

“Biomedical Engineering: Connecting People, Engineering and Healthcare”

“生物醫學工程：聯繫人才、工程和保健行業”

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 香港醫療及保健器材行業協會 副主席

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 香港醫療及保健器材行業協會 培訓教育小組主席



Mission

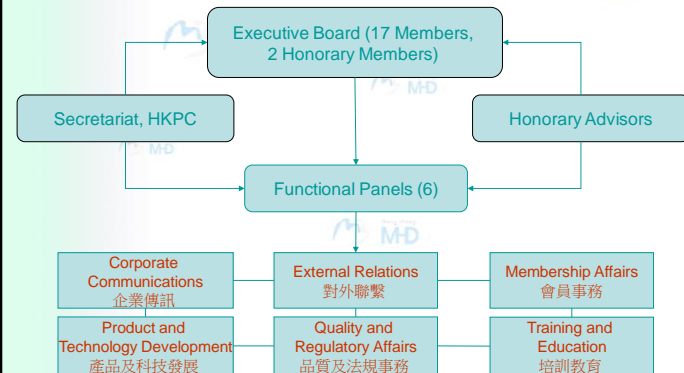
- ◆ To contribute to the local knowledge-based economy as an innovation and technology industry by servicing the medical and healthcare device industries in building internal competencies, setting and observing professional and industrial standards, publicizing our competitiveness locally and internationally, facilitating national and international cooperation in advancing the industries, and supporting and advising on Medical Device policies and regulations.
- ◆ As integral members of healthcare delivery, to ensure that safe and effective medical devices ultimately benefit the public.



Medical Device Industries



Organization



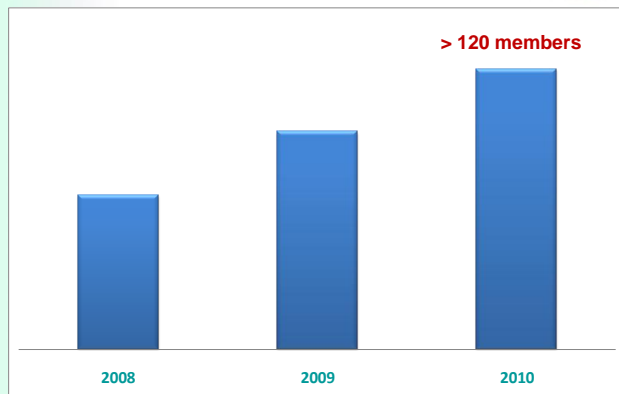
Executive Board 2011-2012

	Name	Company
Chairman	Prof. John Chai	Fook Tin Group Holdings Limited
Deputy Chairman	Mr. Albert Lee	Providence Enterprise Limited
Vice Chairman	Ir. Andros Chan	Pharos Medical Device Limited
	Mr. Benjamin Chan	MediConcepts Limited
	Ms. Maria Chiang	Chen Chien Holdings Limited
	Ms. Teresa Li	Great Eastern Healthcare Limited
Treasurer	Mr. Otto To	Vincent Medical Mfg Company Limited
Secretary General	Ms. Martha Hao	Defond Group
Executive Board Member	Dr. William Cheung	Allan International Holdings Limited
	Mr. Mark Ho	Pacific Medical Systems
	Mr. Hugo Wong	Mayfair Medical Supplies Limited
	Mr. James Li	Healthcare Technology International Limited, AML Group
	Ir. Richard Lun	ConXept Limited
	Mr. Henry Lam	Associated Medical Supplies Company Limited
	Mr. Henry Hu	MTI Marketing (Asia) Limited
	Mr. Fred Tung	Johnson & Johnson (HK) Ltd.
	Mr. Kevin Orr	Winner Medical (Hong Kong) Limited

