

5th KAPAL Annual Conference

November 7 - 9, 2019

Institute for Bioscience and Biotechnology Research (IBBR), Rockville, MD, USA



Collaboration and Innovation in Biosciences

Organized by



Hosted by



Osong Bio Valley



Osong High-tech Composite Medical Complex

- Specialized research complex for the development of advanced medical products
- Regulatory Exemptions and Tax Benefits for Healthcare Research Institutes

Osong Cosmetics Industry Complex (Completed in 2023)

- Construction of industrial complex as the hub of beauty industry for R&D, manufacturing, distribution and sales on cosmetics.

Osong Bio Industry Complex (Completed in 2023)

- Construction of industrial complex for bio-convergence industry including bio-medicine, medical equipment and cosmetics.

Osong Biotechnology Complex

- Korea's only national bio-science complex
- Generates highly interlinked effects by utilizing infrastructure obtained in advanced medical complex

Osong 2nd Bio-health Technopolis

- IT-BT High-tech industry facilities and research facilities
- Expansion of diverse living environment, including production facilities, residential spaces and cultural facilities

Healthcare Administration Town

- Government-led bio-cluster, with a one-stop service system, for healthcare
- Six major national health and medical institutions

Osong 3rd Bio-health Technopolis (Completed in 2026)



Global Biotechnology Cluster



CHUNGCHEONGBUK-DO

WELCOME MESSAGE

Dear Participants,

On behalf of the organizing committee, it is my great pleasure to welcome you to the 5th KAPAL Annual Conference (KAC) 2019. We are very excited to see this conference has become a platform for innovation and collaboration among Korean and American Bioscience companies, institutes, and scientists. One of the KAPAL's missions is to expand a broad knowledge of drug development and life sciences, and we have experts from a variety of areas in biopharmaceuticals including lawyers, investors, regulators, researchers, and clinicians at the 5th KAC 2019. I believe that every participant will have a great opportunity to establish potential collaborations and working relationships and to expand professional networks during the next 2 days.

I thank all the organizers who have worked restlessly to put together an amazing program with outstanding speakers. The program of 5th KAC 2019 includes a special FDA session for the regulation of cell and gene therapy products and a session for Artificial Intelligence (AI) and Machine Learning in Bioscience in which we will be able to grasp the landscape of AI fundamental and application in bioscience. You will find many must-attend talks and sessions in the program that is packed with information.

The 5th KAC 2019 is aligned with the 11th Annual Bioscience and Engineering Symposium (ABES) on November 9th. The 11th ABES is organized by NIH-Korean Scientists Association (KSA), which you will find speakers of in-depth knowledge and experience in fundamental research where we always seek the next big thing. I hope all participants entertain these back-to-back events to build their portfolio of professional networks and innovative collaborations.

This year's conference would have not been possible without the heartfelt support from organizations such as the Embassy of the Republic of Korea, the State of Maryland, Chungbuk-do, and KOTRA. We sincerely thank all companies and organizations providing sponsorships making these events successful every year. Also, we thank the governor of the State of Maryland, Larry Hogan, who has provided welcoming remarks to the 5th KAC 2019. Lastly, we thank all speakers, organizing committees, and participants and look forward to having a successful 5th KAC 2019 and 11th ABES.

Luke Yun Suk Oh, Ph.D.

President, Korean-American Professional Association in Life Sciences (KAPAL)



LARRY HOGAN
GOVERNOR

STATE OF MARYLAND
OFFICE OF THE GOVERNOR

November 7, 2019
KAPAL 5th Annual Conference

A Message from Governor Larry Hogan

Dear Friends,

It is my great pleasure to welcome you to the Korean-American Professional Association in Life Sciences (KAPAL) 5th Annual Conference, and to congratulate and thank KAPAL for its hard work and dedication to this important industry.

Innovations in the life sciences industry have led to great improvements in the quality of life for people around the world. As leaders in the life sciences, both Korea and the United States continue to offer important educational assets, highly-skilled workforces, and world-class companies. Through effective academic collaboration, public education, and promotion of the life sciences industry, new discoveries are being made every day in fields such as gene and cell therapy, vaccine development, and biopharmaceuticals, and the research done in our laboratories, changes lives far beyond our borders.

Our administration remains committed to collaborating with the best and the brightest in the industry to develop an environment in our state that encourages new discoveries and innovative solutions that improve quality of life for all. In this regard, we are very pleased that KAPAL has selected Maryland to host this growing conference again this year, and welcome all of this year's attendees.

We are appreciative of KAPAL's leadership and commitment to ensuring a strong and fruitful partnership between the United States and Korea, and sincerely hope this year's conference promotes new ideas, new business connections, new inspirations, and new friendships.

Sincerely,

A handwritten signature in blue ink, reading 'Larry Hogan'.

Larry Hogan
Governor

KAC + ABES 2019 PROGRAM

Program Chair: JK Song, Ph.D.

Thursday, November 7, 2019

5:00 – 6:00 pm

Registration & Networking

Opening Remarks

6:00 – 6:30 pm



Luke Oh
President
KAPAL



Young Jin Jang
Minister for Economic Affairs
Embassy of the Republic of
Korea



Larry Hogan
Governor
State of Maryland

6:30 – 6:35 pm

Group photo

6:35 – 7:40 pm

Dinner

Hosting sponsor presentation

7:40 – 7:50 pm

Osong, the Best Bio-Cluster in Korea
Maeng Eun-young (Director, Chungcheongbuk-do)

Keynote presentation I

7:50 – 8:30 pm

Fulfilling the promise of biosimilars
Dr. Christopher Hansung Ko (CEO, Samsung Bioepis)

Keynote presentation II

8:30 – 9:10 pm

***Clinical Development of BBT-877, a Potent Autotaxin Inhibitor,
to Treat Idiopathic Pulmonary Fibrosis***
Dr. Yong-Hee Lee (SVP, Bridge Biotherapeutics)

9:10 – 10:30 pm

Networking & End of Day 1

Friday, November 8, 2019

8:00 – 8:40 am

Breakfast

Session I: Emerging Korean Bioindustry

Moderated by Dr. JK Song

Orally Active Platform Technology for gene, peptide, protein therapy

Dr. Dong Yun Lee (Co-Founder & Director, KB BIOMED Inc.)

8:40 – 9:25 am

Platform for Value Creation Using Natural Resources and Bio-convergent Technology

Dr. Kil-Young Yun (CEO, D'doruroo Co., Ltd.)

Cis-regulatory modules (CRMs), the non-coding biomarkers for drug discovery and precision medicine

Dr. Joonyul Kim (CEO, Ciscovery Bio)

Session II: Investment and legal strategy for drug development

Moderated by Dr. Cheol Lee

9:25 – 10:25 am

Financing Biotech & Medtech Companies in Maryland

Dr. Ernesto Chanona (Manager, State of Maryland Dept. of Commerce)

Patent Law Challenges for Korean Biotech Companies

Carla Ji-Eun Kim, Esq. (Director, SKGF)

10:25 – 10:40 am

Coffee Break

Session III: Working with Contract Research Organization

Moderated by Dr. Eunkyung An

Understanding CRO Activities in Clinical Trials

Mr. Hugh Lee (CEO, KCRN Research)

10:40 – 11:40 am

Clinical and Regulatory Considerations for Cell and Gene Therapy Development Programs

Dr. Steve Winitzky (VP-Technical, Parexel)

Session IV: Republic of Korea, Ministry of Food and Drug Safety

Moderated by Dr. Cheol Lee

Regulatory Systems of Biologics Products

11:40 – 12:20 pm

Dr. MiRyeong Jin (Scientific Officer, Nat'l Inst of Food and Drug Safety, Korea)

The regulation of Gene and Cell therapy products in Korea

Dr. Jounghye Baek (Scientific Officer, Nat'l Inst of Food and Drug Safety, Korea)

12:20 – 1:20 pm

Lunch

Keynote presentation III

Moderated by Dr. Hae-Young Ahn

1:20 – 2:00 pm

Drug Development and Regulatory Science Evolution

Dr. Edward D. Bashaw
(Sr Science Advisor, FDA)

Session V: US FDA, Cell and Gene Therapies

Moderated by Dr. Hae-Young Ahn

Introduction

Dr. Hae-Young Ahn (CEO and Founder, Ahn Bio Consulting)

CMC-related Regulatory and Technical Considerations on the Development of Biotechnology Products

2:00 – 3:40 pm

Dr. Jun T. Park (SVP, Helixmith)

Role of clinical pharmacology in cell and gene therapy

Dr. Iftekhhar Mahmood (Ret., CBER, FDA)

Regulatory Considerations: Clinical Development of Cellular and Gene Therapy Products

Dr. Lei Xu (Chief Medical Officer, CBER, FDA)

