

Regulatory forum

Newsletter – HK and Asia Regulatory

Nov, 10

Number 12

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Convener Contact

Jack Wong



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The Regulatory Forum's roles and successes

The Regulatory Forum, is a regular meeting opens to all companies or individuals, with the following terms of reference:

- To hold regular meetings where medical device experts from different regions in Asia can share: good regulatory practice in relation to medical devices (and pharmaceuticals); discuss harmonization; and inform participants of regional regulatory developments; and
- To provide updates on AHWP matters from both industry and government AHWP representatives via the Regulatory Forum newsletter, which is distributed to more than 5,000 readers globally. Its content is published in a number of leading industry publications including Clinica World Medical Technology News, The Regulatory Affairs Journal, The Journal of Medical Device Regulation, The China Medical Journal and The Medical Device Manual.

Previous Forum newsletters can be downloaded from the following link:

www.bsiamerica.com/HongKongRegForum

Meetings

The Regulatory Forum holds a number of meetings throughout Asia each year. The participation of forum is free of charge.

2010 Forum Schedule

23 Feb HK, 25 Mar US, 6 Apr Taiwan, 28 May HK, 22-25 Jun UK, 12-13 Jul Japan, 27 Aug HK, 1 Sept Taiwan, 18-19 Nov Korea, 23 Nov HK, 8 Dec Taiwan

2011 Forum Schedule (tentative)

25 Feb HK, 27 May HK, 26 Aug HK, 25 Nov HK

* Please contact Jack Wong if you would like to participate in any of these forums

AHWP Annual meeting

The Forum and newsletter serves as the platform for AHWP representatives to update Asian regulatory issues. AHWP is the key regional regulatory group among regulators and industries to harmonize and share good regulatory practices in Asia

For your record, we will have **AHWP Annual meeting** to be held in Saudi Arabia on 27 Nov – 1 Dec

Detail of the meeting information can be found in the AHWP website www.ahwp.info

AHWP TC meeting

AHWP Technical Committee meeting was held in Chinese Taipei on 7 Sept supported by TaiwanFDA.

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Dr Kang Jaw-Jou (Director-General of Department of Health, Taiwan FDA) gave opening and welcome to participants

Ms Joanna Koh (AHWP TC Chair) welcomes participants and thank you TaiwanFDA to organize this event

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During the meeting, some key highlights:



WG01 (Working Group 1)

Comparison of STED and CSDT was presented and members are welcome to give their comment. Aim to present in SG1 meeting in Oct 10 and AHWP annual meeting in Nov 10

AHWP CSDT finalization timeline would be discussed/agreed during Nov 10 AHWP meeting

WG01a

Work Item	Deadline
<ul style="list-style-type: none">● Gap analysis of IVD medical devices regulations in member economies● Feasibility study on adoption of the classification and conformity assessment of IVD medical devices proposed by GHTF	Mar 28, 2010 (Extended to Jul 31, 2010)
Liaise to GHTF in developing related documents on clinical evidence for IVD medical devices	Jul 31, 2010
Liaise to GHTF in developing related documents on the Essential Principles and labeling of IVD medical devices	Dec 31, 2010
Holding workshop on GHTF documents on IVD medical devices regulations	The next annual AHWP meeting (Nov 2010)
Feasibility study on the adoption of the IVD STED, definition and concepts on clinical evidence of IVD medical devices proposed by GHTF	Sep, 2011

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WG05

Current Status on Work Item	<ol style="list-style-type: none">1) Established close collaboration with SG5 – Chair & Co-chair of AHWP WG5 are members of SG5 and participate in SG5 meeting/s & discussions on SG5 GD2) VC of SG5 attended AHWP meeting in Nov '09 and TC meeting in May '10 respectively and provided overview training on SG5 GD namely Clinical Evidence – key definitions & concepts (SG5/N1R8:2007) & Clinical Evaluation (SG5/N2R8:2007)3) WG5 members completed 1st review of SG5 GDs: a) AE reporting during clinical investigation (GHTF SG2-SG5); b) Post-market Clinical Follow up Studies (GHTF/SG5/N4:2010); c) Clinical Investigations (GHTF/SG5/N3:2010); d) Clinical Evidence – Key Definitions & Concepts (SG5/N1R8:2007) & e) Clinical Evaluation (SG5/N2R8:2007)
Steps Forward	<ol style="list-style-type: none">1) SG5 representative to train WG5 members SG5 GD in details eg. Logic, thought processes etc behind the final doc. On 26 Nov 20102) Explore feasibility to form GHTF Advisory & Expert Panel by Dec 2010<ul style="list-style-type: none">- Once Advisory & Expert Panel formed: Quarterly Tcon/face to face training 2011 and support WG5 in making recommendations to AHWP member economies on feasibility of adoption

WG06

Yiting, Jack and Dr Kelly had a teleconference on 6 Sept and agreed

- AHWP and GHTF can jointly work out a Regulatory training
- AHWP training syllabus and template was prepared and will be passed to AHWP & GHTF's regulators representative to comment and start prepare training material
- AHWP and GHTF will discuss again around Nov 10 on what training platforms we can use
- AHWP finance arrangement will be communicated to GHTF

We aim for 2011 launch of the training

WG03

A QMS survey was initiated

Objectives

- To understand the status of current and proposed Quality Management System regulations and requirements of AHWP member economies
- To identify similarities in Quality Management System regulations and requirements of AHWP member economies and explore opportunities for sharing
- To identify major areas of differences in Quality Management System regulations and requirements of AHWP member economies for investigation and deliberation to explore opportunities for harmonization
- To identify areas or topics for recommendation to GHTF for the

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development of new guidance documents or revision of existing guidance documents

Next Steps

- Compile responses from all member economies to be collected by TC representatives (
- Collate and analyze data
- Present findings
- Identify opportunities for development (new guidance documents, training)

WG04

Current status

After TC meeting in Singapore, WG4 members proposed a survey in June. Draft Questionnaires were developed in July
Questionnaires reviewed by WG members in Aug. via telcon.

Next steps

Action item	Due	Responsibilities
Feedback on "Questionnaires"	Sept.18	All members
Finalizing Questionnaires	Setp.24	E.H.
Gathering answers from both Industry and Regulator in each AHWP member economy	Oct.15	All members
Analyze the answers and prioritize the key action items	Oct.30	E.H.
Top priority work item will be taken for WG4 to focus on.	Nov.	All members
Auditing status at AHWP member economies and New action item progress will be presented at AHWP annual meeting.	Dec.	TBD

Special Task Group – Legal Entity

Resolved to set up the AHWP Administration Services Ltd in Hong Kong in the 14th AHWP Meeting in Nov 2009

No further comments received after the discussion in the 10th AHWPTC Meeting in May 2010

- AHWP Representatives (Regulator) could join as Regulator Members (limited to 1 for each member economy)
- AHWP Representatives (Industry) could join as Industry Members (limited to 1 for each member economy)

- Others could join as Associate Members (limited to 100 for each member economy)

Representatives and interested persons could join as:

- Founding Regulator Members;
- Founding Industry Members; or
- Founding Associate Members

The Memorandum and Articles of Association will be finalized
The Company will seek tax exemption status before full operation
It was stressed the members are not paid for the above roles

Special Task Group – Nomenclature

2 AHWP members to be nominated to the Board of Trustees of GMDN

Proposed participants from AHPW is China and Singapore

Fees for regulators not finalized yet

GMDN Agency considering National License

ECRI will give presentation in AHWP Saudi meeting. AHWP has no decision on which nomenclature system yet. Still in negotiation phase. Japan is not using GMDN but JMDN.

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BSI was also invited to join the Regulator meeting in the evening to discuss conformity assessment development in Asia



White Coat Ceremony, School of Pharmacy, Chinese University of Hong Kong

The mission of the School of Pharmacy is to foster a nurturing and challenging environment to prepare the next generation of innovators and leaders in pharmacy practice. The education of a health care profession is more than imparting knowledge. The White Coat Ceremony is symbolic of the rite of passage of the pharmacists-in-training in their journey toward serving society as pharmacists. It is designed to reflect the responsibility, professionalism and commitment expected of our graduates.