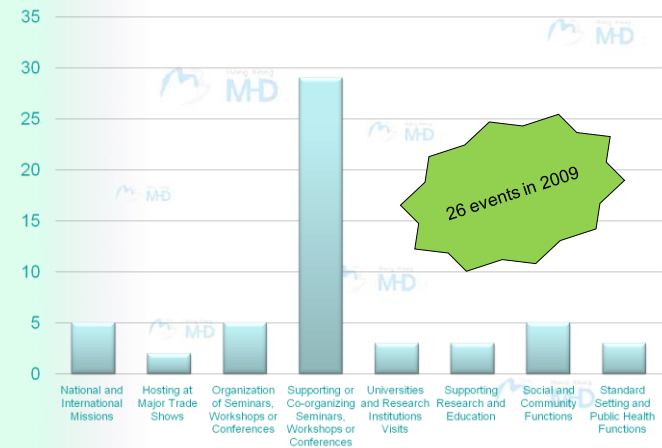
Honorary Appointments

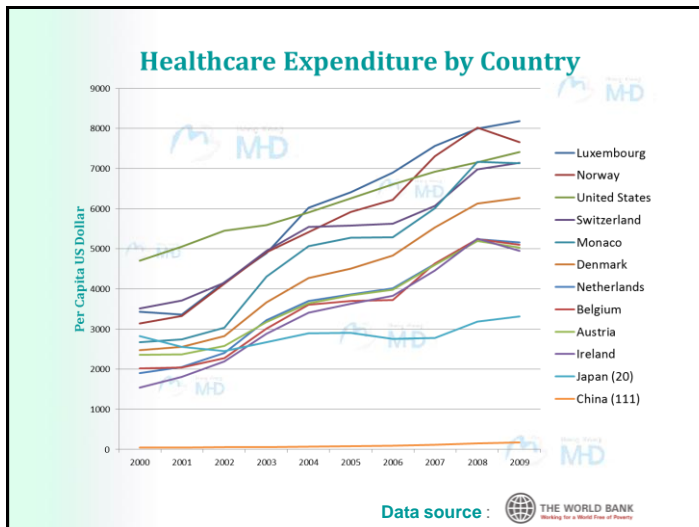
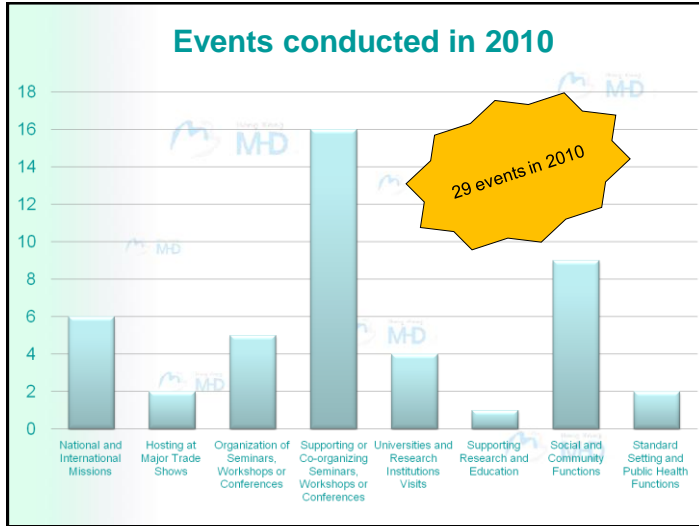
	Name	Company / Institution
Honorary Chairman	Prof. John Mok	Automatic Manufacturing Limited
Honorary Board Members	Mr. Ralph Chow	Hong Kong Trade Development Council
	Mr. Joseph Poon	Hong Kong Productivity Council
	Ir. Derek Louie	Hong Kong Productivity Council
Honorary Advisors	Dr. Homer Tso	Chairman, Dental Council of Hong Kong
	Prof. Michael Yang	City University of Hong Kong
	Prof. Arthur Mak	Hong Kong Polytechnic University
	Prof. King Chow	Hong Kong University of Science and Technology
	Prof. Aaron Ho	Chinese University of Hong Kong
	Prof. Paul Cheung	University of Hong Kong
	Dr. Lilian Leong	Immediate Past President, Hong Kong College of Radiologists
Honorary Legal Advisor	Mr. Nicholas Chan	Squire, Sanders & Dempsey
Honorary Auditor	Mr. Eugene Liu	RSM, Nelson Wheeler

