



VISION 管略

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**HKQAA Hong Kong Registration –
Environmental Friendly Construction Site**

香港品質保證局香港註冊 — 環境友善建築地盤

**Sustainable Building Index Introduced in Guangzhou
在廣州率先引入樓宇可持續發展指數**

**New Revision to ISO 13485 for Medical Devices Comes into Effect
新修訂版ISO 13485醫療器械質量管理體系標準正式生效**



香港品質保證局

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VISION encourages article submissions. Submitted articles should include both printed and soft copy in Word or Rich Text format. Contributions should reach the Chief Editor by fax: (852) 2202 9222 and e-mail: vision@hkqaa.org.

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Contributing to a Green Construction Site

Construction is a key driver of national economies but it may also be a source of damage to the environment. The United Nations Environmental Programme revealed that the construction sector and buildings account for 40% of global energy use, 30% of energy-related greenhouse gas emissions, 12% of water use and 40% of waste. Construction site may also bring adverse impact on Hong Kong's environment. Environmental Protection Department received a total of 4,851 unfavourable responses about air, noise, water or waste pollution from construction activities in 2015.

HKQAA is dedicated to promoting environmental protection and sustainable development in the society. Over the years, we have developed new initiatives to help improve the sustainability performance of the business sector. To meet industry needs and public expectations, we recently launched the "HKQAA Hong Kong Registration – Environmental Friendly Construction Site". This scheme encourages constructors to monitor and control their impact on the environment during the construction process in order to help reduce energy consumption and pollution, as well as conserve the ecosystem.

Through providing the recommended green practices, we strive to help improve industry's sustainability performance. Our ultimate goal is to motivate more organisations to 'walk the talk' by incorporating green practices into their daily operations. This will help raise the industry level, enhance its public image and benefit society in the long run.

Urban development inevitably affects nature to some extent but we must do our best to minimise its impact and the industry is playing a vital role. HKQAA will continue to develop new services to promote good practice to industry so as to jointly create a sustainable future.

推動建築地盤實踐環保

建築是推動國家經濟發展的重要力量，但同時亦可能為環境帶來損害。據聯合國環境署披露，建造業及樓宇佔據了全球40%的能源使用，30%的溫室氣體排放，12%的用水及40%的廢物。在香港，建築地盤或多或少對環境帶來影響，2015年，環境保護署共收到4,851個關於建築活動的污染反饋，當中涉及空氣、噪音、水源或廢物等問題。

多年來，香港品質保證局致力促進環保及社會的可持續發展，積極開拓嶄新服務，助工商界提升可持續發展表現。為配合業界需要和公眾期望，本局推出「香港品質保證局香港註冊 — 環境友善建築地盤」，鼓勵承建商監控建築過程對環境的影響，減少污染及耗用能源，為保護生態環境作出貢獻。

此計劃提供建議的環保做法，協助業界改善可持續發展表現，我們期望可推動更多機構付諸實踐，將環保做法融入日常營運，長遠地優化行業水平，提高其公眾形象，同時亦惠及社會。

城市發展不免對大自然構成一定影響，因此我們須盡力減低對環境造成的傷害，而工商界更從中擔當著舉足輕重的角色。本局會繼續開發更多新服務，向業界推廣良好做法，攜手開創可持續發展的未來。

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HKQAA Hong Kong Registration – Environmental Friendly Construction Site

香港品質保證局香港註冊 — 環境友善建築地盤

Construction is one of the drivers of economic and social development but may be a major cause of pollution and negative impacts on the ecosystem which draws public attention. According to the Environmental Protection Department (EPD), in 2015 there were 1,239 unfavourable responses about noise and 886 about air nuisance from construction activities. This shows that the construction industry needs to better monitor and control the impact of construction processes on the environment to meet public expectations with regard to their environmental performance.

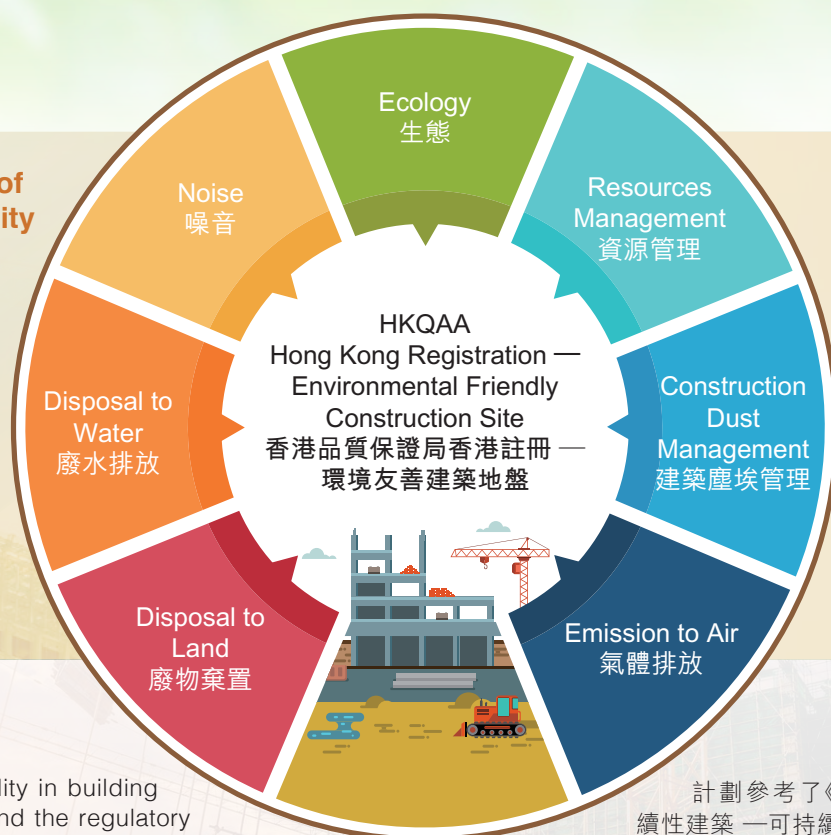
HKQAA has launched the HKQAA Hong Kong Registration – Environmental Friendly Construction Site to encourage organisations in the construction sector to minimise their adverse impact on the environment and society in construction operations. The scheme promotes recommended green practices so as to help improve the industry's sustainability performance and its public image.

建築是促進經濟及社會發展的動力。惟在建築過程中，地盤或會對生態帶來負面影響或污染，引起公眾關注。根據環境保護署2015的統計數字，有關建築活動的噪音反饋有1,239宗，空氣滋擾有886宗。由此可見，建築行業需要加強監察及控制建築過程對環境之影響，以滿足公眾對其環保表現的期望。

為配合業界及社會發展，本局推出香港品質保證局香港註冊 — 環境友善建築地盤，鼓勵從事建築業的機構，在作業時盡力減低對環境及社會的負面影響。計劃推廣綠色建議做法，協助業界改善可持續發展表現及形象。

Seven Environmental Aspects of Construction Sites' Sustainability Performance

七項環境範疇
衡量建築地盤的可持續發展表現



With reference to ISO 21929 Sustainability in building construction - Sustainability indicators and the regulatory requirements of EPD for construction sites, seven aspects will be assessed in the scheme: ecology, resources management, construction dust management, emission to air, disposal to land, disposal to water, and noise. Twenty recommended practices are provided to help enhance the sustainability performance of construction sites. This initiative is intended to encourage the industry to reduce pollution and the consumption of resources during the construction process.

計劃參考了《ISO 21929 可持續性建築 — 可持續發展指標》及環境保護署對地盤的條例要求，從而制訂七個範疇以作評審，包括生態、資源管理、建築塵埃管理、氣體排放、廢物棄置、廢水排放，以及噪音，並提供二十個建議做法，推動業界在建築過程中，減少污染和耗用資源。



Checklist of Recommended Practices 建議做法清單

Aspect 範疇	Recommended Practice 建議做法
Ecology 生態	Protection of trees on construction site 保護地盤內樹木
	Monitoring ecological mitigation on construction site 監察地盤生態，緩和對生態的影響
Resources Management 資源管理	Management of construction materials and equipment 建築物料及器材管理
	Management of energy resources 能源管理
	Management of water resources 水資源管理
Construction Dust Management 建築塵埃管理	Control of dust generation in material handling 在處理物料時控制塵埃產生
	Using hoarding / dust screen to prevent dust generation on construction site 使用圍板 / 隔塵幕以避免在地盤產生塵埃
	Controlling dust emission in excavation 在開鑿時控制塵埃散布
	Controlling dust emission in dust vehicle processes 在操控塵埃器械時控制塵埃散布
	Controlling dust emission in demolition work 在進行拆除工作時控制塵埃散布
Emission to Air 氣體排放	Controlling dust emission in drilling and blasting 在鑽控及爆破時控制塵埃散布
	Controlling air pollution in construction plant and equipment 控制建築場所及器材所產生的空氣污染
	Controlling volatile organic compound emission on construction site 控制地盤的易燃有機化合物排放
Disposal to Land 廢物棄置	Preventing illegal open burning on construction site 避免在地盤非法公開燃燒
	Working procedures to minimise construction waste 減少地盤廢物的工序
	Working procedures to manage chemical waste 管理化學廢物的工序
Disposal to Water 廢水排放	Minimising solid waste in construction processes 在建築過程中減少固體廢物
	Treatment of waste water generated from construction site 處理地盤產生的污水
Noise 噪音	Water quality monitoring during construction processes 在建築過程中監測水質
	Control of noise generated in construction processes 在建築過程中控制噪音

Eligibility

This registration is site-based and the site has to be in progress. Any company which is the constructor on a construction site and able to control the building processes can register its site with the scheme. The main constructor of the registered site will receive a registration mark so that it can demonstrate its commitment to urban sustainability and environmental protection, and improve its brand image and reputation.

