生技產業品質管理和市場進入的挑戰與機會
- ISO 13485:2016與MDSAP

Chris Lee 李宗晏

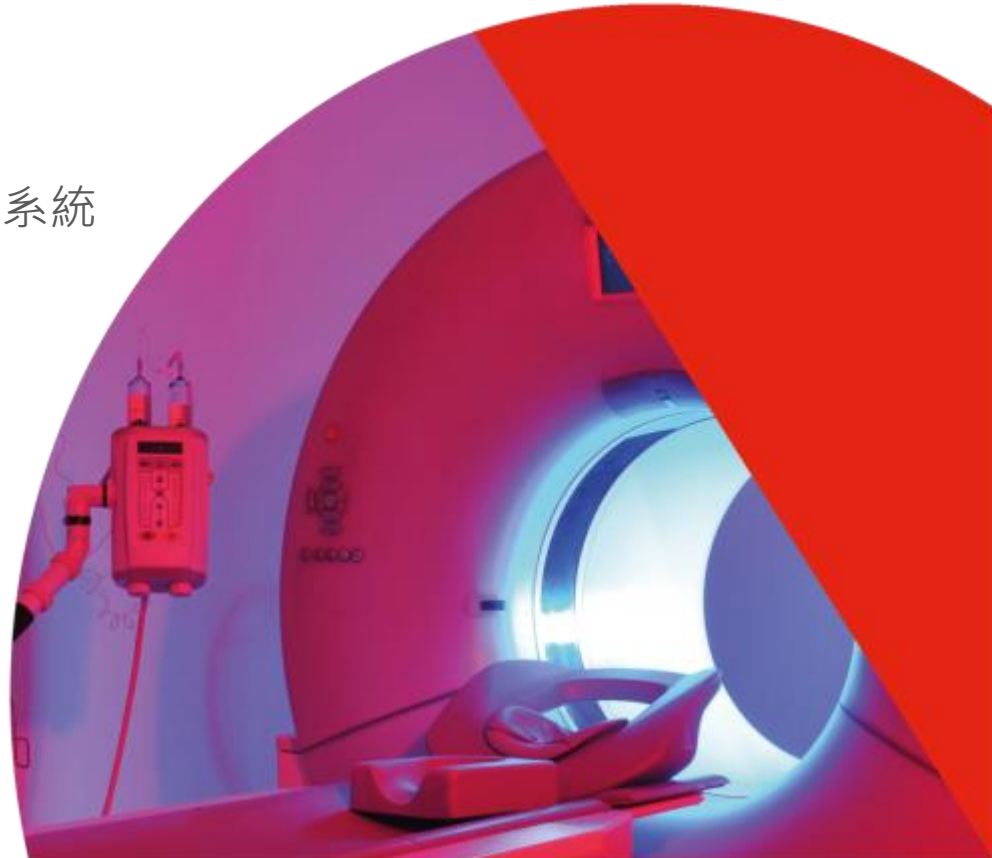
Manager , BSI Taiwan Business Solutions Department

UK Superbrands 2018

By Royal Charter

Agenda

- ISO 13485:2016醫療器材品質管理系統
- MDSAP全球醫療器材單一稽核方案
- Support from BSI



ISO 13485:2016醫療器材品質管理系統

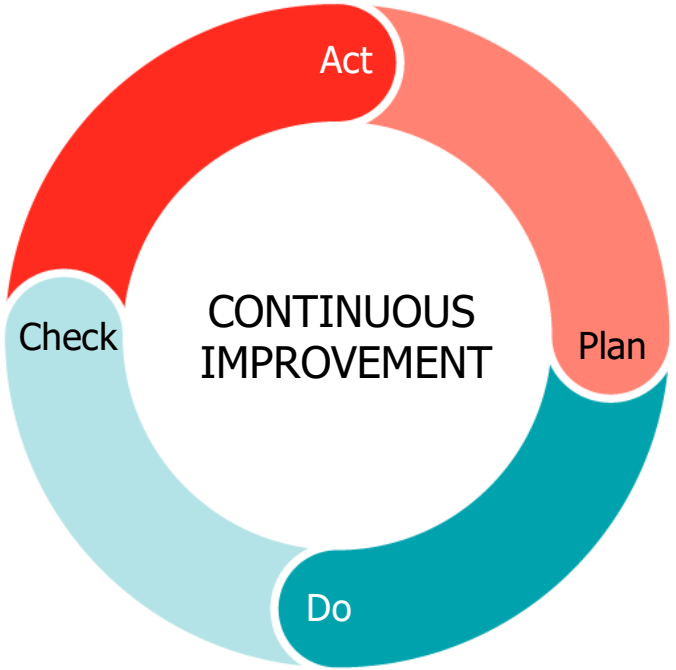
“我們重複的行為造就了我們,
因此卓越不是一個行為,
而是一種習慣.” 【亞里斯多德】

“We are what we repeatedly do.
Excellence, is not an act but a habit.”
【Αριστοτέλης】

什麼是品質管理系統?