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This year's White Coat Ceremony will be on 14 September 2010. It is our honor that BSI (as adjunct tutors in CUHK) is invited to participate in this ritual. As one of the nominated adjunct tutors, it is my pleasure to take up the specific role in assisting to put the white coat on the pharmacy students. This ritual represents the passing on of professionalism to the pharmacists-in-training.



Regulatory presentation in Fuzhou University, China

BSI was invited to give Asia regulatory update in a conference organized among universities in China, Taiwan, Hong Kong and Macau (2010 年两岸四地生物医学工程学术会议议程) on 25 September



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Regulatory presentation in RAPS annual conference, USA

BSI was invited to give Asia regulatory update in RAPS (Regulatory Affairs Professional Society) in US on 25 Oct



Hong Kong Regulatory Forum Update



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The last regulatory forum in Hong Kong was organized by BSI on 27 Aug.

In the beginning of the forum, Mr. Jack Wong (VP – Regulatory Affairs, BSI) gave an opening speech and introduced this Regulatory Forum. The forum is a regular meeting open to all companies or individuals with the following terms of reference since 2006.

- Providing Asian Harmonization Working Party (AHWP) updates by AHWP non-government and government representatives
- Maintaining a regular gathering of regulatory and non-regulatory staff in medical device fields, and
- Creating a platform for different trade associations, industries and DOH to discuss and updates the medical device regulatory development in Hong Kong.

The first speaker is Mr Mark Lau from MDCO, Department of Health in HK to update the latest regulation change

Follow by Ms Janet Lai to introduce the latest Food labeling law in HK

Camon Sin (the chair of LRP Panel) gave update on LRP development

Jack also gave update on Pharmaceutical and Traditional Chinese Medicine Panel update

Sabrina Chan (Executive Director of HKAPI) update HKAPI activities

Finally, Tammy Wong (MD of Enston Healthcare Ltd.) shared her experience on health food registration in Hong Kong

Hong Kong LRP Panel

Before Regulatory Forum on 27 Aug afternoon, we have LRP panel meeting on 27 Aug morning.



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Established in 2009, the LRP (Local Responsible Person) Panel is a voluntary joint-effort of professionals from the medical device industry and other related fields with an aim to collaborate with authorities on the topics of medical device regulatory governance in HKSAR, and the sharing of regulatory practices and information for the interests of the LRPs and the ultimate benefit of the health and safety of patients.

Current structure of LRP Panel

Chair: Camon Sin (Medtronic)

Vice-Chairs: Ms. Carmen Lai (Amgen)

Billy Wong (MediConcepts)

Bryan So (HKPC)

Adviser: Jack Wong (BSI)

Legal Adviser - Ms Monita Lau (Or & Lau)

Secretary: Ms. Tammy Wong (Enston Healthcare)

Student helpers: Alan Ng, Janice Tsui

Latest discussion and updates can be found in the website below:

http://www.bsigroup.cn/zh-cn/Training/Training-course-areas/Medical-devices/About_LRP_Panel/

Next LRP Panel meeting will be 23 Nov morning in HKPC
Feel free to contact us if you want to attend or join LRP

Meeting with Department of Health

BSI had a meeting with key government officials of Department of Health to discuss medical device regulatory system in Hong Kong on 6 Oct



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(from left to right)

Dr Teresa Li, Principal Medical & Health Officer. Dr Li takes care the MDCO in Hong Kong

Jack Wong, BSI

Dr Heston Kwong , Assistant Director (Special Health Services)

Ms Linda Woo, Chief Pharmacist. Linda also take care the Pharmaceutical Services in Hong Kong

Ms Sabrina Chan, Executive Director of HKAPI

(rear row)

We have key regulatory staff from Bausch & Lomb (Kenneth), DKSH (Lawrence), Abbott (Terrenz), Alcon (Ricky), MDCO (Mark Lau), GE (Carmen) and Baker McKenzie (Gloria)

Hong Kong Pharmaceutical and Traditional Chinese Medicine Regulatory Panel

Further to the success of LRP Panel above, a new Panel which focus on Pharmaceutical and Traditional Chinese Medicine Regulatory was formed on 29 Jun 2010

Summary of discussion/conclusion on 29 Jun meeting

Name of Panel: Pharmaceutical and TCM Regulatory Panel

Chair: Karen Lo (Hospira)

Co-Chairs:

Multinational - Susanna Yim (Janssen)

Retail – Stephen Lam (Mannings)

Distributor – Lawrence Yiu (DKSH)

Academic – TBC

Secretariat/ Convenor:

Jack (BSI)

Luciano (HKMRS)

Concerns discussed

- TCM (DOH manpower, implementation time very soon around 1 Dec 10, Others are fine e.g. classification service is around 2 months, product approval is around 3 months)

- Rx (rely on company to handle classification, recent requirement of full manufacturer address on label, need idea to make product changes quicker e.g. use of notification for minor changes)

We also setup the group in LinkedIn.com using the group “HK Pharmaceutical & Traditional Chinese Medicine Regulatory Panel”

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Meeting with Department of Health

BSI had a meeting with the team of Pharmaceutical Services of Department of Health. Ms Linda Woo present the latest regulatory requirement, provide feedback to companies questions on 12 Oct





Guest articles – by Mr Erik Vollebregt

Reprocessing and refurbishing of medical devices

Reprocessing and refurbishing of medical devices

Introduction

Reprocessing and refurbishing medical devices is a practice that has been allowed in Europe and the US for many years, although the national positions on refurbishing differ quite a lot in the EU as the subject has not been harmonised in the EU. The European Commission is now planning to tackle this subject in the upcoming Recast of EU medical devices legislation.

Refurbishing and reprocessing of medical devices has recently become a prominent subject in the cooperation between the EU and China in the Healthcare Equipment Working Group that forms part of the EU-China Trade Project. At this stage the focus has been on the refurbishing of electromedical equipment, while much can be said about refurbishing and reprocessing of other types of medical devices, such as balloon catheters.

The Healthcare Equipment Working Group concluded in its recent report that "There is no clear regulation in place to supervise and regulate refurbished medical equipment in China. The lack of such a regulatory framework denies Chinese healthcare providers access to affordable and advanced medical technology from an earlier generation, while creating a vacuum which encourages second-hand equipment of questionable quality to circulate in a grey market which jeopardises market order and the safety of citizens. The resources consumed in the R&D, production and maintenance of large medical imaging devices is too much to idle the equipment before it reaches the end of its planned service life. Such practices result in a waste of resources and work against the principles of a recycling economy and the Scientific Development Concept (SDC).", states the European Business in China Position Paper 2010/2011 in the Healthcare Equipment Working Group section on p. 267

As China currently prohibits reprocessing and refurbishing of medical devices, while the market is urging the authorities to allow it, and other Asian countries have different rules that allow it to differing extentx, the developments in the EU moving in the direction of EU wide harmonisation of reprocessing and refurbishing of medical devices in the EU set out below may be interesting for the readers of this newsletter.

Reprocessing of medical devices

On 28 April 2010 the Commission published the SCENHIR's opinion on reprocessing of medical devices, which was adopted by the SCENHIR on 15 April 2010. This opinion was commissioned pursuant to article 12a of the Medical Devices Directive, which called upon the Commission to "no later than 5 September 2010, submit a report to the European Parliament and to the Council on the issue of the reprocessing of medical devices in the Community. In the light of the findings of this report, the Commission shall submit to the European Parliament and to the Council any additional proposal it may deem appropriate in order to ensure a high level of health protection." The Commission published its report based on the factual information contained in the SCENHIR report on 27 August 2010.¹

In this article I will explore regulatory obligations both for the OEM as for the reprocessor, as well as product liability consequences of reprocessing. I will use the concept of OEM (original equipment manufacturer) to refer to the manufacturer that originally put the medical device on the market before it was reprocessed for the first time.

