



# VISION 管略

Issue 63 第六十三期 | 4 · 2017

**HKQAA Hong Kong Registration –  
Environmental Friendly Construction Site  
香港品质保证局香港注册 — 环境友善建筑地盘**

**Sustainable Building Index Introduced in Guangzhou  
在广州率先引入楼宇可持续发展指数**

**New Revision to ISO 13485 for Medical Devices Comes into Effect  
新修订版ISO 13485医疗器械质量管理体系标准正式生效**

**HKQAA**  
HONG KONG QUALITY ASSURANCE AGENCY  
香港品质保证局

## 03 Feature 专题特写

HKQAA Hong Kong Registration —  
Environmental Friendly Construction Site  
香港品质保证局香港注册 — 环境友善建筑地盘

## 05 Technical Corner 技术研讨

Sustainable Building Index Introduced in Guangzhou  
在广州率先引入楼宇可持续发展指数

New Revision to ISO 13485 for Medical Devices  
Comes into Effect

新修订版ISO 13485医疗器械质量管理体系标准  
正式生效

## 11 HKQAA Updates 本局快讯

## 13 News &amp; Trends 新闻搜索

## 14 Welcome on Board 迎新天地

## 15 Training Schedule 培训课程

## Article Contributions 欢迎投稿

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.

## 推动建筑地盘实践环保

建筑是推动国家经济发展的重要力量，但同时亦可能为环境带来损害。据联合国环境署披露，建造业及楼宇占据了全球40%的能源使用，30%的温室气体排放，12%的用水及40%的废物。在香港，建筑地盘便或多或少对环境带来影响，2015年，环境保护署共收到4,851个关于建筑活动的污染反馈，当中涉及空气、噪音、水源或废物等问题。

多年来，香港品质保证局致力促进环保及社会的可持续发展，积极开拓崭新服务，助工商界提升可持续发展表现。为配合业界需要和公众期望，本局推出「香港品质保证局香港注册 — 环境友善建筑地盘」，鼓励承建商监控建筑过程对环境的影响，减少污染及耗用能源，为保护生态环境作出贡献。

此计划提供建议的环保做法，协助业界改善可持续发展表现，我们期望可推动更多机构付诸实践，将环保做法融入日常营运，长远地优化行业水平，提高其公众形象，同时亦惠及社会。

城市发展不免对大自然构成一定影响，因此我们须尽力减低对环境造成的伤害，而工商界更从中担当著举足轻重的角色。本局会继续开发更多新服务，向业界推广良好做法，携手开创可持续发展的未来。

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# HKQAA Hong Kong Registration – Environmental Friendly Construction Site

## 香港品质保证局香港注册 — 环境友善建筑地盘

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.

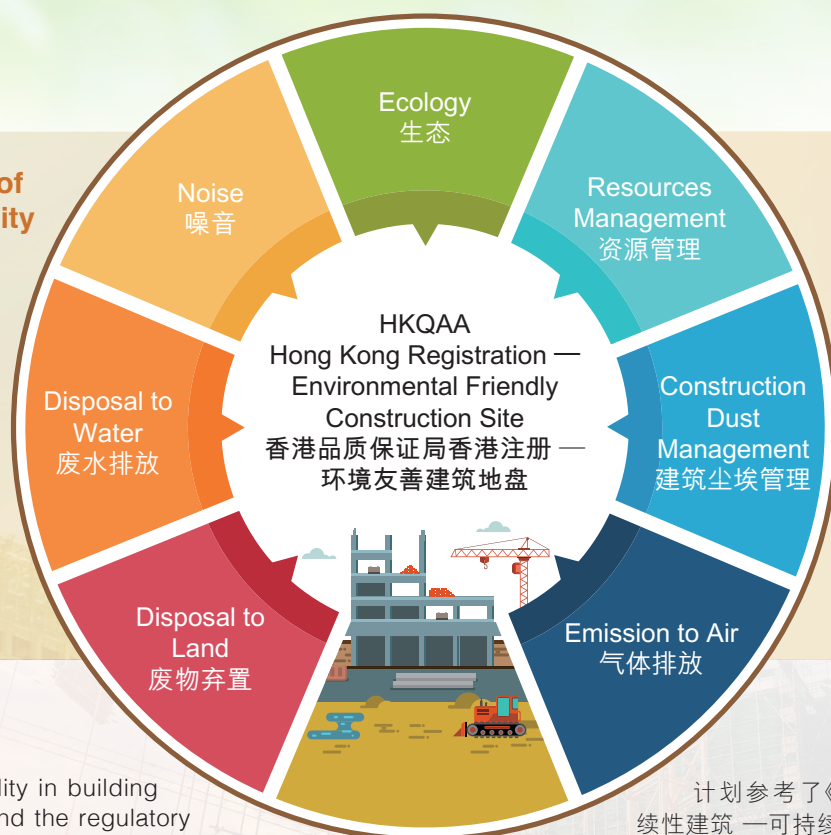
HKQAA has launched the HKQAA Hong Kong Registration – Environmental Friendly Construction Site to encourage organisations in the construction sector to minimise their adverse impact on the environment and society in construction operations. The scheme promotes recommended green practices so as to help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

建筑是促进经济及社会发展的动力。惟在建筑过程中，地盘或会对生态带来负面影响或污染，引起公众关注。根据环境保护署2015的统计数字，有关建筑活动的噪音反馈有1,239宗，空气滋扰有886宗。由此可见，建筑行业需要加强监察及控制建筑过程对环境之影响，以满足公众对其环保表现的期望。

为配合业界及社会发展，本局推出香港品质保证局香港注册 — 环境友善建筑地盘，鼓励从事建筑业的机构，在作业时尽力减低对环境及社会的负面影响。计划推广绿色建议做法，协助业界改善可持续发展表现及形象。

### Seven Environmental Aspects of Construction Sites' Sustainability Performance

七项环境范畴  
衡量建筑地盘的可持续发展表现



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.

