Infectious disease hospital and faculty in microbiology at the University of Buenos Aires, School of Medicine in Buenos Aires, Argentina. Author & Co-Author of multiple scientific publications and presentations at international scientific meetings.

silvia@heloullc.com

**ABSTRACT:** Drug discovery is defined as the process by which potential new therapeutic entities are first identified using a combination of computational, experimental, translational and clinical models. Despite scientific and technological advances, it nevertheless remains a long, costly, difficult and labor intensive process with a high failure rate. Drug design is the separate creative process of inventing and identifying new medications based on knowledge of a biological target. This involves the creation of molecules that are appropriate in shape/charge to the molecular target with which they will interact and bind. The complementary stages of Drug Development include (in alphabetical order), bioanalytical measurement, discovery, formulation development, delivery, drug disposition and pharmacokinetics, preclinical (animal) toxicology and product characterization. In the United States, an Investigational New Drug (IND) application is submitted to the FDA (US Food and Drug Administration) as the first step towards clinical assessment, as it requests authorization from the FDA to administer an investigational drug or biological product to humans. The new therapeutic agent then enters a First-In-Human (FIH) study.

This overview covers the principles/practices concerning five areas:

- 1 Pre-discovery stage, or understanding the pathophysiology and proposing targets;
- 2 Drug discovery stage,
- 3 Preclinical development stage, which focuses on clarifying the mechanism of action (MOA), investigating potential toxicity, validating efficacy in various in vitro and in vivo models, and starting evaluation of the formulation;
- 4 Clinical stage, which investigates the drug candidate in humans;
- 5 Review, approval and post-market monitoring stage.

#### BIBLIOGRAPHY

- Singh N, Vayer P, Tanwar S, Poyet J-L, Tsaioun K and Villoutreix BO (2023), Drug discovery and development: introduction to the general public and patient groups. Frontiers in Drug Discovery. 3:1201419. doi: 10.3389/fddsv.2023.120141
- Zhou S-F and Zhong W-Z Drug Design and Discovery: Principles and Applications. Molecules 2017, 22, 279; doi: 10. 3390/molecules22020279
- Jeffrey S Barrett. Fundamentals of Drug Development. Hoboken, NJ, USA, Wiley, 2022.
- Frank S David. The Pharmagellan Guide to Analyzing Biotech Clinical Trials. Pharmagellan LLC, New Haven CT, 2022.
- David Mantus, Douglas J. Pisano. FDA Regulatory Affairs. Third Edition. CRC Press/Taylor & Francis Group, Boca Raton, FL, 2014.
- Shein-Chung Chow, Jen-Pei Liu. Design and Analysis of Clinical Trials. Concepts & Methodologies. Third Edition. Hoboken, NJ, USA, Wiley, 2014.

#### Title: Introduction to FDA's Investigational New Drug Application (IND)



#### Marci Aderiye, MS, RAC

Senior Director of Regulatory Affairs at PPD

**Biographical Information:** Marci Aderiye is the Senior Director of Regulatory Affairs at PPD, a Thermo Fisher Company and leads the US Regulatory Affairs Solutions team in the US. She has over 30 years of experience and has been with PPD since 2018. Marci provides operational leadership, strategic regulatory intelligence, and guidance for product development from preclinical stages through to registration and product optimization.

Her expertise spans a broad range of therapeutic areas, including infectious diseases such as HIV and Tuberculosis, respiratory conditions like RSV, and various vaccines, including those for BCG, Hepatitis B, Covid-19, and HIV. Marci has a strong track record in managing cross-functional teams, preparing and submitting high-quality regulatory documents, and responding to regulatory agency inquiries. Marci has file numerous submissions, conducted GLP and GCP audits, hosted FDA inspections and has

attended multiple FDA meetings. She also acts as the US Agent for more than 30 clients. Marci is dedicated to ensuring compliance and excellence in clinical and observational trials for pharmaceutical, biotechnology, and vaccine sponsors.

**Overview:** The presentation provides a comprehensive overview of the FDA's Investigational New Drug (IND) application process, detailing the regulatory framework, types of IND applications, key components, submission and review processes, and ongoing maintenance requirements. It also highlights the roles and responsibilities of the U.S. Regulatory Agent and the importance of FDA meetings.

#### Title: Artificial Intelligence (AI) in drug development: present status and prospects



Jinguen Rheey, PhD

CEO, Gradiant Bioconvergence

**Biographical Information:** Jinguen currently serves as the CEO of Gradiant Bioconvergence and Head of Investment at Gradiant, roles he has held since June 2020. His academic credentials include a PhD from École Normale Supérieure in Paris, a Master's degree from The George Washington University in Washington DC, and a Bachelor's degree from POSTECH in Pohang, Korea.

Abstract: Artificial intelligence (AI) technologies have become a fundamental part of lives impacting how

we live, work, and interact with the world around us. Among such advancements, AI has the potential to revolutionize the drug discovery and development process. The AI market in drug discovery is growing annually by 21.5% with an increasing interest from global big pharma and investors. This presentation details the current status and prospects of AI in drug discovery.

#### Title: Considerations and steps to operationalize a clinical trial



May Litt. MBA, CCRA, RAC. CEO, Litt Consulting Group, LLC.

**Biographical Information:** May Litt, MBA, CCRA, RAC is a clinical operations professional with over 18 years of experience in clinical operations roles. Previous roles include site level management, sponsor and CRO leadership roles. May Litt founded Litt Consulting Group in 2022. Litt Consulting offers clinical operations strategy, consulting and clinops staffing services to biotechs, pharma and device companies looking to operationalize studies in N. America.

**Overview:** May Litt will be presenting on strategies for operationalizing a clinical trial in the US including lessons learned from operationalizing a phase 1 oncology trial for an APAC biotech.