The SCENHIR report

The SCENHIR report finds that reprocessing of single use devices entail certain risks. First, the chemicals and procedures used for cleaning, disinfection and sterilization may interact with the device which may result in changes in the physicochemical properties of the material of the device. This may result in a reduced performance of the device, for example, loss of flexibility due to changes in the plastic materials, reduced smoothness by altered surface coatings, etc. Secondly, whether due to the design of the SUD or the procedure used, chemical contaminants may remain in the device posing a hazard for reuse.

The report concludes from this that in order to prevent the potential hazards associated with the reprocessing of SUDs the whole reprocessing cycle starting with the collection of the SUD after first use until the final sterilization step should be evaluated and validated for its efficacy.

These potential hazards are however difficult to identify and quantify. The report states that published data on the hazards and risks are very limited. Some simulation studies and a few clinical studies have shown that reprocessing of SUDs may result in inadequate cleaning, disinfection and/or sterilization leaving a bioburden on the reprocessed SUDs. The report goes on to state that in

¹ COM(2010) 443 final

Reprocessing of medical devices

general, there is a lack of data specifically dealing with clinical outcomes for patients associated with reprocessed SUDs particularly with regard to possible delayed effects, for example, infectious diseases and/or immunological complications. In addition to the possibility of chemical and microbial residues remaining in the devices as a result of improper cleaning, disinfection, and/or sterilization, as well as alteration of the material characteristics of the devices after reprocessing, there are some other aspects that may introduce a potential hazard and thus a risk for each subsequent use of the reprocessed SUD. These include: possible loss of documentation and information; problems of traceability during the lifetime of a particular device; possible errors in reassembling of devices (some devices need to be assembled on location); and educational and training issues for complex medical procedures.

Despite the absence of data, the report concludes that number of situations in which an increased risk from using a reprocessed SUD may occur have been identified; in particular an increased risk may be present with the use of a re-processed SUD in invasive medical procedures (designated critical use), and the use of a reprocessed SUD with certain design features that make it unsuitable for reprocessing and re-use.

The Commission report

The Commission's report confirms the findings of the SCENHIR report: it finds that national law differs widely on the subject of reprocessing of single use devices.² It further confirms the SCENHIR's findings in the field of safety and incidents: "The number of documented incidents is very small, although it can be speculated that the reporting of incidents is incomplete. However, regarding adverse events, there may be a "grey" area for which the recognition and reporting of incidents is difficult, such as a prolonged surgical procedure due to stiffness of a reprocessed single use catheter, and a prolongation of hospital stays. Furthermore, long-term effects may not be identified and attributed to the use of reprocessed medical devices."³

With respect to liability considerations the report stresses a type of liability often overlooked in this respect: the liability of the doctor applying the reprocessed SUD.⁴ The report states that doctors should be informed if the SUDs that they use are reprocessed, so

² Par. 3.2 Report

³ Report, p. 8

⁴ Par. 3.4.2.1 Report

Reprocessing of medical devices

they can make their own safety assessment and prevent unnecessary complications.

The report is very vague about the liability of the OEM in case of reprocessed SUDs and refers the OEM's duty to state in the instruction for use contains information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be reused. It goes on to state that "the responsibility of the original manufacturer shall be clarified in case of reprocessed single use medical device failure and medical complication due to and only to the reprocessing practice".⁵ I agree that this is the case and confirm the obvious lack of legal guidance there. It should be pointed out however that this leaves the entire spectrum between the situation where there is an obvious defect due to the device itself and between the situation where there is a defect "due to and only to the reprocessing practice". In practice, of course, it will almost never happen that it is completely clear whether a malfunction of a reprocessed SUD is "due to and only to the reprocessing practice". The most important question in our view is the burden of proof in the case of a malfunctioning reprocessed SUD. I am of the opinion that the manufacturer should not bear the burden of proof to demonstrate that the defect was caused by the reprocessing. The burden of proof should rather be on the reprocessing party. This would be fair, since the reprocessing party should have in place a fully validated procedure for reprocessing that enables the reprocessing party to demonstrate that the procedure was completely and diligently followed. It would help in this respect of the Commission were to produce guidelines or even mandatory requirements on validating reprocessing procedures.

The conclusion of the report on the point of liability seems to leave all options open: "Regarding the liability, it would be necessary to clarify the responsibilities of each stakeholder and to inform healthcare professionals in case they are using reprocessed single use medical devices, as their responsibility may be engaged in case of adverse events. The requirements regarding the labelling of reprocessed single use medical devices shall be clarified, in particular for the purpose of traceability of these devices." This conclusion adds an important point that was not discussed in relation to liability: traceability. Strong obligations with respect to traceability are an indispensable condition for ensuring that in case of a device malfunction there is sufficient information for the OEM and the reprocessor to

⁵ Par 3.4.2.2 Report

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determine where the root cause of the failure of the device took place.

The report concludes that there is insufficient information to draw a conclusion on the net environmental benefits if one takes all reprocessing related factors into account, such as transport and use of chemicals.⁶

From all of this the Commission concludes that more work is needed and that the Recast is the right instance to implement measures: "In the light of the above, taking into account the potential hazards and risks identified by the SCENHIR in terms of the remaining contamination, persistence of chemical residues and alteration of the functionality, the Commission will assess which are the appropriate measures to be put forward in the context of the Recast of the Medical Devices Directives with regards to the reprocessing of single use medical devices in order to ensure a high level of protection for patients. This assessment will also take into account potential economic, social and environmental consequences that any envisaged measure may have."⁷ This conclusion will be disappointing for those who were expecting the Commission to step up in the report and set out clear policy objectives with respect to reprocessing of SUDs.

Conclusion

It will be interesting to see how the law on refurbishment and reprocessing will develop in the EU, China and other countries in Asia. At present the momentum seems right to achieve maximum standardization of rules and standards in several of the bigger medical devices markets, and provide legal certainty for both the OEMs and specialised service providers as well as a fair balance with respect to issues like product liability, while at the same time ensuring patient safety.

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⁶ Par. 3.6.1 Report

⁷ Par. 4 Report

Guest articles – by Emily Yuan

The compilation key points of the "12th five-year" planning of health development in China was determined

Compiling the "12th five year" planning of health development shall further clarify the following 5 points:

1. Scientifically setting goals and targets. To put forward some targets which can reflect the new characters and new tasks of health development in the medical security, health resources, health investment and other aspects, and try to bring the population life expectancy and infant mortality targets which are internationally recognized and can generally reflect the level of health work and economic social development into the national development targets.
2. Deepening the medical and health system reform as a guide. Based on consolidating the five achievements of key reforms, to insist on preserving the basis, strengthening grass-roots and establishing mechanisms, and to strengthen the responsibilities of the government, and to increase the health input, and to fulfill the public welfare of medical and health sector, to mobilize the enthusiasm of many medical staffs and provide the basic medical and health system to the public as the public goods.
3. Starting to meet the basic needs of people: to fully utilize and optimally allocate the available medical and health resources, and solve the long-term problems with the combination of current problems, to put forward important projects in the health system during the period of "12th five-year".
4. Organizing the fulfillment of the national health action plan: to organize a series of national health action plans which is practicable, can be prevented and controlled, and cost-effective, and to strengthen the effective intervention for the significant and long-term problems, and to promote the continuous improvement of national health level. To study and put forward the action plans focusing on the prevention and control of major diseases, on the health of key population and the health risk factors.
5. Improving the security measures: to establish the harmonious and integrated medical and health management system, to establish and improve the health input mechanism of the government, to establish the effective and standard operating mechanism of medical and health institutions, to strengthen the construction of medical and health personnel, to vigorously promote the construction of medical and health infomationization, and to establish and improve the medical legal system.