A QMS is a set of processes that allows implementation and maintenance of quality assurance.

It ensures manufacturers consistently provide a high quality, safe product that meets market demand, and allows for adjustment to the manufacturing process should any issues arise.



什麼是醫療器材?

	Medical Device 醫療器材
中華民國 藥事法 第十三條	本法所稱醫療器材，係用於診斷、治療、減輕、直接預防人類疾病、調節 生育，或**足以影響人類身體結構及機能**，且非以藥理、免疫或代謝方法作用於人體，以達成其主要功能之儀器、器械、用具、物質、軟體、體外試 劑及其相關物品。

Orthopaedic 骨科

Dental 牙科

Active Implantable Devices 植入帶電

Active Devices 帶電醫材

IVDs 體外診斷

Vascular 心血管

General Devices 一般醫材

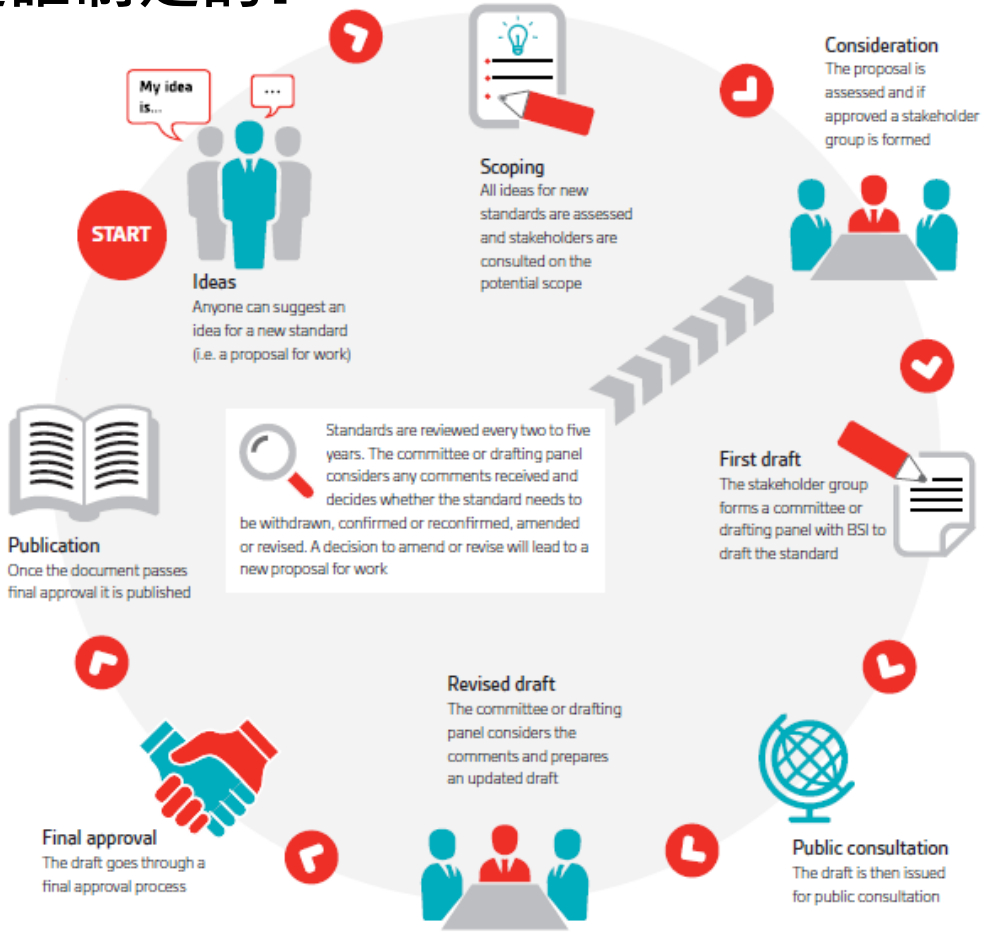
Biological Substances 動物組織

Drug-Device Combination 含藥醫材

ISO 13485是誰制定的?