適用範圍

註冊以地盤為單位，註冊的地盤須正進行工程。任何能控制建築過程的承建商，都可為其地盤申請註冊。成功註冊的機構可獲發註冊標誌，彰顯其對城市可持續發展及保護環境的貢獻，提升品牌形象及商譽。

Registration Process 註冊流程



Sustainable Building Index Introduced in Guangzhou

在廣州率先引入樓宇可持續發展指數

Guangzhou, one of the major cities in China, is the core of the Pearl River Delta and has been repeatedly ranked as the best city for business in the Mainland by Forbes China. Guangzhou Tianhe Central Business District (CBD), mainly driven by commercial and financial services, is currently experiencing the fastest economic development in southern China, becoming an integrated top-tier agglomeration of corporate headquarters, trade sectors and iconic business streets.

HKQAA was appointed by Tianhe CBD Administrative Committee to provide assessment services for the Sustainable Building Index (SBI) in the district. This helps promote quality property management, increase the value of buildings and improve the overall image of the CBD while maintaining the edge of the new buildings and improving the social value of existing buildings. Twenty-one buildings, which take hundreds of millions of RMB of tax revenue, have already completed SBI assessments. Assessments for another 27 buildings will commence this year.

Stimulating the Value of Tianhe CBD Buildings

The introduction of SBI has a profound significance for Tianhe CBD. It encourages buildings to review and enhance their operations to optimise various initiatives and reduce energy consumption, thus enhancing customer satisfaction and building value. It also motivates other buildings in the district to improve their services in order to take the overall property management of Tianhe CBD to the next level. The analysis of buildings' sustainability performance helps them deliver world class and standardised property management services and encourages sustainability management practices, thus creating an influential premium business district with quality services.



▲ Tianhe CBD
天河 CBD 全景

Performance of Assessed Buildings

Based on the HKQAA SBI, the assessment methodology and principles make reference to national laws and regulations, as well as the latest international standards, and statistics from Tianhe CBD. The assessment consists of three aspects, the environment, society and the economy, and is divided into 24 performance indicators and eight add-on elements, to evaluate building sustainability performance objectively.

At present, the average score of the assessed buildings is 2.55 (out of 3). This means that the buildings have developed an awareness of sustainability management and been able to incorporate it into daily operations.

As for the environment, many buildings in the region have launched energy saving and carbon reduction measures and projects to reduce energy consumption effectively. The average annual greenhouse gas emission figure is 38.25mt/1,000m², which scores 3 marks. Since the government has begun promoting recycling for only a short time, there is a need to raise public

廣州—中國重點城市之一，是珠三角的核心，並多次獲評福布斯中國大陸最佳商業城市。其中廣州市天河中央商務區 (CBD) 是以商貿及金融服務業為主導，聚集企業總部、商貿功能及特色商業街為一體的高端綜合功能區，亦是南中國城市化發展最快、綜合配套設施最完善的平台。

為塑造優質物業服務品牌、提升樓宇價值和 CBD 的整體形象，天河 CBD 管委會委任香港品質保證局，提供樓宇可持續發展指數評定服務，藉此保持新建樓宇的發展優勢及提升現有樓宇的社會價值。目前，天河 CBD 內 21 棟億元稅收樓宇完成了可持續發展指數的評定，其餘 27 棟億元稅收樓宇亦於今年開展評定工作。

指數助提高天河 CBD 樓宇價值

在天河 CBD 引入樓宇可持續發展指數具有深遠意義，不但可以推動各樓宇在營運時查漏補缺，不斷優化各項措施，減少資源消耗，從而提升客戶滿意度及樓宇價值；亦促進區域內其他樓宇改善物業管理服務，以提升天河 CBD 整體的物業管理水平。此外，通過分析樓宇的可持續發展表現數據，利於建立一套與國際接軌及規範化的物業管理服務，推動天河 CBD 可持續發展的管理文化，以優質的樓宇服務，塑造極具影響力的高級核心商務區。

參加評定的樓宇情況

評定的方法及準則以「香港品質保證局樓宇可持續發展指數」為基礎，並參考了內地相關的法律法規及最新國際標準，同時結合天河 CBD 的區域調查研究數據，以環境、社會和經濟的三大範疇為框架，再分成 24 項評定指標及八個加分項目，客觀地評定樓宇的可持續發展表現。

現階段，已接受評定樓宇的平均得分為 2.55 分 (滿分為 3 分)，表現不俗。反映了區域內樓宇均具備樓宇可持續發展的管理意識，並系統地實踐在樓宇及其設施的日常管理上。

環境方面，區域內不少樓宇均積極開展節能減排計劃及實施節能工程等措施，有效降低能源消耗。樓宇的溫室氣體 (GHG) 每年平均排放量為每 1,000 平方米



Zhujiang New Town, Tianhe CBD
天河CBD珠江新城全景

awareness and room for improvement in recycling performance. The average annual quantity of waste recycled is 175.49kg/1000m², scoring 2 marks. Tianhe CBD is currently formulating and facilitating the recycling management mechanism, and enhancing publicity work to promote continuous improvement.

There are national laws and regulations on fire and elevator safety on the Mainland, and building safety and daily maintenance are also emphasised. The performance of Tianhe CBD buildings on fire, elevator and escalator safety is outstanding and meets the highest level. The buildings have dozens of different emergency plans in the form of printed copies or wall installations, and organise drills regularly to demonstrate the importance of building safety control. With the increasing importance of barrier-free accessibility, a further improvement in related facilities in Tianhe CBD is needed, however.

Rental rate is a key indicator of a building's economic performance. Located in the central area of the city, with convenient transportation, Tianhe CBD enjoys a pro-business environment which attracts both local and international enterprises. 90% of the buildings lease out 85% or above of their space, and in this assessment, 3 marks are scored.



Tianhe CBD Administrative Committee visited HKQAA headquarters
天河CBD管委會訪問香港品質保證局香港辦公室



38.25公噸，達到3分，表現理想。然而，由於國家較遲開始推廣廢物回收，市民的環保意識較弱，因此樓宇在廢物回收的表現相對遜色，平均每年廢物回收量為每1,000平方米175.49公斤，只達到2分。天河CBD管委會正就此制定並推行廢物回收管理制度和加強宣傳工作，鼓勵樓宇持續改善。

另外，內地就樓宇防火及電梯安全定立了不少法律和法規，亦注重樓宇日常安全的維修及保養。而天河CBD樓宇在防火、電梯和自動扶手電梯安全等指標表現出色，均符合最高標準。各樓宇制定了十至數十種不同的應急方案，釘裝成冊，或將應急方案裝裱在牆上，又定期安排演習，以示對樓宇安全管理的重視。另一方面，隨著無障礙設施越來越受關注，天河CBD樓宇需要持續優化相關設施。

出租率是反映樓宇經濟表現的重要指標。天河CBD位處城市中央地段，交通便利，擁有濃厚的商務氣氛，吸引國內外企業落戶。在是次評定中，樓宇的出租率也表現理想，基本達到3分，九成樓宇的租售率達85%或以上。

Sharing by Participating Buildings 參與評定的樓宇分享



Mr Zhang Jun
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Guangzhou Branch, Shanghai
Poly Property Hotel Management
Group Co., Ltd.
上海保利物業酒店管理集團
有限公司廣州分公司
總經理張軍先生

"CITIC Plaza has operated for over 20 years and is one of Guangzhou's landmarks. As its property management services provider, Poly Property has adopted the concept of 'making a better life', aiming to provide customers with a quality experience. In recent years, we have been determined to implement automation and environmental quality control, which have gained reputation. After participating in the SBI assessment, we have a clear understanding of building sustainability to increase the social value of CITIC Plaza."

「中信廣場作為廣州市地標性建築之一，運作已超過20年。肩負中信廣場的物業管理之重任，保利物業一直實行『讓生活更美好』的物業服務理念，務求帶給客戶持續的價值體驗。近年來，我們致力開展樓宇電腦智能化和環境質量管控的工作，並取得了良好的口碑。通過參與樓宇可持續發展指數的評定，我們更清楚樓宇可持續發展的方向，有助提升中信廣場的社會價值。」



Mr Pan Shao Hua
Project Assistant General
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Bank of Guangzhou Tower
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廣州銀行大廈服務中心
項目副總經理
潘兆華先生

"After the Bank of Guangzhou Tower passed the SBI assessment, we have incorporated the aspects of the Index into daily management services using a people-oriented hotel management style. We have therefore created a comfortable, safe and environmentally friendly business environment. We will continue to enhance building sustainability to raise our competitiveness and overall value, and fulfill our commitment to social responsibility."

「廣州銀行大廈率先通過樓宇可持續發展指數評定後，我們將該指數融合貫徹到日常管理服務中，結合『以人為本』的酒店式服務理念，營造更清新、舒適、安全、節能環保的商務辦公環境。我們將不斷推動樓宇可持續發展，以提升市場競爭力及整體價值，彰顯社會責任。」

Good Practices in Building Sustainability 樓宇可持續發展的良好做法

Buildings such as Guangzhou International Finance Centre, CITIC Plaza, R&F Centre, Bank of Guangzhou Tower, Teem Tower and Leatop Plaza, demonstrate outstanding performance in facilities and sustainability management.