计划参考了《ISO 21929 可持续性建筑 — 可持续发展指标》及环境保护署对地盘的条例要求，从而制订七个范畴以作评审，包括生态、资源管理、建筑尘埃管理、气体排放、废物弃置、废水排放，以及噪音，并提供二十个建议做法，推动业界在建筑过程中，减少污染和耗用资源。





## Checklist of Recommended Practices 建议做法清单

Aspect 范畴	Recommended Practice 建议做法
Ecology 生态	Protection of trees on construction site 保护地盘内树木
	Monitoring ecological mitigation on construction site 监察地盘生态，缓和对生态的影响
Resources Management 资源管理	Management of construction materials and equipment 建筑物料及器材管理
	Management of energy resources 能源管理
	Management of water resources 水资源管理
Construction Dust Management 建筑尘埃管理	Control of dust generation in material handling 在处理物料时控制尘埃产生
	Using hoarding / dust screen to prevent dust generation on construction site 使用围板 / 隔尘幕以避免在地盘产生尘埃
	Controlling dust emission in excavation 在开凿时控制尘埃散布
	Controlling dust emission in dust vehicle processes 在操控尘埃器械时控制尘埃散布
	Controlling dust emission in demolition work 在进行拆除工作时控制尘埃散布
	Controlling dust emission in drilling and blasting 在钻挖及爆破时控制尘埃散布
Emission to Air 气体排放	Controlling air pollution in construction plant and equipment 控制建筑场所及器材所产生的空气污染
	Controlling volatile organic compound emission on construction site 控制地盘的易燃有机合成物排放
	Preventing illegal open burning on construction site 避免在地盘非法公开燃烧
Disposal to Land 废物弃置	Working procedures to minimise construction waste 减少地盘废物的工序
	Working procedures to manage chemical waste 管理化学废物的工序
	Minimising solid waste in construction processes 在建筑过程中减少固体废物
Disposal to Water 废水排放	Treatment of waste water generated from construction site 处理地盘产生的污水
	Water quality monitoring during construction processes 在建筑过程中监测水质
Noise 噪音	Control of noise generated in construction processes 在建筑过程中控制噪音

## 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.

## 适用范围

注册以地盘为单位，注册的地盘须正进行工程。任何能控制建筑过程的承建商，都可为其地盘申请注册。成功注册的机构可获发注册标志，彰显其对城市可持续发展及保护环境的贡献，提升品牌形象及商誉。

## Registration Process 注册流程





# Sustainable Building Index Introduced in Guangzhou

## 在广州率先引入楼宇可持续发展指数

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/1,000m<sup>2</sup>, which scores 3 marks. Since the government has begun promoting recycling for only a short time, there is a need to raise public

广州—中国重点城市之一，是珠三角的核心，并多次获评福布斯中国大陆最佳商业城市。其中广州市天河中央商务区（CBD）是以商贸及金融服务业为主导，聚集企业总部、商贸功能及特色商业街为一体的高端综合功能区，亦是南中国城市化发展最快、综合配套设施最完善的平台。

为塑造优质物业服务品牌、提升楼宇价值和CBD的整体形象，天河CBD管委会委任香港品质保证局，提供楼宇可持续发展指数评定服务，藉此保持新建楼宇的发展优势及提升现有楼宇的社会价值。目前，天河CBD内21栋亿元税收楼宇完成了可持续发展指数的评定，其余27栋亿元税收楼宇亦于今年开展评定工作。

### 指数助提高天河CBD楼宇价值

在天河CBD引入楼宇可持续发展指数具有深远意义，不但可以推动各楼宇在营运时查漏补缺，不断优化各项措施，减少资源消耗，从而提升客户满意度及楼宇价值；亦促进区域内其他楼宇改善物业管理服务，以提升天河CBD整体的物业管理水平。此外，通过分析楼宇的可持续发展表现数据，利于建立一套与国际接轨及规范化的物业管理服务，推动天河CBD可持续发展的管理文化，以优质的楼宇服务，塑造极具影响力的高级核心商务区。

### 参加评定的楼宇情况

评定的方法及准则以「香港品质保证局楼宇可持续发展指数」为基础，并参考了内地相关的法律法规及最新国际标准，同时结合天河CBD的区域调查研究数据，以环境、社会和经济的三大范畴为框架，再分成24项评定指标及八个加分项目，客观地评定楼宇的可持续发展表现。

现阶段，已接受评定楼宇的平均得分为2.55分（满分为3分），表现不俗。反映了区域内楼宇均具备楼宇可持续发展的管理意识，并系统地实践在楼宇及其设施的日常管理上。

环境方面，区域内不少楼宇均积极开展节能减排计划及实施节能工程等措施，有效降低能源消耗。楼宇的温室气体（GHG）每年平均排放量为每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/1000m<sup>2</sup>, 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管委会访问香港品质保证局香港办公室



38.25公吨，达到3分，表现理想。然而，由于国家较迟开始推广废物回收，市民的环保意识较弱，因此楼宇在废物回收的表现相对逊色，平均每年废物回收量为每1,000平方米175.49公斤，只达到2分。天河CBD管委会正就此制定并推行废物回收管理制度和加强宣传工作，鼓励楼宇持续改善。