ISO/TC 210

Quality management and corresponding general aspects for medical devices



BSI is Participating Member

BS EN ISO 13485:2016

Incorporating corrigenda March 2016 and December 2016

BSI Standards Publication

Medical devices — Quality management systems — Requirements for regulatory purposes (ISO 13485:2016)

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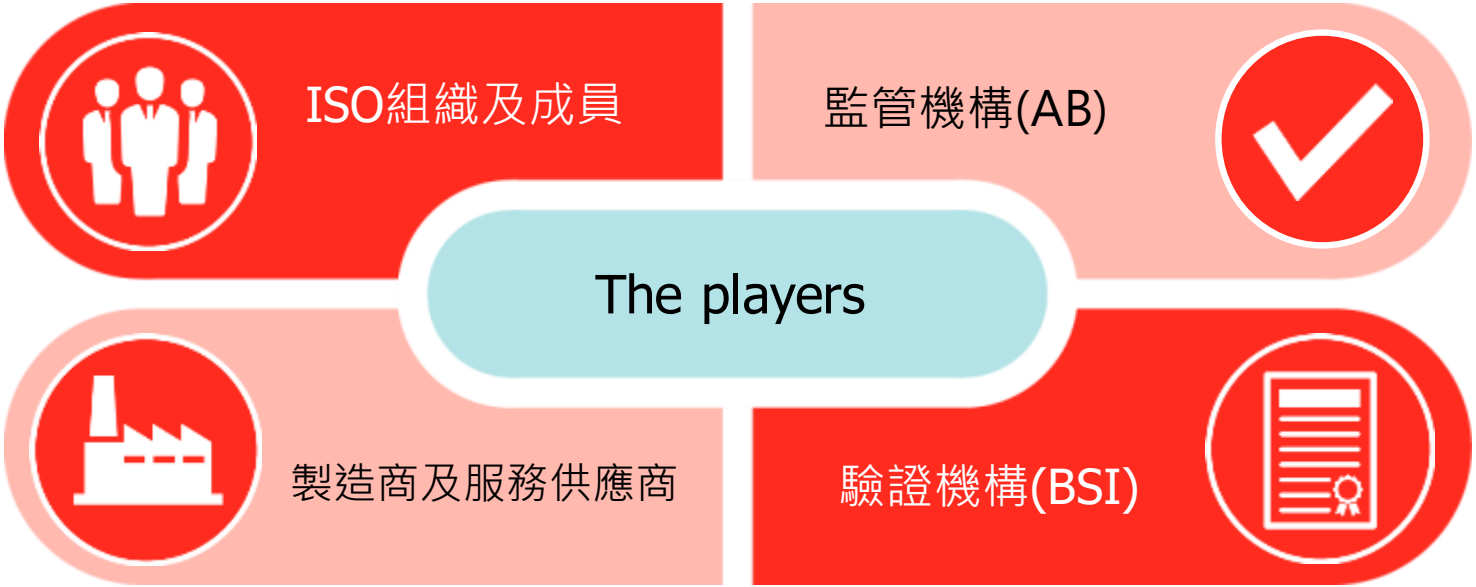
誰參與ISO 13485認證流程?



ISO 13485:2016強調的區域

Regulatory Requirements

法規要求

Risk Management

風險管理

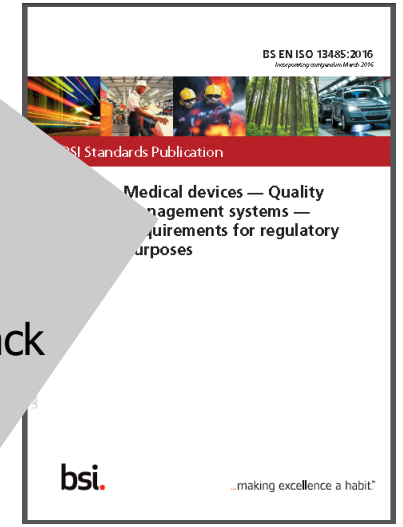
Validation, Verification & Design Transfer驗證、確效及設計移轉