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Others and Special Offers to Forum participants

1. JMDR special offer to Regulatory Forum participants

Journal of Medical Device Regulation offers special pricing to forum participants. Please use the code "HK0808" code when making an order

Details can be found at the later part of newsletter

2. Special offer to Regulatory Forum participants from Medical Device Manual

The Medical Devices Manual is a practical, comprehensive guide for all those working with medical devices. Euromed Communication is offering a Special Offer £200 (original price £290) for Regulatory Forum participants. An order form can be found at the later part of newsletter

3. Clinivation WorldView special offer to Regulatory Forum participants

Clinivation WorldView is the medical device and diagnostic industry's most comprehensive, authoritative, and up-to-date enterprise solution for On-Demand Global Regulatory Intelligence. Providing clear, step-by-step market clearance regulations, processes, and guidance for >99% of the world markets, only Clinivation WorldView delivers tried-and-true intelligence from certified, practicing professionals with real-world experience

BSI is also a subscriber of Clinivation WorldView and partner for Asia promotion. Please contact Jack Wong (jack.wong@bsigroup.com) for special Forum pricing. Detail of the WorldView can be found at the later part of newsletter

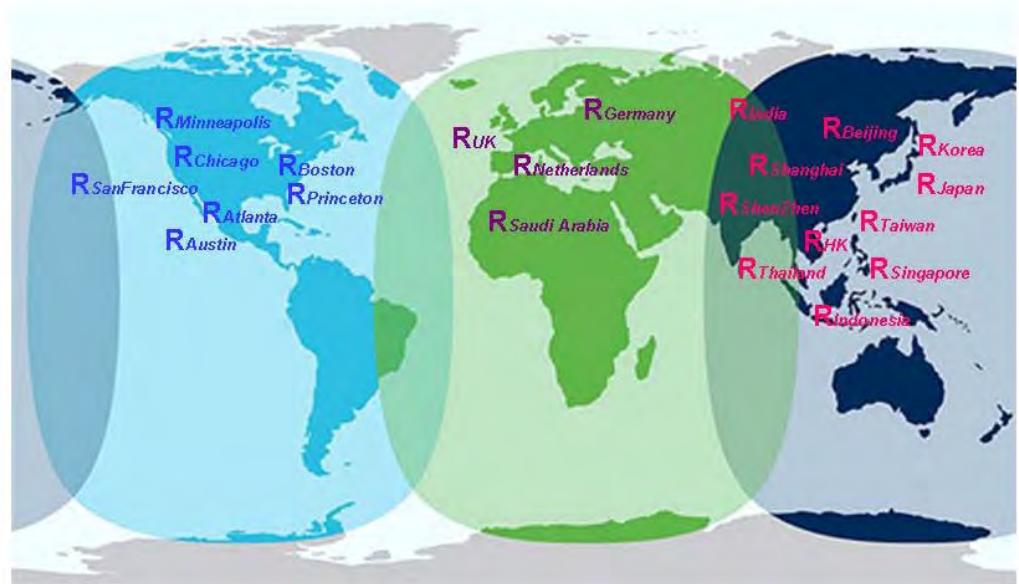
Asia Regulatory Trainings

More than 550 graduates

BSI organized the first Asia regulatory training since 2007. Today, we have more than 550 graduates which including participants from government officials, industry colleagues, university students, retailers, lawyers, consultants etc.

Expand globally

In 2010, we extended our Asia trainings to US and Europe.



Asia Regulatory Trainings delivered globally

Alumni

Due to large number of graduates and request from graduates, we have create a forum using LinkedIn to facilitate experience sharing and networking. The link is name of the group in www.Linkedin.com is "Asia Regulatory Affairs"

Please feel free to join

Currently, we have the following trainings available :

1. **Hong Kong Medical Device Regulatory and LRP Certificate (held in HK)**
2. **Hong Kong Pharmaceutical Regulatory Certificate (held in HK)**
3. **Good Clinical Practice Basic and Advance courses (held in HK) with details can be found in the later part of newsletter**
4. **Global Medical Device Regulatory Certificate (held in China, Taiwan, US, EU and Japan)**
5. **China Medical Device Regulatory Certificate (held in China, Taiwan)**

Detail of the above course and graduate list can be found in later part of this newsletter

Pictures of our recent regulatory trainings in US, Taiwan, Thailand





Training registration or query
Jack.wong@bsigroup.com

** Email Jack (jack.wong@bsigroup.com) if you do not want to receive this newsletter*

BSI Regulatory trainings detail and graduates list

Contact Jack Wong (BSI) for detail of the training: jack.wong@bsigroup.com

Medical Device/Hong Kong LRP Regulatory training

2 days training

Hong Kong Department of Health (MDCO) shared experience on LRP requirements. MDCO may check their legal entities, distribution records, technical documentations, promotional materials compliant with the UMAO (Undesirable Medical Advertisement Ordinance), labeling compliance, special listing information, the process and implementation of all the required SOP submitted to MDCO. MDCO may also collect products from market to conduct inspections or testings.

LRP training syllabus

A LRP training was developed in line with a syllabus agreed by MDCO and CABs as follow:

MDACS and MDCO introduction

Basic medical device regulatory

- definition of medical device
- medical device classification
- tracking of specific medical devices
- special listing information
- Obligation of LRP
- UMAO
- Pharmaceutical product definition and regulatory requirement in HK

Product knowledge on intended uses and contra-indication

Preparation for application submissions

Practical session

- Distribution record SOP implementation
- Complaint handling SOP implementation
- Maintenance and services arrangements SOP implementation
- Product alert, modifications and recall SOP implementation
- Adverse event reporting SOP implementation
- Prepare for MDCO audit

Others

- AHWP, GHTF introduction
- Basic ISO 9000 and 13485 understanding

Graduated/Attendance list

Name	Organization
Kimberly Knish	AGA Medical Corporation
Mary Korte	AGA Medical Corporation
Ricky Ho	Alcon
Afaf Alfakheri- PMP	AlFaisaliah Medical Systems
Kai Yi Sung (Rita)	AlphaRx Inc.
Christina Wong	Altera International Ltd
Ada Wong	AMO
Susan Leung	Asia Cardiovascular Products Ltd
William Ku	Asia Cardiovascular Products Ltd
Joey Chow	ASTRI
Deborah Kwong	BD
Carol Chen	BD
Ivy Kwok	BD
Petty Fan	BD
Gloria Poon	Baker & McKenzie
Mr. Cheney Lu	Baker & McKenzie
Jackeline Chan	Bausch & Lomb
Kenneth Choi	Bausch & Lomb
Flora Lee	Bayer HealthCare Ltd
Jo Choi	Bayer HealthCare Ltd
Manson Chung	Bayer HealthCare Ltd
Catherine Cheng	Bayer HealthCare Ltd
Charlotte Leung	Biosensors International
Maggie Leung	Boston Scientific
Christine Tsai	Boston Scientific
James Fan	Boston Scientific
Mandy Yau	Baxter Healthcare Ltd
Cecilia Chan	British Consulate General
Jane Hong	Cardinal Health
Jean Zhang	Caridian BCT
Pauline Chan	Caridian BCT
Suzuki, Atsuko	Caridian BCT
Leung, Man Cho	Chinese University of HK, School of Pharmacy
Fong, Yui Kau	Chinese University of HK, School of Pharmacy
Mok, Siu Man Shirley	Chinese University of HK, School of Pharmacy
Chan, Ka Yan	Chinese University of HK, School of Pharmacy
Chan, Yat Hei	Chinese University of HK, School of Pharmacy
Leung, Man Cho	Chinese University of HK, School of Pharmacy
Winki Ip	Chinese University of HK, School of Pharmacy
Janice Tsui	Chinese University of HK, School of Pharmacy
Alan Ng	Chinese University of HK, School of Pharmacy
Audrey Shum	Clifford Chance
Dr Francis Kua	Constraint Management Center
Mr K K Chow	Constraint Management Center
Fatima Lai	Consulate General of Canada
Olivia Chan	Dentsply
Vissica Wong	Dentsply
Martha Lee	DKSH