#### Title: Strategic US IP Protection Subtopic 1: IP Protection for Companies Conducting Business in the US Subtopic 2: Utilizing Freedom-to-Operate Analysis to Avoid Patent Infringement



#### Yong Ha Kim

Director, KOIPA U.S. Capital IP Center

**Biographical Information:** Yong Ha Kim serves as the Director of KOIPA U.S. Capital IP Center. She is an experienced IP attorney in domestic and international trademark prosecution, technology transactions, and patent prosecution. While at law firms, Yong Ha advised clients on, patent and trademark dispute and prosecution issues. As the Director of KOIPA U.S. Capital IP Center, Yong Ha helps companies establish creative patent strategies by leveraging her engineering background. Yong Ha is fluent in English, Korean, and German and is a licensed attorney in Korea and the United States (New York, Maryland, and Washington, D.C.).



#### James Kwangho Jang

Attorney, Bookoff McAndrews, PLLC.

**Biographical Information:** James Jang helps technology companies secure patent protection and evaluate patent-related risks and opportunities. He is experienced in all aspects of intellectual property law, including patent prosecution, opinion work, client counseling, and litigation. James has extensive experience in patent prosecution, handling both domestic and international patent prosecution matters. He has worked with clients ranging from large global corporations to small start-up companies. James is skilled in a wide array of technologies, including electronics, medical devices,

display devices, computer and software technology, power systems, hydraulic systems, construction machinery, pump controls, fiber-optics, payment systems, antennas, health and cosmetic appliances, advanced materials, and variety of miscellaneous mechanical, electrical, and electromechanical devices.

James's experience extends to district court and ITC litigation, offering valuable insights for developing high-value patent portfolios and assessing third-party patents. He also handled U.S. inter partes review proceedings and assisted foreign counsel with European oppositions.

James joined BoMc after practicing as a patent practitioner for ten years at a large international general practice firm. Before practicing law, James worked as a research engineer at one of the largest display manufacturers in the world. His engineering experience ranged from developing panel design and manufacturing technology for display devices to developing electrical circuit design for semiconductor chips.

#### **Bar Admissions**

Illinois; U.S. Patent and Trademark Office

Education: The George Washington University Law School, J.D., with honors, 2014 Seoul National University, M.S., Materials Science & Engineering, 2007 Seoul National University, B.S., Materials Science & Engineering, cum laude, 2005

Professional Recognition: Recognized in The Best Lawyers: Ones to Watch® in America for Intellectual Property in Chicago, 2024



#### Sangwoo Ahn

Partner, Bookoff McAndrews, PLLC.

**Biographical Information:** Sangwoo focuses his practice on patent counseling and opinions, patent prosecution, and portfolio management. Sangwoo is a former primary patent examiner at the U.S. Patent and Trademark Office (USPTO) and has over 15 years of experience focused on computer, electrical, and mechanical technologies. He leverages a wealth of knowledge in patent prosecution and complex IP issues to help clients obtain robust patent protection for their innovations. During his tenure at the USPTO, Sangwoo determined patentability of applications covering various software technologies, including database management, search engines and guery optimization, artificial

intelligence, cryptography, Internet-based technologies, and cloud and distributed computing. He also

trained and mentored assistant examiners on various examining procedures and patent quality. Furthermore, Sangwoo clerked for an administrative patent judge at the Patent Trial and Appeal Board (PTAB), reviewing complex issues raised on appeals and drafting opinions.

Leveraging his deep understanding of the USPTO's inner workings, Sangwoo is adept at navigating and finding solutions to various hurdles that arise during patent prosecution. He collaborates with companies in building high-value patent portfolios spanning a wide array of technologies, including software, semiconductors, and mechanical devices. He also specializes in analyzing IP assets in both defensive and offensive postures, including validity determination, infringement analysis, freedom to operate analysis, and competitive landscape studies.

#### **Bar Admissions**

District of Columbia; Maryland; U.S. Patent and Trademark Office

**Education:** The Catholic University of America, Columbus School of Law, J.D., cum laude, 2012 University of Maryland, College Park, B.S., Electrical Engineering, 2005

Professional Recognition: Recognized by IAM Patent 1000 as a "Leading Patent Professional" for Patent Prosecution, 2024. Recognized by The Legal 500 for patent prosecution (including re-examination and post-grant proceedings) (nationwide), 2023-2024.

#### **Title: Due Diligence Considerations in Transactions**



#### Yoon Hyun (Allison) Cho

Senior Associate, Morrison & Foerster

**Biographical Information:** Yoon Hyun (Allison) Cho is a senior associate in Morrison & Foerster's Finance group in New York. Allison advises a diverse set of clients, including venture and growth stage companies, across the healthcare, finance, technology and entertainment sectors. Allison also leads various transactions while conducting due diligence on behalf of her clients. Allison advises financial institutions and companies in all aspects of domestic and cross-border financing transactions, including venture debt financing, acquisition and leveraged financing and asset-based financing. Prior to joining Morrison & Foerster, Allison was an associate at another major law firm in New York. She is fluent in Korean and maintains basic communication skills in Mandarin.



Sophia Han Partner, Kirkland&Ellis

**Biographical Information:** Sophia Han is a tax partner in the New York office of Kirkland & Ellis LLP. Sophia's practice focuses on the tax aspects of various transactions, including domestic M&A and the renewable energy sector. She regularly provides transactional advice, conducts due diligence, and in addition, advises project sponsors, private equity funds, tax equity investors and lenders on various tax planning questions related to energy tax credits, project developments and financings, and M&A transactions for wind, solar and energy storage assets. Sophia represents clients on a variety of other federal income tax matters. Her experience also includes advising clients across a variety of industries, including medical device, and retail and tech.

**Abstract:** We will discuss important corporate and tax due diligence considerations that companies must consider when entering into transactions such as M&A, licensing, and others. Red flags – or even orange flags – can sometimes put transactions at risk. The panelists will discuss what transaction partners look for and assess when conducting due diligence.

#### Title: FDA medical device clearance and approval process



Philip Won, PhD, JD.

Associate, Alston & Bird, LLP.

