



China Workshop

Challenges and Opportunities of IVD Market Entry

A value-added workshop for AACC exhibitors

organized by

AACC Clinical Lab Expo

and

The U.S. Commercial Service

As an extension of the international programs and export assistance activities associated with the Clinical Lab Expo, we are pleased to announce this China workshop for Expo exhibitors that are considering or currently exporting to China. The Chinese IVD market is challenging, perplexing and full of potential for IVD companies. Here are some facts:

- China is spending \$120 billion this year to establish universal healthcare coverage
- China will build 400 hospitals per year for the next 10 years
- The China IVD market grew by 25-30% in 2009
- The China IVD market is estimated at \$2.0 billion
- The China IVD market will grow 15%-20% per year for the next five years
- By 2015 (or earlier), China will be the third largest IVD market in the world
- 50% of IVD sales in China are from foreign companies.

Learn about the following at this complimentary workshop:

- U.S. Department of Commerce/U.S. Embassy Support
- Chinese markets, hospital categories and IVD growth statistics
- Different classes of Chinese clinical laboratories via a photo tour
- The Chinese regulatory and device approval process
- Traveling to China and familiarizing yourself with the Chinese culture

Please see the agenda below for the speakers' topics and abstracts.

There is no charge for the China Workshop, however, you must be an AACC exhibitor to register.

All exhibitors are welcome. Space is limited, please limit reservation to two persons from per company.

Register online: [China IVD Workshop Registration](#)

Workshop Agenda

China: Challenges and Opportunities of IVD Market Entry

Anaheim California, July 26, 2010

1:00-3:00 PM

1:00 PM

Moderator

Jennifer Loffredo, Global Health Care Team Leader
U.S. Commercial Service, U.S. Department of Commerce

Bio

Jennifer Loffredo is an International Trade Specialist with the US Commercial Service, which is a part of the International Trade Administration of the US Commercial Service. She joined the US Commercial Service in 1997. In the fall of 2007, Jennifer was appointed to be the US Commercial Service's Global Healthcare Team Leader. In this position, she manages a worldwide team of domestic and international trade specialist that cover the medical industry. Before relocating to Michigan, Jennifer was a native to Arkansas. Jennifer earned her B.A. in Psychology with a focus in Neuroscience from Vanderbilt University in Nashville, Tennessee.

1:05

Welcome from China

Speaker TBA
Principal Commercial Officer Beijing, Health Care Market
U.S. Embassy Beijing, Commercial Section

1:20

U.S. Department of Commerce Support Capabilities for China Entry

Kelly Holloway-Jarman, China Business Information Center
U.S. Commercial Service, U.S. Department of Commerce

Abstract

For U.S. companies, the U.S. Commercial Service provides many support, introductory and due-diligence services to enable successful market entry. Ms. Jarman will provide map of these services and how to access them.

Bio

Kellie Holloway-Jarman is the Project Director for the U.S. Department of Commerce's China Business Information Center, the federal government's most comprehensive information resource for exporting to China. Following her 2004 departure from the American Embassy in Beijing, China, she was asked to direct a national China outreach and trade promotion campaign for the U.S. Commercial Service. In this capacity, she liaises with six offices in China, Washington DC, and the 108 US district offices of the Commerce Department. This effort evolved into the establishment of the China Business Information Center where Kellie manages its web content, export counseling services and educational outreach programming.

Ms. Jarman has a BSBA in Marketing from the University of Arizona supplemented with course work from the University of Copenhagen and a MBA in International Management from Thunderbird School of Global Management.

1:40

Overview: China IVD Business Outlook

Nat Whitney: Whitney Research, Beijing, China

Abstract

The Chinese IVD market has been growing at a rate of 25% for the past several years and is expected to grow 15-20% each year for the next five years. Discussed here will be where the opportunities and steps to successful market entry or expansion

Bio

Nat Whitney, owner and President of Whitney Research, has over 40 years of experience in all facets of the IVD industry. His long history in China dating back to 1983, when he was the Asia Technology Marketing Manager for Corning Glass Works, Medical Division. He held numerous management positions in R&D, manufacturing, and international marketing at Ciba Corning Diagnostics/Chiron/Bayer/Siemens. Whitney Research is exclusively focused on the China IVD market, providing general and customized market research for manufacturers, major research firms, investment groups and NGOs. His clients include Goldman Sachs, Gerson Lehman Group, the Bill & Melinda Gates Foundation, Foundation for Innovative New Diagnostics and some of the leading manufacturers in the IVD industry in US and Europe. Nat also presented at numerous conferences hosted by Gerson Lehman Group, CMEF and AACC.

2:10

Photo Tour through City Class III, Class II and Class I Clinical Laboratories, Community Health Centers, and County, Township laboratories down to the village clinics

Nat Whitney: Whitney Research. Beijing

2:20

China Regulatory Requirements for IVD Products

Chang-Hong Whitney, Principal

Whitney Consulting, Boston

Abstract

To gain access to Chinese market, foreign companies must follow the SFDA approval process. Provided in the presentation will be the step-by-step process to gain SFDA approval

Bio

Chang-Hong Whitney has spent over 20 years in the medical device industries in both China and the US. She began to consult for international medical companies since 1994. In recent years, she has been focusing on the Chinese regulatory affairs and compliance. She has been presenting in various industrial and professional conferences such as Regulatory Affairs Professional Society Annual Conference, Florida International Medical Expo, Asia Pacific Regulatory Conference, AACC and CMEF. Mrs. Whitney also hosts the China Column on Medical Product Outsourcing Magazine and Regulatory Affairs Journal. Mrs. Whitney holds MBA from Babson College and undergraduate degrees in electrical engineering and international business. She is a member of Regulatory Affairs Professional Society (RAPS) and a member of the regulatory affairs certification board. She is on the Healthcare Council of Gerson Lehman Group, providing assessment to financial institutions interested in the Chinese medical market.

Whitney Consulting is exclusively focused on China regulatory affairs on medical device and operates from their offices in Beijing and Boston.

2:40

Moderator

Jennifer Loffredo, Global Health Care Team Leader
U.S. Commercial Service, U.S. Department of Commerce

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