個別樓宇如廣州國際金融中心、中信廣場、富力中心、廣州銀行大廈、粵海天河城大廈及利通廣場，在配套設施及可持續管理表現突出。



Guangzhou International Finance Centre has launched a wide range of plans and services. It has adopted different energy saving installations, for example, heat recovery equipment for water-side equipment and heat recovery ventilation, to match its green management policies.

廣州國際金融中心推行多元化的規劃及服務，如採用冷凝水熱回收系統和全熱回收新風機組等不同的新型節能環保設備，突顯了這座地標的綠色管理方針。

CITIC Plaza is one of the first Tianhe CBD landmark buildings. Although it has been in operation for over 20 years, it has maintained a steady sustainability performance, with its professional property management services and facility maintenance. The Plaza holds more than 200 training sessions every year, and constantly improves the services of property management staff. To implement comprehensive building safety management, it has set up strategic emergency zones for fires, explosions and floods, and keeps up with the Public Security Bureau to make timely safety monitoring feedback.

中信廣場作為天河CBD第一代標誌性建築，雖然已經達到20年樓齡，但憑著專業的物業管理服務及設施保養，讓樓宇保持穩定的可持續發展表現。廣場每年舉行超過200場培訓，不斷提高物業管理人員的服務水平；針對消防、防爆、防洪等方面設置應急戰備專區，同時向公安局及時反饋安全監控信息，以實現全方位的樓宇安全管理。



R&F Centre is the headquarters of R&F Properties, which emphasises smart management and caring services. It has developed a "Smart Cruising Steward" system which can flexibly manage facility operations and maintenance under various circumstances. In addition, the building offers concierge services like car cleaning and glasses cleaning to demonstrate its caring services.

富力中心是廣州富力地產集團總部辦公大樓，十分重視智能化管理及貼心服務方面的表現。富力中心自主開發「巡航管家」系統，因應情況，靈活管理樓宇設施的運作及維修狀況。此外，物業亦提供如洗車、免費洗眼鏡等禮賓服務，展現其貼心服務。



Bank of Guangzhou Tower is a super grade A office building in Zhujiang New Town which has adopted a hotel management style, offering professional and personalised services to satisfy customers' needs. It uses a Daily Energy Consumption Graph to monitor unusual energy consumption, analyse clients' commuting habits, optimise facility operation time and increase energy saving efficiency.

廣州銀行大廈為珠江新城地標性的超甲級寫字樓，結合酒店式服務，提供專業及個人化服務，以滿足客戶需求；另外，大廈建立「日能耗曲線圖」，監控能源消耗的異常情況，分析客戶上下班情況，優化設備運作時間，提升節能效率。



Teem Tower is a top office building which provides professional and systematic management services with the motto of attention, devotion, sincerity, dedication and concentration. It has adopted comprehensive and strict security management to ensure that the building is safe.

粵海天河城大廈作為頂級寫字樓，秉持「關心、愛心、真心、熱心、專心」的服務理念，提供專業且系統化的管理與服務，全面實施嚴格的保安管理，確保各類安全防範措施完善。



Leatop Plaza has received a number of international and national building awards, such as LEED Platinum certification. The Plaza is adopting advanced energy saving measures. It also applies smart management like online parking space checking and restaurant reservation.

利通廣場在建築和管理方面獲得多個國家及世界級優秀建築獎，並榮獲LEED鉑金級認證。樓宇在硬件方面採用先進的節能環保措施，軟件方面則實現樓宇的智能管理，如提供車位查詢、網上訂餐等體驗式服務。



New Revision to ISO 13485 for Medical Devices Comes into Effect

新修訂版ISO 13485醫療器械質量管理體系標準正式生效



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Chairman, ISO Technical Subcommittee on Quality Systems (ISO/TC 176/SC2)
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國際標準化組織質量體系技術委員會 (ISO/TC 176/SC2) 主席

A medical device is any product intended for use in the diagnosis, prevention and treatment of medical conditions. Medical devices can range from simple products like wound dressings to dentist chairs, cardiac pacemakers, life-support machines and even in vitro diagnostic reagents. They are subjected to (mandatory) regulatory requirements in most countries of the world, as governments seek to protect the health and safety of their citizens from shoddily designed or manufactured products. Many medical devices are invasive by nature – they probe in and around the human body. While some explore the anatomy, cut away disease and repair damage, others remain inside the body, such as a prosthetic hips, artery stents, heart valves or pacemakers.

ISO 13485 was first published in 1996 with the title “Medical devices - Quality Management Systems - Particular requirements for the application of ISO 9001”. It was subsequently revised in 2003 when it was renamed “Medical devices – Quality Management Systems - Requirements for regulatory purposes”) and the latest version has just been published as ISO 13485:2016.

Scope and Regulatory Emphasis of ISO 13485

ISO 13485:2016 specifies requirements for a quality management system where an organisation needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. Regulations differ widely from one country to another, so ISO 13485 does not itself define the detailed regulatory requirements, but asks a medical devices organisation to identify those regulatory requirements that are relevant to its individual situation and incorporate them into its QMS. Products which may be considered to be medical devices in some jurisdictions but not in others include:

- aids for persons with disabilities;
- devices incorporating animal and/or human tissues;
- disinfection substances;
- devices for in vitro fertilization or assisted reproduction technologies.

ISO 13485 is designed to be used by organisations throughout the life cycle of a medical device, from initial conception to production and post-production, including final decommissioning and disposal. It also covers aspects such as storage, distribution, installation and servicing, and the provision of associated services. Even in the previous (2003) version, ISO 13485 adopted a risk-based approach to regulatory compliance, and this has been further emphasised in the 2016 revision.

Because of its regulatory nature, although ISO 13485 has been traditionally based on ISO 9001, some elements of ISO 9001 have never been included. For example, whilst ISO 9001 requires continual improvement of the quality management system and the evaluation of customer satisfaction, ISO 13485 does not do so, but instead requires the evaluation of feedback regarding the use of the medical device:

「醫療器械」是指任何用作診斷、預防及治療疾病的產品，小至傷口敷料、心臟起搏器，大至牙科椅、維持生命儀器，以至體外診斷試劑也包含在內。在大部分國家，政府都會對這些醫療產品作出規管，以免生產商粗製濫造，危害市民健康安全。不少醫療器械會被放進人體內，除了用作檢查身體、治療疾病外，有些更會長期留在病人體內，好像人造髖關節、心血管支架、人造心瓣或心臟起搏器等。

ISO 13485 於 1996 年首次出版，名為《醫療器械—質量管理體系—應用 ISO 9001 的具體要求》，其後於 2003 年改版，名為《醫療器械—質量管理體系—用於法規的要求》，最新版本為 ISO 13485：2016。

ISO 13485 的適用範圍及規管重點

ISO 13485：2016 說明了質量管理體系的要求，證明提供醫療器械及相關服務的機構能滿足客戶及相關法規要求。由於每個國家的法例都有所不同，所以 ISO 13485 並沒有定義詳細的法規要求，而是要求醫療機構根據自身情況，自行辨識相關的法規要求，並融入在其質量管理體系中。一些醫療產品在個別地區並不會被視為醫療器械，包括：

- 殘障人士的輔助器材
- 含有動物及 / 或人體組織的儀器
- 消毒物質
- 進行體外受孕或輔助生育技術的儀器

ISO 13485 適用於任何參與醫療器械生命週期的機構，由設計、生產、停止運作到棄置，以至儲存、分發、安裝、維修，以及提供相關服務。在 2003 年的版本中，ISO 13485 已經就法規規管加入基於風險的概念，而 2016 年新版更加強了這方面的內容。

雖然 ISO 13485 建基於 ISO 9001，但由於前者以符合法規為核心性質，因此並無包含部份 ISO 9001 的內容。例如 ISO 13485 並沒有像 ISO 9001 般要求機構持續改善其質量管理體系，以及評估其客戶滿意度，但卻要求機構評估其醫療器械使用者的意見，包括：

- 醫療器械是否達到預期的使用要求？
- 醫療器械是否符合法規要求？
- 剩餘風險是否受到控制？有沒有發現新的風險？

- Does the medical device meet the intended use requirements?
- Does the medical device meet the regulatory requirements?
- Are residual risks still controlled and have new risks been identified?

As an effective complement to ISO 13485, ISO 14971 ("Medical devices - Application of risk management to medical devices") describes a systematic approach to risk management that can be applied throughout the medical device's life cycle.

ISO 13485:2016 – What has changed?

The main driver for the revision was to reflect the latest developments in technology as well as the increased expectations of manufacturers and regulators. ISO 13485:2016 also promotes greater transparency of the requirements and alignment between the regulators, auditing bodies and manufacturers of medical devices. Such organisations can be involved in one or more stages of the life-cycle, including design and development, production, storage and distribution, installation, or servicing of a medical device and design and development or provision of associated activities (e.g. technical support). Areas that have been strengthened include the interaction between the QMS and regulatory requirements, the applicability of the standard throughout the medical device's life cycle (for example by including distributors and importers) and the wider incorporation of risk management principles throughout the QMS.

Requirements of ISO 13485:2016 are applicable to organisations regardless of their size and regardless of their type except where explicitly stated. Wherever requirements are specified as applying to medical devices, the requirements apply equally to associated services that may be supplied by the organisation.

Improvements in the new version of the standard include broadening its applicability to include all organisations involved in the life cycle of the product, from concept to end of life, greater alignment with regulatory requirements and a greater focus on post-market surveillance including complaint handling.