**Biographical Information:** Assistant Professor, University of Tennessee (2012-2014) Engineering Reviewer, Food and Drug Administration (2014-2021) Associate, Hyman, Phelps & McNamara, P.C (2021-2024) Associate, Alston & Bird, LLP (2024-present)

**Overview:** This presentation will provide an overview of the medical device development pathway, FDA device classification overview, and premarket submissions for Class II and III devices. Case studies will be presented to provide the practical examples of premarket submissions.

#### Title: The PIE Act: What device companies can say prior to product approval



#### Sung Park

Counsel, Reed Smith LLP

**Biographical Information:** Sung Park is a Counsel in Reed Smith's Life Sciences Health Industry Group. Sung guides companies in developing, distributing, and marketing FDA-regulated products and, when necessary, in responding to regulatory and administrative enforcement actions by federal and state agencies. Sung also provides transaction counsel in navigating thorny issues, such as navigating through licensure issues, analyzing promotional statements, and assessing enforcement risks. Sung understands the unique business landscape of FDA-regulated products, and provides practical advice that suits the needs of the client's business. In particular, Sung has counseled companies on designing regulatory routes for pharmaceutical, digital health, and medical device products. As a bilingual attorney who has worked with many international companies, Sung understands the concerns international manufacturers

and distributors have when attempting to market their products in the United States.



#### Taber Rueter

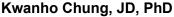
Senior Associate, Reed Smith LLP

**Biographical Information:** Taber Rueter is an associate in Reed Smith's Life Sciences Health Industry Group, practicing primarily in the areas of regulatory compliance and due diligence. His practice includes counselling companies on FDA regulatory compliance, including researching FDA requirements and standards for medical devices and food products and providing practical business advice to companies that manufacture, distribute, and/or sell such products. He also has experience drafting contracts involving food manufacturing and related services, including terms for FDA compliance. In addition, he has helped FDA-regulated companies defend against unfair and deceptive advertising and assisted with advertising and labeling compliance efforts, including for food-related products. He is also actively helping a number of clients

defend against government investigations, including FTC investigations related to data sharing and transmission and DOJ investigations related to health care fraud and abuse.

**Abstract:** FDA laws limit the type and content of communications that can be made about a drug or medical device product's safety or effectiveness prior to FDA's authorization of the product. With that said, a few exceptions to this rule exist, including when communications about a product need to be relayed to payors in order to facilitate expedite patient access upon authorization of the product. Leveraging this exception is critical to ensuring the product's timely availability to patients. Panelists will discuss what this exception allows, and what the associated requirements are.

#### Title: What's left for broad, functional claims?



Partner, Sheppard Mullin (Washington DC; IP & Life Sciences group)

**Biographical Information:** Alex provides strategic IP counsel for procuring, managing, evaluating, enforcing, and defending patents in the areas of biotechnology, pharmaceuticals, chemicals, and medical devices for start-up companies to multinational corporations. He advises on strategic global patent portfolio development, patentability and freedom-to-operate (FTO) opinions, due diligence analyses, and transactional/licensing matters. Further, he has represented clients in patent disputes at the federal district courts (including Hatch Waxman litigation), U.S. International Trade Commission, the Patent Trial and Appeal Board, as well as in trade secret litigations.

**Abstract:** This session will provide brief overview of the seminal US Supreme Court case, Amgen v Sanofi (May 2023), summarizing its key legal issues and implications in life sciences and beyond for broad, functional claims, with practical recommendations for patent practitioners in both patent prosecution and litigation.

#### Title: Trend in early-stage innovation ecosystem in the US



#### lan S. Ryu, PhD

Mentor-in-Residence at Korea Innovation Center, Washington DC

**Biographical Information:** Ian is currently a Mentor-in-Residence at Korea Innovation Center, Washington DC. Ian enjoys partnering with entrepreneurs, working on fascinating ideas and technology to build a new future. In recent years, Ian had been Head of Products and Head of Technology Partnerships at FedTech, overseeing all FedTech's programs ranging from Startup Studio, Accelerator, Technology Scouting, and to Advisory Services. Ian also worked with USU, America's medical school, to establish their technology transfer office to harness innovation with commercial impact. Before joining FedTech, he was at the National Institute of Standards and Technology and Lawrence Berkeley National Laboratory. As a scientist executing pioneering research, Ian worked on developing unique technology solutions across the

biomaterials, photonics and quantum science domains. He earned a PhD in chemistry from the University of California, Berkeley, and a BS in chemistry from Korea University.

**Abstract**: "Placed-based innovation" is a key theme in the recent CHIPS and Science Act. The recent initiatives by the US government and the growing trend and opportunities in early-stage innovation will be discussed. Related non-dilutive funding sources will be addressed together.

#### Title: Investing at the Intersection of Medicine, Regulation, and Innovation



#### Ted (Tae Heum) Jeong, PhD

Founder and Managing Partner, Adelphi Ventures

**Biographical Information:** Dr. Tae Heum Jeong is a founder and Managing Partner at Adelphi Ventures, a healthcare venture capital firm and was a Managing Partner at Kensington-SV Global Innovations, a growth-stage investment firm which he co-founded in 2018. He has more than 25 years of experience as a venture capitalist and a financial executive with substantial capabilities across a range of corporate functional domains, including entrepreneurial strategy, leadership, venture capital, investment banking, and corporate development. As a venture capitalist, Dr. Jeong has been involved in the investments of over 60 companies with successful returns at KSV and Hyundai Ventures. As a science-oriented entrepreneur, he developed and executed business plans with a thorough understanding of biotechnology and pharmaceutical industry, having grown Rexahn Pharmaceuticals

from inception to NASDAQ listed public company. As a seasoned financial executive at Rexahn and Clene, he raised \$200M+ million through private and public offerings to develop multiple therapeutics to cure cancer and CNS disease. Dr. Jeong maintains global and senior-level relationship networks in the healthcare industries and corporate finance communities. He also served on the board of directors of Neurobo Pharmaceuticals, where he was chair of the audit committee and the board of directors of Shuttle Pharmaceuticals, Inc. Dr. Jeong received his bachelor's and master's degrees of science in chemistry from Pohang University of Science & Technology. He also holds a master of science in finance degree from Johns Hopkins University, and a doctorate of management from the University of Maryland.



