

The 1st Korean American Medical Devices Association

KAMDA Conference

October 23, 2025

2025 KAMDA PROGRAM

Registration & Networking

09:30 AM ~ 10:30 AM **Registration** (Reed Smith Conference room)

Opening Remarks

10:30 AM ~ 11:00 AM

Welcome Remark

HeaYeon Lee, Ph.D. (CEO MARA Nanotech, Vice President KAMDA)

Congratulatory Remark

SeongSoo Kim (Consulate General of the Republic of Korea, New York)

SoonMahn Park (Head of Korean Health Industry Development Institute, Boston Office)

SungWoo Baek (Director of New York Global Business Center, Korea SMEs & Startups Agency)

MyeongSeon Kim (Director of Korea Venture Investment Corp., New York office)

Group Photo

Opening Plenary Session

11:00 AM ~ 11:20 AM

HeaYeon Lee, Ph.D. (CEO MARA Nanotech, Conference Chair KAMDA) "Technology Trends and Market Status of Biosensors in U.S."

11:20 AM ~ 12:00 PM

Keynote Speech

YoungHo Choi (Chairman Access Bio, Co-Chair KAMDA) "Significance of KAMDA Establishment & Success Case in the U.S Market (AccessBio)"

12:00 PM ~ 01:00 PM Lunch Time

Session I "Strategies and FDA Considerations for U.S. Market Entry"

01:00 PM ~ 01:40 PM

Special Session I

Haja Sittana El Mubarak, Ph. D. (Wasela Diagnostics LLC) "FDA Trends & Global Regulation Insights"

01:40 PM ~ 02:00 PM

ByungSik Chang, Ph.D. (CEO Nano-Ditech, Co-Chair KAMDA) "FDA Approval Strategies and Success Cases"

02:00 PM ~ 02:20 PM

JungYoup Han, Ph.D. (CSO Target Health, Treasurer KAMDA) "FDA Preparation and Approval Strategy (CRO)"

02:20 PM ~ 02:40 PM

Sung Park (Reed Smith) "Appropriate Risk Allocation in the FDA World"

02:40 PM ~ 02:50 PM Coffee Break

Session II "U.S. Market Entry Strategy and Insights"

02:50 PM ~ 03:30 PM

Special Session II

MinSoo Seo (CEO Taewoong Medical USA) "Understanding the U.S. Healthcare Insurance System (Reimbursement system)"

03:30 PM ~ 03:50 PM

JungHee Cho, Ph.D. (CEO LabG USA, Executive Secretary KAMDA) "Market Entry Strategy for the U.S. (Applications of LDT and CLIA Lab)"

03:50 PM ~ 04:10 PM

Curie Choi (Director Immunostics, Operations Committee KAMDA) "Market Entry Strategy for the U.S. (Case Studies of U.S. Local Company Acquisitions)"

04:10 PM ~ 04:30 PM

Eunjean Je (Morgan, Lewis & Bockius LLP) "Understanding IP and Compliance"

Sponsored Session

4:30 PM ~ 5:15 PM

05:15 PM ~ 05:30 PM Coffee Break

Panel Session "U.S. Market Entry and Medical Device Market Strategy"

05:30 PM ~ 06:30 PM

Panel Discussion

Moderator: HeaYeon Lee, Ph.D. (CEO MARA Nanotech)

Panels: Minsoo Seo (CEO Taewoong Medical USA) / **YoungHo Choi** (Chairman Access Bio) / **ByungSik Chang, Ph.D.** (CEO Nano-Ditech)

JungHee Cho, Ph.D. (CEO LabG USA) / **JungYoup Han, Ph.D.** (CSO Target Health)

06:30 PM ~ 06:40 PM Closing ceremony

06:40 PM ~ 08:30 PM Dinner & Networking