The key changes include:

- A greater emphasis on the responsibilities and commitment of top management to meet applicable regulatory requirements
- Risk management is now emphasised throughout the product life cycle.
- A greater emphasis on appropriate infrastructure, particularly for the production of sterile medical devices, and additional requirements for the validation of sterile barrier properties
- Increased alignment with regulatory requirements and, in particular, regulatory documentation



《ISO 14971 醫療器械—風險管理的應用》作為與 ISO 13485 互補的標準，描述了如何在醫療器械的整個生命週期中，進行系統化的風險管理。

ISO 13485 : 2016 有何修改 ?

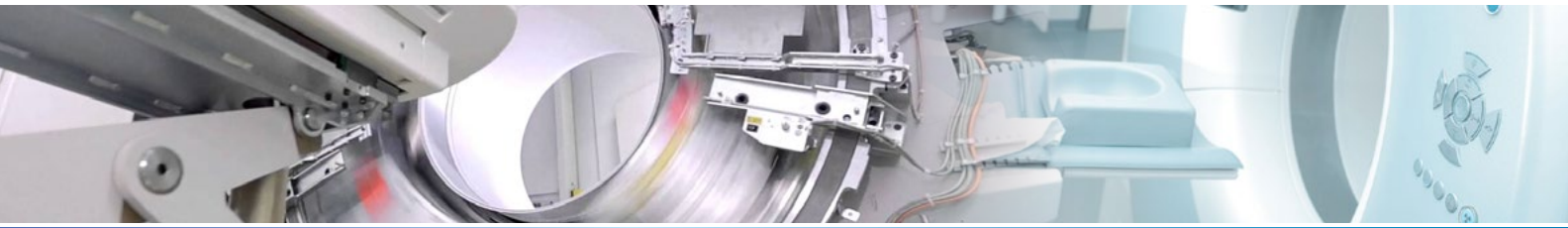
是次修訂 ISO 13485 的主要目的是反映最新的科技發展，以及回應生產商及監管機構日益提升的期望，並推動監管機構、審核機構和醫療器械生產商提升相關要求的透明度，以便互相協調。此標準適用於參與醫療器械生命週期中某個或多個階段的機構，當中包括設計、開發、生產、儲存、分發、安裝和維修，以及設計、開發和提供相關活動（如技術支援）。相較於舊版本，新版本加強了質量管理體系與法規要求的互動、標準在產品整個生命週期中的適用範圍（如包括該醫療器械的分銷商及進口商），於質量管理體系中更廣泛地納入風險管理的原則。

除非有特別指明，否則 ISO 13485 : 2016 的要求適用於任何規模及類型的機構。此外，標準中所有適用於醫療器械的要求，亦同時適用於機構提供之相關服務。

整體而言，新版 ISO 13485 擴大了其適用範圍至與產品的整個生命週期（由構思到棄置）相關的所有機構，增加與法規要求的配合，以及加強產品在推出市場後的監察（如投訴處理）。

以下列出新版本的主要更新內容：

- 加強最高管理層的責任及承擔，以符合適用的法規要求
- 於整個產品生命週期中強調風險管理
- 優化個別適用設施的要求，尤其經消毒的醫療器械之生產，以及就審定無菌屏障性能的額外要求
- 加強與法規要求的配合及進行法規文件記錄



- Broadening of the standard's application to encompass organisations that interact with the medical devices manufacturer, including those involved in :
 - Design and development or repair and maintenance of medical devices
 - Supply of raw materials, components or subassemblies
 - Performance of services such as contract manufacture, sterilization, logistics or calibration of measurement equipment
 - Import or distribution of medical devices
- Additional requirements in the design and development of medical devices, taking into consideration their usability, the use of standards, and a more robust planning for the verification, validation, transfer and records maintenance of the design and development activities
- Harmonisation of validation requirements for different software applications, such as QMS software, process control software, and software for monitoring and measurement
- Definition of skills and experience required for personnel involved in quality management
- Documentation of training and assessment of effectiveness of training.
- Increased controls over supplier and outsourced activities
- Validation of processes for sterile barrier systems as well as sterilisation
- Establishment and maintenance of technical medical device files and design development files
- More focus on post-market activities, including complaint handling and regulatory reporting

Relationship with ISO 9001:2015

Although ISO 13485:2016 was published after ISO 9001:2015, it has not incorporated the “high-level structure” and common text for management system standards prescribed by Annex SL of the ISO Directives, primarily because the revision process began back in 2010, before the publication of Annex SL. This means that the clause structure of ISO 13485:2016 broadly follows that of ISO 9001:2008 and is not aligned directly with ISO 9001:2015. The new standard does however cite ISO 9000:2015 as a normative reference for vocabulary (though some of the ISO 9000 definitions have been adapted for use in the regulatory context), and Annex B of ISO 13485:2015 provides a comparison of content with ISO 9001:2015. As might be expected for a standard aimed at such a highly regulated sector, ISO 13485 prescribes much more documented information than does ISO 9001:2015, including a requirement for a quality manual and a number of other documented procedures.

Transition to ISO 13485 : 2016

The International Accreditation Forum (IAF) has agreed on a three-year transition period for organisations currently certified to the 2003 version of ISO 13485, meaning that any certificates issued to the previous version of the standard will cease to be valid after March 1st 2019.

- 擴大標準的適用範圍至所有與醫療器械生產商有所互動的機構，包括：
 - 參與醫療器械設計、開發、維修及維護的機構
 - 提供原材料、零件或局部裝配的機構
 - 合約製造商或提供消毒、物流、測量儀器校準等服務的機構
 - 醫療器械的進口商或分銷商
- 新增對醫療器械設計及開發的要求，考慮其可用性和對標準的使用，並需詳細規劃該產品的檢查、審定、轉移、以及保存設計和開發活動的記錄
- 統一不同軟件應用的審定要求，包括質量管理體系軟件、流程控制軟件、監察及量度軟件等
- 定義質量管理人員應具備的技能及經驗要求
- 進行培訓時需有文件記錄，並評估培訓的成效
- 提高對供應商及外判工作的控制
- 為無菌屏障系統及消毒過程的進行審定
- 建立與維護醫療科技器械的檔案及設計開發的檔案
- 加強產品推出市場後的監察，如投訴處理及提交規管報告

與 ISO 9001 : 2015 的關係

雖然 ISO 13485 : 2016 遲於 ISO 9001 : 2015 出版，但由於 ISO 13485 早於 2010 年已開展修訂程序，比《ISO 指引》中「附件 SL」的出版還要早，因此 ISO 13485 並非採用「附件 SL」內的「高階架構」及「相同文本」，其條文架構較貼近 ISO 9001 的 2008 年舊版本。不過，ISO 13485 在詞彙的定義上引用了 ISO 9000 : 2015 (雖然當中 ISO 9000 部分詞彙的定義已因應 ISO 13485 的規管內涵而作出修改)，而 ISO 13485 : 2016 的「附件 B」亦提供了與 ISO 9001 : 2015 內容的比較。基於 ISO 13485 針對的是需高度規管的行業，因此在明文依據的要求會比 ISO 9001 : 2015 更多，包括需編寫質量手冊及進行其他文件化程序。

如何過渡至 ISO 13485 : 2016

國際認可論壇 (IAF) 已同意獲 2003 年版 ISO 13485 的認證機構擁有三年過渡期，因此它們現有的證書直到 2019 年 3 月 1 日仍然有效。



Shaanxi Province Quality and Technology Supervision Bureau Visit

香港品質保證局到訪陝西省質量技術監督局

Senior management representatives from HKQAA visited Shaanxi Province Quality and Technology Supervision Bureau (Shaanxi QTS) on 30 March 2017, having previously signed a Memorandum of Understanding (MOU) in October 2016. In the meeting, the two parties emphasised the importance of quality management and brand building for enterprises in Hong Kong and Shaanxi, to benefit the industry and society and support the Belt and Road Initiative.

Four HKQAA representatives, including Dr Michael Lam, Chief Executive Officer, met with Mr Qiao Jun, Secretary and Director of Shaanxi QTS, and representatives from its Quality, Accreditation and Metrology Departments, Institutes of Metrology, and Quality and Inspection, as well as the Shaanxi Province Quality Assessment Centre. Based on the MOU, both parties intend to further strengthen their collaboration so as to enhance the competitiveness of enterprises in both regions.

香港品質保證局去年10月與陝西省質量技術監督局簽訂合作備忘錄後，今年3月30日再專程拜訪該局，與其交流會面，謀求深化雙方合作，促進陝港兩地在質量管理與品牌建設方面取得新的突破，以配合「一帶一路」的建設。

參與是次會面的包括香港品質保證局總裁林寶興博士一行四人、陝西省質量技術監督局黨組書記兼局長喬軍先生、該局質量處、認評處、計量處、陝西省計量院、質檢院，以及質量評審中心等代表。雙方銳意在合作備忘錄的基礎上，深化陝港合作模式，協助兩地企業提升競爭力。



Seminar on Managing Service Quality through the Spirit of a Craftsman

「工匠精神 – 如何管理服務質量」研討會

HKQAA held a seminar on 'Managing Service Quality through the Spirit of a Craftsman' in April 2017. In the seminar, Mr Brian Au from the Hong Kong Broadband Network Company Limited and Mr Mac Leung, a certified tutor from the Peter F. Drucker Academy shared their experiences of managing service quality through mystery shopper programmes, and by using the theory of music and management to provide professional services to customers. The HKQAA speaker also introduced our Mystery Shopping Programme and follow up services to encourage service quality enhancement.