#### Luciana Borio, M.D.

Venture Partner, ARCH Venture Partners

**Biographical Information:** Luciana Borio, M.D., is a Venture Partner at ARCH Venture Partners. In this capacity, she advises on and helps develop new investment opportunities related to biologics manufacturing, clinical trials, novel therapies and areas with large unmet clinical needs. Dr. Borio is a specialist in biodefense, emerging infectious diseases, medical product development, and complex public health emergencies. Prior to joining ARCH, she was a senior vice president at In-Q-Tel, an independent, non-profit, strategic investment firm that works to deliver innovative technology solutions to support the missions of the U.S. Intelligence Community. Past positions include serving as a member of President Biden's transition COVID-19 Advisory Board and Director

for Medical and Biodefense Preparedness at the National Security Council (2017-2019), where she coordinated the response to the Ebola epidemic in West Africa, efforts to combat antimicrobial resistance, and the development of an Executive Order to modernize America's influenza vaccines. Prior to that, she was the Acting Chief Scientist of the U.S. Food and Drug Administration (2015-2017) and the Assistant Commissioner for Counterterrorism Policy of the FDA (2010-2017).

Dr. Borio is an adjunct Assistant Professor of Medicine at Johns Hopkins University (2003-present), where she continues to practice medicine part-time. She is also a senior fellow for global health at the Council on Foreign Relations.

Dr. Borio obtained her M.D. from George Washington University, completed a residency in internal medicine at New York-Presbyterian/Weill Cornell Medical Center, and a combined fellowship in infectious diseases at Johns Hopkins and critical care at the National Institutes of Health.

**Abstract:** Join us for an insightful fireside chat with a leading venture capitalists from Adelphi Ventures and ARCH Venture Partners, who brings a unique background as both an MD and former FDA executive. In this session, we'll explore the future of healthcare innovation and investment through the lens of their expertise in clinical medicine, regulatory strategy, and venture capital. The discussion will cover emerging trends in biotech, pharmaceutical, AI, as well as strategies for navigating regulatory hurdles and FDA approvals. We'll dive into ARCH's approach to evaluating startups with high regulatory risk, how AI and data integration are transforming healthcare, and the role of accelerated approvals in life sciences. Drawing from their experience in both healthcare and investment, our speakers will also share insights on bridging the gap between clinicians and entrepreneurs, mentoring healthcare founders, and balancing risk in early-stage investments.

#### Topic: Strategic Med-Tech Partnerships: Key success factors in developing integrated healthcare solution



#### Kenneth Huh, PhD

Product and Platform Integration Lead, BioTelemetry, Philips

**Biographical Information:** Kenneth has eight years of experience with Philips, where he spent the majority of his tenure in Strategy, M&A, and M&A Integration as a director. He drove milestone acquisitions such as Biotelemetry (\$2.8B) and Capsule (\$600M). Recently, Kenneth has taken on a Solutions & Services District Leader role for Philips Hospital Patient Monitoring, where he engages directly with customers on a day-to-day basis. Prior to Philips, Kenneth was a Strategy Consultant for IQVIA in the APAC region. He holds a PhD in Behavioral Economics from the University of Warwick.

**Topic Summary:** Healthcare providers are increasingly challenged by fragmented point solutions and are seeking integrated value propositions to simplify their purchasing processes, workflows, and backend integration. This situation heightens the significance of

"Strategics"—large med-device and health-tech companies with substantial market presence—as potential partners or acquirers. The presentation highlights the strategic thought processes of these large companies in developing a value proposition and outlines key factors early-stage start-ups must address to accelerate their commercial success.

#### Topic: High-Fidelity CNOT Gate on Fluxonium Qubits: Verifying Analogies with Transversely Coupled Spin-1/2 Systems for 24-Day Stability



#### Hyungheung Cho

Graduate Student, Department of Physics, University of Maryland

**Biographical Information:** Hyunheung Cho is a graduate student specializing in quantum computing, focusing on superconducting qubits, particularly fluxonium qubits. His research emphasizes the fabrication and exploration of fluxonium qubits' computational capabilities. By combining experimental and theoretical approaches, Hyunheung works to enhance the performance, stability, and fidelity of these qubits, contributing to the advancement of scalable quantum computing systems. His efforts aim to push the boundaries of fluxonium qubits, establishing them as a competitive candidate for future quantum computing architectures.

**Abstract:** We report a detailed characterization of two inductively coupled superconducting fluxonium qubits for implementing high-fidelity cross-resonance gates. Our circuit demonstrates behavior closely analogous to two transversely coupled spin-1/2 systems, notably minimizing the generally unwanted static ZZ-interaction despite strong qubit-qubit hybridization. Spectroscopy reveals a spurious LC-mode, arising from the coupling inductance and capacitive links, which has a minor impact on this specific device but requires consideration for future designs.

Leveraging the long coherence time and strong anharmonicity of fluxonium qubits, we achieve a 60 ns direct CNOT-gate using a selective darkening approach, with gate fidelity reaching 99.94%. Remarkably, the fidelity remains above 99.9% for 24 days without recalibration, underscoring the robustness of this approach. This result contributes a reliable, high-fidelity two-qubit gate to the growing suite of superconducting qubit demonstrations with fidelities beyond 99.9%.

#### **Topic: Large Scale Stochastic Modelling of Heterogeneous Cell Populations**



#### Hyeon Jin Cho

Graduate Student, Biological Sciences (Computational Biology, Bioinformatics and Genomics), University of Maryland

**Biographical Information:** Hyeon Jin Cho is a Ph.D. student in the Computational Biology, Bioinformatics and Genetics program at the University of Maryland. I graduated from the University of Illinois at Urbana-Champaign with a B.A in Molecular and Cellular Biology in 2014, then obtained master's degree in Bioinformatics at Johns Hopkins University in 2016. After getting my M.S in Bioinformatics, I worked as a Research Associate of Sequencing Core, primarily working on single-cell analysis at the Lieber Institute for

Brain Development in Baltimore, MD. I am currently in the NCI-UMD partnership program, continuing my Ph.D. with Dr. Daniel Larson at the National Cancer Institute. My research interest is simulating scRNA-seq to observe stochastic dynamics and infer kinetic rates between gene states.