另外，内地就楼宇防火及电梯安全定立了不少法律和法规，亦注重楼宇日常安全的维修及保养。而天河CBD楼宇在防火、电梯和自动扶梯安全等指标表现出色，均符合最高标准。各楼宇制定了十至数十种不同的应急方案，订装成册，或将应急方案装裱在墙上，又定期安排演习，以示对楼宇安全管理的重视。另一方面，随著无障碍设施越来越受关注，天河CBD楼宇需要持续优化相关设施。

出租率是反映楼宇经济表现的重要指标。天河CBD位处城市中央地段，交通便利，拥有浓厚的商务气氛，吸引国内外企业落户。在是次评定中，楼宇的出租率也表现理想，基本达到3分，九成楼宇的租售率达85%或以上。

## Sharing by Participating Buildings 参与评定的楼宇分享



**Mr Zhang Jun**  
General Manager  
Guangzhou Branch, Shanghai  
Poly Property Hotel Management  
Group Co., Ltd.  
上海保利物业酒店管理集团  
有限公司广州分公司  
总经理张军先生

"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."

「中信广场作为广州市地标性建筑之一，运作已超过20年。肩负中信广场的物业管理之重任，保利物业一直实行『让生活更美好』的物业服务理念，务求带给客户持续的价值体验。近年来，我们致力开展楼宇电脑智能化和环境质量管控的工作，并取得了良好的口碑。通过参与楼宇可持续发展指数的评定，我们更清楚楼宇可持续发展的方向，有助提升中信广场的社会价值。」



**Mr Pan Shao Hua**  
Project Assistant General  
Manager  
Bank of Guangzhou Tower  
Service Centre  
广州银行大厦服务中心  
项目副总经理  
潘兆华先生

"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."

「广州银行大厦率先通过楼宇可持续发展指数评定后，我们将该指数融合贯彻到日常管理服务中，结合『以人为本』的酒店式服务理念，营造更清新、舒适、安全、节能环保的商务办公环境。我们将不断推动楼宇可持续发展，以提升市场竞争力及整体价值，彰显社会责任。」



## Good Practices in Building Sustainability 楼宇可持续发展的良好做法

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.

个别楼宇如广州国际金融中心、中信广场、富力中心、广州银行大厦、粤海天河城大厦及利通广场，在配套设施及可持续管理表现突出。



**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.

**广州国际金融中心**推行多元化的规划及服务，如采用冷凝水热回收系统和全热回收新风机组等不同的新型节能环保设备，突显了这座地标的绿色管理方针。

**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.

**中信广场**作为天河CBD第一代标志性建筑，虽然已经达到20年楼龄，但凭著专业的物业管理服务及设施保养，让楼宇保持稳定的可持续发展表现。广场每年举行超过200场培训，不断提高物业管理的服务水平；针对消防、防爆、防洪等方面设置应急战备专区，同时向公安局及时反馈安全监控信息，以实现全方位的楼宇安全管理。



**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**是广州富力地产集团总部办公大楼，十分重视智能化管理及贴心服务方面的表现。富力中心自主开发「巡航管家」系统，因应情况，灵活管理楼宇设施的运作及维修状况。此外，物业亦提供如洗车、免费洗眼镜等礼宾服务，展现其贴心服务。

**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.

**广州银行大厦**为珠江新城地标性的超甲级写字楼，结合酒店式服务，提供专业及个人化服务，以满足客户需求；另外，大厦建立「日能耗曲线图」，监控能源消耗的异常情况，分析客户上下班情况，优化设备运作时间，提升节能效率。



**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.

**粤海天河城大厦**作为顶级写字楼，秉持「关心、爱心、真心、热心、专心」的服务理念，提供专业且系统化的管理与服务，全面实施严格的保安管理，确保各类安全防范措施完善。

**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.

**利通广场**在建筑和管理方面获得多个国家及世界级优秀建筑奖，并荣获LEED铂金级认证。楼宇在硬件方面采用先进的节能环保措施，软件方面则实现楼宇的智能管理，如提供车位查询、网上订餐等体验式服务。



# New Revision to ISO 13485 for Medical Devices Comes into Effect

## 新修订版ISO 13485医疗器械质量管理体系标准正式生效

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**Associate Technical Director, HKQAA**  
**Chairman, ISO Technical Subcommittee on Quality Systems (ISO/TC 176/SC2)**  
**倪国夫博士**  
**香港品质保证局技术总监**  
**国际标准化组织质量体系技术委员会 (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:

「医疗器械」是指任何用作诊断、预防及治疗疾病的产品，小至伤口敷料、心脏起搏器，大至牙科椅、维持生命仪器，以至体外诊断试剂也包含在内。在大部分国家，政府都会对这些医疗产品作出规管，以免生产商粗制滥造，危害市民健康安全。不少医疗器械会被放进人体内，除了用作检查身体、治疗疾病外，有些更会长期留在病人体内，好像人造髋关节、心血管支架、人造心瓣或心脏起搏器等。

ISO 13485 于1996年首次出版，名为《医疗器械—质量管理体系—应用ISO 9001的具体要求》，其后于2003年改版，名为《医疗器械—质量管理体系—用于法规的要求》，最新版本为ISO 13485：2016。