3:40 – 4:00 pm

Coffee Break

4:00 – 4:45 pm

US FDA Panel Discussion

3:00-6:00 pm

**KIAT
K-TAG USA
Chapter annual
meeting**

<p>Session VI: Artificial Intelligence and Machine Learning in Bioscience Moderated by Dr. Sang Tae Park</p> <p><i>Machine Learning and AI approaches to discover genomic and image-based predictive biomarkers for guiding precision oncology care</i></p> <p>4:45 – 6:15 pm Dr. Tae Hyun Hwang (Assistant Professor, Cleveland Clinic)</p> <p>Artificial Intelligence and Machine Learning in Biology : Opportunities and Challenges Jinkyu Yoo (CEO, AITRICS)</p> <p>Decoding Multi-Omics based Big Data with BI/AI Solutions in Health Care Dr. Xuefeng Bruce Ling (Co-Founder, HBI Solutions)</p>	
<p>6:15 – 7:30 pm</p>	<p>Dinner</p>
<p>7:30 – 9:00 pm</p>	<p>After-hour Round Table Discussion Regulation and drug development Moderated by Dr. Heemin Lee</p>
<p>7:00-9:00 pm</p> <p>After-hour Round Table Discussion Growth of Bio Startups in South Korea Moderated by Mr. Taegeun Kim (*Presented in Korean)</p> <p>Topics: <u>BIO - Market Trend and Outlook</u> <u>Information on IPO - KOSDAQ</u> <u>Investment Perspective by VC</u></p> <p>Panelists: Ku Wan-Sung (Bio Analyst, NH Investment & Securities) Jiwook Han (General Manager, NH Investment & Securities) Tae-Woo Kim (Managing Director, Eugene Investment & Securities) Ju-Hyun Oh (Director, Eugene Investment & Securities)</p>	
<p>9:00 pm</p>	<p>End of Day 2</p>
<p>Saturday, November 9, 2019</p>	
<p><u>KIAT Session</u> 1:1 match meetings with Korea Bio-companies from Chungbuk and K-TAG members (All day)</p>	<p>Annual Bioscience and Engineering Symposium (ABES) see p.25 for the program</p>

SPEAKERS



Osong, the Best Bio-Cluster in Korea

Maeng Eun-young

Director of Bio Policy Division, Chungcheongbuk-do

Maeng Eun-young is the head of the Chungbuk-province delegation and currently serves as director of the Bio policy division, Chungbuk-province.

She started a civil service in Chungbuk-province and went through the Ministry of Strategy and Finance in charge of the national budget. Currently, as director of Bio policy division in Chungbuk-province, she is trying to expand the biotechnology industry that the whole world is paying attention to as a future industry to province wide and is trying to realize the goal of "Chungbuk-province, the land of life".



Keynote: Fulfilling the promise of biosimilars

Christopher Hansung Ko, Ph.D.

CEO, Samsung Bioepis

Dr. Ko is the President and Chief Executive Officer of Samsung Bioepis. He joined the company in 2012 as Executive Vice President, Chief Executive Officer.

Prior to joining Samsung Bioepis, Dr. Ko held leadership positions at Samsung Advanced Institute of Technology where he led the Bio & Health Lab and later joined Samsung Strategic Business Development Team as Senior Vice President in 2007. Before joining Samsung Advanced Institute of Technology, he was responsible for corporate development at Dyax until 1999, a biotechnology company based in Cambridge, Massachusetts, where he played a key role in business growth. He was the Chief Executive Officer of Target Quest, a Netherlands-based biotech venture, in 1998. He holds a B.S. in biochemistry from UC Berkeley and a Ph.D. in Molecular Genetics from Northwestern University. He has served as the Vice President of Korea Biotechnology Industry Organization since January 2019.

Abstract: In February 2012, Samsung Bioepis was established with a long-term goal of becoming a leading biopharmaceutical company. We saw a great potential in biopharmaceutical industry which was growing fast, and we decided to enter this industry through biosimilars. We launched our first biosimilar in Europe in January 2016, and since then, our biosimilars have treated more than 170,000 patients in Europe alone. With our efforts to increase patient access to these high-quality biologics, our biosimilar products are now available across five continents. Not many companies doing biosimilars, if any, can claim such a record. I will talk about our journey from the beginning to where we are now, and how our advanced development platform and process innovation have contributed to raising the quality standards for biologics, and share our ongoing commitment to patients, physicians, payers and healthcare systems across the world.



Keynote: Clinical development of BBT-877, a Potent Autotaxin Inhibitor, to Treat Idiopathic Pulmonary Fibrosis

Yong-Hee Lee, Ph.D.
SVP, Bridge Biotherapeutics

Dr. Lee has broad scientific background and experiences in the field of preclinical and clinical drug development (ADME, bioanalysis, safety/toxicology, IND enabling package, clinical pharmacology).

Dr. Lee has over 25 years' experience in the pharmaceutical and biotech industries. His past experiences include various positions at Pfizer consumer products, Cyprotex, Ikaria, Ligand Pharmaceuticals, Lion Biosciences, and LG Life Science.

He received his Ph.D. in Pharmacy from Seoul National University, and started his career as post-doc researcher in University of Southern California for ocular drug delivery research.

Abstract: Idiopathic Pulmonary Fibrosis (IPF) is a progressive, irreversible and fatal lung disease with unmet medical needs. Autotaxin (ATX) is an extracellular enzyme involved in the generation of lysophosphatidic acid (LPA). Preclinical and clinical data have suggested the ATX – LPA – LPA receptor (LPA-R) axis plays a pivotal role in the pathogenesis and the progression of IPF.

BBT-877 is an orally available small molecule inhibitor against ATX. Nonclinical data suggest BBT-877 is a potent, selective, and potentially best-in-class ATX inhibitor. Phase 1 clinical data demonstrate BBT-877 is a safe and well-tolerated drug with excellent pharmacokinetic-pharmacodynamic profiles. This presentation will show and discuss about the preclinical and clinical development. Licensing deal with Boehringer Ingelheim (BI) closed July 16, 2019, and clinical development beyond Phase 1 is conducted by BI.



Orally Active Platform Technology for gene, peptide, protein therapy

Dong Yun Lee, Ph.D.
Co-Founder & Director, KB BIOMED Inc.

Dr. Lee has specialty in Biomaterials Science and Drug Delivery System (DDS). His Research interests include immunomodulating cell & gene therapy, oral anticancer nanomedicine, and smart diagnostic contact-lens system.

Dr. Lee launched KB BIOMED Inc. in 2016 as co-founder and was the director of the company. Prior to joining KB BIOMED, he has worked as a tenured professor in Department of Bioengineering, Hanyang University, Seoul, Korea. He received his B.S. and M.S. in Biochemistry from Hanyang University, and Ph.D. in Materials Science and Engineering (MSE) from Gwangju Institute of Science and Technology (GIST), Gwangju, Korea. He had post-Doc. fellowship in Joslin Diabetes Center, Harvard Medical School.

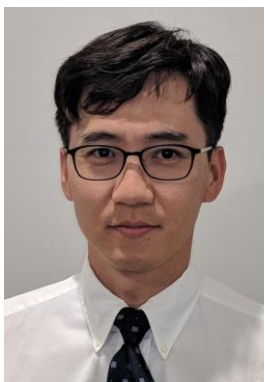


Platform for Value Creation Using Natural Resources and Bio-convergent Technology

Kil-Young Yun, Ph.D.
CEO, D'doruroo Co., Ltd.

Dr. Yun has a strong background in plant science and natural products. He has devoted to the research and development of materials for cosmetics, foods and medicine.

Dr. Yun also has worked to build platform of value chain consists of materialization, commercialization and marketing using natural resources and bio convergent technology. Prior to found D'doruroo Co., Ltd he made significant contributions to the development of molecular markers for economic plant breeding and development of bio-energy. He received his Ph.D. degree in defense mechanism of oxidative stress in plant from Chungbuk National University. He has worked as a research scientist in gene expression network form University of Kentucky, Massachusetts and Main.



Cis-regulatory modules (CRMs), the non-coding biomarkers for drug discovery and precision medicine

Joonyul Kim, Ph.D.
CEO, Ciscovery Bio Inc.

Dr. Kim has four years of experience in managing Proximity Biosciences, a biotech startup developing pairs of aptamers as affinity reagents for diagnostics and therapeutics. With Proximity Biosciences, he secured two non-dilutive funds (NSF STTR phase I and Alabama Launchpad) and two research contracts from private companies. He received his Ph.D. in biochemistry and molecular biology from Michigan State University and completed postdoctoral fellowship training in bioanalytical chemistry at Auburn University.

Abstract: Ciscovery Bio Inc. (est. June 2019) commercializes non-coding biomarkers named *cis*-regulatory modules (CRMs) for drug discovery and precision medicine. CRMs are the major functional elements in the non-coding genome, which constitutes 98% of the human genome and is largely unexplored. We provide solutions to assist (1) biopharma companies and (2) precision medicine companies by harnessing the power of CRMs, which control gene expression.

(1) For biopharma companies, our *in vitro* liver toxicity test system, which uses a large number of CRMs as biomarkers, will comprehensively detect cellular changes in drug-treated cells.