**Abstract:** Cells are genetically identical, but differences in gene expression determine cell types. Transcription, the first step of gene expression, involves transcription factors binding to the DNA promoter, followed by recruitment of proteins like chromatin remodelers, general transcription factors (GTFs), and RNA polymerase II in eukaryotes. Variability in these steps leads to diverse transcriptional outcomes; therefore, it is crucial to thoroughly understand transcription and its dynamics, which will help us understand heterogeneity and stochasticity that lie in the gene regulatory network and eventually affect the overall gene expression of cell populations.

This project will explore transcription dynamics using steady-state and kinetic data. We'll quantify mRNA with single-cell RNA sequencing (scRNA-seq) and single-molecule Fluorescence in situ Hybridization (smFISH), and measure transcription factor dwell time and bursting kinetics with live-cell imaging. By integrating these techniques, we aim to build a detailed computational model to study transcription's temporal dynamics. We will compare existing models, such as the telegraph and kinetic proofreading models, to better understand transcription regulation and its role in diseases caused by transcriptional misregulation, as well as improve gene expression prediction.



#### Yu Jin Lim

Graduate Student, Department of Exercise and Nutrition Science, The George Washington University

**Biographical Information:** Yu Jin was born in Busan, South Korea, and grew up primarily in Seoul, South Korea. She received her BS and MS in Nutrition from Sookmyung Women's University, with her thesis focusing on a mobile application to control sodium intake in hypertensive patients. Currently, Yu Jin is doing her PhD in Exercise physiology and Applied Nutrition at The George Washington University, Milken Institute School of Public Health, and is a fellow at the Co-Design of Trustworthy AI Systems (DTAIS) program at The George Washington University, School of Engineering. Her current research focuses on developing AI tools for nutrition management for public health purposes.

### Topic 1: Effect of dietary Intervention on hypertensive patients: a cross-sectional analysis of the PREMIER Trial

**Abstract:** Previous research has shown that dietary interventions are effective in controlling risk factors for cardiovascular disease and diabetes. Total cholesterol levels are major indicators of cardiovascular and metabolic risk. Improving these measures is key to reducing the likelihood of these critical conditions. Determination of an effective intervention method to successfully assist in controlling the dietary pattern of hypertensive patients that achieves a significant reduction in total cholesterol levels can help tailor future dietary and lifestyle interventions to specific populations or health goals. This analysis includes the participants of the PREMIER trial. The aim is to observe the effect of the intervention on changes in total cholesterol levels. Understanding the effectiveness of dietary intervention can influence public health guidelines on diet and lifestyle to improve population-wide health outcomes.

#### Topic 2: Mobile application intervention to reduce sodium intake on stroke survivors

Abstract: Excessive sodium intake has been known to be a risk factor for cardiovascular diseases, including stroke. Studies have been conducted to find intervention methods that can effectively reduce sodium intake among hypertensive patients, who are at high risk of stroke. An intervention study using a mobile application was conducted at The Catholic University of Korea, Eunpyeong St. Mary's Hospital. Participants of the study were hypertensive patients, with both stroke survivors and those who had never experienced stroke included. This analysis compares the effect of the intervention on stroke survivors and non-stroke survivors. By understanding the difference between stroke survivors and non-stroke survivors, it is expected to develop an intervention method that is better fit for stroke survivors.

#### Topic: How Climate Shapes Wildfire Impacts on Soil Organic Carbon: Insights from Maui, Hawaii



#### Yewon Lee

Graduate Student, Dept. of Geology, University of Maryland

**Biographical Information:** Yewon developed a strong interest in environmental science during her academic journey. She received both her Bachelor of Science and Master of Science degrees in Soil, Water, and Ecosystem Sciences from the University of Florida. Her master's research focused on understanding the environmental impacts of phosphorus movement in soils, particularly in the context of biochar and biosolids applications. Currently, as a PhD student at the University of Maryland, Yewon is investigating the effects of natural disasters on soil organic carbon dynamics. Her work is aimed at addressing significant environmental challenges by exploring the critical interactions between ecosystems and climate events.

**Abstract:** Wildfires are increasing in frequency and intensity globally, significantly impacting biogeochemical cycles, plant communities, ecosystem functions, and water quality. Soil organic carbon (SOC) plays a key role in maintaining soil health, productivity, and functionality. With climate change contributing to more frequent and severe wildfires, SOC chemistry and concentration are altered. Despite extensive studies on post-fire SOC changes, a knowledge gap remains regarding the chemical alterations in wildfire-impacted SOC, as these changes are influenced by multiple factors such as fire duration, biomass, moisture levels, and fire type and intensity. This study examines how climate influences fire's effects on SOC by looking at three recent wildfires on Maui Island, Hawaii, across a rainfall gradient. The quantity and quality of fire-affected SOC were characterized from soil water repellency and pH measurements as well as sequential chemical extractions that extracts various pools of SOC. Results from this study will help improve predictions and management of how increasing wildfires impact soil and ecosystem health.

#### Topic: The Influence of Heat on Animal Fiber Transformation in a Microscopy Approach



#### Hwan Hee Lee

Graduate Student, Dept. of Forensic Science, The George Washington University

**Biographical Information:** Hwan Hee is a second-year Master's student in Forensic Chemistry at The George Washington University. With a Bachelor's degree in Chemistry and Psychology from Kwangwoon University, Hwan Hee is specializing in trace evidence within the broader field of forensic chemistry. Her current research focuses on analyzing various forms of trace materials to aid in forensic investigations. In the future, Hwan Hee aspires to apply her expertise to solve cold cases, contributing to advancements in justice and forensic science.