Number of Membership



Events conducted in 2009



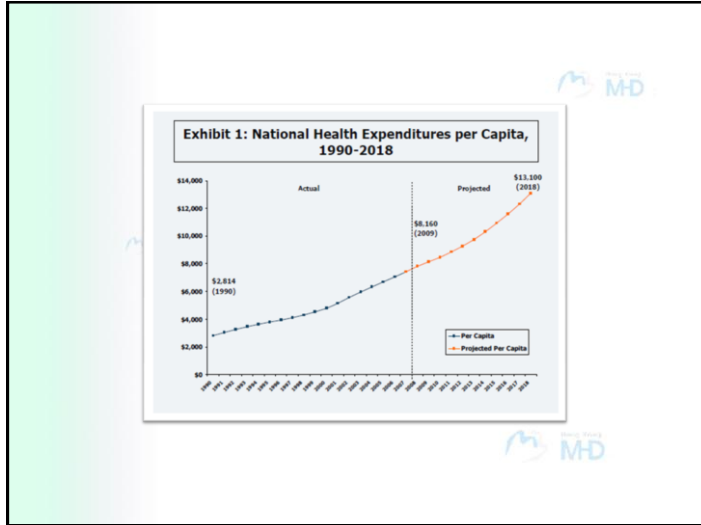


USA

Health Care Spending

Category	Spending Distribution (Total)		Spending Distribution (Public)		Spending Distribution (Private)	
	Spending Distribution (Total)	Spending Distribution (Public)	Spending Distribution (Public)	Spending Distribution (Private)	Spending Distribution (Private)	Spending Distribution (Private)
Hospital Care	31%		40%		27%	
Physician and Clinical Services	21%		17%		28%	
Rx Drugs	10%		8%		14%	
Dental/Other Professional	10%		9%		12%	
Investment	7%	N/A		N/A		
Administration	7%		6%		9%	
Nursing Home	6%		9%		4%	
Government Public Health Activities	3%		6%		0%	
Other Medical Products	3%		1%		5%	
Home Health Care	3%		4%		1%	

Source: <http://www.chcf.org/documents/insurance/HealthCareCosts08.pdf>



World Health Organization

Health topics | Data and statistics | Media centre | Publications | **Countries** | Programmes and projects | About WHO

Countries

China

Map

Statistics

Total population	1,353,311,000
Gross national income per capita (PPP international \$)	6,010
Life expectancy at birth m/f (years)	72/76
Probability of dying under five (per 1 000 live births)	19
Probability of dying between 15 and 60 years m/f (per 1 000 population)	142/87
Total expenditure on health per capita (Int'l \$, 2009)	309
Total expenditure on health as % of GDP (2009)	4.6

Figures are for 2009 unless indicated. Source: Global Health Observatory

World Health Organization

Health topics | Data and statistics | Media centre | Publications | **Countries** | Programmes and projects | About WHO

Countries

Japan

Map

Statistics

Total population	127,156,000
Gross national income per capita (PPP international \$)	35,190
Life expectancy at birth m/f (years)	80/86
Probability of dying under five (per 1 000 live births)	3
Probability of dying between 15 and 60 years m/f (per 1 000 population)	86/42
Total expenditure on health per capita (Int'l \$, 2009)	2,713
Total expenditure on health as % of GDP (2009)	8.3

Figures are for 2009 unless indicated. Source: Global Health Observatory

Medical Device Regulatory and Marketing Course

- ◆ Co-organised by HKMHDIA and the Integrated Vocational Development Centre (IVDC) of Vocational Training Council (VTC)
- ◆ September 2009; March 2010 ; September 2010; March 2011
- ◆ Over 120 graduates

Message from Medical Device Control Office
Department of Health

The building and implementation of an effective regulatory system for medical devices require the cooperation among all parties involved - the government, manufacturers, importers, distributors, users and the general public.

To pave way for the statutory regulation of medical devices in Hong Kong, the Medical Device Control Office (MDCO) of the Department of Health has set up a voluntary listing scheme, the "Medical Device Administrative Control System" (MDACS), since November 2004. Over the years, we have gained valuable experience through operating the MDACS. Such experience serves as a solid foundation over which the government can further refine the proposals for our future legislative framework aimed at upholding the principles of safety and performance of medical devices.

Indeed, upholding these principles of safety and performance is the abiding vision of the government and the trade. It is honing to see that the Hong Kong Medical and Healthcare Device Industries Association (HKMHDA) and the Vocational Training Council (VTC) have taken proactive steps and joined hands in organizing a course dedicated to the intricacies of medical device regulation and marketing which fosters professionalization and ethical practice in the industry.