Lawrence Yiu	DKSH
Chew Ee Ke	Eastman Chemical Asia Pacific
Kayley Wong	Ferring Pharmaceuticals
Carmen Sephton	GE Healthcare
Sabrina Chan	HKAPI (HK Association of Pharmaceutical Industry)
Jenny Wan	HKAPI (HK Association of Pharmaceutical Industry)
Mr CHIU Chi-Sang (LUCIANO BAPTISTA)	HKMRS (Hong Kong and Macau Regulatory Service) Ltd
AU Hiu Yan	The Hong Kong Polytechnic University
Chan Kam Hung, Beny	The Hong Kong Polytechnic University
Chan Sze Chun	The Hong Kong Polytechnic University
CHEN Xi	The Hong Kong Polytechnic University
CHENG Ka Fai	The Hong Kong Polytechnic University
CHOI Ching Hung	The Hong Kong Polytechnic University
CHOI Yuet San	The Hong Kong Polytechnic University
CHU Ka Wan	The Hong Kong Polytechnic University
Chui Tak Kong	The Hong Kong Polytechnic University
Fong Mei Yee	The Hong Kong Polytechnic University
Fung Kai Lok, Vincent	The Hong Kong Polytechnic University
Gao Yi	The Hong Kong Polytechnic University
HSIEH Pui Man	The Hong Kong Polytechnic University
IU Hoi Yan	The Hong Kong Polytechnic University
LAM Dominic Kin Hay	The Hong Kong Polytechnic University
LAU Kwan Nok	The Hong Kong Polytechnic University
LEE Chun	The Hong Kong Polytechnic University
Lee Kwok Tung	The Hong Kong Polytechnic University
LEUNG Chin U	The Hong Kong Polytechnic University
LUK Hon Kit	The Hong Kong Polytechnic University
Peng Huimei	The Hong Kong Polytechnic University
POON Pik Chi Melody	The Hong Kong Polytechnic University
SHIH Sung Yuen	The Hong Kong Polytechnic University
SUSANTO Evan Aditya	The Hong Kong Polytechnic University
TANG Pak Tim	The Hong Kong Polytechnic University
Tsang Fu Keung	The Hong Kong Polytechnic University
TSUI Pui Yee	The Hong Kong Polytechnic University
Wang Xun	The Hong Kong Polytechnic University
WONG Wing Yan	The Hong Kong Polytechnic University
WU Chun Yu	The Hong Kong Polytechnic University
Zheng Dan	The Hong Kong Polytechnic University
K C Lee	Hong Kong Standards and Testing Centre Limited
Carmen Lai	Hospira Ltd
Vincci Ip	Hospira Ltd
Karen Lo	Hospira Ltd
Pandora Cheung	InvestHK
Maggie Ho	Janssen Pharmaceutical
Jenny Ho	Johnson & Johnson Medical
Frederic Campana	LNE Shanghai
Holly Lee	Lumenis
Stephen Lam	Mannings MNS
Doris Cheng	Medtronic
Janice Wei	Medtronic
Emily Chiang	Medtronic

Jessie Wong	Medtronic
Erica Poon	Merck Pharmaceutical
Sun Qin	Molnlycke Healthcare
Monita Lau	Or & Lau, Solicitors
Edgar Leung	Orbit Medical Device Company Ltd
Iva Ng	OrbusNeich Medical Co Ltd
Phyllis Ng	PMRHK
Carin Ribbesjö-Lundqvist	Q-Med
Fanny Wong	Q-Med
Ulf Lundqvist	Q-Med
Ronald Lo	Roche Diagnostics (HK) Ltd
Abdulielah. K . Al-Mutairi	Saudi FDA, Saudi Arabia
KHALIL .H . AL GHAMDI	Saudi FDA, Saudi Arabia
AMJAD . S .ALGHAMDI	Saudi FDA, Saudi Arabia
Faisal . A . Alshehri	Saudi FDA, Saudi Arabia
Ziad. F. Alsabelah	Saudi FDA, Saudi Arabia
ALI . M .ALHAWAS	Saudi FDA, Saudi Arabia
Sultan . A . ALkanhal	Saudi FDA, Saudi Arabia
HUSSAM . M . ALAEQ	Saudi FDA, Saudi Arabia
Fahad . H . Al-Mujalli	Saudi FDA, Saudi Arabia
Abdulrahman . A .Al-Swayed	Saudi FDA, Saudi Arabia
Majed .A . Al-Qhtani	Saudi FDA, Saudi Arabia
Felicia Chau	Siemens Medcial Solutions Diagnostics Ltd
Grace Au	SSL Healthcare
Kamswee Koo	SSL Healthcare
Natalie Yan	SSL Healthcare
Sue Lin	SSL Healthcare
Ersula Chin	SSL Healthcare
Ronan Chan	St Jude Medical
Cat Hui Yuen Ting	St Jude Medical
Peter Kyong-Ho Lee	Straumann
Jo Ann Choo	Straumann
Kyungsun Yoon	Straumann
Emily Li	Stryker (Beijing) Healthcare Products Co. Ltd
Eddie Ngan	The MacKay Group
Iris Wong	W L Gore & Associates (HK) Ltd
Karen Lee	Wyeth
Tammy Wong	(Freelance Marketing Expert)
Carl Au	(Personal)
Crystal Chan	(Personal)
Jacqueline Cheng Chi Ying	(Personal)
朱惠如	BSI 英國標準協會
何家樑	台北醫學大學 生醫器材研發中心
宋威徹	(Personal)
李永全	TFDA
李珮瑜 (Maggie Li)	嬌生股份有限公司
林文彥	BSI 英國標準協會
林志魁	BSI 英國標準協會
林倩如 (Cherry Lin)	美商亞培股份有限公司台灣分公司
林清祺 (Frank)	京達醫材科技股份有限公司
徐嫻謙	台北醫學大學 產學育成營運中心

張郁婷	冠亞生技股份有限公司
張智維	台北醫學大學 產學育成營運中心
張善鈞 (Sam)	和康生物科技股份有限公司
郭銘芳	中原大學
陳誌雄	交通大學科技法律研究所
彭國勝	TFDA
程瀚毅	台北醫學大學 生醫器材研發中心
華子玲 Linda Hua)	朋馳企業有限公司
黃佩珍	交通大學
黃欣宜	台北醫學大學
黃俊傑	台北醫學大學
黃慧婷	國立台北科技大學
黃惠雯	(Personal)
楊賜春	BSI 英國標準協會
葉小芬	友華生技醫藥股份有限公司
董冠麟	(Personal)
詹育豪	台北醫學大學 生醫器材研發中心
劉延賦	台北醫學大學
劉雅芳(Liu Ya Fang)	台北醫學大學
蔡琺萱 Shirley Tsai	SHL Group
鄭為仁	台北醫學大學 生醫器材研發中心
盧仁傑	台北醫學大學
謝雅如 Sheena Hsieh	普生股份有限公司
顏士傑 Jay Yen	揚博科技(股)公司
巫雪蘭 Erika Wu	Jagwire 佳承精工股份有限公司
陳雍蓁 (Aggie Chen)	Jagwire 佳承精工股份有限公司

Contact Jack Wong (BSI) for detail of the training:
jack.wong@bsigroup.com

Pharmaceutical Regulatory training

After discussion with the HK PDA (Hong Kong Pharmaceutical Distributors Association) and Department of Health (Pharmaceutical Section) a Regulatory certificate training was developed. The coming training is 3 Jun, Tina Yap (chair of HKPDA) and Anthony Chan (Chief Pharmacist of DOH) will attend and give opening speech

Details of the training course can be found below

Regulatory Certificate Program

1 day training

Why attend?

