

Resume

# Name: Davey Dehui Han

Phone: (8610) 64813589 (home), 13501126282 (mobile)

Email: davey.han@biohanconsulting.com; davey\_dehui\_han@263.net

**EDUCATION:**

9/93 - 6/95 **Master of Science: Health Economics and Policy**

 University of Minnesota, with scholarship of the World Bank Economic

 Development Institute.

7/95- 4/97  **Post-Doctorate Associate: Epidemiology & Clinical Research,**

University of Minnesota Hospital, Dept. of Epidemiology and Clinical Research, USA.

9/79 - 7/84 **Medical Doctor: Preventive Medicine**

 Tongji Medical University, China

**WORK EXPERIENCE**

**10/2013- present: BioHan Biotechnology Consulting (Beijing) Co Ltd**

* **Founder and President, BioHan Consulting**
* **Head of China Operation for Brandwood biomedical as partner**
* Provide consultancy on strategy for product market approval to medical device & diagnostic (MD&D) companies; and manage type test and clinical trials for product pre- market approval for China.
* Help device manufacturers to submit for pre-market approval for China market, and act as legal representative authorized for ensuring post-market compliance
* Study and analysis on market intelligence, government healthcare policy & relevant regulations, summarize and report the study results & impact of new policies on medical market for medical device industry group and provide recommendations to the MD&D companies.
* Speaker/presenter invited to various conference or forums, recently such as CIMDR(China International Medical Device Regulatory Forum), Asia Pacific Device Summit, Minimum Invasive Medical Forum, China MD&D Clinical Trial Leader Summit, Webinar of US Embassy Commercial Service, as well as the drug and device companies.

**11/2010-10/2013: IMS Market Research & Consulting Co. Ltd**

**(the largest consulting firm in healthcare services**

* + - * + **Director,** Government & External Affairs
				+ **Director General,** IMS China Institute for Healthcare Informatics
				+ **China Consultant**, U.S. Medical Imaging Technology Alliance

 **Government Relations**

* Created IMS partnership & relations with government departments related to pharmaceutical and medical device industry, including MOH, SFDA, NDRC, MOFCOM, MIIT, MOFHRSS(16), as well as provincial authorities
* Joined establishment of IMS China Institute, organized / Hosted IMS Seminar on Application of Healthcare Informatics and Economics Research in Policy Making, which was attended by all relevant government depts., pharmaceutical & medical device industry associations.
* Sponsored and coordinated high level officials including Minister of Health to attend the America-China Health Summit at Harvard. Joined planning of IMS speaking to the summit.

**Government Policy & Regulations Involvement, Sponsor for Health Policy Research**

* Attended govt’s meeting on draft regulation or guideline related to drug and medical device pre-market and post-market surveillance and adverse event reporting;
* Provided information and data analytic results to Ministry of Commerce to involve in policy making process, related to international practices of drug distribution channels, market shares between hospitals and retail pharmacies.
* Planned and hosted IMS training session on Evidence Based Policy Decision for SFDA Information Center, as well as joined by Test & Inspection Institute and Drug Evaluation Center.
* Led eight (8) research projects of IMS Institute in health economics, drug policy, health insurance and healthcare reform assessment in cooperation with WHO, gov’t institutions and academies

**Support Healthcare Industry Business**

* Planning and leading the IMS training program of IMS Institute on Pharmaceutical Business Management and Development for industry top executives, in cooperation with Peking University
* Leading IMS initiative to organize the serial roundtables (close-door) of high-level gov’t official and industry executive on prospective healthcare policy topics, in collaboration with Shanghai Health Authorities & Fudan Hospital Management Institute
* Discussing cooperative training program with MofHRSS on medical insurance management for gov’t officials
* As consultant to MITA, leading China initiatives to influence gov’t policies & regulations, and organizing workshop on harmonization of product technical standards of medical devices.