香港品質保證局於2017年4月舉辦了「工匠精神 – 如何管理服務質量」研討會。研討會邀得香港寬頻網絡有限公司的區永康先生，以及彼得德魯克管理學院認可講師梁銳光先生任演講嘉賓。研討會上分享了有關如何利用神秘顧客服務，管理服務質量，以及如何利用交響樂管理，打造專業的服務團隊。此外，本局講者亦介紹了有關本局的神秘顧客服務及後續服務，協助企業提升服務質素。



Obtain the HKCAS Accreditation for ISO 22000 Certification and ISO 14064-1 Verification

本局現提供香港認可處認可之ISO 22000 認證服務及 ISO 14064-1 核查服務

HKQAA is pleased to announce the provision of Hong Kong Accreditation Service (HKAS) accredited services for ISO 22000 Food Safety Management System Certification and ISO 14064-1 Greenhouse Gas Verification.

HKQAA successfully obtained accreditation for ISO 22000 Certification on 13 March 2017 from HKAS through the Hong Kong Certification Body Accreditation Scheme (HKCAS). ISO 22000 is applicable to all suppliers, manufacturers, distributors and retailers in the food supply chain.

HKQAA obtained the accreditation for ISO 14064-1 Verification on 11 April 2017. ISO 14064 encourages businesses and organisations to take the initiatives to determine their greenhouse gas emissions and enhance the consistency, credibility and transparency of their greenhouse gas quantification, monitoring and reporting. It is applicable to all types and sizes of organisations.

For further details on HKQAA's certification, verification and supporting services, please contact us at:

香港品質保證局現已提供香港認可處認可之ISO 22000 食品安全管理體系認證服務及ISO 14064-1 溫室氣體排放核查服務。

本局於2017年3月13日透過香港認可處香港認證機構認可計劃(HKCAS)正式取得ISO 22000 認證服務之認可資格。ISO 22000 認證適用於各食品供應鏈中的供應商、製造商、經銷商和零售商。

此外，本局於2017年4月11日亦取得ISO 14064-1 核查服務之認可資格。ISO 14064 鼓勵業界主動量度溫室氣體排放，增加機構在溫室氣體量化、檢查和報告方面的一致性、可信度和透明度，適用於各類型及規模的機構。

欲知更多有關本局所提供的認證、核查和支援服務，請聯絡我們：

Hong Kong Quality Assurance Agency 香港品質保證局

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As one of the leading and most trusted conformity assessment bodies in the region, HKQAA keeps developing and introducing innovative services to meet the needs of the market and individual organisations. We are pleased to tailor a wide range of services to satisfy specific client requirements, including verification, assessment, certification, registration, survey, research, training and other professional services.

Contact our Business Team for customised services that focus on your specific business goals.

作為亞太區內最具規模及領導地位的合格評定機構之一，香港品質保證局持續開發及推出不同類型的創新服務，以回應市場及個別機構的需求。我們樂意為您度身制訂各種服務，範圍遍及核查、評審、認證、註冊、培訓、調查、研究及其他專業服務。

請與我們的業務部聯絡，我們會摯誠為您制訂切合業務需要的服務。

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International 國際

ISO 26000 Workshop Held in Stockholm, Sweden

A workshop hosted by Swedish Standards Institute was held at the beginning of March 2017 to discuss the synergies between ISO 26000 (Guidance on Social Responsibility) and ISO's suite of management system standards. Although ISO 26000 is not a management system standard, and contains no requirements, it can be effectively applied within the framework of any organisation's existing management system based on standards such as ISO 9001 or ISO 14001. A follow-up workshop will be held in London in May 2017, after which ISO/IWA 26 (International Workshop Agreement) is expected to be published later in the year.

New Version of ISO/IEC 17021-3 Published

ISO/IEC 17021 Part 3, the standard that defines the competence requirements for quality management system auditors and other certification body support staff, has been updated to align with ISO 9001:2015. The new standard, published in March 2017, includes additional requirements to address topics such as understanding the organisational context, the role of leadership throughout the organisation and "risk-based thinking".

ISO Updating Brochure on the Integrated Use of Management System Standards

A task force of ISO's Joint Technical Coordination Group is currently updating this popular book to take into account recent developments including the publication of Annex SL to the ISO Directives, which established a common high-level structure for all ISO management system standards.

Work Continues on the Future ISO 45001

The ISO Project Committee ISO/PC 283 continues to work to resolve the conflicting comments that prevented approval of the first Draft International Standard version of ISO 45001 (Requirements for a Health and Safety Management System) which is being developed to replace OHSAS 18001. The committee is currently in the final stages of preparing the "DIS2", which, if approved, will mean that the International Standard could be published in early to mid-2018.

New ISO 9004 Standard Reaches Draft International Standard Stage

Working Group ISO/TC176/SC2/WG2 has recently completed the incorporation of all comments received from ISO member bodies after circulation of the Committee Draft for approval, and has now finalised the Draft International Standard. The group will meet again in Indonesia in September 2017 to evaluate additional comments on the DIS, and it is expected that ISO 9004:2018 ("Quality of an organisation – Guidance to achieve sustained success") will be published early in 2018. ISO 9004 does not contain any requirements, and is not suitable for certification purposes, but it does include a maturity model that can be used for an organisation to make self-assessments in order to move beyond the ISO 9001 requirements and become successful in the long term.

ISO 26000 工作坊於瑞典斯德哥爾摩舉行

由瑞典標準協會舉辦的工作坊於2017年3月初舉行，旨在討論ISO 26000(社會責任指引)與ISO一系列管理體系標準之間的協同效應。即使ISO 26000不是一個管理體系標準，亦不包括要求，它仍可有效地融入於任何機構現有的ISO 9001或ISO 14001等管理體系框架之中。跟進工作坊將於2017年5月在倫敦舉行，而ISO/IWA 26(《國際工作坊協議》)預期將於同年稍後時間出版。

新版 ISO/IEC 17021-3 出版

ISO/IEC 17021 第三部分列明對質量管理體系審核員及其他認證機構技術支援人員之能力要求，已修訂為與ISO 9001:2015保持一致。新標準於2017年3月出版，內容包括了解機構內涵、「基於風險的思維」及貫徹整個機構的領導角色等議題的附加要求。

ISO 更新管理體系標準綜合使用小冊子

ISO 聯合技術協調小組的一個專責小組正更新此小冊子，加入出版ISO 指令附件SL等最新發展，為各ISO 管理體系標準建立了一個通用的高階架構。

ISO 45001 籌備工作繼續進行

ISO 項目委員會ISO/PC 283繼續解決導致原定取代OHSAS 18001的ISO 45001(職業安全健康管理體系要求)在第一次國際標準草案(DIS)被投否定票的意見。委員會現正籌備國際標準草案第二版(DIS2)，如獲得通過，此國際標準便可於2018年初至中期出版。

新版 ISO 9004 標準進入國際標準草案階段

ISO/TC176/SC2/WG2 工作小組於委員會通過決議草案後，結合所有ISO 成員機構的意見，現已落實國際標準草案。小組將於2017年9月在印尼再次會面，以評估對國際標準草案的補充意見，並預期ISO 9004:2018(《機構質素－實踐持續成功之指引》)將於2018年初出版。雖然ISO 9004不包括任何要求，亦不適宜作認證之用，但它包含一個成熟的模型，協助機構進行自我評估，在ISO 9001的要求上再邁進一步，以取得長遠的成功。

New Certified Clients 新認證客戶

November 2016 to January 2017
2016年11月至2017年1月

Memorable Moments 紀念一刻



Hong Kong Quality Assurance Agency (HKQAA) has been helping industrial and commercial bodies to develop effective management systems to achieve organisational and business goals since 1989.



From November 2016 to January 2017, we have been pleased to welcome 49 organisations to our community. Among them, they have obtained 70 certificates of BFA MS, HACCP, ISO 9001, ISO 14001, ISO 22000, ISO 27001, ISO 50001, OHSAS 18001, QSPS-AC, QSPSC, SA 8000, SQM and WSMST-COM. We believe the new members will contribute to the overall success of the brand that adds values to stakeholders.



香港品質保證局自1989年成立以來，致力協助工商界實施管理體系，有效地達至機構和營商目標。



由2016年11月至2017年1月期間，香港品質保證局共頒發70張證書，包括BFA MS、HACCP、ISO 9001、ISO 14001、ISO 22000、ISO 27001、ISO 50001、OHSAS 18001、QSPS-AC、QSPSC、SA 8000、SQM及WSMST-COM。在此謹祝賀49家機構加入獲認證的行列。本局深信，新成員的加入將可為我們的品牌和持份者帶來更大的裨益。