(2) For precision medicine companies, our database of functional CRM variants will facilitate the prediction of patient-specific liver toxicity effect of a set of drugs. CRMs are highly potent biomarkers for precision medicine because sequence variations are responsible for $\geq 90\%$ of gene expression variations among human individuals.



Financing Biotech & Medtech Companies in Maryland

Ernesto Chanona, Ph.D.

Manager, Maryland Dept. of Commerce

Ernesto is an economic developer for the biotechnology industry at the Maryland Department of Commerce.

Dr. Chanona began his career as an undergraduate research assistant at Johns Hopkins University and completed his undergraduate degree at the university's Department of Biology. He then attended the University of North Carolina at Chapel Hill for his doctorate in pharmacology. Upon completion of his doctorate he pursued a postdoctoral fellowship at the National Cancer Institute in Bethesda where his research aimed at untangling the complex relationship between colorectal cancer, the mucosal immune system and the gut microbiota as an approach to developing targeted immunotherapies.

As part of his work at the Department of Commerce, Ernesto uses a database he developed of the types of technologies and the therapeutic areas of interest of Maryland-based medtech and biotech companies. He uses this portfolio to connect companies, services, academic researchers at universities and those at the National Institutes of Health. Through the state's bilateral strategic partnerships, he fosters foreign direct investment to Maryland through trade delegations. In turn, he also helps companies in Maryland to market and export their innovations and services at international trade shows.

Abstract: Maryland is home to the fourth largest life sciences cluster in the U.S., with a diverse ecosystem of more than 2,300 life sciences firms, including 500+ biotech and medtech companies. We have the highest concentration of employed doctoral scientists and engineers in the nation across our private sector, our academic research centers like Johns Hopkins University and the University of Maryland, and our 70 federal research laboratories located across 60 federal agencies, including the NIH, FDA, NIST and the U.S. Army Medical Research and Materiel Command. When scientists from these research institutions are driven to commercialize their technology, however, financial support is one of the most difficult hurdles for their companies to overcome. In this talk, we will explore ways in which local government agencies and the private sector provide financial opportunities for emerging companies located in Maryland.



Patent Law Challenges for Korean Biotech Companies

Carla Ji-Eun Kim, Esq.

Director, Sterne, Kessler, Goldstein & Fox

Carla Ji-Eun Kim is a director in Sterne Kessler's Biotechnology & Chemical Practice Group. Carla advises a diverse group of biotechnology companies on building worldwide exclusivities around their products.

In her practice, Carla focuses on finding and creating innovative ways to extend exclusivities that are well integrated with her clients' technological and business objectives. For example, Carla counsels her clients on

the preparation, prosecution, and management of complex worldwide patent portfolios in areas of biotechnology such as therapeutic antibodies, antisense technologies, personalized medicine, vaccines, nucleic acid therapies, formulations, bioinformatics, pharmaceuticals, and cell culturing/bioprocessing methods. Carla also has extensive experience in IP due diligence investigations and freedom to operate studies, and she prepares patentability, validity, and noninfringement opinions in connection with licensing, acquisition, and investment.

Carla received her J.D. from the University of Minnesota Law School, cum laude, her M.S. in pharmacology from the University of Minnesota and her M.S. in cell and molecular biology from the University of Pennsylvania. Carla's graduate research focused on molecular genetic mechanisms of DNA repair in mammalian cancer cells and developing an anti-angiogenic approach to cancer therapy and treatment. She earned her B.A. in biology, magna cum laude, from the University of Wisconsin, Stevens Point. Carla is an Adjunct Professor at George Mason University School of Law, teaching patent prosecution.

Abstract: There are many legal challenges that all biotechnology and/or pharmaceutical companies face. However, for Korean companies, they can encounter additional unique issues due to the early stage of drug development, limited experience in FDA approval, differences in patent law between Korea and the US/Europe, and cultural background. These unique issues can impact the strategy for patent filing and prosecution, patent term extension, and enforcement. This presentation will identify some of the unique challenges faced by Korean companies and provide potential solutions to address the challenges.



Understanding CRO Activities in Clinical Trials

Hugh Lee
CEO, KCRN Research

Hugh Lee founded KCRN Research, LLC offering clinical and regulatory services (former KOSRAP with consulting services) in May 2012 and the current title is CEO & Founder, KCRN Research, LLC.

KCRN Research is a contract research organization (CRO) located in Germantown, MD and is currently running 10 pre-IND and IND regulatory projects and 8 phase 1 and 2 clinical trials for the drug developments of pharmaceutical/biotech companies. Prior to founding KCRN Research, Hugh had 6-year experiences of clinical operations managing regulatory and clinical projects at US Office of HanAll BioPharma Co., Ltd. and Rexahn Pharmaceuticals, Inc. and 4-year laboratory experiences at Ohio State University, Seoul National University Hospital, and Seoul St. Mary's Hospital. Hugh holds two Master's degrees in Bioscience Regulatory Affairs at Johns Hopkins University and Agricultural Biotechnology at Seoul National University.

Abstract: Sponsors (pharmaceutical companies or biotech companies) outsource their work to a Contract Research Organization (CRO). A CRO is a company which holds a contract with the sponsor to perform work on their behalf. The sponsor can outsource any of all activities ranging from protocol development to monitoring to statistical analysis. When the obligations of the sponsor are transferred to a CRO, the CRO becomes responsible, from a legal and regulatory standpoint, for fulfilling the obligations. Therefore, it is important to understand CRO activities in clinical trials to develop and manage clinical trials.



Clinical and Regulatory Considerations for Cell and Gene Therapy Development Programs

Steve Winitsky, M.D.

VP - Technical, Parexel Consulting

Dr. Winitsky has over 11 years of former FDA experience as a Medical Officer, Team Leader, and Acting Branch Chief in the Office of Tissues and Advanced Therapies (OTAT) in the Center for Biologics Evaluation and Research (CBER).

Dr. Winitsky gained extensive experience with review and supervision of cell and gene therapy files and combination biologic and device files. He served as the primary clinical reviewer for approximately 90% of the cardiovascular files regulated by OTAT/OCTGT, along with oversight of numerous files covering multiple clinical indications (e.g., inborn errors of metabolism, infectious disease, solid organ transplant, orthopedics, endocrinology, immunology, rheumatology, in utero repair) as Team Leader and Branch Chief. During his time in OTAT/OCTGT, he was involved in Working Groups that were responsible for drafting and finalizing FDA and CBER Guidance and implementing PDUFA and 21st Century Cures initiatives. He also reviewed or supervised the review of numerous Fast Track, Regenerative Medicine Advanced Therapy (RMAT), and Breakthrough Designation request applications.

Abstract: The presentation will cover general clinical and regulatory considerations for cell and gene therapy products. These issues, which have implications on the design of the clinical development program, regulatory pathway, and labeling, are important to discuss with your contract research organization (CRO) to facilitate efficient development of cell and gene therapy products.



Regulatory Systems of Biologics Products

MiRyeong Jin, Ph.D.

Scientific Officer, NIFDS Korea

Dr. Jin is a Scientific Officer in Biologics Division, National Institute of Food and Drug Safety (NIFDS), Ministry of Food and Drug Safety (MFDS).

Currently Dr. Jin reviews Safety & Efficacy of bacterial vaccine, botulinum toxin products. Previously she worked at the Cell and Gene Therapy Product Division, where she reviewed Safety & Efficacy of CTP, GTP, recombinant protein products.

Dr. Jin received her B.S. in Pharmacy from Won Kwang University, M.S. and Ph.D. in Pharmacy from Chung Ang University.

Abstract: Biological products are defined as medicinal products based on substances or materials derived from humans or other living organisms, which require special controls to protect public health and include vaccines, protein recombinant products, cell therapy products, gene therapy products, etc. Regulation on pharmaceuticals approval, notification and review was published in 1998, and the regulatory framework for biological products was separated from that for drug products in 2003. The differences that reside between

the frameworks for chemical drugs and biological products are that only chemical drugs have generic drugs, and that data protection is given to chemical drugs during their re-evaluation period. IND application approvals for biological products accounted for about 35% of the total IND approvals in 2018. Currently, the ratio between domestic developers and importers of biological products is approximately 1:1. Given the Korean government's goals that it will increase its annual R&D investment in the biopharmaceutical industry to around USD 4 billion until 2025, and help attain USD 50 million annual export of biopharmaceuticals, we can expect continued growth of the bio-industry.

The regulation of Gene and Cell therapy products in Korea



Jounghee Baek, Ph.D.

Scientific Officer, NIFDS Korea

Dr. Baek is a Scientific Officer in Cell and Gene Therapy Product Division, National Institute of Food and Drug Safety (NIFDS), Ministry of food and Drug Safety (MFDS). She has a specialty in Specifications and Analytical Procedures.

Currently Dr. Baek reviews Quality Control of cell therapy products and gene therapy products. Her research interest includes the development of quality evaluation methods. Previously she worked at the Advanced Therapy Product Research Division, where she reviewed Quality Control of recombinant protein products, therapeutic monoclonal antibodies, and gene therapy products

Dr. Baek received her B.S. in Biology and M.S. in Biochemistry from Korea University, and Ph.D. in Life Science from Kyoto University.