**5/2005 – 10/2010:** **Siemens China Ltd. Healthcare Sector, Beijing**

* + - * + **General Manager,** Regulatory Affairs and Quality Management (5/05-12/07)
				+ **Director,** Government & Key Customer Relations (01/08-05/10)

 **Roles in Associations:**

* + - * + **Co-Chair,** Asia Harmonization Working Party in Medical Device Regulation (05/05-06/08)
				+ **Co-Chair,** Medical Device Working Group, EU Chamber of Commerce (05/07-05/10)
				+ **SubGroup Chair**, WG5 Clinical Investigation, Asia Harmonization Working Party(5)

**Government Relations**

* Developed, maintained and managed relationship with government authorities including SFDA(1), MOH(2), CQC(3), AQSIQ(4), Ministry of Commerce, National Development and Reform, Ministry of Industry and Information Technology, Ministry of Science and Technology, Shanghai CIQ, SH FDA.
* Communicated with government technical reviewers and key medical opinion leaders for product regulatory approval, and manage to speedup priority product registration.
* Attended SFDA meetings to discuss SFDA regulation (revision) of medical device & IVDs registration, Involve in development process of SFDA technical evaluation guidance for imaging diagnostic and clinical test products.

**Pre-Market Approval of Medical Devices**

* Built up, coached and managed the RA&QM team responsible for product market approval (SFDA registration and China Compulsory Certification) of all Siemens Med products in China.
* Made strategic plan for medical device registration and certification in cooperation with business groups; created scoreboard for product submission and progress monitoring; discussed with RA managers and specialists on weekly base to get solution for outstanding issues in product registration /certification; and interacted with business managers at weekly Business Improvement Team meeting.
* Created Siemens Guidance for Medical Device Pre-market Approval Requirements and Process in P.R. China, as well as Siemens Guidance for Labeling Requirements in China.
* Guided pre-market clinical studies for Immunological and diagnostic products including class III IVD regents for infectious diseases and tumors.

**Quality Management and Post-Market Surveillance**

* Led joint effort to deal with regulatory challenges in product inspection and post-market surveillance, and communicate with government authorities to handle product compliance issue and customer complaint, advised quality team to report adverse event to the authorities and involve in product re-evaluation process.
* Directed establishment of Standard Operating Procedures in RA&QM according to government regulations and Siemens Med requirements. Guided development of SOP for post-market surveillance, adverse event reporting, and Common Complaint Handling in China.
* Coordinated auditing of authorities to Siemens manufacturing operations and Customer Service organization; Achieved “Business License for Medical Device Distributor” from SFDA.
* Joined Siemens Med Quality Board as China-Med Quality Representative to discuss global quality documents and analyze the Metrics for Quality Statistics.

**Industry Associations and Policy Analysis**

* Represented Siemens with the industry/trade associations including AmCham(10), AdvMed(11), EUCCC(12), COCIR(13), NEMA/MITA(14), and CAMDI(15). Co-Chaired EUCCC Healthcare Working Group and also Co-Chaired AHWP (2005-2008).
* Monitored changes and trends in government regulation and policies related to product market access, provided regulatory advice to R&D team to help product commercialization, and provided top management with Healthcare Government Monthly Report.
* Led Industry Group (EUCCC, COCIR) to communicate with government authorities in medical device administration, pricing policy, health care reform, government procurement regulations.
* Conducted AHWP(5) Annual Survey on Regulatory Framework and report the survey results to AHWP annual conference, and as Subgroup Chair, lead AHWP Working Group of Clinical Investigation, and be active in Technical Committee of AHWP as the Primary Industry Representative of China.