### ISO 13485的适用范围及规管重点

ISO 13485：2016说明了质量管理体系的要求，证明提供医疗器械及相关服务的机构能满足客户及相关法规要求。由于每个国家的法例都有所不同，所以ISO 13485并没有定义详细的法规要求，而是要求医疗机构根据自身情况，自行辨识相关的法规要求，并融入在其质量管理体系中。一些医疗产品在个别地区并不会被视为医疗器械，包括：

- 残障人士的辅助器材
- 含有动物及 / 或人体组织的仪器
- 消毒物质
- 进行体外受孕或辅助生育技术的仪器

ISO 13485适用于任何参与医疗器械生命周期的机构，由设计、生产、停止运作到弃置，以至储存、分发、安装、维修，以及提供相关服务。在2003年的版本中，ISO 13485已经就法规规管加入基于风险的概念，而2016年新版更加强了这方面的内容。

虽然ISO 13485建基于ISO 9001，但由于前者以符合法规为核心性质，因此并无包含部份ISO 9001的内容。例如ISO 13485并没有像ISO 9001般要求机构持续改善其质量管理体系，以及评估其客户满意度，但却要求机构评估其医疗器械使用者的意见，包括：

- 医疗器械是否达到预期的使用要求？
- 医疗器械是否符合法规要求？
- 剩馀风险是否受到控制？有没有发现新的风险？



- 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 医疗器械—风险管理的应用》作为与 ISO 13485 互补的标准，描述了如何在医疗器械的整个生命周期中，进行系统化的风险管理。

### ISO 13485 : 2016 有何修改？

是次修订 ISO 13485 的主要目的是反映最新的科技发展，以及回应生产商及监管机构日益提升的期望，并推动监管机构、审核机构和医疗器械生产商提升相关要求的透明度，以便互相协调。此标准适用于参与医疗器械生命周期中某个或多个阶段的机构，当中包括设计、开发、生产、储存、分发、安装和维修，以及设计、开发和提供相关活动（如技术支援）。相较于旧版本，新版本加强了质量管理体系与法规要求的互动、标准在产品整个生命周期中的适用范围（如包括该医疗器械的分销商及进口商），于质量管理体系中更广泛地纳入风险管理的原则。

除非有特别指明，否则 ISO 13485 : 2016 的要求适用于任何规模及类型的机构。此外，标准中所有适用于医疗器械的要求，亦同时适用于机构提供之相关服务。

整体而言，新版 ISO 13485 扩大了其适用范围至与产品的整个生命周期（由构思到弃置）相关的所有机构，增加与法规要求的配合，以及加强产品在推出市场后的监察（如投诉处理）。

以下列出新版本的主要更新内容：

- 加强最高管理层的责任及承担，以符合适用的法规要求
- 于整个产品生命周期中强调风险管理
- 优化个别适用设施的要求，尤其经消毒的医疗器械之生产，以及就审定无菌屏障性能的额外要求
- 加强与法规要求的配合及进行法规文件记录







- 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.

- 扩大标准的适用范围至所有与医疗器械生产商有所互动的机构，包括：
  - 参与医疗器械设计、开发、维修及维护的机构
  - 提供原材料、零件或局部装配的机构
  - 合约制造商或提供消毒、物流、测量仪器校准等服务的机构
  - 医疗器械的进口商或分销商
- 新增对医疗器械设计及开发的要求，考虑其可用性和对标准的使用，并需详细规划该产品的核查、审定、转移、以及保存设计和开发活动的记录
- 统一不同软件应用的审定要求，包括质量管理体系软件、流程控制软件、监察及量度软件等
- 定义质量管理人员应具备的技能及经验要求
- 进行培训时需有文件记录，并评估培训的成效
- 提高对供应商及外判工作的控制
- 为无菌屏障系统及消毒过程的进行审定
- 建立与维护医疗科技器械的档案及设计开发的档案
- 加强产品推出市场后的监察，如投诉处理及提交规范报告

### 与 ISO 9001 : 2015 的关系

虽然 ISO 13485 : 2016 迟于 ISO 9001 : 2015 出版，但由于 ISO 13485 早于 2010 年已开展修订程序，比《ISO 指引》中「附件 SL」的出版还要早，因此 ISO 13485 并非采用「附件 SL」内的「高阶架构」及「相同文本」，其条文架构较贴近 ISO 9001 的 2008 年旧版本。不过，ISO 13485 在词汇的定义上引用了 ISO 9000 : 2015 (虽然当中 ISO 9000 部分词汇的定义已因应 ISO 13485 的规管内涵而作出修改)，而 ISO 13485 : 2016 的「附件 B」亦提供了与 ISO 9001 : 2015 内容的比较。基于 ISO 13485 针对的是需高度规管的行业，因此在明文依据的要求会比 ISO 9001 : 2015 更多，包括需编写质量手册及进行其他文件化程序。

### 如何过渡至 ISO 13485 : 2016

国际认可论坛 (IAF) 已同意获 2003 年版 ISO 13485 的认证机构拥有三年过渡期，因此它们现有的证书直到 2019 年 3 月 1 日仍然有效。





## Shaanxi Province Quality and Technology Supervision Bureau Visit

### 香港品质保证局到访陕西省质量技术监督局

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.

香港品质保证局去年10月与陕西省质量技术监督局签订合作备忘录后，今年3月30日再专程拜访该局，与其交流会面，谋求深化双方合作，促进陕港两地在质量管理与品牌建设方面取得新的突破，以配合「一带一路」的建设。

参与是次会面的包括香港品质保证局总裁林宝兴博士一行四人、陕西省质量技术监督局党组书记兼局长乔军先生、该局质量处、认评处、计量处、陕西省计量院、质检院，以及质量评审中心等代表。双方锐意在合作备忘录的基础上，深化陕港合作模式，协助两地企业提升竞争力。



## Seminar on Managing Service Quality through the Spirit of a Craftsman

### 「工匠精神－如何管理服务质量」研讨会

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.