Abstract: In the MFDS, each department has its own responsibilities and duties related to the regulation of these products. MFDS is working for quality management such as GMP inspection, RMP evaluation and so on. Main responsibilities of NIFDS include evaluation and research, a significant part of which is IND and NDA evaluation. Advanced biotherapy products (ATPs) are reviewed by Cell and Gene Therapy Products Division at NIFDS. As a scientific reviewer there, I will present current regulatory activities including recently market-authorized products in Korea, and also, an overview of a new Korean law, New Advanced Regenerative Medicine and Advanced Biopharmaceuticals Act. Comparison between our current regulatory system and the new ATPs law will help the audience better understand the intent and purpose of the legislation. In addition, several expedited review programs in the new regulatory system will be presented. Besides, this presentation will include considerations for CTP and GTP development and our commercialization supporting program for researchers and companies.



Keynote: Drug Development and Regulatory Science Evolution

Edward D. Bashaw, Pharm.D.

Senior Science Advisor to the Office of Clinical Pharmacology
Division of Clinical Pharmacology-3
US Food and Drug Administration.

Dr. Bashaw received his BS in Pharmacy and Doctor of Pharmacy from the University of Kentucky in 1986. Upon completion of a residency at the National Institutes of Health-Clinical Center, Dr. Bashaw accepted a commission in the United States Public Health Service as a reviewer in the Division of Biopharmaceutics. In his 32 yrs at the FDA he has been a primary reviewer, team leader, deputy division director and division director across a number of therapeutic areas including, but not limited to neuropharmacology, surgical drugs, anti-inflammatory, over-the-counter, and pulmonary drugs in addition to his current responsibilities.

He was appointed the Director of the Division of Clinical Pharmacology-3 (DCP-3) in March 2006. As the Director of DCP-3, Dr. Bashaw oversaw the work of 26 PhDs. and PharmDs supporting the review of drugs in the reproductive-urologic, gastrointestinal and dermatologic areas. He held that position until Dec 2017 when he retired from the US Public Health Service with 30yrs of service. While a Commissioned Officer at the FDA, Dr. Bashaw received over 30 awards for performance and/or scientific merit, including the Public Health Service Meritorious Service Medal which was given for scientific excellence. This is the second-highest award a PHS Officer can receive.

In May 2018 Dr. Bashaw returned to the FDA as the Senior Science Advisor to the Office of Clinical Pharmacology. In this position he primarily oversees the activities related to the assessment of dermal absorption with regards to antiseptics and sunscreens, in addition, he is the Office representative on a number of cross Office working groups including nanotechnology and orphan diseases. He is a highly regarded and internationally recognized expert in these areas and has published widely and has represented the FDA internationally as an invited speaker in England, Holland, France, Korea, and China.



FDA session: Cell and Gene Therapies

Hae-Young Ahn; Ph.D., RAC

CEO & President, AhnBio Consulting, Inc.

Dr. Ahn is the principal consultant as well and her expertise is on building drug development strategies and regulatory strategies. Prior to founding AhnBio in January, 2018, she was the deputy director in Division of Clinical Pharmacology 3, Office of Clinical Pharmacology, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA).

Dr. Ahn joined the FDA in 1990 as a research scientist. During her tenure at the FDA, she held several positions in the Office of Clinical Pharmacology including a clinical pharmacology and biopharmaceutic reviewer, the metabolic and endocrine clinical pharmacology team leader and deputy division director. She also served as a senior advisor to the Office of New Drugs (OND) Associate Director for Therapeutic Biologics on broad policy and

strategic initiatives related to biosimilars, follow-on protein products, and other related complex products. She participated in many important CDER coordinating committees and working groups such as Complex Drug Substance Coordinating Committee, Biopharmaceutical Coordinating Committee, Non-glycosylated peptide working group, Biosimilar Implement Committee, Biologic Oversight Board, and Hepatic Impairment working group.

She received her B.S. in pharmacy from Ewha Womans University, M.S. in pharmaceuticals from Seoul National University, and Ph.D. in pharmaceuticals from West Virginia University. She also received a postdoctoral training in pharmaceuticals at the University of Michigan.



CMC-related Regulatory and Technical Considerations on the Development of Biotechnology Products

Jun T. Park, Ph.D.

SVP, Licensing and Regulatory Affairs, Helixmith

Dr. Park leads the licensing and regulatory affairs (LARA) unit, which oversees regulatory works focused on the development of DNA-based gene therapy products to promote advanced therapy markets in areas such as the nervous system and cardiovascular disease. He also leads all CMC-related projects to commercialize several Helixmith products, including phase 3 clinical trials currently underway at the US FDA.

Previously Dr. Park was a product quality reviewer for the Office of Biotechnology Product (OBP)/CDER/FDA for 11 years. He reviewed the CMC section of biotech and biosimilar products and participated in the inspection of the cGMP manufacturing facilities.

Prior to joining the FDA in 2006, he participated in the production and characterization of various monoclonal antibodies, antigens and enzymes and construction of a small cGMP facility at the DoD Edgewood Chemical and Biological Center (ECBC) in the United States.

Before joining the ECBC, he was a group leader at Alpha Beta Technology, a Massachusetts biotechnology company, and involved in developing carbohydrate drugs as immunomodulator, wound healing or cholesterol lowering agents.

He earned his bachelor's degree and master's degree in chemical engineering from Yonsei University and KAIST, Seoul, Korea, respectively, and received his Ph.D. in biochemical engineering from Worcester Polytechnic Institute in Massachusetts, USA.

Abstract: A comprehensive understanding of product quality and manufacturing, along with appropriate preclinical and clinical trial programs, is essential to a successful drug development program. Biotechnology products have complex biologic features that raise important and unique chemical, manufacturing and control (CMC)-related issues for regulatory review and marketing approval. Therefore, Dr. Park will discuss CMC-related topics such as regulatory considerations and recent CMC paradigm shifts (e.g., FDA fast program, cell and gene therapy products, etc.).



Role of clinical pharmacology in cell and gene therapy

Iftekhar Mahmood, Ph.D.

Pharmacologist (Ret.), FDA

Dr. Mahmood is an independent consultant and has more than 25 years of FDA experience in clinical pharmacology related to small and large molecules and worked both in Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER).

At the FDA, Dr. Mahmood worked on neurological products (9 years), therapeutic proteins (antibodies and non-antibodies) (4 years), coagulation factors, and immunoglobulins (12 years). He helped in establishing a robust clinical pharmacology program in the Office of Blood Review and Research (OBRR) and the Office of Tissue & Advanced Therapeutics (OTAT), CBER. In CBER, he led a team of clinical pharmacologists and preclinical pharmacologists for two years.

He was the member of several working groups in CDER and CBER which wrote guidance for industry.

Dr. Mahmood received three research grants from CDER for conducting research in the area of anti-epilepsy drugs, pediatric clinical pharmacology, and drug-drug interaction.

Dr Mahmood besides his reviews of INDs, NDAs, and BLAs was involved with clinical pharmacology research (both small and large molecules) and published more than 100 research papers in peer-reviewed scientific journals. His research works mainly focused in allometric scaling and pediatric drug development. He also edited and wrote several scientific books.

He holds a Bachelor of Pharmacy degree and a Ph. D. degree in Pharmaceutical Sciences (specialization in Pharmacokinetics) from University of Missouri at Kansas City, USA.

Abstract: Clinical pharmacology is an integral part of modern day drug development process. Pharmacokinetics (PK) and pharmacodynamics (PD) are the cornerstone of clinical pharmacology and the main objective of the assessment of PK and PD of a drug is to find an optimal dose in a given patient population. However, for the cell and gene therapy (CGT), the role of clinical pharmacology is not well defined. The FDA guidance states "The traditional PK study designs are generally not feasible for CGT products; thus, such data are not available to guide clinical trial design. Due to various issues, such as species specificity and immunogenicity, extrapolation from a CGT product dose administered in animals to a clinical dose can be less reliable than the customary allometric scaling typically used for small-molecule pharmaceuticals". Through the examples of some of the FDA approved cell and gene therapy products, this presentation will highlight the role of clinical pharmacology for the optimal dose selection in the patients. Furthermore, the role of clinical pharmacology for CGT products in pediatrics will also be emphasized.



Regulatory Considerations: Clinical Development of Cellular and Gene Therapy Products

Lei Xu, M.D., Ph.D.

Chief Medical Officer, FDA

Dr. Lei Xu is the Branch Chief of General Medicine Branch 2 in the Division of Clinical Evaluation and Pharmacology/Toxicology (DCEPT), Office of Tissue and Advanced Therapies (OTAT), Center for Biologics Evaluation and Research (CBER) at the FDA.

Dr. Xu joined CBER, FDA in 2009 as a Medical Officer evaluating clinical trials of gene and cell therapy products primarily for neurological, and ophthalmological disorders. Oversight of several additional clinical areas, including pulmonology, dermatology and wound care, were added upon her appointment as Branch Chief in 2017. In this position, she is responsible for monitoring trials of investigational products for safety and efficacy. She is also responsible to manage, organize, and direct all of the regulatory review operations, program segments, functions and activities of the Branch.