Regulatory is critical to your business (Quicker and Quality registration approval means significant competitive advantage) and fatal to your business (Regulatory requirement is legal requirement, non-compliance means penalty and imprisonment)

Topics to be covered:

10:30am - 12:30am

Roles/Values of industry/Distributor (to be presented by HKPDA)

What are pharmaceutical products

What product needs to be registered and how to do classify them

Whom to deal with and how to work with government

What materials need to be submitted and why they are required

How to review the material before submission

1:30pm - 3:30pm

What to do if DOH raised questions

How to manage regulatory projects

How to do handle product recalls and re-labeling

UMAO understanding

3:30pm - 4:00pm

A 30mins examination will be arranged at the end

* Certificates will be issued to participants who passed the exam

Graduates list

Name	Organization
Vam Cheng	Allergan
Geoffrey Kok	Allergan
Rose Mak	American Consulate General
Yolanda Yan	Amgen
Susie Chan	AMO Asia Ltd
Susanna Leung	Asia Cardiovascular Products Ltd

Yemie Tsang	AstraZeneca
Stanley Yu	AstraZeneca
Susanna Yim	Bausch & Lomb (HK) Ltd
Mr Cheney Lu	Baker & McKenzie
Stephanie Poon	Baker & McKenzie
Gloria Poon	Baker & McKenzie
Jingyan Wei	Baker & McKenzie
Catherine Cheng	Bayer HealthCare Ltd
Flora Lee	Bayer HealthCare Ltd
Vivien Lee	B Braun Medical
Tracey Xie	Bright Future
Cecilia Chan	British Consulate General
Loong Chu	Canada Govt of Alberta
Winki Ip	Chinese University of HK, School of Pharmacy
Timothy Chan	Chinese University of HK, School of Pharmacy
Leung Man Cho	Chinese University of HK, School of Pharmacy
Fong Yui Kau	Chinese University of HK, School of Pharmacy
Mok Siu Man	Chinese University of HK, School of Pharmacy
Chan Ka Yan	Chinese University of HK, School of Pharmacy
Chan Yat Hei	Chinese University of HK, School of Pharmacy
Janice Tsui	Chinese University of HK, School of Pharmacy
Alan Ng	Chinese University of HK, School of Pharmacy
Chadwick Lie	Chong Lap (HK) Co Ltd
Sidney Ng	CK Life Sciences Int'l., Inc.
Keith Kei	CK Life Sciences Int'l., Inc.
Audrey Shum	Clifford Chance
Fatima Lai	Consulate General of Canada
Winnie Chung	Consulate General of Canada
Dr Francis Kua	Constraint Management Center
Mr K K Chow	Constraint Management Center
Michael Li	CSL Biotherapies Asia Pacific Ltd
Dominic Chan	Daiichi Sankyo Hong Kong Limited
Ho Ping Him	Daiichi Sankyo Hong Kong Limited
Lawrence Yiu	DKSH
Lewis Huen	DKSH
Louisa Ip	Dorsey & Whitney
Katherine Lai	Ferring
Agnes Sin	Fresenius Kabi Asia Pacific Ltd
Fanny Liang Yinxing	GE
Wendy Cheng	Gakderna Hong Kong Ltd
Pang Chuen Yee	Hing Wing Co Ltd
Wilson Lun	Hing Wing Co Ltd
Lam Chi Fung	Hing Wing Co Ltd
Sabrina Chan	HKAPI (HK Association of Pharmaceutical Industry)
Jenny Wan	HKAPI (HK Association of Pharmaceutical Industry)
Mr CHIU Chi-Sang (LUCIANO BAPTISTA)	HKMRS (Hong Kong and Macau Regulatory Service) Ltd
Pandora Cheung	InvestHK
Simon Tsang	InvestHK
Amy Ying	InvestHK
Maggie Ho	Janssen Pharmaceutical
Florence Law	Janssen Pharmaceutical

Jenny Ho	Johnson & Johnson Medical
Kanes Hau	Johnson & Johnson Medical
Janet Lai Mei Ho	Lundbeck Hong Kong
Chris Kai Cheong Chow	Lundbeck Hong Kong
Edgar Shiu Lam Liu	Lundbeck Hong Kong
Vincent Wong Ka-Chun	Mannings
Michael Chan	Mannings
Rene Kam	Mannings
Stephen Lam	Mannings
Carrie Li	MDCO
Doris Cheng	Medtronic
Comte Chan	Mentholatum Asia Pacific Ltd
Vincent Tsui	Mentholatum Asia Pacific Ltd
Emily Lee	Merck Sharp & Dohme
Erica Poon	Merck Pharmaceutical
Kane Leung	Novo Nordisk Hong Kong Ltd
Daniel Cheung	Novo Nordisk Hong Kong Ltd
Suk Chan	Novo Nordisk Hong Kong Ltd
Stanley Chan	Novo Nordisk Hong Kong Ltd
Monita Lau	Or & Lau, Solicitors
Sophie Li	OrbusNeich Medical (Shenzhen) Co., Ltd.
Patrick Lam	Orient Europharma Co., Ltd.
Phyllis Ng	PMRHK
Eddie Ngan	PMRHK
Lin Pui Yi	PuraPharm
Lau Sing Chau (Darren)	PuraPharm
Corinna Li	Reckitt Benckiser Hong Kong Ltd.
Jenny Leung	Reckitt Benckiser Hong Kong Ltd.
Anthy Ng	Reckitt Benckiser Hong Kong Ltd.
Sandy Kam	SAN Marketing Consultant Limited
Britta Snackers	Sandoz
Tony Ko	Servier
Maria Kong	Servier
Tess Yeung	Servier
Sean Morley	Starcon Corporation
Raymond Lee	Stiefel Laboratories (HK) Ltd
Peggy Yau	Synovate Healthcare
Jennifer Lee	Synovate Healthcare
Jesscia Chan	Takeda
Timothy Chan	TCM Healthcare (London) Ltd
Quincy Leung	UCB Pharma Ltd
Bill Guan de Qi	VTC
Raccoon Chung	Watsons
May Yip	Watsons
Danny Chan	Watsons
Derek Chow Chun-Pong	Watsons
Accacia Ku	Wyeth
Karen Lee	Wyeth
Vincci Yip	Wyeth
Calvin Chan	Wyeth
Tammy Wong	(Freelance Marketing Expert)

Carl Au	(Personal)
Crystal Chan	(Personal)
Janet Lai	(Personal)
Sung Kai-Yi	(Personal)
Lawrence Ho	(Personal)
May Hung	(Personal)

Contact Jack Wong (BSI) for detail of the training: jack.wong@bsigroup.com

China and Global Medical Device Regulatory training

2 Days training

Why attend?

Regulatory function is vital to business. Late registration or late renewal could create significant business impact. Regulatory regulation is also keep on changing. In the past, there is no formal regulatory training certificate in Asia.

We work with different regulatory experts globally and proudly create the FIRST Regulatory Affairs Certificate in China. This certificate program is designed for regulatory, commercial and quality staff Medical Device business is getting global and hence this training will not only cover China regulatory but also key countries globally.

Not only acquiring knowledge, BSI would like to create a platform for regulatory staff to gather regularly to build stronger regulatory network

BSI will also share some key regulatory processes experiences e.g. how to manage regulatory projects, how to handle product recalls etc

Topics to be covered:

Introduction of GHTF and AHWP

What is medical device

How to classify medical device

Basic 9000 and 13485 introduction

US and Europe medical device regulatory

Asia medical device regulatory and trend (Japan, Korea, India, Hong Kong, Taiwan, Singapore, Malaysia, Thailand, Philippines etc)

Graduates list

Name	Organization
Sudesh Samuel	3M
Vicky Chai 柴荻菲	Alcon
Shining Wu 吴晋芳	Alcon
Lynn Gu 顾 娟	AMO
Helen WANG	AMO
Wendy WONG	AMO Singapore Pte Limited
潘 石	B Braun 贝朗医疗(上海)有限公司
Kathy 许葵	BCCE
Erica 刘明珠	BCCE
Ellen 姜云丹	BD 碧迪医疗器械（上海）有限公司
Cherry 陈华	BD 碧迪医疗器械（上海）有限公司
Harvey Wu 吴辉	Biomet
David 党大伟	Boston Scientific 波科国际医疗贸易(上海)有限公司
Jane Hong 洪佳	CareFusion
章 坚	CARIDIAN BCT
Huang Wei 黄伟	Celestica
袁斌华	China SZ FDA 医疗器械监管处