香港品质保证局于2017年4月举办了「工匠精神－如何管理服务质量」研讨会。研讨会邀得香港宽频网络有限公司的区永康先生，以及彼得德鲁克管理学院认可讲师梁锐光先生任演讲嘉宾。研讨会上分享了有关如何利用神秘顾客服务，管理服务质量，以及如何利用交响乐管理，打造专业的服务团队。此外，本局讲者亦介绍了有关本局的神秘顾客服务及后续服务，协助企业提升服务素质。





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

### 本局现提供香港认可处认可之ISO 22000 认证服务及 ISO 14064-1 核查服务

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:

香港品质保证局现已提供香港认可处认可之ISO 22000 食品安全管理体系认证服务及ISO 14064-1 温室气体排放核查服务。

本局于2017年3月13日透过香港认可处香港认证机构认可计划(HKCAS)正式取得ISO 22000 认证服务之认可资格。ISO 22000 认证适用于各食品供应链中的供应商、制造商、经销商和零售商。

此外，本局于2017年4月11日亦取得ISO 14064-1 核查服务之认可资格。ISO 14064 鼓励业界主动量度温室气体排放，增加机构在温室气体量化、检查和报告方面的一致性、可信度和透明度，适用于各类型及规模的机构。

欲知更多有关本局所提供的认证、核查和支援服务，请联络我们：

**Hong Kong Quality Assurance Agency 香港品质保证局**

**Email 电邮：** [hkqaa@hkqaa.org](mailto:hkqaa@hkqaa.org)

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Shanghai 上海 – (86 21) 6876 9911  
Guangzhou 广州 – (86 20) 8383 3777



## 特订服务 Customised Services

### We Customise Services to your Needs 致力开发创新服务 切合客户独特需要

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.

作为亚太区内最具规模及领导地位的合格评定机构之一，香港品质保证局持续开发及推出不同类型的创新服务，以回应市场及个别机构的需求。我们乐意为您度身制订各种服务，范围遍及核查、评审、认证、注册、培训、调查、研究及其他专业服务。

请与我们的业务部联络，我们会竭诚为您制订切合业务需要的服务。

**Tel 电话：** (852) 2202 9111 | **E-mail 电邮：** [hkqaa@hkqaa.org](mailto:hkqaa@hkqaa.org)



## International 国际

### 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 工作坊于瑞典斯德哥尔摩举行

由瑞典标准协会举办的工作坊于2017年3月初举行，旨在讨论ISO 26000（社会责任指引）与ISO一系列管理体系标准之间的协同效应。即使ISO 26000不是一个管理体系标准，亦不包括要求，它仍可有效地融入于任何机构现有的ISO 9001或ISO 14001等管理体系框架之中。跟进工作坊将于2017年5月在伦敦举行，而ISO/IWA 26（《国际工作坊协议》）预期将于同年稍后时间出版。

### 新版ISO/IEC 17021-3出版

ISO/IEC 17021 第三部分列明对质量管理体系审核员及其他认证机构技术支援人员之能力要求，已修订为与ISO 9001:2015保持一致。新标准于2017年3月出版，内容包括了解机构内涵、「基于风险的思维」及贯彻整个机构的领导角色等议题的附加要求。

### ISO 更新管理体系标准综合使用小册子

ISO 联合技术协调小组的一个专责小组正更新此小册子，加入出版ISO 指令附件SL等最新发展，为各ISO管理体系标准建立了一个通用的高阶架构。

### ISO 45001 筹备工作继续进行

ISO 项目委员会ISO/PC 283继续解决导致原定取代OHSAS 18001的ISO 45001（职业安全健康管理体系要求）在第一次国际标准草案(DIS)被投否定票的意见。委员会现正筹备国际标准草案第二版(DIS2)，如获得通过，此国际标准便可于2018年初至中期出版。

### 新版ISO 9004 标准进入国际标准草案阶段

ISO/TC176/SC2/WG2 工作小组于委员会通过决议草案后，结合所有ISO成员机构的意见，现已落实国际标准草案。小组将于2017年9月在印尼再次会面，以评估对国际标准草案的补充意见，并预期ISO 9004:2018《机构素质—实践持续成功之指引》将于2018年初出版。虽然ISO 9004不包括任何要求，亦不适宜作认证之用，但它包含一个成熟的模型，协助机构进行自我评估，在ISO 9001的要求上再迈进一步，以取得长远的成功。



## New Certified Clients 新认证客户

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

## Memorable Moments 纪念一刻



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.