Her Branch is responsible for reviewing all the data from clinical trials. Her branch reviewed all the clinical data that lead to FDA-approval of the first two directly administered gene therapy products: voretigene neparvovec (Luxturna) for the treatment of retinal dystrophy due to RPE65 mutation, and onasemnogene abeparvovec (Zolgensma) for the treatment of spinal muscular atrophy. In addition to her regulatory experience, she is actively involved in FDA guidance development, including the Guidance for Industry: Expedited Programs for Serious Conditions, and Guidance for Industry: Gene Therapy for Retinal Disorders.

Dr. Xu received her M.D. from Central South University Xiangya School of Medicine in China, and her Ph.D. in neuroscience from Yale University in New Haven, Connecticut. She completed residency training in Neurology at Loyola University Chicago. She is board-certified in Neurology by the American Board of Psychiatry and Neurology. She published more than 10 research papers in peer-review journal prior to joining FDA, and published 2 papers after joining FDA.

Abstract: Dr. Xu will provide an overview of cellular and gene therapy products regulated by Office of Tissues and Advanced Therapies in CBER, FDA. She will then focus on both early and late clinical development of cellular and gene therapy products with emphasis on unique aspects of these product. Finally, she will introduce the five expedited programs that are currently available to facilitate the development of investigational products (drugs and biologics) for serious conditions.



Machine Learning and AI approaches to discover genomic and image-based predictive biomarkers for guiding precision oncology care

Tae Hyun Hwang, Ph.D.

Assistant Professor, The Cleveland Clinic Lerner College of Medicine

Dr. Hwang leads Machine Learning and Artificial Intelligence research at the Cleveland Clinic.

Dr. Hwang completed his Ph.D. in computer science and engineering from the University of Minnesota, Twin Cities in 2011, and was an assistant professor at the University of Texas Southwestern Medical Center before joining Cleveland clinic at 2017. His research interest is focused on developing novel machine learning and AI algorithms to ultimately help patients with cancer. He is a recipient of the American Cancer Society Young Investigator Award and Lung Cancer SPORE Career award. He serves as a bioinformatics core director of NASA Specialized Centers of Research (NSCOR) and has been served as a co-director of Data Analysis Core for UTSouthwestern Medical Center Kidney Cancer SPORE. He and his colleagues have developed biomarkers that are currently being used in the clinical setting, including AR-V7 as a resistant biomarker for Androgen Deprive Therapy in prostate cancer. Most recently, he and his group developed and licensed a biomarker for a first-in-class oral HIF2-alpha inhibitor, PT2399, in patients with clear cell renal cell carcinoma (ccRCC) to set the stage for biomarker-driven clinical trials to Peloton Therapeutic (now merged by Merck with \$2.5B acquisition).

Abstract: Despite the increasing use of tumor DNA profiles of cancer patients, there are very few clinically available biomarkers to guide treatments for patients. In addition, due to medical conditions, patient unwillingness, etc., tissue biopsy is often not available for advanced/metastatic cancer patients ended up with no DNA profiles. To address these barriers, we develop novel machine learning and AI algorithms based on the tumor DNA profiles and/or image data (e.g., H&E histopathology image) to identify novel signatures deliver genome/image-driven oncology care including immunotherapy.

I will present our ongoing efforts to develop novel machine learning and AI algorithms utilizing various data, including genomic and image data that can be useful in clinical settings. I will also introduce our most recent ongoing work to understanding response and non-response mechanisms of AntiCD19 CAR-T therapy in lymphoma using single cell RNA sequencing from our Phase 1 study.



Artificial Intelligence and Machine Learning in Biology : Opportunities and Challenges

Jinkyu Yoo
CEO, AITRICS

Jinkyu Yoo is a serial entrepreneur and CEO of AITRICS that is AI solution startup.

The main business area of AITRICS is healthcare including clinical data analysis, cancer research and drug discovery. AITRICS has published several papers at NeurIPS, ICML or ICLR that are top machine learning conferences. Before founding the companies, he worked at Samsung Electronics as a software engineer. He received his B.S. and M.S. in computer science from Seoul National University. His interest is applying AI to real-world problems.

Abstract: Deep learning describes a class of machine learning algorithms that learn patterns from data in end to end manners with minimizing feature engineering. These algorithms have recently shown impressive results across a variety of domains such as autonomous driving, speech recognition or machine translation. Biology and medicine are data-rich area, but the data are complex and often ill-understood. Hence, deep learning techniques may be particularly well suited to solve problems of these fields. I will introduce modern deep learning techniques and their applications to biomedical problems. Also, I will present their opportunities and challenges.



Decoding Multi-Omics based Big Data with BI/AI Solutions in Health Care

Xuefeng Bruce Ling, Ph.D.

Co-Founder, HBI Solutions

Dr. Ling is a founder of mProbe as well as a co-founder of HBI Solutions. He focuses on analytic solution development, including predictive modeling.

Dr. Ling is a principal investigator in the Department of Surgery at Stanford University School of Medicine, responsible for translational medicine efforts to deliver next-generation diagnostic devices and potential new therapies that clinicians will use for years to come. His computational lab currently focuses on novel statistical learning algorithm innovation, large-scale scientific computing and robust experimental design. He previously served as research director at Amgen & Tularik Inc. to tap the power of high-throughput biotechnologies and computational innovations to advance their drug discovery programs. As an executive function head, Dr. Ling contributed significantly to pharmaceutical development at Tularik Inc., which was acquired by Amgen for \$1.3 billion and gave Amgen access to a trove of potential medications for cancer and inflammatory diseases. Prior to that, he was associate director of research at DoubleTwist Inc., responsible for innovative genomic algorithm development and database architect for its flagship product.

Abstract: Emerging multifactorial diseases are usually with poorly defined etiology and pathogenesis mechanisms, of which the current diagnosis/prognosis is based on clinical signs and lacks sensitivity and specificity and carries a poor prognosis for adverse outcomes. Thus, there is a need to provide a definitive diagnosis/prognosis risk stratifications with the opportunity for better monitoring of the condition's progression and, thus, improved outcomes and economic benefits. One approach is to leverage high throughput biology data sets through analytics production to provide a more technically and bioinformatically tractable, physiologically relevant, chemically comprehensive, and cost effective assessment of multi-factorial non-communicable diseases. We have employed a comprehensive unbiased multi-'omics' approach, integrating big datasets of genomics, metabolomics, and proteomics to define the multi-omics molecular "portrait" and relative health risk against the population baseline. Another approach is the population risk analytics approach, integrating both structured and unstructured clinical information, to risk stratify the population to allow preventive or targeted care. Data-driven healthcare is defined as usage of big data, representing the collective learning in treating hundreds of millions of patients, to provide the best and most personalized care. Big-Data based BI/AI (Business Intelligence/Artificial Intelligence) in health care is starting to improve practice quality and outcomes, and reduce practice-induced adverse outcomes. We share the vision of innovating health care management at a lower cost through the disruptive Big-Data based solutions.

CONFERENCE ORGANIZERS



Luke YS Oh, Ph.D.

President, KAPAL

Over 14 years of experience in biopharmaceuticals for small molecules and antibodies. Worked as associate director at Questcor Pharma and Mallinckrodt Pharmaceuticals. Spearheaded immunology research group in Human Genome Sciences. Research scientist and council member at Vertex Pharmaceuticals. PhD in Neuroimmunology at McGill University and postdoctoral fellowship at UCONN.



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IRTA fellow, NIAID, NIH
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Ph.D. in Immunology and Microbiology, The University of Florida College of Medicine



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LL.M., Yonsei University
B.S., Yonsei University
Admitted in DC and MA



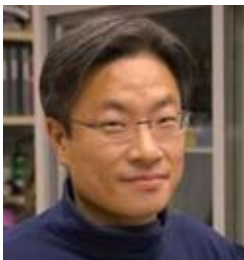
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Previously worked as Director, Clinical Research Marketing, Inc
Associate Director, KCRN Research, LLC
Team Leader, Bison Medical co., Ltd
MBA, Hood College



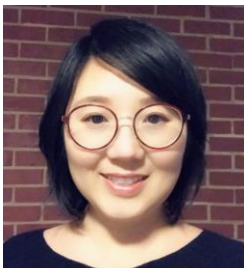
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Previously worked as Principal Scientist, G+FLAS Lifesciences
Postdoc & Research Fellow, NCI, NIH
Ph.D. in Biochemistry & Molecular Biology, Environmental Toxicology, Michigan State University



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Scientist, Kelly Government Solutions
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Scientist, Oncoplex Diagnostics
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Ph.D. in Biochemistry and Molecular Genetics, The George Washington University

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Principal Investigator, International Scientific Standard

FDA DMEP/OND/CDER

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Associate Professor, Oral Robert University Medical School

Ph.D. in Pharmacology, Ohio State University Medical School



Hae-Young Ahn; Ph.D., RAC

CEO & President, AhnBio Consulting, Inc.