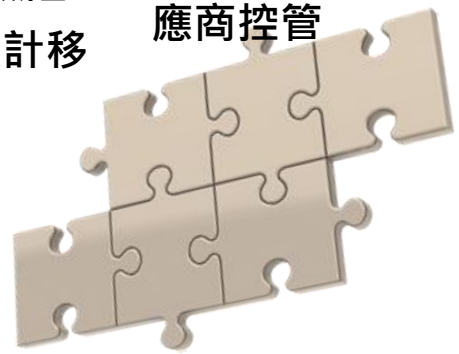
Outsourced Processes & Supplier Control

委外作業與供應商控管

Feedback

回饋





Improved linkage of clauses

增進條款間的連結

ISO 13485:2016 認證前準備工作

Understand 瞭解

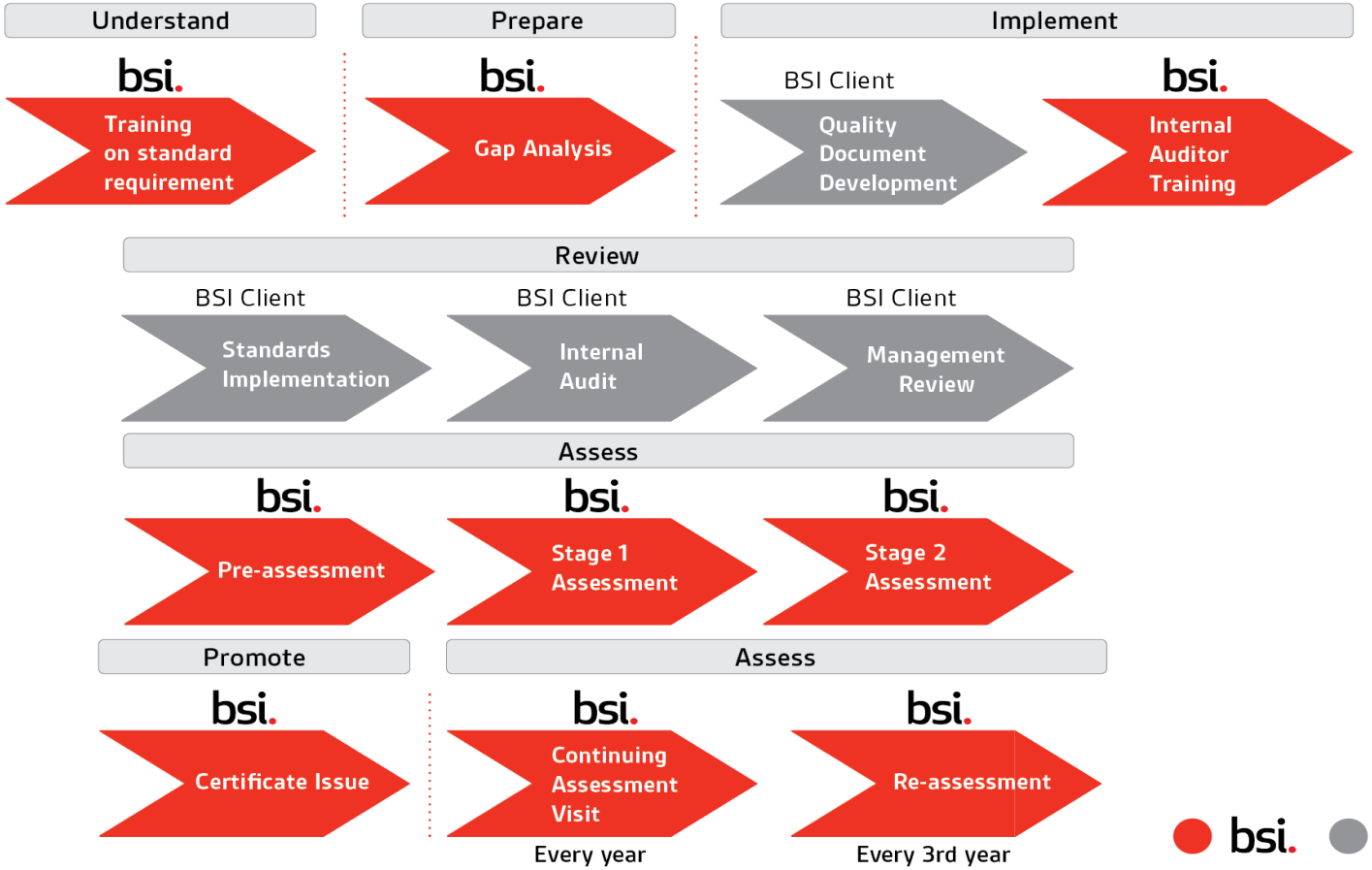
- **Webinars** 國外專家解說
- **白皮書** 快速掌握重點
- **專家評論** 要求逐項解釋
- **常見問題** 重要觀念釐清
- **研討會** 國內專家互動

Prepare 準備

- 買單一標準 / 多標準訂閱 → **取得標準**
- 公開課程 / 企業包班 → **教育訓練**
- 內部溝通 / 成立專案 / 差異分析 → **啟動轉版**
- 準備度評估清單 → **自我評估**

Audit 稽核

ISO 13485認證稽核流程



取得ISO 13485證書，準備進軍國際！

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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: MEDCOM International Co., Ltd.
10F & 15F
No. 920, Chung-Cheng Rd.
Zhonghe Dist.
New Taipei City
235
Taiwan

Holds Certificate No: MD 671681

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design and manufacture of P.C.B.A (printed circuit board assembly) and system assemblies used for medical devices (Data Transmission Gateway).