香港品质保证局自1989年成立以来，致力协助工商界实施管理体系，有效地达至机构和营商目标。





































由2016年11月至2017年1月期间，香港品质保证局共颁发70张证书，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。在此谨祝贺49家机构加入获认证的行列。本局深信，新成员的加入将可为我们的品牌和持份者带来更大的裨益。





## Mainland China 中国内地

May - Aug 2017 2017年5月至8月

Course Title 课程名称	Duration (Day) 课程长度 (天)	Fee (per head) RMB 收费 (每人) 人民币	Course Code & Date 课程编号及日期			
			May 五月	Jun 六月	Jul 七月	Aug 八月
Standard & Systems Training 标准体系培训						
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	 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	 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	 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	 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 电信业质量管理内审员培训	 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)	 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	 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	 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	 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	 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	 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	 2	RMB 2,500		ISE9P/GZ06A GZ 27-28		
SA 8000:2014 Social Accountability Management Systems - Intenal Auditor Training SA 8000:2014 社会责任管理体系内部审核员培训	 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	 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	 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	 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	 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 现场管理 5S Site Management	 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)	 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	 1	RMB 1,500	GM17P/GZ05A GZ 31			GM17P/GZ08A GZ 21
Lean Production-IE Technology 精益生产之 IE 手法	 2	RMB 2,500				GM22P/SH08A SH 28-29
Flexie Production Planning Management 柔性生产计划与排程管理	 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	 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	 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	 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	 2	RMB 2,400		EO05P/SH05A SH 15-16		
Project Management 项目管理	 2	RMB 3,000			MS17P/GZ07A GZ 26-27	
Statistical Process Control SPC 统计过程控制	 1	RMB 1,000		MS20P/GZ06A GZ 08		
Failure Mode and Effects Analysis FMEA 潜在失效模式分析	 1	RMB 1,000	MS04P/GZ05A GZ 12			MS04P/GZ08A GZ 22
Seven QC Tools (Traditional & New) QC 七大手法	 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	 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	 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	 2	RMB 2,400				GM07P/GZ08A GZ 07-08
Time Management 时间管理	 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	 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	 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	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	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	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	1	RMB 1,500		M519P/GZ06A GZ 19		
Coaching Skills 教练技巧	2	RMB 2,800	GM24P/GZ05A GZ 04-05			GM4P/SH08A SH 30-31

For registration and enquiry  
报名及查询

Hong Kong Office 香港办事处 • Tel 电话: (852) 2202 9111 • Email 电邮: training@hkqaa.org






































HKQAA Certification (Macau) Ltd. 标准认证服务(澳门)有限公司 • Tel 电话: (853) 2875 1199

HKQAA Certification (Shanghai) Ltd. 标准认证服务(上海)有限公司 • Tel 电话: (86 21) 6876 9911

HKQAA Certification (Shanghai) Ltd. Guangzhou Branch 标准认证服务(上海)有限公司广州分公司 • Tel 电话: (86 20) 8383 3777

For training course details and online registration, please visit HKQAA website 详细课程资料及网上报名, 请浏览香港品质保证局网页 <http://www.hkqaa.org>



Course Title 课程名称	Duration (Day) 课程长度 (天)	Fee (per head) HKD 收费 (每人) 港币	Course Code & Date 课程编号及日期				
			May 五月	Jun 六月	Jul 七月	Aug 八月	
Quality and Integrated Management Systems 质量和综合管理							
ISO 9001:2015 Quality Management Systems - Understanding & Application ISO 9001:2015 质量管理体系 - 理解与应用		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 质量管理体系 - 内部质量管理体系审核员培训		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 质量管理体系 - 管理者代表的重要须知		1	HKD 1,680/ HKD 1,580*	MT23C/HK-05A 15			
ISO 9001:2015 Quality Management Systems Documentation ISO 9001:2015 质量管理体系文件		1	HKD 1,680/ HKD 1,580*			QMS4C/HK-07A 20	
ISO 9001:2015 Quality Management Systems - Advanced Internal Auditing Techniques ISO 9001:2015 品质管理体系 - 进阶内部审核技巧		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) 质量管理体系 - 主任审核员证书培训课程		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 综合管理体系 - 建立与审核方法		2	HKD 3,500/ HKD 3,300*		IMS2C/HK-06A 20-21		
Understanding and Application of an Integrated Management System 综合管理体系 - 理解与应用		2	HKD 3,500/ HKD 3,300*		IMS5C/HK-06A 20-21		
Environmental Conservation 环境保育							
ISO 14001:2015 Environmental Management Systems - Understanding & Application ISO 14001:2015 环境管理体系 - 理解与应用		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 环境管理体系 - 内部环境管理体系审核员培训		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 环境管理体系 - 实施及文件指引		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 环境管理体系 - 主任审核员证书培训课程		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 能源管理体系 - 理解与应用		1	HKD 1,200/ HKD 1,080*			EM07C/HK-07A 10	
ISO 50001:2011 Energy Management Systems - Internal Auditor Training ISO 50001:2011 能源管理体系 - 内部审核员培训		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 能源管理系统 - 主任审核员证书培训课程		5	HKD 9,000/ HKD 8,000*				EM10C/HK-08A 14-18
GreenHouse Gas Verifier Training 温室气体验证员		2	HKD 3,500/ HKD 3,300*		EM09C/HK-06A 08-09		
Environmental Management Course for Food and Beverage Industry 餐饮业环境管理课程		2	HKD 2,500		M067C/HK-06A 12 & 19		
Occupational Health and Safety Management 职业健康和安全							
OHSAS 18001:2007 Occupational Health and Safety Management Systems - Understanding & Application OHSAS 18001:2007 职业健康和安全管理体系 - 理解与应用		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 职业健康和安全管理体系 - 内部职业健康和安全管理体系 审核员培训		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&I/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) 职业健康和安全管理体系 - 主任审核员证书培训课程		5	HKD 12,000/ HKD 11,500*		OHS/IRCA/06 05-09		
Hygiene, Food Safety & Wine Storage 卫生、食品安全及酒贮存							
ISO 22000:2005 Food Safety Management Systems - Understanding and Application ISO 22000:2005 食品安全管理体系 - 理解与应用		1	HKD 1,600/ HKD 1,500*			HA5C/HK-07A 31	
ISO 22000:2005 Food Safety Management Systems - Internal FSMS Auditor Training 食品安全管理体系 - 内部审核员培训		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 实施食品安全管理体系课程		2	HKD 3,700/ HKD 3,500*		HA9C/HK-06A 08-09		
CQI & IRCA Certified FSSC 22000 Lead Auditor (Food Safety Management Systems based on ISO22000:2005 & ISO/TS22002-1:2009) Training Course (17512) FSSC 22000 主任审核员证书培训课程		5	HKD 12,000/ HKD 11,500*	IRCA/FSMS/05 15-19			
Hygiene Control System - Understanding & Implementation 卫生监控系统 - 理解与实施		1	HKD 1,600		GP02C/HK-06A 22		
Nutritious Soft Meals Course 营养软餐课程		2	HKD 2,500	M064C/HK-05A 25 & 29			
Personal Enrichment & Certification (M501) 个人提升和专业资格							
Mind Map® for Creative Problem Solving Workshop Mind Map® 创意解难工作坊		1	HKD 2,300/ HKD 1,980*	M504C/HK-05A 25			
大笑瑜伽领袖认证课程		2	HKD 2,700/ HKD 2,400*			M082C/HK-07A 18 & 24	
True Colors® 证书课程 个人致胜关键		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		