Abstract: Animal fibers are commonly used in textiles and are frequently present in households due to pet

ownership. As a result, animal fibers often appear in everyday environments and can be potential evidence at crime scenes. This study aims to replicate the findings of Henson and Rowe and explore the effects of heat on various animal fibers using various microscopes including bright-field microscopy, dark-field microscopy, polarized light microscopy, and phase contrast microscopy. A Zeiss microscope photomicrograph 2 was utilized to perform4 different microscopes. Human hair samples were obtained from a Caucasian male with white hair, while canine fibers were sourced from a male Maltese with white fur. Other animal samples including horse fibers, camel fibers, deer fibers, rabbit fibers, and boar fibers were purchased from Amazon. All the samples were subjected to temperatures between 100°C and 300°C using a hair straightener and oven. In replicating Henson and Rowe's research, human hair exhibited bubbling structures and an increase in diameter when exposed to heat. These changes were also observed in all the animal fibers.

#### Topic: Navigating the US Market: A Strategic Blueprint for Korean Startups



#### Jim Chung

Former Assoc. VP for Research, Innovation & Entrepreneurship at the George Washington University

**Biographical Information:** Jim Chung is the former Assoc. VP for Research, Innovation & Entrepreneurship at the George Washington University, where he founded its Office of Innovation and Entrepreneurship in 2010, facilitating the launch of 350+ startups that have raised over \$1.8 billion. He has supported global innovation initiatives in 22 countries, served as a co-principal investigator for the NSF I-Corps, and holds advisory roles on multiple boards. An experienced investor and mentor, Jim has worked with a wide variety of tech companies, government agencies, and non-profits to support innovation ecosystems worldwide. He has an academic background from Stanford, MIT, Harvard, and the University of Tokyo, and has been a researcher in Korea at ETRI, KAIST, and STEPI.

**Overview:** Korean startups entering the US must have a viable business model informed by an understanding of local customers and markets. This is best accomplished by a rigorous customer discovery process that tests hypotheses firsthand about why the company will be successful here.

Talking to US customers, investors, and partners with a strategic blueprint before launch will save precious time and money. Learn how to find customers, get interviews, ask questions, and learn the right lessons for a successful go-to-market plan.

#### Topic: Access to Capital and Building Strong Banking Relationships for Startups



#### Ruth Kim

Relationship Manager, Vice President at M&T Bank

**Biographical Information:** As a dedicated business banker at M&T bank, I am helping small businesses and startups in our community access the financial solutions they need to thrive. With a strong foundation in accounting from my experience working at CPA firms, I bring a unique perspective to the table-understanding not only the banking process but also the financial intricacies businesses face. This allows me to guide my clients through the critical steps of securing capital, building banking relationships, and preparing the necessary documentation for financial success. My goal is to empower entrepreneurs by providing tailored banking services that support growth and long-term sustainability.



#### Fred Seo

Relationship Manager, M&T Bank

**Overview:** This session will provide an essential guide for startups looking to establish and grow their business in the U.S. Attendees will learn how to effectively manage their credit, utilize financial services, and explore loan options, including the requirements for loan requests, along with banking products tailored for early-stage companies. We'll also discuss key factors to consider when choosing the right banking partner, as well as the essential banking services every startup needs, from business accounts to merchant services and cash management solutions. This session is designed to help startups build a solid financial foundation and leverage banking services to fuel their growth.

#### **Soft-landing Program- Maryland**

#### Jessica Reynolds

Senior Director, Office of International Investment and Trade, Maryland Department of Commerce

#### Soft-landing Program- Fairfax County, Virginia

#### John Hoeveler

Manager, National Business Investment- apital Attraction, Life Sciences and Quantum Technology, Fairfax County Economic Development Authority (FCEDA)

**Biographical Information:** John Hoeveler graduated from Marquette University with a master's degree in economics. From 2008 to 2013, he worked at the USDA, focusing on international programming. Following that, he managed a Small Business Administration commercial Ioan fund. In 2023, he joined the FCEDA, where he continues to contribute to economic development initiatives with a focus on health and capital attraction.









# KAPAL Committee



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#### **Executive Committee Members**



**Jihoon Park** President



Han-sol Park Vice President



**Eunjung Choi** Admin Dir.



Byung Ha Lee Exec. Dir.



Sang Tae Park

Exec. Dir.



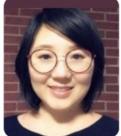
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Young O Hahm BD Dir.



Kwan-Ho Chung General Dir.



**Eunkyung An** Exec. Dir.



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**Heemin Rhee** 

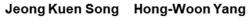


Hae-Young Ahn



Luke YS Oh





#### **KAPAL-** California

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James Y. Lee Program Dir.



Jake Hostetler Community Engage Dir.



Yong Seok Choi General Dir. Heejo Gene



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# **NOMEHOMETSEROO FHE BEST SERVICE is**

- + Approved data to overseas as well as domestic IND & NDA.
- + Support your research base on the OECD guideline for the Testing of Chemicals.
- + Our regulatory experts ensure that all testing meets worldwide standards for quality and compliance.

# **High Quality Non-Clinical Service**

# 01 Safety Evaluation

- Reproductive and General toxicity
- Developmental toxicity Genotoxicity Antigenicity
- / Turnorigenicity Immunotoxicity Carcinogenicity Local toxicity
- Safety pharmacology

· In vitro 3T3 NRU phototoxicity test In vitro eye irritation test (RhCE) · In vitro skin irritation test (RhE)

# 02 Medical Device Toxicity

- Genotoxicity (in vivo, in vitro)
- Systemic toxicity (acute, subacute, subchronic)
- Local effects after implantation (subcutaneous/muscle)
  - Skin sensitization test
- Intracutaneous(intradermal) irritation test] Irritation study (Skin irritation test,
- Cytotoxicity (method: extraction, direct contact, indirect contact)

# 03 Chemical / Pesticide Toxicity

CI, micro CI, C-arm, X-ray, DEXA, Ultrasound system, etc.