徐良	China SZ FDA 医疗器械监管处
Lina 张丽娜	Cochlear
Marshall 汪笑天	GE 医疗集团
Linda Shi 石群	Gore
聂晶	J&J (Shanghai)
Jessie Li 李晓华	J&J Medical
Mary Wang 王慧玲	J&J Vision Care
Andy 罗 峰	Jyton 北京捷通康诺医药科技有限公司
Mandy 刘潋泽	Jyton 美国埃默高集团中国办事处
Michelle Yan 闫春霞	KCI Medical
Holly Lee 李英	Lumenis
Bao Fei Fei	Macau University
Chan Ieng Lam	Macau University
Chan Ieng Lam	Macau University
Che Oi Lam	Macau University
Cheang Mei Lin	Macau University
Chen Cong	Macau University
Choi In Leng	Macau University
Gao Hua	Macau University
He Xiu Qiong	Macau University
Hu Ching Yuan	Macau University
Kuan Wai Chu	Macau University
Lam In Kei	Macau University
Leong Iat Ngai	Macau University
Li Ling	Macau University
Li Yan	Macau University
Mok Weng Han	Macau University
Pan Wei	Macau University
Qian ZhongShu	Macau University
Tam Un Wa	Macau University
Wong Mei I	Macau University
Wu Hio Tong	Macau University
Yin Shi	Macau University
Zhang YiRan	Macau University
賈永亮	Macau University
張時開	Macau University
Jun Chen 陈均	Medtronic
Lucy 项传青	Microport 微创医疗器械（上海）有限公司
Oscar 杨 龙	Mindray
Wilson 谭传斌	Mindray
Patrick 汪新兵	Mindray
Arianti Anaya	Ministry of Health of Indonesia
Lili Sadiyah	Ministry of Health of Indonesia
Eva Silvia	Ministry of Health of Indonesia
Ninik Haryati	Ministry of Health of Indonesia
Retno Dewi Martami	Ministry of Health of Indonesia
Eva Zahrah	Ministry of Health of Indonesia
Masrul Masrul	Ministry of Health of Indonesia
Huang Jin	OrbusNeich Medical(Shenzhen)Co.,Ltd.

Elly Wang 黄静珊	Pari (HK) Ltd
Alexis Kwan	Providence Enterprise
梁振士	SFDA 北京医疗器械检验所
杨建刚	SFDA 天津医疗器械检验中心
Bruce 张晓霞	Siemens 西门子听力仪器(苏州)有限公司
Susan 须星	Smith & Nephew 施乐辉医用产品(苏州)有限责任公司
Jane Chen 陈建萍	Starch Medical
Chris Sugg	Stryker
Maggie Wu 吴晓菁	Stryker
April Dong	Stryker
Eva 王莉	Stryker 史赛克(北京)医疗器械有限公司
Linda 信红岭	Stryker 史赛克(北京)医疗器械有限公司
Teresa 徐航	Sysmex 希森美康医用电子(上海)有限公司
Lisa Zhu 朱雯晴	Zimmer
Cherry Yang 杨秀萍	Zimmer
Cindy 杨怡斐	Zimmer 捷迈(上海)医疗国际贸易有限公司
Catherine 杨瑜静	Zimmer 捷迈(上海)医疗国际贸易有限公司
曾祺 Jenny Zeng	莱茵技术(上海)有限公司 TUV Rheinland
Rebecca 胡庆炜	利奥电池系统(上海)有限公司
Emy 王温燕	利奥电池系统(上海)有限公司
Ryan 陈昌顺	美国翰宇国际律师事务所上海代表处
Susan 余自云	上海开创生物技术有限公司
Lisa 邵春燕	上海开创生物技术有限公司
Jason 曾勇为	上海思宜科国际贸易有限公司
Merry TONG	斯腾爽健贸易(上海)有限公司 SSL
Martin 马征宇	斯腾爽健贸易(上海)有限公司 SSL
Simon XUE	屹龙商务服务(苏州)有限公司 Hill Rom
Emily HU	屹龙商务服务(苏州)有限公司 Hill Rom

***Students completed the
CSDT and Medical Device Regulatory training***

Name	Organization
Ade Herawati P	Johnson & Johnson Indonesia (Medical Division)
Yohana Astrida Gumelar	PT. Nugra Karasera
Vincentia Mega Devita	Ministry of Health of Indonesia
Nuning Lestin Bintari, S. Farm. Apt	Ministry of Health of Indonesia
Dr Sujitno Fadli	PT. Enseval Medika Prima
Ervani Setya Susanti, S.Farm, Apt	EXI Consulting
Wenda Nur Aida, S.Si, Apt	EXI Consulting
Angela Roselyn	PT. Transmedic Indonesia
Dedi Ardilia	PT. Transmedic Indonesia
Niki Nuryadin	PT. Sarandi Karya Nugraha
Ir. Zulfikar Hasibuan	PT. Sarandi Karya Nugraha
Mira Indriani, S. Farm., Apt	PT. Johnson & Johnson Indonesia
Wahyu Eko Fitriono	PT. Abadinusa Usaha Semesta
Annisa	Ministry of Health of Indonesia
Nurul Intan K.S S.Si, Apt, MBA	PT. Behrindo Nusa Perkasa
Kitty Mao Yiqing	GE Healthcare
Sabrina	PT. Sali Polapa Bersama
Wimbardi	PT. Sali Polapa Bersama
Fatma	EXI Mgt System
R. Henrarto	EXI Mgt System

Global Medical Device Regulatory Seminar

1 Day Seminar

Topics to be covered:

GHTF and AHWP introduction

AHWP and ASEAN update

Asia regulatory update (HK, Singapore, Malaysia, Thailand, Taiwan, Korea)

India update

China update with project management discussion

Graduates list

Name		Organization
Hakim	Shazia	(Personal)
Adepoju	Bandeled	(Personal)
	Zhenghong Tao	Abiomed
Van rooij	Pamela	Acist
Bernardy	J	Aeris Therapeutics
Sachdea	Sandy	Align Technology, Inc
Stegmeier	Barb	Alquest, LLC
Allen	Thomas	Applied Nanoscience Inc.
Weisel	Marisa	Arrow International Inc
Willman	Danielle	Arrow International Inc
	Fort Laurence	Artefact Medical Care
Charest	Ann	Arteriocyte Medical Systems
McKay	Randy	BD
Pieratos	David	Becton Dickinson and Company
Dominguez	Connie	Biomet
	Dr. Jens Hagen	Bluestar Silicones Germany GmbH
Shoemaker	Christine	Boston Scientific
Verdooren	Milena	Boston Scientific
Theisen	Akiko	Boston Scientific Corporatino
Sachs-Campbell	Kay	Boston Scientific Corporation
Barklind	Eckhart	Boston Scientific Corporation
Lind	Laura	Boston Scientific Corporation
Pundock	Julia	C.R. Bard
Jones	Cinthia	C.R. Bard
Kelley	Peter	CapsuleTech, Inc.
	Elisabeth Stanek	CeramTec AG
	Jenny Jones	Civco Medical solutions
Thompson	Patricia	Clarity Medical Systems Inc.
Seeger	Gary	Clarity Medical Systems Inc.
McAvoy	Theresa	Codman & Shurtleff, Inc.
Forte	Carl	ConvaTec
	Chie Iwaishi	Cordis Corporation, a Johnson & Johnson company
Wu	Bonnie	Decus Biomedical
Knight	Rita	DePuy Spine
Leavitt	Susan	DePuy Spine, Inc.
Parsons	Bob	Devicix LLC
	Peter Koster	DSM Biomedical
Bhayani	Nazira	Ethicon, Inc., a Johnson & Johnson Company
McGinley	Kathryn	Extremity Medical, LLC