Former Deputy Director, Division of Clinical Pharmacology, CDER, FDA

29 years of experience in US FDA

Postdoctoral training in pharmaceuticals at the University of Michigan

Ph.D. in pharmaceuticals from West Virginia University.



Hong-Woon Yang, Ph.D.

Senior Scientist, Sanofi

Over 16 years of experience in small molecule-based drug discovery

Previously worked at Array BioPharma, CoMentis, and GlycoMimetics

Postdoc, Johns Hopkins University

PhD in Chemistry, Texas A&M University

The 11th Annual Bioscience and Engineering Symposium, 2019



Date and Time: Sat, November 9th, 2019, 8:00 am – 6:00 pm
Venue: Institute of Bioscience and Biotechnology Research
9600 Gudelsky Drive, Rockville, MD 20850

Dear Participants of the 2019 ABES,

On behalf of the ABES 2019 Organizing Committee, I would like to welcome all of you to the 2019 Annual Bioscience and Engineering Symposium (ABES). ABES is an annual flagship event organized by the NIH-KSA (Korean Scientists Association) to promote scientific exchange and networking among Korean and Korean-American Scientists and Engineers in the Washington D.C. Metropolitan area and vicinity.

I am pleased that ABES 2019 will be held jointly with KAPAL Annual Conference (KAC) 2019. This year, we are honored to have three high profile keynote speakers, Prof. Hongkun Park (Harvard), Dr. John Schiller (NCI) and Dr. Johng Sik Rhim (formerly, NCI), and a special speaker, Dr. Chan-Mo Park (Pyongyang Univ. of Science and Technology). In addition, we have invited twenty young Korean-American Scientists and engineers to present their exciting research. We also have Table talk career discussions where seven established professionals will offer their career advice for young fellows. These career discussions will be led by Dr. Sue Goo Rhee (NHLBI), Dr. Chan-Mo Park (Pyongyang Univ. of Science and Technology), Dr. Hee-Yong Kim (NIAAA), Prof. Eun-Suk Seo (Univ. of Maryland), Dr. Luke Oh (President of KAPAL), Dr. Namcheol Kim (US Pharmacopeial Convention), and Dr. Yongsul Jeong (US Patent & Trademark Office).

Finally, I would like to thank the following sponsors who have provided generous support for the 2019 ABES and NIH-KSA monthly seminar series: KSEA (Korean American Scientists and Engineers Association), KUSCO (Korea-US Science Cooperation Center), KAPAL (Korean-American Professional Association in Life Sciences), Psomagen, and other private sponsors. I hope that the symposium will provide you with valuable opportunities for scientific exchange, collaboration and networking with other fellow scientists and engineers.

Kyung Sang Lee, Ph.D.
President of NIH-Korean Scientists Association

ABES 2019 Organizing Committee members

Chair: Kyung S. Lee, Ph.D. (NCI/NIH), **Co-Chair:** Jaewoo Choi, Ph.D. (NCI/NIH)

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Jung-Eun Park, Ph.D., NCI, parkju@mail.nih.gov

KEYNOTE SPEAKERS



Dr. Hongkun Park

Mark Hyman Jr. Professor of Chemistry and Professor of Physics
Harvard University

1990 B.S. Chemistry, Seoul National University, Seoul, Korea
1996 Ph.D. Chemistry, Stanford University, Palo Alto, CA
1996-1999 Postdoctoral fellow, Lawrence Berkeley National Laboratory

[Title: A Nanoscientist's Journey to Biomedical Research](#)



Dr. John Schiller (2017 Lasker Award recipient)

Deputy Chief, Distinguished Investigator, National Cancer Institute, NIH
1975 B.S. University of Wisconsin-Madison
1978 M.S. University of Washington
1982 Ph.D. University of Washington

[Title: HPV virus-like particles: Nature's nanoparticles for prevention and treatment of cancer](#)



Dr. Johng Sik Rhim

Former NCI investigator

1957 M.D. Seoul National University
Fellow, Children's Hospital Research Foundation in Cincinnati, OH
Fellow, Baylor University College of Medicine in Houston, TX

[Title: Advances in human cell models for the study of cancer: 50 years of human cell transformation](#)



Dr. Chan-Mo Park

Chancellor, Pyongyang University of Science & Technology

1958 B.S. Seoul National University, Seoul, Korea
1969 Ph.D. University of Maryland College Park
Former President of POSTECH

[Title: How computers changed my life](#)

2019 ANNUAL BIOSCIENCE AND BIOENGINEERING SYMPOSIUM

- 8:00-9:00 Registration and breakfast
- 9:00 Welcome remarks: NIH-KSA president
- 9:05 Welcome remarks: Mr. Young Jin Jang, Minister for Economic Affairs, Embassy of the Republic of Korea
- 9:10-10:00 Keynote Session I: Prof. Hongkun Park, Harvard University
Title: A Nanoscientist's Journey to Biomedical Research
- 10:00-11:00 Bioscience Session I, Chair: Dr. Jaewoo Choi, NCI
(5 short talks 10 min talk with 2 min Q & A)
- 11:00-11:08 Coffee break
- 11:08-12:20 Bioscience Session II, Chair: Dr. Youngchan Kim, NIAAA
(6 short talks, 10 min talk with 2 min Q & A)
- 12:20-1:30 Lunch (Table talk for career discussions)
- Dr. Sue Goo Rhee, *NHLBI/NIH, Former distinguished professor of Ewha Womans Univ and Yonsei Univ and First National Honor Scientist of Korea*
 - Dr. Chan-Mo Park, *Chancellor, Pyongyang Univ. of Science and Technology, N. Korea and Former President of POSTECH (Topic: Inter-Korean collaboration in Science and Technology)*
 - Dr. Hee-Yong Kim, *NIAAA/NIH, Chief, Laboratory of Molecular Signaling*
 - Prof. Eun-Suk Seo, *Univ. of Maryland, Department of Physics.*
 - Dr. Luke Oh, *President of Korean-American Professional Association in Life Sciences*
 - Dr. Namcheol Kim, *U.S. Pharmacopeial Convention*
 - Dr. Youngsul Jeong, *U. S. Patent and Trademark Office*
 - Dr. Sang M. Chung, *U. S. Food and Drug Administration*
- 1:30-2:15 Keynote Session 2: Dr. John Schiller, NIH distinguished investigator, NCI/NIH
Title: HPV virus like particles: Nature's nanoparticles for prevention and treatment of cancer
- 2:15-3:15 Bioscience session III, Chair: Dr. Jung-Eun Park, NCI
(5 short talks, 10 min talk with 2 min Q & A)
- 3:15-3:25 Coffee break
- 3:25-4:25 Bioengineering session I, Chair: Dr. Donghun Park, *Lab. for Physical Science/ Univ. of Maryland*
(5 talks, 10 min talk with 2 min Q & A)

- 4:25-4:55 Keynote Session 3: Dr. Johng Sik Rhim, Former Associate director, Center for Prostate Disease Research, USUHS
Title: Advances in human cell models for the study of cancer: 50 years of human cell transformation
- 4:55-5:15 Special session: Dr. Chan-Mo Park, Chancellor, PyongYang Univ. of Science and Technology, N. Korea and Former President of POSTECH
Title: How computers changed my life
- 5:15-5:30 Awards and closing remarks
- 6:00 ABES dinner

THE LIST OF SHORT TALKS

Bioscience Session I

Chair: Dr. Jaewoo Choi (NCI)

(5 speakers; each 10 min + 2 min Q&A)

1. Therapeutic potential of interleukin-22 in nonalcoholic steatohepatitis
Seonghwan Hwang, Ph.D., NIAAA
2. Patients with activating mutations in GNAI2 reveal a novel Gai2-mediated Ras regulatory mechanism augmenting T cell activation
Hyoungjun (June) Ham, Ph.D., NIAID
3. KLHL14 is a novel tumor suppressor gene in diffuse large B-cell lymphoma
Jaewoo Choi, Ph.D., NCI
4. M2-like, dermal macrophages are maintained via IL-4/CCL24 mediated cooperative interaction with eosinophils in cutaneous leishmaniasis
Sang Hun Lee, Ph.D., NIAID
5. Population variability in neurotoxicity outcomes modeled in vitro with diversity outbred neural progenitor cells
Dahea Yoo, Pharm.D., Ph.D., NIEHS

Bioscience Session II

Chair: Dr. Youngchan Kim (NIAAA)

(6 speakers; each 10 min + 2 min Q&A)