06 Bio-Imaging Service

- data submission to the Ministry of Environment (ME) and High-quality and reliable toxicity study services for the Rural Development Administration (RDA)
- A large number of toxicology experts who have no problem
  - responding to regulatory body in the future!

# Giobal GLP State OECD KOSDAD LISTED COMPANY



# 240, Nampyeong-ro, Yangji-myeon, Cheoin-gu, Nonclinical Research Institute

Tel:

E-mail. webmaster@csco.co.kr +82-31-329-9900

# Corestemchemon US Inc. E-mail. kimys@csco.co.kr

# SEND

STANDARD for EXCHANGE of **NONCLINICAL DATA** 

Local Lymph Node Assay (BrdU-FCM, -ELISA)

04 Alternative Toxicity

# SEND

CORESTEMCHEMON is the best service by introducing Instem's Provantis Program. committed to delivering

> · Menopausal disorder Pollutants eliminator

05 Efficacy Evaluation

Beauty & Health

Internal organs

Digestion system

Immunity

 Metabolism · Anti-cancer

Nervous system

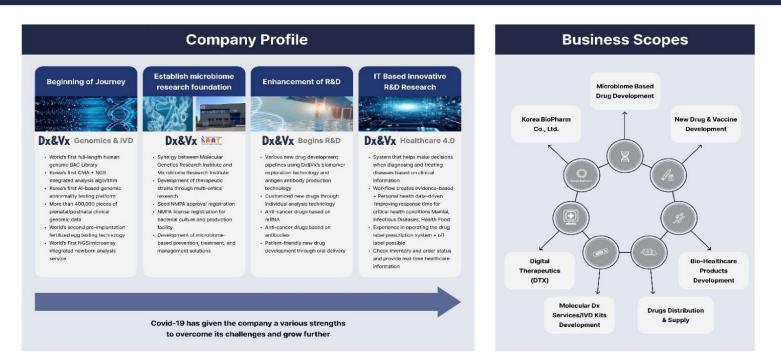
started after December 18, 2016 new drugs to the US FDA is to support submission of submitted to the agency + Raw data of toxicology animal studies using SEND.



**GLP CERTIFIED ORGANIZATION** 

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#### Diverse and Superior Pipeline of New Drugs for Future Sustainable Growth



#### **Digital Health-Care Pipeline Ecosystem KHUB & CLIDEX**

|                                 |                          |  | CLIDEX Genomic DB   |
|---------------------------------|--------------------------|--|---|
| Telemedicine (Remote Treatment) | Remote Mind-Counselor    | CLIDEX MDT /<br>New PMS (Post Marking Survival) Model  | Genomic Data as a Core of Our Business  |
|                                 |                          | PHR Gathering Interface & Analysis System<br>- (Step 1) Health Examination Data (From Shingyeongworf)<br>- (Step 2) Individuals PHR Internation based on Questionnaire<br>- (Step 2) Individuals Information from cigluid devices and<br>keep data for 3 weeks<br>- #Emergency Patient ClassTeation System – Al Utilization<br>(Zero-knowledge Health Certificate) | Core Competency<br>- Having a Worlds first human whole genome "BAC library"<br>- Gain a Korea's first DNA chip manufacturing & its licensing<br>- Korea's first OMA - NGS integrated analysis algorithm<br>- Korea's linst Al-taxed genome analysis lists plaiform<br>- Korea's lingest prenatallocistatic clinical genome data with<br>more than 400,000 cases |
| Reservation & Prescription      | Reservation & Counseling | <ul> <li>PMS Clinical Trials</li> <li>Integrating diverse biological, genetic, and clinical data to<br/>visualize to as a cohort analysis framework</li> <li>Visualize hormarial Analysis Results Based on Disability</li> <li>New drugs can be used as basic clinical data to predict<br/>officacy and stability</li> </ul>                                       | Service<br>- Genome Analysis using CMA + NGS using BAC DNA Chip<br>- Sales of manufactured DNA Chip products and raw materials<br>- Row materials (FBH probe, Kienow enzyme), Analysis softwa<br>- Discover biomarker for new dugs for rare diseases and care<br>- Providing important data during the new drug development                                     |



Huons Group is a global healthcare and pharmaceutical company based in Korea, innovating in medical solutions since 1965 to improve human health. From pharmaceuticals to medical devices, beauty & aesthetic, and nutritional supplements & foods, Huons Group is transforming into Korea's leading 'Total Healthcare Group' and expanding its presence in the global market.

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Supplying FDA-approved products to the US market.

- 1% and 2% Lidocaine HCI Injection
- 0.75% Bupivacaine Injection in 8.75% Dextrose
- 1% Lidocaine HCI Injection
- 0.9% Sodium Chloride Solution
- 2% Lidocaine HCl with Epinephrine Inj. (1:100,000)

#### **BIO-PHARMACEUTICALS**

• Human Recombinant Hyaluronidase (IV  $\rightarrow$  SC)

#### NUTRITIONAL SUPPLEMENTS

 Comprehensive Liposome Vitamin Products for Anti-oxidant, Immune, and Energy

#### EYE DROPS

• 0.5% Carboxymethyl Sodium Eye Drops



USA West Office: 200 Spectrum Center Drive, Suite 4036, Irvine, CA 92618



Edward Kim birdie84@huonsusa.com (949) 491-0649



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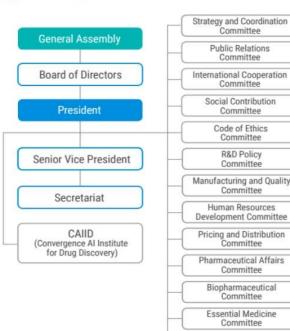


### About KPBMA

#### The Korea Pharmaceutical and Bio-Pharma Manufacturers Association(KPBMA)

is the largest association representing the Korean pharmaceutical and biotech industry. Established in 1945 under the authorization of the Ministry of Health and Welfare (MoHW), KPBMA is dedicated to advancing national healthcare through the sustainable development of the pharmaceutical sector.