I wish the Medical Device Regulatory and Marketing Course every success and look forward to continued collaborations with the trade in pursuing our common vision.

Dr Teresa Li
Principal Medical and Health Officer
Medical Device Control Office
Department of Health

Medical Device Regulatory and Marketing Course

Enrollment Form

NOTES FOR APPLICANTS

- Please use one form for each course and photocopy the form as needed.
- Payment of course fee can be made by cheque, credit card or cash. Please refer to the "Payment Method" section for details.
- Applicants for the Medical Device Regulatory and Marketing Course only, please use a correct Chinese address to "Course Organizing Council".
- All checks are payable to "Medical Device Control Office" and must be accompanied by a valid identification card. Incomplete forms and forms received without payment will be rejected on an unrefunded basis.

DECLARATION

- I declare that no information provided in this enrollment form is false and of my knowledge, belief and opinion, true.
- I acknowledge and agree that no personal data will be used by VTC for the enrollment and administrative related purpose.
- I acknowledge and agree that no personal data will be used by VTC for the promotion of courses, at any time, save those VTC is using to disseminate its promotional materials.
- I acknowledge and agree VTC to check my CV (past or present) for the purpose of the course.
- I understand that should provide as much information as possible, so that my application can be processed efficiently.
- I understand that course fees, cost are not refundable, except for cases of unexpected application and course cancellation. Fees paid and passed credits are not transferable.

Applicant Information

Organization (Please do not use address on your HKID card): _____
 English (surname) _____ (given name) _____ Chinese _____
 HKID No. _____ Age _____ Gender: Male Female
 Issuing address: _____
 Company of employment: _____
 Position: _____ Email Address: _____
 Telephone (day time): _____ (home) _____ Fax: _____
 Continuation: Please specify how you would like to be notified: (If by email, please provide an email address if specified, we will notify you by email.)

Payment Method

Cheque/Credit Card: Please attach a cheque or credit card (for further notes on a visa requirement, we will contact you by email. Double check before card is used by phone.)
 Amount: HK\$ 2,500 Cheque No.: _____

Applicant Signature _____ **Date** _____

Student Research Award

- ◆ HKU, CUHK, PolyU & HKUST
 ➤ Biomedical Engineering Course
- ◆ Over 20 undergraduate and graduate students have been awarded

HKMHDA Annual Dinner 2009



HKMHDA Annual Dinner 2010



- ◆ Organized visits to different universities, research and clinical trial centers to provide collaboration opportunities for our members with the academics

	2009	2010
Mar	The University of Hong Kong of Clinical Trial Centre and Genome Research Centre	Biomedical Product Development Collaboration Opportunity at Poly U: Technological Seminars and Laboratories Visit
Apr		Biomedical Product Development Collaboration at HKU: Technological Seminars and Opportunity Matching
May	The Department of Biomedical Engineering, Jinan University, Guangzhou	
Aug		Medical/Healthcare Technology Collaboration Opportunity at CityU
Oct	The Department of Biomedical Engineering, The Chinese University of Hong Kong	
Nov		Biomedical Product Development Collaboration at HKUST: Technological Seminars and Opportunity Matching



Hong Kong International Medical Devices and Supplies Fair

November 4-6, 2009 and November 3-5, 2010



Outward Bound Corporate Challenge 2010

November 14, 2010



HKMHDIA Team:

Mixed Division -
CLP Power
Plates-
Champion

Fujikon Cups for
Manufacturing
Industry Group -
1st Runner-up

HKU MedE Alumni in Industry

◆ Charles Chu (2006)

- Engineer on Product Development & Registration
- Vincent Medical Manufacturing Co. Ltd.



Conference on Cardiology
Interventional Therapy (2011)



US Medical Device Design and
Manufacturing (MD&M) Shows (2011)

HKU MedE Alumni in Industry

◆ Peter Tang (2006), Territory Sales Manager,
Johnson & Johnson (Hong Kong) Ltd.

◆ Kyle Ho (2008), Project Engineer,
Medu-Scientific Ltd.