Mainland China 中国内地

May - Aug 2017 2017年5月至8月

Course Title 課程名稱	Duration (Day) 課程長度 (天)	Fee (per head) RMB 收費 (每人) 人民幣	Course Code & Date 課程編號及日期			
			May 五月	Jun 六月	Jul 七月	Aug 八月
Standard & Systems Training 標準體系培訓						
ISO 9001:2015 Quality Management System - Internal Auditor Training ISO 9001:2015 质量管理体系内部审核员培训	P 3	RMB 1,800		VM3P/GZ06A GZ 20-22	VM3P/SH07A SH 18-20	VM3P/GZ08A GZ 01-03
ISO 9001:2015 Documented Information - Document Structures and Document System Establishing Training ISO 9001:2015 质量管理体系文件化信息之文件结构与编制培训	P 1	RMB 1,200	QMS4P/SH05A SH 24	QMS4P/GZ06A GZ 24		QMS4P/GZ08A GZ 10
ISO 9001:2015 Quality Risk Management Implementing ISO 9001:2015 质量风险管理实务	P 1	RMB 1,200			QM07P/GZ07A GZ 28	
IECQ HSPM QC080000 Hazardous Substance Management System - Internal Auditor Training IECQ HSPM QC080000 有害物质管理体系内部审核员培训	P 2	RMB 2,400		IE01P/GZ06A GZ 01-02		IE01P/SH08A SH 07-08
TL 9000 R6.0/R5.0 Telecommunication Quality Management System - Internal Auditor Training TL 9000 R6.0/R5.0 电信业质量管理体系内审员培训	P 3	RMB 3,800	TL04P/GZ05A GZ 08-10		TL04P/SH07A SH 24-26	
TL 9000 R5.5/R5.0 Quality Management Systems - Auditing TL 9000 R5.5/R5.0 电信业质量管理体系审核员 (QuEST Forum 授权课程)	P 5	RMB 16,000		TL02P/GZ06A GZ 12-16		TL02P/GZ08A GZ 14-18
IATF 16949:2016 Automobile Industry Quality Management System - Internal Auditor Training IATF 16949:2016 汽车行业质量管理体系内审员培训	P 3	RMB 2,500			MT68P/GZ07A GZ 17-19	
IATF 16949:2016 Automobile Industry Quality Management System Conversion Training IATF 16949:2016 汽车行业质量管理体系转版培训	P 2	RMB 1,600	MT71P/GZ05A GZ 11-12			MT71P/SH08A SH 22-23
VDA 6.3 Process Audit VDA 6.3 过程审核	P 1	RMB 1,200	EO06P/GZ05A GZ 19		EO06P/GZ07A GZ 17	
ISO/IEC 27001:2013 Information Security Management Systems - Internal Auditor Training ISO 27001:2013 信息安全管理体系内部审核员培训	P 3	RMB 2,800	ISE7P/SH05A SH 16-18	ISE7P/GZ06A GZ 05-07		
ISO 14971 Risk Management System for Medical Device ISO 14971 医疗器械行业风险管理体系内部审核员培训	P 2	RMB 2,400				RM16P/GZ08A GZ 30-31
ISO/IEC 20000:2011 Information Technology Service Management System - Internal Auditor Training ISO/IEC 20000:2011 IT 信息技术服务体系内部审核员培训	P 2	RMB 2,500		ISE9P/GZ06A GZ 27-28		
SA 8000:2014 Social Accountability Management Systems - Internal Auditor Training SA 8000:2014 社会责任管理体系内部审核员培训	P 2	RMB 1,500			SA01P/GZ07A GZ 10-11	
ISO 14001:2015 Environmental Management Systems - Internal Auditor Training ISO 14001:2015 环境管理体系内部审核员培训	P 2	RMB 1,200	EMS3P/GZ05A GZ 22-23		EMS3P/SH07A SH 26-28	
OHSAS 18001:2007 Occupational Health and Safety Management Systems - Internal Auditor Training OHSAS 18001:2007 职业健康安全管理体系内部审核员培训	P 3	RMB 1,800		OHS9P/SH06A SH 12-15		OHS9P/GZ08A GZ 09-11
ISO 50001:2011 Energy Management Systems - Internal Auditor Training ISO 50001:2011 能源管理体系 - 内部审核员	P 2	RMB 1,500			EM08P/GZ07A GZ 03-04	
Hygiene Control System - Understanding & Implementation 卫生监控系统 - 理解与实施	P 1	RMB 1,000	GP02P/GZ05A GZ 24			
Production/Quality/Supply Chain/Customer Service Management 生产 / 质量 / 供应链 / 客服管理						
5S Site Management 5S 现场管理	P 1	RMB 1,200				GP09P/GZ08A GZ 04
JIT (Just In Time) of Lean Production 精益生产之JIT(准时生产)	P 2	RMB 2,500	GM21P/GZ05A GZ 02-03		GM21P/SH07A SH 03-04	
Waste Elimination in Lean Production 精益生产之浪费消除	P 1	RMB 1,500	GM17P/GZ05A GZ 31			GM17P/GZ08A GZ 21
Lean Production-IE Technology 精益生产之IE手法	P 2	RMB 2,500				GM22P/SH08A SH 28-29
Flexie Production Planning Management 柔性生产计划与排程管理	P 2	RMB 2,500	EC08P/SH05A SH 22-23			
Field Efficiency Improvement and Cost Control 现场效率改善与成本控制	P 2	RMB 2,500		GM15P/GZ06A GZ 24-25		
Supply Chain Quality and Risk Management 供应链源流质量与风险管理	P 2	RMB 2,500		GM13P/GZ06A GZ 05-06		GM13P/GZ08A GZ 23-24
Key to Strong Enterprise — Quality Circle Operation 强企之本——品质圈QCC运作	P 2	RMB 1,800	ES28P/GZ05A GZ 25-26		ES28P/SH07A SH 20-21	
Management Practice of Quality Cost 质量成本管理	P 2	RMB 2,400		EO05P/SH05A SH 15-16		
Project Management 项目管理	P 2	RMB 3,000			MS17P/GZ07A GZ 26-27	
Statistical Process Control SPC统计过程控制	P 1	RMB 1,000		MS20P/GZ06A GZ 08		
Failure Mode and Effects Analysis FMEA潜在失效模式分析	P 1	RMB 1,000	MS04P/GZ05A GZ 12			MS04P/GZ08A GZ 22
Seven QC Tools (Traditional & New) QC七大手法	P 2	RMB 2,400			GM12P/GZ07A GZ 18-19	
Risk Assessment for Safety Management Implementation 安全管理之风险评估及措施	P 1	RMB 1,200	OH04P/SH05A SH 15	OH04P/GZ06A GZ 08		
Advanced Study for Supplier Quality Engineers 供应商质量工程师研修班	P 2	RMB 2,500		MS19P/GZ06A GZ 29-30		MS19P/SH08A SH 10-11
Management Development Training 管理发展培训						
Communication Skills 沟通技巧	P 2	RMB 2,400				GM07P/GZ08A GZ 07-08
Time Management 时间管理	P 1	RMB 1,000		MS18P/SH06A SH 31	MS18P/GZ07A GZ 07	
TTT Training on Internal Lecturer - Professional Presentation Skill TTT内部培训师培训之专业演示技巧	P 2	RMB 2,800				GM06P/GZ08A GZ 28-29
Manufacturing workshop Management practices - Group Leader Management 制造车间管理实战 - 班组长工作篇	P 2	RMB 2,400			MT33P/GZ07A GZ 20-21	
Management Skills for Middle Management 中层管理人员管理技能培训	P 2	RMB 2,400	MS14P/GZ05A GZ 16-17			MS14P/SH08A SH 02-03
Mind Map@ : 思维导图轻松提升工作效率	P 1	RMB 2,000		M504P/GZ06A GZ 23		
Countdown@ : 为项目工作团队而设的战略游戏工作坊	P 1	RMB 1,500	M520P/GZ05A GZ 18		M520P/SH07A SH 28	
Zodiak@ : 商业策略、决策及财务游戏工作坊	P 1	RMB 1,500		M519P/GZ06A GZ 19		
Coaching Skills 教练技巧	P 2	RMB 2,800	GM24P/GZ05A GZ 04-05			GM4P/SH08A SH 30-31

For registration and enquiry
報名及查詢

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For training course details and online registration, please visit HKQAA website 詳細課程資料及網上報名, 請瀏覽香港品質保證局網頁 <http://www.hkqaa.org>