Bindon	Adele	Fisher & Paykel Healthcare
Daken	Reena	Fisher & Paykel Healthcare
Traylor	Melissa	FzioMed, Inc.
	Melissa M. Traylor	FzioMed, Inc.
Gray	David	GE Healthcare
Keren	Don	Genetix Corp
	Dr. Jens Heilmann	Geuder AG
Fox	Kristi	Greatbatch Medical
Springer	Shannon	Greatbatch Medical
Reed	Melissa	Greatbatch Medical
	Erik Vollebregt	Greenberg Traurig
	Lei Huang	Greenberg Traurig
Kahwati	Sheila	Gyrus ACMI
	Shazia Hakim	Hansen Medical, Inc.
Wartman	James	Hoya Surgical Optics
	Markus Spitzner	Human GmbH
Zeira	Gabriele	iCAD Inc.
	Tim van Leuken	IGZ (Inspectie voor de gezondheidszorg)
Oppenheimer	Darin	Imaging Sciences International
Hendricks	Linda	Integra LifeSciences Corporation
Rogers	David	Integra LifeSciences Corporation
Klosterman	James	Lake Region Medical
Mortensen	Karen	Lake Region Medical
Conway-Myers	Barbara-Ann	Leica Biosystems, Richmond
Singh-Rodriguez	Soumya	Leica Microsystems
Le Bars	Anna	Luminex Molecular Diagnostics Inc
Osborn	Erin	MEDRAD
Zanotto	Tina	MEDRAD
Siravanta	Mani	Mentor Worldwide LLC
Moua	Mai Kou	Mentor Worldwide LLC
Co	Steven	Merz Aesthetics, Inc.
Schultz	Kelsi	MeVis Medical Solutions, Inc.
Jossy	John	NeoVista, Inc.
	Rainer Maas	NEUROMetrix, Inc.
Gardanier	Paul	OptiMedica
Rule	Ed	Optos
McLeod	Corrine	Orthovita
Liang	BeeChoo	Pacific Biosciences
Martin	Roger	Pacific Biosciences, Inc
	Justin Choy	PerkinElmer Illumination Inc.
	George Lucas	Possis
GORANOV	KONSTANTIN	SALUTARIS
Chang	Elaine	Siemens
McGeown	Agnes	Smith & Nephew, Inc.
Kelly	Joan	Smith & Nephew, Inc.
Saraceno	Susan	Smith & Nephew, Inc.
Obreztchikova	Maria	St. Jude Medical
Nord	Marlena	St. Jude Medical
Burdel	Colleen	Stryker Orthopaedics
Klapper	Carolan	Superscrew Superspring Co
Bunnewith	Gary	TechDevice Corporation
Teshima	Yukiko	Teshima International Corporation
	Charlene Brumbaugh	Thoratec corp
Harrison	Andrew	Young Innovations
Hardy	Ashley	Zimmer Dental, Inc.
	30 participants on 13 Aug 2010 (names cannot be disclosed)	Japan



GOOD CLINICAL PRACTICE (GCP) Training Courses

INTRODUCTION TO GCP Certificate (2 days training)



This Introductory GCP course will provide basic knowledge about clinical research, the application of regulations within clinical research and the history of GCP.

After completing the course, participants will:

1. Recognise the basic principles of ICH GCP and the regulatory environment
2. Describe the basic requirements for conducting studies
3. Be familiar with the responsibilities of the Investigator, Sponsor, Monitor and IRB/Ethics Committee
4. Be aware of the significant milestones in the history of GCP development in clinical trials within the historical perspective of the Nuremberg Code, the Declaration of Helsinki, and the Belmont Report,
5. Understand the objectives of regulations pertaining to Institutional Review Boards (IRBs)
6. Understand regulatory requirements and ethical considerations involved in the informed consent process
7. Identify the activities involved in study initiation meetings investigator meetings; the conduct of study initiation visits; and preparing the site for study participation
8. Understand the collection and evaluation of research data for completeness, compliance, and accuracy through periodic monitoring visits; discuss reporting and follow-up including Adverse Events
9. Compare and contrast the auditing and monitoring functions and understand the consequences of fraud and misconduct
10. Describe how to conduct a site closeout visit and site follow-up

Why should you take this course?

This course serves as a foundation course in GCP and provides some regulatory knowledge. Understanding how GCP impacts clinical research is essential to anyone working directly or indirectly on clinical trials. Compliance with GCP translates to credible data and ensures that study subjects and their rights are protected.

Although borne as a guideline, in many parts of the world GCP is now a legal requirement for conducting clinical research. Currently, this is the only GCP training program in Hong Kong.

Candidates who successfully pass the assessment for this course will be awarded an official GCP certificate and may be admitted directly to the advanced course in GCP.

Who benefits by participating in this course?

The course is appropriate for anyone conducting or supporting clinical research including; research staff at a hospital, medical device or pharmaceutical industry workforce, research coordinators, clinical research associates, R&D engineers, regulatory staff, IRB members, government officials and anyone interested in pursuing clinical research as a career path.

ADVANCED GCP AND STUDY-SITE MANAGEMENT (2 days training)



This Advanced GCP and Study Site Management course provides more in-depth knowledge and practical applications of GCP and its impact at the study site.

After completing this course, participants will:

1. Understand aspects of clinical trials that are governed by regulations and guidelines.
2. Describe how essential documents permit evaluation of the conduct of a trial and the quality of the data produced.
3. Be aware of the elements of the Informed Consent Form and understand the ethical principals
4. Recognize the various aspects of human research protections including the ICH definitions of AEs (adverse events) and SAEs (serious adverse events).
5. Know the SAE reporting requirements common to all sponsors and IRBs/IECs.
6. Understand the role of the investigator and other study team members in terms of submitting a protocol to the IRB; setting up local procedures; source documentation management and control; and working relations with Sponsors.
7. Appreciate the rationale and issues surrounding the monitoring visit and the audit process both from a site, a sponsor and a regulatory perspective.
8. Describe how a clinical trial is managed at the study site.
9. Discuss mechanisms to implement and ensure the quality of the processes and deliverables involved in clinical research.
10. Discuss the philosophy and rationale for the development and implementation of Study Site Standard Operating Procedures.

Why should you take this course?

This course will build upon the content of the course 'Introduction to GCP' to help further the understanding how the theory of GCP is put into practice. At present, this is the only GCP training program in Hong Kong.

Candidates who successfully pass the assessment for this course will be awarded an official Advanced GCP certificate.

Who benefits by taking the advanced course?

This course is intended for physicians, research staff, clinical research nurses or other clinical research personnel who wish to deepen their understanding of GCP. The course is appropriate for anyone conducting or supporting clinical research, medical device or pharmaceutical industry workforce, R&D engineers, regulatory staff, IRB members, government officials and anyone interested in pursuing clinical research as a career path

CERTIFICATES

Participants who achieve an examination mark of 70% in the multiple-choice examination that contains 50 questions will be issued with a Certificate.

COURSE INSTRUCTORS



James Thorburn

Currently, Director of Clinical Research at Clinical Trial Concepts Ltd. James has over twenty years of medical and clinical research experience in UK, Europe and Hong Kong; he was formerly responsible for the organisation and teaching of Good Clinical Practice and other clinical research courses at the Faculty of Medicine, The University of Hong Kong.



Tiffany Bauguess-Beeson

Tiffany has over 10 years of experience in Clinical Research. She has managed all aspects of clinical research involving medical devices for various companies and has a wide range of clinical trial experience in different therapeutic areas. Tiffany has worked in the USA, Canada, Europe, Mexico and the UK and is currently Director of Clinical Research Operations at Clinical Trial Concepts Ltd.



Guneet Makkar

Educated India and Hong Kong, Guneet brings with her a wealth of in-depth academic medical experience. She has over 15 years of experience in clinical work and practice, which includes extensive scientific and clinical research, teaching and medical writing. Guneet is currently Medical Director for Clinical Trial Concepts Ltd.



Jack Wong

Currently Vice President, Regulatory Affairs, Asia and General Manager, Hong Kong at BSI (British Standards Institution). Jack has over 13 years of Regulatory, Clinical Trial and Pharmacovigilance experience in Asia, a good knowledge of medical devices, pharmaceuticals, consumer healthcare, biological and nutritional products.

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Enquiries

- Professor Zhang Ming
- Tel.: (852)3400 8578, Fax: (852)2362 4365
- Email Address: hti.dept@polyu.edu.hk
- Website: <http://www.polyu.edu.hk/hti>
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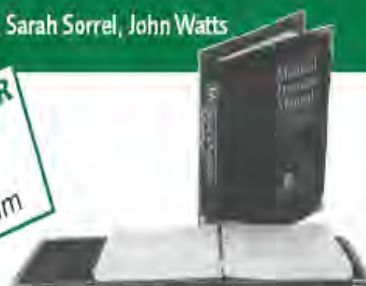
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Editors: John Adcock, Sarah Sorrel, John Watts

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