6. Micro/Nano mechanics and photonics for biomedical applications
Pilgyu Kang, Ph.D., George Mason University
7. MRI confirms large particle Nipah virus aerosol exposure in African green monkey mimics human neurological disease manifestation
Ji Hyun Lee, Ph.D., NIAID
8. Fructose-1,6-bisphosphate prevents pulmonary fibrosis by regulating extracellular matrix deposition and inducing phenotype reversal of lung myofibroblasts
Henrique Bregolin Dias, Ph.D., NCI
9. MicroRNA-mediated control of developmental lymphangiogenesis
Hyun Min Jung, Ph.D., NICHD
10. Naïve pluripotency supports differentiation of diabetic patient iPSC into vascular progenitors capable of superior engraftment and migration in the mouse ischemic retina
Tea Soon Park, Ph.D., NEI
11. Functional rather than architectural role of mammalian mediator in Promoter-enhancer interaction
Seolkyoung Jung, Ph.D., NIAMS

Bioscience Session III

Chair: Dr. Jung-Eun Park (NCI)

(5 speakers; each 10 min + 2 min Q&A)

12. A mutation in CCDC53 affects PTH/PTHrP receptor trafficking and impairs skeletal growth, causing disproportionate short stature
Youn Hee Jee, M.D., NICHD
13. An inherent self-assembling capacity of pericentriolar coiled-coil proteins drives the formation of a nanoscale cylindrical architecture at human centrosomes
Jong il Ahn, Ph.D., NCI
14. Aldh2 deficiency promotes alcohol-associated liver cancer by activating oncogenic pathways via oxidized DNA enriched extracellular vesicles
Won Hyo Seo, D.M.V., Ph.D., NIAAA
15. Deficiency of hepatic cannabinoid 1 receptor (CB1R) ameliorates fatty liver and improves glucose homeostasis via regulation of PI3K-mTORC1 axis
Yoo Kim, Ph.D., NIA
16. Cockayne syndrome group B deficiency reduces H3K9me3 chromatin remodeler SETDB1 and exacerbates cellular aging
Jong-Hyuk Lee, Ph.D., NIA

Bioengineering Session I

Chair: Dr. Donghun Park (Univ. of Maryland)

(5 speakers; each 10 min + 2 min Q&A)

17. Noninvasive optical measurement of microvascular cerebral blood flow in children with sickle cell disease
Seung Yup Lee, Ph.D., Georgia Institute of Technology/Emory University
18. Deep learning-based subcellular phenotyping of cell edge dynamics reveals fine differential drug responses
Kwonmoo Lee, Ph.D., Worcester Polytechnic Institute
19. Biliary and urinary-specific NIR fluorescent dyes for image-guided surgery
Jaemyeong Cha, Ph.D., George Washington University School of Medicine and Health Sciences
20. 3D printing technology for bioengineering applications
Byungseok Yoo, Ph.D., University of Maryland, College Park
21. Laser based imaging systems for microscopy
Yung Jun Yoo, Ph.D., Thorlabs Imaging Systems

PAST PRESIDENTS

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1990	Dr. Johng Sik Rhim
1991	Dr. Johng Sik Rhim
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2014	Dr. Byung-Kook Lee
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BROOKLYN, NEW YORK

CAMBRIDGE, MASSACHUSETTS



Tera: 10¹², a lot of

Immune: immune cells, Treg

TeraImmune, Inc is a pre-clinical stage immune cell therapeutics company based in Rockville, Maryland. TeraImmune focuses on the development of the **regulatory T cell (Treg) therapy** in **hemophilia A (HA)** with FVIII anti-drug antibody (ADA).



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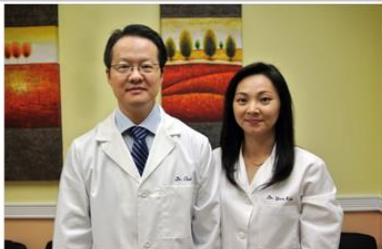
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진료분야: 모든 일반내과 질환의 진단 및 치료 전공 & 경력: 일반내과, 서울의대 졸업, Providence Hospital 내과 전문의 수료, 워싱턴 Hospital Center, 종양학(각종 암) 및 혈액학 전공, 미국 내과 전문의 (American Board Certified in Internal Medicine)

Choi & Koh Chiropractic Clinic

최근봉 & 고유라 척추신경 클리닉



Dr. Choi

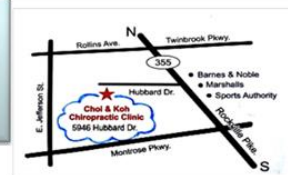
Dr. Koh

EVALUATION

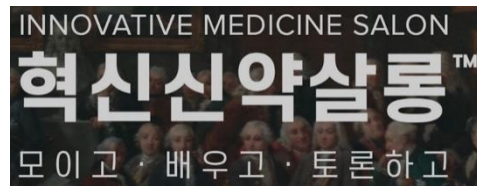
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COREE THERAPEUTICS PROGRAM

ROME, ITALY

- COREE THERAPEUTICS R&D Center
- AAT Advanced Analytical Technologies

BEIJING, CHINA

- COREE THERAPEUTICS R&D Center
- Ofmom China Factory nutritional food and research

LOS ANGELES, USA

- COREE THERAPEUTICS Center

SEOUL, KOREA

- Hanmi Fine Chemical
- COREE THERAPEUTICS R&D Center
- Hanmi R&D Center

Program Features:

- CENTER
- APP
- Conventional diagnostics and multi omics - data generation
- Data integration into global Biobank and COREE Algorithm powered by AI
- COREE EXPERT GROUP
- Onsite / Remote Connected platform with supply

Health science is in our DNA.

Maryland leads the world in adult stem cell production and vaccine development, is home to the NIH, FDA, NIST, and has the largest concentration of employed doctoral scientists and engineers in the nation. Let's talk business.

Open. [Maryland.gov/biohealth](https://www.Maryland.gov/biohealth)



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NEW DRUG · FOOD · COSMETIC · MEDICAL DEVICE · CHEMICAL AND PESTICIDE

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High - Quality Services

Chemon's services were formally approved by MFDS, RAD and NIER.

• Safety Evaluation

- General Toxicity Study
- Reproductive and Developmental Toxicity Study
- Genetic Toxicity Study
- Antigenicity Study
- Immunotoxicity Study
- Carcinogenicity/Tumorigenicity Study
- Local Toxicity Study
- Safety Pharmacology Study
- **Cosmetic Alternative Toxicity Study**
- **Ecotoxicity Study**
- **Medical Device Toxicity Study**

• Efficacy Evaluation

- Anti-cancer
- Metabolism
- Digestion System
- Immunity
- Nerve System
- Menopausal Disorder
- Pollutants Eliminator
- Internal Organs
- Beauty & Health

• Bioimaging Services (CT, micro CT, C-arm, X-ray, etc.)



• HEAD OFFICE

Tel : +82-31-888-6633~4 / Fax : +82-31-888-6640
15F, Gyeonggi Bio Center, 147, Gwanggyo-Ro, Yeongtong-Gu, Suwon, Gyeonggi-Do, 16229, S.Korea

• NON-CLINICAL RESEARCH INSTITUTE

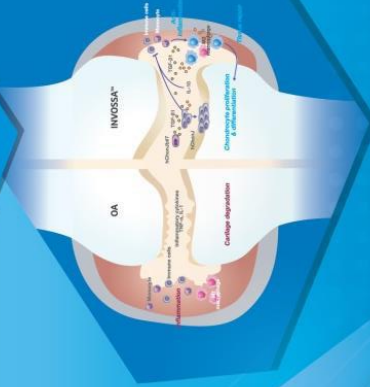
Tel : +82-31-329-9900 / Fax : +82-329-9901~2
240, Nampyeong-Ro, Yangji-Myeon, Cheoin-Gu, Yongin, Gyeonggi-Do, 17162, S.Korea

• CHUNCHEON BIO RESEARCH CENTER

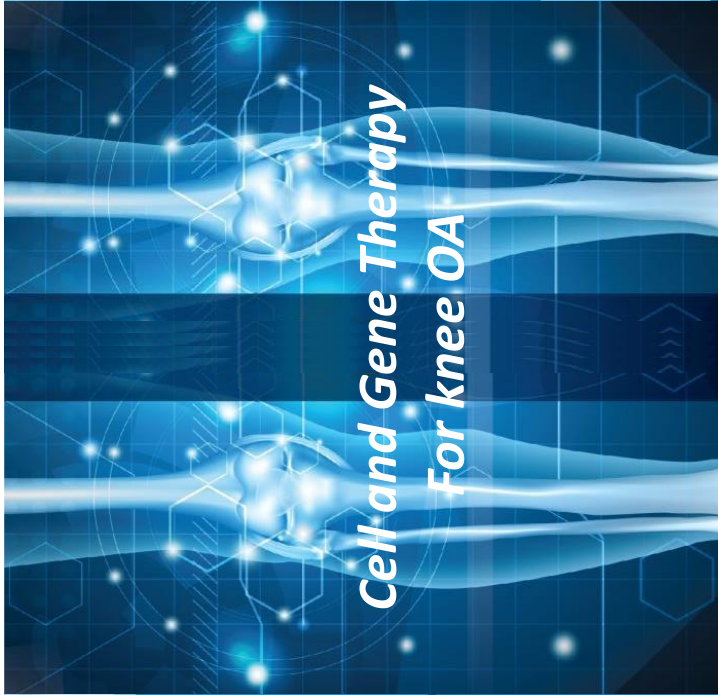
Tel : +82-33-258-6651 / Fax : +82-33-258-6650
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For knee OA