Course Title 課程名稱	Duration (Day) 課程長度 (天)	Fee (per head) HKD 收費 (每人) 港幣	Course Code & Date 課程編號及日期			
			May 五月	Jun 六月	Jul 七月	Aug 八月
Quality and Integrated Management Systems 質量和綜合管理						
ISO 9001:2015 Quality Management Systems - Understanding & Application ISO 9001:2015 質量管理體系 - 理解與應用	1	HKD 1,580	VM1C/HK-05A 02	VM1C/HK-06A 01	VM1C/HK-07A 06	VM1C/HK-08A 02
ISO 9001:2015 Quality Management Systems - Internal QMS Auditor Training ISO 9001:2015 質量管理體系 - 內部質量管理體系審核員培訓	2	HKD 3,300	VM3C/HK-05A 22-23	VM3C/HK-06A 12-13	VM3C/HK-07A 11-12	VM3C/HK-08A 14-15
The Must-know Essentials for Quality System Management Representative 質量管理體系 - 管理者代表的重要須知	1	HKD 1,680/ HKD 1,580*	MT23C/HK-05A 15			
ISO 9001:2015 Quality Management Systems Documentation ISO 9001:2015 質量管理體系文件	1	HKD 1,680/ HKD 1,580*			QMS4C/HK-07A 20	
ISO 9001:2015 Quality Management Systems - Advanced Internal Auditing Techniques ISO 9001:2015 品質管理體系 - 進階內部審核技巧	2	HKD 3,500/ HKD 3,300*			QMS5C/HK-07A 12-13	
CQI & IRCA Certified ISO 9001:2015 Lead Auditor (Quality Management Systems) Training Course (18030) 質量管理體系 - 主任審核員證書培訓課程	5	HKD 12,000/ HKD 11,500*	QMS/IRCA/05 08-12			
ISO 9001:2015 Series - QMS Auditor/Lead Auditor Transition Training Course (IRCA Approved)	2	HKD 4,800/ HKD 4,300*	QM06E/HK-05A 09-10		QM06E/HK-07A 17-18	
Integrated Management Systems Set Up & Audit Approach 綜合管理體系 - 建立與審核方法	2	HKD 3,500/ HKD 3,300*		IMS2C/HK-06A 20-21		
Understanding and Application of an Integrated Management System 綜合管理體系 - 理解與應用	2	HKD 3,500/ HKD 3,300*		IMS5C/HK-06A 20-21		
Environmental Conservation 環境保育						
ISO 14001:2015 Environmental Management Systems - Understanding & Application ISO 14001:2015 環境管理體系 - 理解與應用	1	HKD 1,730/ HKD 1,630*	EMS2C/HK-05A 31		EMS2C/HK-07A 05	
ISO 14001:2015 Environmental Management Systems - Internal EMS Auditor Training ISO 14001:2015 環境管理體系 - 內部環境管理體系審核員培訓	2	HKD 3,400/ HKD 3,300*		EMS3C/HK-06A 19-20		EMS3C/HK-08A 03-04
ISO 14001:2015 Environmental Management Systems - Implementation and Documentation ISO 14001:2015 環境管理體系 - 實施及文件指引	1	HKD 1,680/ HKD 1,580*			EMS8C/HK-07A 26	
Risk and Opportunities based approach and Aspect Identification with Life Cycle Perspective	1	HKD 1,680				EM19C/HK-08A 07
CQI & IRCA Certified ISO 14001:2015 Lead Auditor (Environmental Management Systems) Training Course (18040) ISO 14001:2015 環境管理體系 - 主任審核員證書培訓課程	5	HKD 12,000/ HKD 11,500*		EMS/IRCA/06 12-16		
CQI & IRCA Certified ISO 14001:2015 Auditor Transition (Environmental Management Systems) (17967)	2	HKD 4,800/ HKD 4,300*		EM20E/HK-06A 05-06		
ISO 50001:2011 Energy Management Systems - Understanding & Application ISO 50001:2011 能源管理體系 - 理解與應用	1	HKD 1,200/ HKD 1,080*			EM07C/HK-07A 10	
ISO 50001:2011 Energy Management Systems - Internal Auditor Training ISO 50001:2011 能源管理體系 - 內部審核員培訓	2	HKD 3,500/ HKD 3,300*		EM08C/HK-06A 22-23		
ISO 50001:2011 Energy Management Systems Auditor/Lead Auditor Training Course ISO 50001:2011 能源管理系統 - 主任審核員證書培訓課程	5	HKD 9,000/ HKD 8,000*				EM10C/HK-08A 14-18
GreenHouse Gas Verifier Training 溫室氣體驗證員	2	HKD 3,500/ HKD 3,300*		EM09C/HK-06A 08-09		
Environmental Management Course for Food and Beverage Industry 餐飲業環境管理課程	2	HKD 2,500		M067C/HK-06A 12 & 19		
Occupational Health and Safety Management 職業健康和安全管理						
OHSAS 18001:2007 Occupational Health and Safety Management Systems - Understanding & Application OHSAS 18001:2007 職業健康和安全管理體系 - 理解與應用	1	HKD 1,730/ HKD 1,630*			OHS8C/HK-07A 06	
OHSAS 18001:2007 Occupational Health and Safety Management Systems - Internal OHS Auditor Training OHSAS 18001:2007 職業健康和安全管理體系 - 內部職業健康和安全管理體系審核員培訓	2	HKD 3,400/ HKD 3,300*	OHS9C/HK-05A 18-19			OHS9C/HK-08A 16-17
Preparatory Course for ISO 45001 (Occupational Health & Safety Management Systems)	1	HKD 1,680/ HKD 1,580*			OH18C/HK-07A 07	
Understanding of Factories and Industrial Undertakings (Safety Management) Regulation (F&U(SM)R) for OHSAS 18001 Practitioners	1	HKD 1,500				OH15C/HK-08A 16
OHSAS 18001 Auditor Course for Registered Safety Officers / Auditors	2	HKD 3,200		OH16C/HK-06A 20-21		
CQI & IRCA Certified OHSAS 18001:2007 Lead Auditor (OH&S Management Systems) Training Course (17436) 職業健康和安全管理體系 - 主任審核員證書培訓課程	5	HKD 12,000/ HKD 11,500*		OHS/IRCA/06 05-09		
Hygiene, Food Safety & Wine Storage 衛生、食品安全及酒貯存						
ISO 22000:2005 Food Safety Management Systems - Understanding and Application ISO 22000:2005 食品安全管理體系 - 理解與應用	1	HKD 1,600/ HKD 1,500*			HA5C/HK-07A 31	
ISO 22000:2005 Food Safety Management Systems - Internal FSMS Auditor Training 食品安全管理體系 - 內部審核員培訓	2	HKD 3,500/ HKD 3,300*	HA7C/HK-05A 08-09			HA7C/HK-08A 28-29
ISO 22000:2005 Food Safety Management Systems Implementation Course ISO 22000:2005 實施食品安全管理體系課程	2	HKD 3,700/ HKD 3,500*		HA9C/HK-06A 08-09		
CQI & IRCA Certified FSMS 22000 Lead Auditor (Food Safety Management Systems) based on ISO22000:2005 & ISO/TS22002-1:2009) Training Course (17512) FSMS 22000 主任審核員證書培訓課程	5	HKD 12,000/ HKD 11,500*	IRCA/FSMS/05 15-19			
Hygiene Control System - Understanding & Implementation 衛生監控系統 - 理解與實施	1	HKD 1,600		GP02C/HK-06A 22		
Nutritious Soft Meals Course 營養軟餐課程	2	HKD 2,500	M064C/HK-05A 25 & 29			
Personal Enrichment & Certification (M501) 個人提升和專業資格						
Mind Map® for Creative Problem Solving Workshop Mind Map® 創意解難工作坊	1	HKD 2,300/ HKD 1,980*	M504C/HK-05A 25			
大笑瑜伽領袖認證課程	2	HKD 2,700/ HKD 2,400*			M082C/HK-07A 18 & 24	
True Colors® 證書課程 個人致勝關鍵	1	HKD 1,800/ HKD 1,600*		M083C/HK-06A 12		
The 7 Habits of Highly Effective People Signature Program	2	HKD 10,000/ HKD 9,000*	PC01C/HK-05A 17-18			
Hogan Assessment Certification Workshop 2016	2	HKD 18,500		PC06E/HK-06A 07-08		