#### Organization



#### Members



### Main Activities

- Bridge the Government and Private Sectors & Facilitate Policy Improvements
- Launch Open Innovation Platforms such as:
  - K-SPACE (Korea Superior Pharma-pipeline Accelerating Collaboration Evolution)
     KIMCo (Korea Innovative Medicines Consortium)

Vaccine Committee

- International Cooperation, which involves:
- Regulatory Harmonization, Networking Events, Seminars, Delegation Programs, etc.
- Support ISO37001 Certification and Establish Compliance Guidelines
- Operate Training Courses such as:
  - GMP, Marketing, Data Integrity, Global Business Development, etc.
- Provide Information and Publish such as:
   Membership Directory, Industry Databook, Pharmaceutical Production Performance Report
- · Nurture Professionals in AI-driven New Drug Development through CAIID
- Conduct Research and Analysis on Industry Issues

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#### Your Genomics Experts

Since 2004, Psomagen (formerly Macrogen USA) has provided superior data quality and next-level technical support to our clients. Our North American researchers are able to complete multiomics projects and get actionable results, all from one service provider.

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Our customers at pharmaceutical, industrial, and academic institutions use Psomagen for reliable, high-quality data. We work hard to ensure your samples are treated with care, and that they produce meaningful results.

#### **Multiomics Capabilities**

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#### **Certified Labs**

Our labs are CLIA-certified and CAP-accredited. Plus, we're preferred providers for 10x Genomics, IDT, and other top-notch omics technology companies.

#### **US-Based Operations**

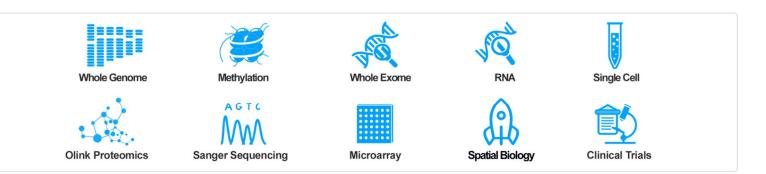
We have four US-based labs, plus a Rockville, MD customer service hub. Your samples never travel far!

#### **Collaborative Approach**

Our team is practically an extension of yours: resourceful, responsibe, and by your side every step of the way.

#### **High-Quality Data**

We have nearly 20 years of genomics research experience. our data exceeds manufacturer benchmarks, and we stay up-todate on industry training and certifications.







# 2024 KAPAL 8th Annual Conference

A proud sponsor of the 8th annual Korea-American Professional Association in Life Sciences (KAPAL) Conference, Reed Smith is home to a full-service FDA practice with particular experience guiding clients entering the U.S. market through FDA regulations and compliance. With a global reach, the firm helps clients assess risks, develop tailored strategies, and facilitate product commercialization across borders.

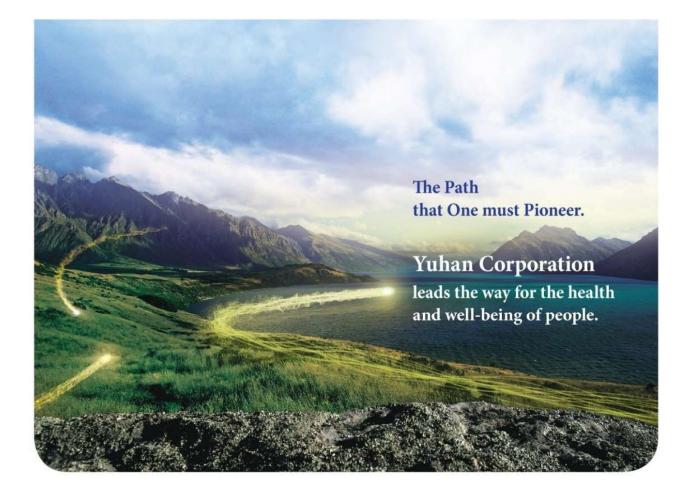


Sung Park Counsel, Washington D.C. +1 202 414 9262 spark@reedsmith.com





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# The Way of Yuhan

Yuhan Corporation, a group loved by the people and grown together with the people For the last 90 years, the corporate culture of honesty and integrity, and the strong beliefs in social responsibility are what made Yuhan what it is today.

Looking back on the path that we moved on and thinking of the path ahead, Yuhan will make the leap as a global pharmaceutical company through innovative new drug development, and by enabling healthiness and happiness for all the people in the world.

In the next 100 years, Yuhan Corporation will follow the noble spirit of our founder, Dr. New Ilhan, and write the history of challenge and development moving forward.

Our challenge has already begun.



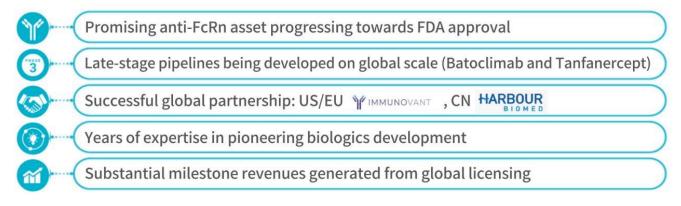


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# FCEDA SERVICES

The Fairfax County Economic Development Authority (FCEDA) provides a wide array of free, confidential services and information to assist new, expanding and relocating American and international businesses. Headquartered in Tysons, Fairfax County's largest business district, the FCEDA also maintains offices in major technology centers around the world: Bangalore/Mumbai, Berlin, London, Los Angeles and Seoul.

#### HOW WE CAN HELP



IDENTIFY COMMERCIAL REAL ESTATE OPTIONS



OFFER WORKSHOPS FOR NEW AND EXISTING BUSINESSES



PROVIDE MARKET AND INDUSTRY



RECOMMEND BUSINESS DEVELOPMENT CONNECTIONS AND SUPPORT



PROVIDE SUPPORT FOR MARKETING/ PUBLIC RELATIONS VISIBILITY



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> Ellington West CEO & Co-founder, Sonavi Labs

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