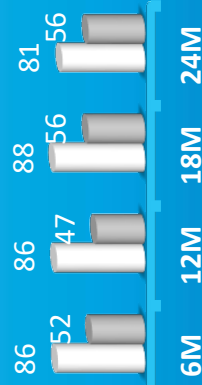


Intra-articular
Single Injection

Sustained efficacy
over 2 years

Achieved 80~85%
response rate

■ INVOSSA ■ Placebo



[OMERACT1-OARSI]² RESPONSE RATE (%)

Source: US Phase II Clinical Trial (TGC09201)

1 OMERACT: Outcome Measures in Rheumatology

2 OARSI: Osteoarthritis Research Society International



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“미동부 최대 규모의 젊고 우수한 글로벌 인재 커뮤니티”

NYKB는 미동부 뉴욕지역에 위치한 10개 대학 및 연구소의 한인 생명과학자들로 구성된 비영리 단체입니다. 2019년 기준 약 170명의 우수한 인재 (91% 포닥)들이 활발하게 활동 중이며, NYKB 정기 학술학회, 월례세미나 지원, 채용설명회 개최 등 다양한 학술 및 인적 네트워킹을 도모하고 있습니다. NYKB는 한국의 미래 생명 과학을 이끌어가고 있는 실질적인 글로벌 인재풀인 동시에, 미동부 최대 규모의 우수한 젊은 한인과과학자 커뮤니티로 성장해 가고 있습니다.

< NYKB 소속 대학 및 연구소 >

Albert Einstein College of Medicine / Columbia University / Weill Cornell Medical College
Icahn School of Medicine at Mount Sinai / New York University / Rutgers University / Rockefeller University
Stony Brook University / Cold Spring Harbor Laboratory / Memorial Sloan Kettering Cancer Center

“NYKB 인재 채용 홍보 지원 서비스”

- NYKB 회원들 대상 채용 정보 이메일 발송
- NYKB 홈페이지 및 공식 Facebook에 채용 관련 안내문 게시
- 뉴욕 현지 면접 및 채용 설명회 개최를 위한 장소 섭외 및 홍보
- NYKB 정기 학술학회에서 채용 설명 시간 배정 및 채용상담부스 제공
- NYKB 정기 학술학회 프로그램북 내 인재 채용 홍보페이지 제공



2019 NYKB Conference
LG화학생명과학연구소 채용설명회



2019년 5월 GC 녹십자 채용면접/설명회

“최근 3년 채용설명회 개최 내역”

2019.06.13	성균관대학교 총장 주재 간담회 (Weill Cornell Medicine)
2019.05.29	GC 녹십자 채용면접/설명회 (Rockefeller University)
2019.04.27	LG 화학 생명공학연구소 면접/채용설명회 (Manhattan)
2018.07.31	DGIST 우수 인재 초청간담회 개최 (Rockefeller University)
2018.06.04	KIST 채용설명회 개최 (Rockefeller University)
2017.10.10	연세대학교 의과대학 채용설명회 개최 (Rockefeller University)

NYKB Website: <http://www.nykb.org>

NYKB E-mail: nykb2008@gmail.com

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L&J BIO'S GOAL IS TO DEVELOP A PROTEIN THERAPEUTICS
FOR DISEASE MODIFYING IN A VARIETY OF NEUROGENERATIVE
DISEASE BASED ON THE DUAL ACTION THERAPY (DAT) PLATFORM.



L&J Bio



JOIN OUR TEAM: BRIDGE BIOTHERAPEUTICS

경기도 판교에 위치한 신약개발 전문기업, 브릿지바이오테라퓨틱스에서 함께할 인재를 모집합니다. 저희는 신약 과제를 초기 도입하여, 전임상 및 임상 개발을 진행한 후 기술수출하는 사업모델(NRDO)을 가진 바이오텍입니다. 최근 BBT-877 과제를 Boehringer Ingelheim사에 총 1조 5000억규모로 기술수출하는 가시적인 성과를 거둔 바 있습니다.

Bridge Biotherapeutics, Inc., a clinical-stage biotech company based in Pangyo, South Korea is dedicated to turning our cutting-edge innovations into breakthrough therapeutic options that would address highly unmet medical needs for patients around the world. Recently, Boehringer Ingelheim picked up one of our assets, BBT-877, for \$1.4 billion, which is the largest license deal in the Korean biotech industry.

1. Biology / Pharmacology : No Wet-lab Work

- 타겟 검색, 약효 평가, 약리기전 연구
- 생명과학 및 약리학 전공자 (박사이상)
- 영어 능통자 우대, 제약사/바이오텍 업무 경험자 우대
- Project Leader로 내부 연구소 및 외부 CRO와 협력 과제 진행

2. 원료 의약품 개발 및 생산관리 : No Wet-lab Work

- 약학, 화학 등 관련 전공 석사학위 이상 소지자
- 의약화학 또는 유기합성 관련 분야 3년 이상 경력자
- 연구소 경력 우대
- 영어 speaking, writing, reading 가능자/능통자 우대
- Project Leader로 내부 연구소 및 외부 CRO와 협력 과제 진행

3. 완제 의약품 개발 및 생산관리 : No Wet-lab Work

- 약학, 화학 등 관련 전공 석사학위 이상 소지자
- 제제관련 분야 3년 이상 경력자
- 연구소 경력 우대
- 영어 speaking, writing, reading 가능자/능통자 우대
- Project Leader로 내부 연구소 및 외부 CRO와 협력 과제 진행

브릿지바이오테라퓨틱스
공식 홈페이지



기술이전 및 각종 소식

회사에 대한 자세한 사항은 공식 홈페이지를 참고해주시기 바라며, 금번 인재 채용 관련 궁금하신 사항은 제 5회 KAPAL 연례회의 키노트 발표에 참가하시는 **브릿지바이오테라퓨틱스 이용희 박사**님께 문의 부탁드립니다.

For more detailed information, please visit our website or you may also contact **Dr. Yong-Hee Lee** from Bridge, who will be on a keynote speech at the conference. (Yong-hee.lee@bridgebiorx.com)



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PLATFORM & DEVELOPMENT, KIAT



4차 산업혁명 시대 중소·중견기업의 글로벌 시장 진출을 위해
산업기술 정책수립, R&D 지원, 기술사업화, 글로벌 수출로 이어지는
전주기적 종합지원으로

기업에 실제 도움이 되는 비즈니스 모델을 창출하고
혁신적 산업기술 생태계를 구축합니다.

기술강국 대한민국, Platform & Development (P&D)
KIAT가 실현해 가겠습니다.

KIAT 한국산업기술진흥원



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database of 50 million patients
with 5 years clinical history.



PROBLEM

Healthcare is reactive with
a focus on treating
existing diseases



SOLUTION

Shift to population screening
and precision molecular
diagnostics

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with Hyleukin-7™ and Beyond

Hyleukin-7™: The Only Clinical Stage Long-Actin IL -7



- Overcomes key limitations of rIL-7 through extended half-life and less frequent dosing
- As a key T-cell amplifier, Hyleukin-7™ invigorates the immunity to overcome many known limitations of current therapeutics
- Well tolerated safety profile and ideal clinical dosing interval for combination therapy
- Partnered with leading I-O players for combination clinical trials with approved checkpoint inhibitors

Uniquely positioned to address unmet medical needs in Immuno-Oncology

Hyleukin-7™ Development Pipeline

Product	Development Stage			
	Preclinical	Phase 1	Phase 2	Phase 3
Oncology				
Monotherapy	Single Dose – GBM Ph1b/2a			
	Multiple Doses – GBM Ph1b/2a			
Checkpoint Inhibitor Combinations	Pembrolizumab ¹ - Triple Negative Breast Cancer (TNBC) Ph1b/2a			
	Atezolizumab ² - High risk skin cancers (MCC, cSCC, Melanoma) Ph1b/2a			
CAR-T Combinations				
Infectious Diseases				
Monotherapy	Idiopathic CD4 Lymphocytopenia – Orphan Designation			
	Adjuvant with Vaccines - Elderly Cancer Survivors			
Additional Development				
Monotherapy	Acute Radiation Syndrome			

1. Clinical Trial Collaboration with Genexine and Merck, 2. Clinical Trial Collaboration with Roche



Core Values of KOTRA



【 Customer 】
KOTRA puts itself in its customers' shoes and provides services they want and need.



【 Challenge 】
KOTRA achieves ongoing innovation through creativity and passion. It creates new markets and a better future.



【 Service 】
KOTRA champions responsible and ethical management. Through sacrifice and service, it leads in the way of social contribution and the creation of strong economies.



【 Global 】
KOTRA strives to become a global leader by developing globally minded human resources and creating global networks and business systems.

SAMSUNG BIOEPIS

Passion for Health

Samsung Bioepis is a biopharmaceutical company focused on increasing patient access to high-quality medicines through the development of biosimilars.