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Hong Kong 香港

May - Aug 2017 2017年5月至8月

Course Title 課程名稱	Duration (Day) 課程長度(天)	Fee (per head) HKD 收費(每人)港幣	Course Code & Date 課程編號及日期			
			May 五月	Jun 六月	Jul 七月	Aug 八月
Team Building						
Zodiak: The Game of Business Finance and Strategy	1 to 2		我們專為企業提供度身定造的培訓，詳情可與本局課程經理洽談。 Mr. Anson Wong (2202 9395 / 6111 3855) / anson.wong@hkqaa.org			
Team Collaboration in LEGO® SERIOUS PLAY®	1 to 2					
Team Collaboration in Meaningful Micro-Film Production	1 to 2					
Law and Legislation (Hong Kong, Macau & China) 法律與法規 (香港, 澳門及中國)						
Negotiation and Mediation Skills for Managers and Professionals	1	HKD 1,500	M911C/HK-05A 05			M911C/HK-08A 10
Fundamental Law for Office Administrators 行政人員基礎法律知識	1	HKD 1,500			M920C/HK-07A 18	
Hong Kong Competition Law Fundamentals for Managers and Professionals 管理者必須認識的香港競爭法	1	HKD 1,500			M914C/HK-07A 05	
Legal Fundamentals of Tendering	1	HKD 1,500		M909C/HK-06A 06		
Fundamental Contract Law for Managers and Professionals 管理者必須認識的合同法	1	HKD 1,500	M906C/HK-05A 29			M906C/HK-08A 29
Fundamentals of Negligence for Managers and Professionals 與疏忽有關的基礎法律、承擔責任及賠償風險	1	HKD 1,500			M907C/HK-07A 31	
Safety and Environmental Offences in Construction Projects 「知法守法」課程系列－解構違反安全及環保法例事故	1	HKD 1,500		M908C/HK-06A 14		
香港食物安全管理法律實務	1	HKD 1,500			M922C/HK-07A 07	
場所與設施管理必用法律	1	HKD 1,500		M923C/HK-06A 26		
Management Tools, Skill for Improvement 管理工具和技巧						
ISO 37001 Anti-Bribery Management Systems - Introduction	Half day	HKD 980		A001C/HK-06A 02		
ISO 55001:2014 Asset Management System - Understanding & Application ISO 55001:2014 資產管理體系 - 理解與應用	1	HKD 1,600/ HKD 1,500*		SM04C/HK-06A 14		
Implementation of HKQAA 5S in the Workplace Operation 實施 HKQAA 5S 在工作間的營運	1	HKD 1,600/ HKD 1,500*	GP03C/HK-05A 31			GP03C/HK-08A 24
Workshop on Developing Supervisory Skills & Leadership Charisma 強勢督導管理培訓工作坊	1	HKD 1,080/ HKD 980*	M022C/HK-05A 26			
Workshop on Performance Management through KPI Setting 企業及部門績效管理培訓工作坊	1	HKD 1,080/ HKD 980*			M021C/HK-07A 24	
Workshop on Strategic Compensation System Design 策略性薪酬設計培訓工作坊	1	HKD 1,080/ HKD 980*			M023C/HK-07A 21	
Workshop on Business Process Improvement 業務流程改善培訓工作坊	1	HKD 1,080/ HKD 980*		M024C/HK-06A 26		
Workshop on Effective Project Management 有效項目管理培訓工作坊	1	HKD 1,080/ HKD 980*	M025C/HK-05A 23			M025C/HK-08A 22
Workshop on Effective Communication & Influencing Skills 有效溝通及影響技巧培訓工作坊	1	HKD 1,080/ HKD 980*		M028C/HK-06A 22		M028C/HK-08A 18
Workshop on Competency-based Interviewing Skills 以職能為主之招聘面試技巧培訓工作坊	1	HKD 1,080/ HKD 980*			M081C/HK-07A 05	
Logical Thinking for Problem Solving Workshop 邏輯思考解決問題工作坊	1	HKD 1,700/ HKD 1,500*		M069C/HK-06A 23		
幽默演說技巧工作坊	1	HKD 1,100/ HKD 980*		M074C/HK-06A 20		
「活學幽默 - 廣結人脈」工作坊	1	HKD 350	M075C/HK-05A 12		M075C/HK-07A 07	
Workshop on Building Your Influencing Power 影響力提升工作坊	1	HKD 1,400/ HKD 1,150*	M079C/HK-05A 09			
Corporate Wellness Program 企業身心健康課程	1	HKD 2,800/ HKD 2,300*		M080C/HK-06A 19-20		
Business English Series 職場實用英語系列						
Professional Written Replies to Complaints Workshop	1	HKD 1,400/ HKD 1,150*		M065E/HK-06A 02		
Report Writing Workshop	1	HKD 1,400/ HKD 1,150*			M066E/HK-07A 07	
Effective Communication in Meetings	1	HKD 1,400/ HKD 1,150*			M076E/HK-07A 10	
Effective Presentation Skills	1	HKD 1,400/ HKD 1,150*	M077E/HK-05A 09			M077E/HK08A 09
Business Continuity Management, Risk and Crises Management 營運持續管理體系、風險及危機管理						
ISO 22301 Business Continuity Management Systems - Understanding & Application ISO 22301 營運持續管理體系 - 理解與應用	1	HKD 1,600		RM01C/HK-06A 19		
ISO 31000:2009 Principles and Guidelines for Risk Management - Understanding & Application ISO 31000:2009 風險管理的原因及指引 - 理解與應用	1	HKD 1,600		RM04C/HK-06A 19		
Customer Service: From Good To Great 顧客服務：邁向優越						
ISO 10002:2014 Customer Satisfaction - Guidelines for Complaints Handling - Understanding & Application 客戶滿意度 - 投訴處理指引 - 理解與應用	1	HKD 1,280	MT14C/HK-05A 16			MT14C/HK-08A 08
Effective Compliant Handling and Risk Management in the Customer Service Centre	1	HKD 1,200	EW53C/HK-05A 15			
Corporate Social Responsibility 企業社會責任						
How to Prepare Corporate Sustainability Report? 如何撰寫企業持續發展報告	1	HKD 1,600		SR01C/HK-06A 07	SR01C/HK-07A 21	
Telecommunications, Information Security and Management 電信、資訊保安與管理						
ISO/IEC 27001:2013 Information Security Management Systems - Internal Auditor Training ISO/IEC 27001:2013 信息安全管理体系 - 內部審核員培訓	2	HKD 3,500/ HKD 3,200*		ISE7C/HK-06A 14-15		
ISO/IEC 27001:2013 Information Security Management Systems - Understanding & Application ISO/IEC 27001:2013 信息安全管理体系 - 理解與應用	1	HKD 1,600/ HKD 1,500*	ISE3C/HK-05A 10			ISE3C/HK-08A 16
Implementation of ISO/IEC 27001:2013 Information Security Management Systems ISO/IEC 27001:2013 實踐信息安全管理体系	2	HKD 3,500/ HKD 3,300*		ISE5C/HK-06A 14-15		

Remarks 備註 * Please refer the early bird payment deadline to our website 請於本局網頁參看優先報名之付款詳情
The course schedule is subject to change. Please refer to the most updated schedule in our web-site 課程內容或會略為改動，最新詳情請參看本局網頁
Organisations contracted HKQAA as their management system certification service providers have no obligation to enroll in any HKQAA training services
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Last Updated Date : 10 Apr 2017

Conducted in Cantonese 以廣東話授課 | Conducted in English 以英語授課 | Conducted in Putonghua 以普通話授課

For enquires, please contact our Training Service Unit at Tel : 2202 9111 Our web-site : http://training.hkqaa.org Email : training@hkqaa.org

Governance, Risk and Compliance Management in the Era of Sustainability 可持續發展的策略視野：管治、風險與合規管理

Kickoff Ceremony of HKQAA Hong Kong Registration – Food Waste Recycling 香港品質保證局香港註冊 — 廚餘回收啟動儀式

Officiating Guest 主禮嘉賓：

Mr Wong Kam-sing, GBS, JP, Secretary for the Environment, the Government of the HKSAR
香港特區政府環境局局長**黃錦星先生**, GBS, 太平紳士

Programme 焦點專題

Morning Session (9:15am - 12:00pm)
上午專題環節（上午9時15分至中午12時正）

Language: English
語言：英語

- Path to Sustainability: Governance and Strategic Management of Public Utilities
邁向可持續發展：公共設施的管治與策略性管理
- Strengthen Risk and Compliance Management with the New Sustainability Reporting Standard
善用可持續發展報告新標準，加強風險及合規管理
- Green Financing: Create Value through Sustainable Properties
綠色金融：透過可持續物業創造價值
- Stay Ahead of the Privacy Management Trends: Local and International Perspectives
緊貼私隱管理的國際與本地趨勢
- Food Waste Recycling: Sustainable Management of Resources
廚餘回收：資源的可持續管理
- The Role of ISO standards in Governance, Risk and Compliance Management for Today's Business
ISO標準在現今企業管治、風險與合規管理之角色

Afternoon Session (2:00 - 4:45pm)
下午專題環節（下午2時正至下午4時45分）

Language: English
語言：英語

- Sustainable Urban Planning Transcending 2030: Strategies for a Smart, Green and Resilient City
跨越2030年的可持續城市規劃：智能、環保及具抗禦力的城市策略
- Policy and Market Drivers for Green Building Initiative: Trends and Development
促進綠色建築倡議的政策與市場動力：趨勢及發展
- Optimise Asset Performance, Manage Diversified Risks
優化資產表現，管理多元風險
- Digital Innovation and Reindustrialisation: Implications for Operation and Security Management
數碼創新及再工業化：對營運與安全管理之啟示
- Ageing Society and Workforce: Management Challenges and Opportunities
熟齡化社會與勞動力的管理挑戰及機遇
- From Sustainable Construction to Sustainable Procurement: The Past and Future of ISO's Sustainability Standards
由可持續發展建築到可持續採購：ISO標準的過去與未來

Breakout Session (3:15 - 3:55pm)
分場環節（下午3時15分至3時55分）

Shantung Room, 8/F
8樓山東廳

2017 HKQAA CSR Index Presentation Ceremony (by invitation only)

2017香港品質保證局社會責任指數頒授典禮（只限獲邀人士）

18/05/2017

9:15am - 4:45pm

Ballroom, 7/F, Cordis, Hong Kong at Langham Place,
Mongkok, Kowloon, Hong Kong

香港旺角香港康得思酒店七樓宴會廳

Speakers 嘉賓講者

Prof Alfred Chan Cheung-ming, SBS, JP 陳章明教授, SBS, 太平紳士	Chairperson, Equal Opportunities Commission 平等機會委員會主席
Dr Nigel H Croft 倪國夫博士	Chairman, ISO Technical Subcommittee on Quality Systems 國際標準化組織質量體系技術委員會主席
Dr MeiKei leong 楊美基博士	Chief Technology Officer, Hong Kong Applied Science and Technology Research Institute Company Limited 香港應用科技研究院有限公司首席科技總監
Dr Calvin Lee Kwan 關凱臨博士	General Manager - Sustainability, Link Asset Management Limited 領展資產管理有限公司可持續發展總經理
Ms Brenda Kwok 郭美玲女士	Chief Legal Counsel, Privacy Commissioner for Personal Data, Hong Kong 香港個人資料私隱專員公署首席律師
Mrs Kwok Wong Wing Ki, Vicki 郭黃穎琦女士	Deputy Director of Environmental Protection, Environmental Protection Department, the Government of the HKSAR 香港特區政府環境保護署副署長
Mr Joseph Law 羅嘉進先生	Senior Director - Planning & Development, CLP Power Hong Kong Limited 中華電力有限公司策劃及發展高級總監
Ms Li Chi Miu, Phyllis, JP 李志苗女士, 太平紳士	Deputy Director of Planning (Territorial), Planning Department, the Government of the HKSAR 香港特區政府規劃署副署長(全港)
Sr Wong Bay 黃比測量師	Chairman, Hong Kong Green Building Council 香港綠色建築議會主席
Mr Yu Kam Hung 余錦雄先生	Executive Committee Member, China Real Estate Chamber of Commerce Hong Kong and International Chapter Limited; Consultant, PSA (HK) Surveyors Limited 全國工商聯房地產商會香港及國際分會執行委員；國眾聯(香港)測量師行顧問
Ms Yuan Yuan 袁圓女士	Head of GRI Regional Hub China, Global Reporting Initiative 全球報告倡議組織大中華區主管

Governance, Risk and Compliance Management in the Era of Sustainability 可持續發展的策略視野：管治、風險與合規管理

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www.hkqaa.org/symposium2017

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