# Hong Kong 香港

May - Aug 2017 2017年5月至8月

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Course Title 课程名称	Duration (Day) 课程长度 (天)	Fee (per head) HKD 收费 (每人) 港币	Course Code & Date 课程编号及日期			
			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	我们专为企业提供度身定造的培训，详情可与本局课程经理洽谈。 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) 法律与法规 (香港，澳门及中国)						
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 行政人员基础法律知识		1	HKD 1,500		M920C/HK-07A 18	
Hong Kong Competition Law Fundamentals for Managers and Professionals 管理者必须认识的香港竞争法		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 管理者必须认识的合同法		1	HKD 1,500	M906C/HK-05A 29		M906C/HK-08A 29
Fundamentals of Negligence for Managers and Professionals 与疏忽有关的基础法律、承担责任及赔偿风险		1	HKD 1,500		M907C/HK-07A 31	
Safety and Environmental Offences in Construction Projects 「知法守法」课程系列－解构违反安全及环保法例事故		1	HKD 1,500	M908C/HK-06A 14		
香港食物安全管理法律实务		1	HKD 1,500		M922C/HK-07A 07	
场所与设施管理必用法律		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 资产管理体系 - 理解与应用		1	HKD 1,600/ HKD 1,500*		SM04C/HK-06A 14	
Implementation of HKQAA 5S in the Workplace Operation 实施 HKQAA 5S 在工作间的营运		1	HKD 1,600/ HKD 1,500*	GP03C/HK-05A 31		GP03C/HK-08A 24
Workshop on Developing Supervisory Skills & Leadership Charisma 强势督导管理培训工作坊		1	HKD 1,080/ HKD 980*	M022C/HK-05A 26		
Workshop on Performance Management through KPI Setting 企业及部门绩效管理培训工作坊		1	HKD 1,080/ HKD 980*		M021C/HK-07A 24	
Workshop on Strategic Compensation System Design 策略性薪酬设计培训工作坊		1	HKD 1,080/ HKD 980*		M023C/HK-07A 21	
Workshop on Business Process Improvement 业务流程改善培训工作坊		1	HKD 1,080/ HKD 980*		M024C/HK-06A 26	
Workshop on Effective Project Management 有效项目管理培训工作坊		1	HKD 1,080/ HKD 980*	M025C/HK-05A 23		M025C/HK-08A 22
Workshop on Effective Communication & Influencing Skills 有效沟通及影响技巧培训工作坊		1	HKD 1,080/ HKD 980*	M028C.HK-06A 22		M028C.HK-08A 18
Workshop on Competency-based Interviewing Skills 以职能为主之招聘面谈技巧培训工作坊		1	HKD 1,080/ HKD 980*		M081C/HK-07A 05	
Logical Thinking for Problem Solving Workshop 逻辑思考解决问题工作坊		1	HKD 1,700/ HKD 1,500*		M069C/HK-06A 23	
幽默演说技巧工作坊		1	HKD 1,100/ HKD 980*		M074C/HK-06A 20	
「活学幽默 - 广结人脉」工作坊		1	HKD 350	M075C/HK-05A 12		M075C/HK-07A 07
Workshop on Building Your Influencing Power 影响力提升工作坊		1	HKD 1,400/ HKD 1,150*	M079C/HK-05A 09		
Corporate Wellness Program 企业身心健康课程		1	HKD 2,800/ HKD 2,300*		M080C/HK-06A 19-20	
Business English Series 职场实用英语系列						
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 营运持续管理体系、风险及危机管理						
ISO 22301 Business Continuity Management Systems - Understanding & Application ISO 22301 营运持续管理体系 - 理解与应用		1	HKD 1,600		RM01C/HK-06A 19	
ISO 31000:2009 Principles and Guidelines for Risk Management - Understanding & Application ISO 31000:2009 风险管理的原因及指引 - 理解与应用		1	HKD 1,600		RM04C/HK-06A 19	
Customer Service: From Good To Great 顾客服务：迈向优越						
ISO 10002:2014 Customer Satisfaction - Guidelines for Complaints Handling - Understanding & Application 客户满意度 - 投诉处理指引 - 理解与应用		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 企业社会责任						
How to Prepare Corporate Sustainability Report? 如何撰写企业持续发展报告		1	HKD 1,600		SR01C/HK-06A 07	SR01C/HK-07A 21
Telecommunications, Information Security and Management 电信、资讯保安与管理						
ISO/IEC 27001:2013 Information Security Management Systems - Internal Auditor Training ISO/IEC 27001:2013 信息安全管理体系 - 内部审核员培训		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 - 理解与应用		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 实践信息安全管理体系		2	HKD 3,500/ HKD 3,300*		ISE5C/HK-06A 14-15	