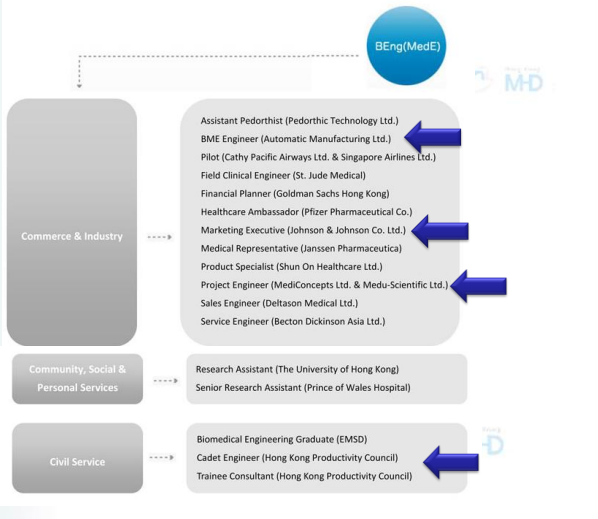
◆ Andy Lau (2010), Project Engineer,
Medu-Scientific Ltd.

◆ Henry Yip (2010), Project Engineer,
Medu-Scientific Ltd.

“Hire for attitude. Train for skill.”

The screenshot shows the Southwest Airlines website with a prominent 'SOUTHWEST MEDIA' banner. Below the banner, there are sections for 'Media Channels' (Press Releases, Fact Sheets, Our People, etc.) and 'Our Leaders', which includes a photo of Herbert D. Kelleher, Founder and Chairman Emeritus.

Sharing from HKU MedE Alumni Edwin Wong (2009)



HKU MedE - HKMHDA Mentorship Program

- **One-to-one Mentorship Program**
 - **Mentor: HKMHDA Member Company**
 - **Period: One year**
 - **Target: HKU MedE Student**

Coming Soon

Product Design & Development

Product Design Engineer / Manager

1. Understand the design principles of medical device;
2. Understand the regulatory requirements of medical device safety and efficacy, e.g. FDA – PMA, 510(k), SFDA, MDD; and
3. Integrate with production and quality system, e.g. QMR, ISO13485, cGMP

Quality & Regulatory Affairs

Regulatory Affairs Engineers/Specialists:

- a) Product registration/consultant;
- b) Conformity Assessment Bodies – BSI, UL, TUV, SGS; Product and or system reviewer;
- c) Medical device regulators – MDCO (HK)....
- d) Clinical Research CRO; and
- e) Hospital or Health Centre;

Business Development, Marketing & Sourcing

◆ Business Development

- Develop to different product categories
- Product portfolio & integration

◆ Marketing, Distribution & Service

- Product registration & traceability

◆ Sourcing

- Source suitable products from developed areas to China and vice versa

Patent & Technology Scout/Lawyer

Patent & technology scouting:

- a) Patent Lawyer (Application & Litigation);
- b) Technology Lawyer (R&D & Licensing Contract); and
- c) Technology Valuator (Investment or M&A).

Research & Academic

Further study for PhD & Post-Doc

1. Medical Engineering for product invention, development & implementation;
2. Employed at university or research institution (Local or overseas; research or teaching); and
3. Entrepreneur in Research Venture, e.g. Stanford University.

Personal Observations

Graduates	HK	Chinese	Overseas
Language –			
English	⬇	⬆	↔
PTH	⬆	↔	⬆
Cantonese	↔	⬆	↔
Technical Competence			
	↔	↔	↔
Integrity			
	↔	⬆	↔

Personal Observations

Business Practices	⬇	↔	↔
Legal Mindset	↔	⬆	↔
International Exposure	⬆	⬆	↔
Hand-on	⬇	⬇	⬇
Attitude	⬇	⬇	↔

Coming Workshops for BME Professionals

- ◆ **USA Medical Device Pre-market Notification 510(k) Writing Skill Workshop**
 - > Date: 14-16 June 2011
 - > Organizer: HKMHDIA
 - > Venue: HKPC Building, Kowloon Tong
- ◆ **Seminar on Nano-Medical Device Technology, Regulatory and Risk Management**
 - > Date: 17 June 2011
 - > Organizer: HKMHDIA
 - > Venue: HKPC Building, Kowloon Tong
- ◆ **Two-day Certificated Practical Training Course on Medical Device Product Registration in China**
 - > Date: 14 -15 July 2011
 - > Organizer: Hong Kong Productivity Council
 - > Venue: HKPC Building, Kowloon Tong