**5/1997 – 4/2005: ST. JUDE MEDICAL, INC. BEIJING REP OFFICE**

* + - * + **Analyst,** Marketing & Clinical Research (1997-1998)
				+ **Manager**, Regulatory Affairs & Clinical Research (1999-2003)
				+ **Senior Manager**, Asia Regulatory Affairs (2003-2005)
				+ **Chair**, AmCham Medical Device Forum (2000-2002)

* Directed product regulatory team for product registration; Developed product licensing plan & strategy with marketing team; Managed product registration with SFDA and CCC certification with AQSIQ;
* Was responsible for regulatory compliance including product quality tracking;Coordinated the audit by Chinese authorities to Manufacturing Quality Systems worldwide;
* Guided development of operation procedures & policies, as well as quality management documents of St Jude Medical Ltd in China;
* Supported and coordinated product tendering activities, and helped with tendering strategy & filing;
* Managed price submission to authorities, and communicated with the price authorities in pricing policy-making;
* Managed clinical study projects in cooperation with medical key opinion leaders, and facilitated KOLs’ participation and presentation at academic symposium;
* Conducted post-market clinical studies, and developed clinical databases for patient’s follow-up and clinical outcome research, and presented studies at academic symposium;
* Observed and monitored medical business environment changes in regulations, policies, and reported to Asian Operation and the U.S. headquarters;
* Developed and maintained working relation with government departments (including MOH, SFDA, AQSIQ, NDRC(6) & CQC), medical institutions, test bodies and medias;
* Wrote and promulgated alert or advisory notice to employees when company was involved in urgent event or crisis. Response to media as/if authorized by company.
* Led AmCham-China Medical Device Forum in regulatory topics, as chairman of Medical Device Forum, China-American Chamber of Commerce.

**01/1991 - 09/1993**: **MOH HEALTH ECONOMICS INSTITUTE**

The Ministry of Health, Beijing, China

* + - * + **Division Director,**
				+ **Coordinator of Training & Research Network**
* Designed and conducted study on health care reform for urban employees in China. (The study was funded by the Ministry of Health and the World Health Organization).
* Summarized and evaluated international healthcare insurance systems in different countries. Provided the final report with recommendations to the Ministry and the Research Department of the State Council.
* Customized health expense components and developed the method to estimate health care expenses per capita in China.
* Coordinated the research and training activities of China Network for Research and Training of Health Economics, in cooperation with the World Bank Economic Development Institute.
* Communicated on cooperative training and research activities as liaison between the China Network of Health Economics and the Economic Development Institute of the World Bank.

**08/1984 - 12/1990: THE DEPARTMENT OF IMMUNOLOGY & BIOTECHNOLOGY**

**RESEARCH**

**THE DEPT OF HEALTH POLICY AND MANAGEMENT**

**Chinese Academy of Medical Sciences, Beijing, China**

* **Assistant Research Professor**
* Joined Bio-medical technology and Immunology research projects, and developed the R&D Database of China Bio-Technology in collaboration with Ministry of Health;
* Participated in academic team responsible for designing and analysis the national survey on health service demands of urban population;
* Searched and translated information representing the most updated research outcomes in foreign Immunology and Biotechnology, and provided the summaries to health care policy makers.
* Represented Chinese Ministry of Health to attend a WHO’s workshop on health services research in Malaysia.

**Notes:**

(1) SFDA: State Food and Drug Administration

(2) MOH: Ministry of Health

(3) CQC: China Quality Certification Center

(4) AQSIQ: General Administration of Quality Supervision, Inspection and Quarantine of P.R. China

(5) AHWP: Asian Harmonization Working Party for medical device regulation and standardization

(6) NDRC: National Development and Reform Commission

(7) MIIT: Ministry of Industry and Information Technology

(8) MOST: Ministry of Science and Technology

(9) MofCom: Ministry of Commerce

(10) AmCahm: American Chamber of Commerce in China

(11) AdvaMed: Advanced Medical Technology Association

(12) EUCCC: EU Chamber of Commerce in China

(13) COCIR: European Committee of Radiology, Medical Electronic and Healthcare Information

Industry

(14) MITA: Medical Imaging Technology Alliance

(15) CAMID: China Association of Medical Device Industry

(16) MOFHRSS: Ministry of Human Resource and Social Security

(17) WHO: World Health Organization