Remarks  
备注

\* Please refer the early bird payment deadline to our website 请于本网页查看优先报名之付款详情  
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## Governance, Risk and Compliance Management in the Era of Sustainability 可持续发展的策略视野：管治、风险与合规管理

### Kickoff Ceremony of HKQAA Hong Kong Registration – Food Waste Recycling 香港品质保证局香港注册 — 厨余回收启动仪式

**Officiating Guest 主礼嘉宾：**

**Mr Wong Kam-sing**, GBS, JP, Secretary for the Environment, the Government of the HKSAR  
香港特区政府环境局局长**黄锦星先生**, GBS, 太平绅士

#### Programme 焦点专题

##### Morning Session (9:15am - 12:00pm)

上午专题环节（上午9时15分至中午12时正）

Language: English

语言：英语

- Path to Sustainability: Governance and Strategic Management of Public Utilities  
迈向可持续发展：公共设施的管治与策略性管理
- Strengthen Risk and Compliance Management with the New Sustainability Reporting Standard  
善用可持续发展报告新标准，加强风险及合规管理
- Green Financing: Create Value through Sustainable Properties  
绿色金融：透过可持续物业创造价值
- Stay Ahead of the Privacy Management Trends: Local and International Perspectives  
紧贴私隐管理的国际与本地趋势
- Food Waste Recycling: Sustainable Management of Resources  
厨余回收：资源的可持续管理
- The Role of ISO standards in Governance, Risk and Compliance Management for Today's Business  
ISO标准在现今企业管治、风险与合规管理之角色

##### Afternoon Session (2:00 - 4:45pm)

下午专题环节（下午2时正至下午4时45分）

Language: English

语言：英语

- Sustainable Urban Planning Transcending 2030: Strategies for a Smart, Green and Resilient City  
跨越2030年的可持续城市规划：智能、环保及具抗御力的城市策略
- Policy and Market Drivers for Green Building Initiative: Trends and Development  
促进绿色建筑倡议的政策与市场动力：趋势及发展
- Optimise Asset Performance, Manage Diversified Risks  
优化资产表现，管理多元风险
- Digital Innovation and Reindustrialisation: Implications for Operation and Security Management  
数码创新及再工业化：对营运与安全管理之启示
- Ageing Society and Workforce: Management Challenges and Opportunities  
熟龄化社会与劳动力的管理挑战及机遇
- From Sustainable Construction to Sustainable Procurement: The Past and Future of ISO's Sustainability Standards  
由可持续发展建筑到可持续采购：ISO标准的过去与未来

##### Breakout Session (3:15 - 3:55pm)

分场环节（下午3时15分至3时55分）

Shantung Room, 8/F

8楼山东厅

2017 HKQAA CSR Index Presentation Ceremony (by invitation only)

2017香港品质保证局社会责任指数颁授典礼（只限获邀人士）



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楼宴会厅

## Speakers 嘉宾讲者

**Prof Alfred Chan Cheung-ming, SBS, JP**

陈章明教授, SBS, 太平绅士

Chairperson, Equal Opportunities Commission

平等机会委员会主席

**Dr Nigel H Croft**

倪国夫博士

Chairman, ISO Technical Subcommittee on Quality Systems

国际标准化组织质量体系技术委员会主席

**Dr MeiKei leong**

杨美基博士

Chief Technology Officer, Hong Kong Applied Science and

Technology Research Institute Company Limited

香港应用科技研究院有限公司首席科技总监

**Dr Calvin Lee Kwan**

关凯临博士

General Manager - Sustainability, Link Asset Management Limited

领展资产管理有限公司可持续发展总经理

**Ms Brenda Kwok**

郭美玲女士

Chief Legal Counsel, Privacy Commissioner for Personal Data,

Hong Kong

香港个人资料私隐专员公署首席律师

**Mrs Kwok Wong Wing Ki, Vicki**

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Deputy Director of Environmental Protection,

Environmental Protection Department, the Government of the HKSAR

香港特区政府环境保护署副署长

**Mr Joseph Law**

罗嘉进先生

Senior Director - Planning & Development,

CLP Power Hong Kong Limited

中华电力有限公司策划及发展高级总监

**Ms Li Chi Miu, Phyllis, JP**

李志苗女士, 太平绅士

Deputy Director of Planning (Territorial), Planning Department,

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**Sr Wong Bay**

黄比测量师

Chairman, Hong Kong Green Building Council

香港绿色建筑议会主席

**Mr Yu Kam Hung**

余锦雄先生

Executive Committee Member, China Real Estate Chamber of

Commerce Hong Kong and International Chapter Limited;

Consultant, PSA (HK) Surveyors Limited

全国工商联房地产商会香港及国际分会执行委员; 国众联(香港)测量师行顾问

**Ms Yuan Yuan**

袁圆女士

Head of GRI Regional Hub China, Global Reporting Initiative

全球报告倡议组织大中华区主管



## Governance, Risk and Compliance Management in the Era of Sustainability 可持续发展的策略视野：管治、风险与合规管理

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