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2017-08-10
Latest Revision Date: 2017-08-10

Effective Date: 2017-08-10
Expiry Date: 2020-08-09

Page: 1 of 2

...making excellence a habit.

Key standards and regulations for the development of medical devices

1: CONCEPT

2: PLANNING

ISO 13485	Medical devices. Quality management systems. Requirements for regulatory purposes.
BS EN 60601-1	Medical electrical equipment. General requirements for basic safety and essential performance.
ISO 14971	Medical devices. Application of risk management to medical devices.
ISO 14155	Clinical investigation of medical devices for human subjects. Good clinical practice.
ISO 10993	Biological evaluation of medical devices. Tests for irritation and skin sensitization.
BS EN 62366-1	Medical devices: Application of usability engineering to medical devices.
ISO 15223-1	Medical devices. Symbols to be used with medical device labels, labeling and information to be supplied. General requirements.

Note: The above publications are generally referred to as 'horizontal standards', applicable to all types of medical devices. More detailed, product-specific requirements can be found in what are known as 'vertical standards', for example ISO 80601-2-13 Medical Electrical Equipment Particular Requirements for basic safety and essential performance of an anesthetic workstation.

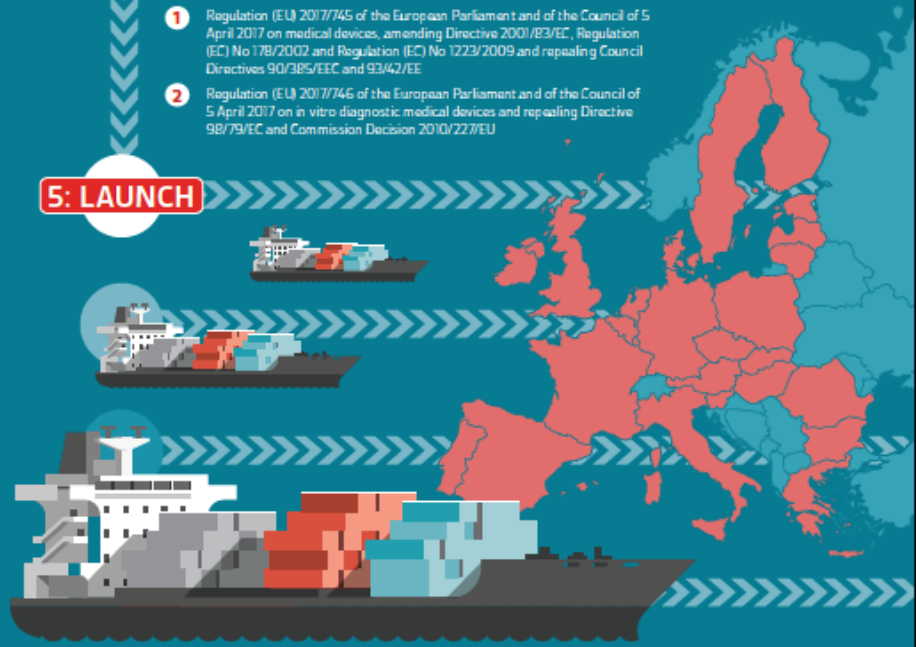
3: DESIGN

4: VALIDATION

Regulations

1. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EE
2. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

5: LAUNCH



Medical devices imported by the EU in 2015

- **Medical instruments** — US $39.7 billion
- **Orthopedic appliances** — US $25.3 billion
- **Medical x-ray apparatus** — US $2.02 billion
- **Medical, surgical or laboratory sterilizers** — US $245 million
- **Medical apparatus using alpha, beta or gamma radiation** — US $112 million

MDSAP全球醫療器材單一稽核方案

International Medical Device Regulatory Forum (IMDRF)
國際醫療器材法規主管機關論壇

IMDRF International Medical Device Regulators Forum

- IMDRF Management Committee (MC) regulators:
  IMDRF管理委員會成員
  - Australia, Brazil, Canada, China, the European Union, Japan, Russia, and the United States of America
- Observers:
  觀察員
  - WHO - World Health Organization
    世界衛生組織
  - APEC LSIF (Asia Pacific Economic Cooperation Life Science Innovation Forum)
    亞太經濟合作 生命科學創新論壇

World Health Organization

APEC Life Sciences Innovation Forum

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MDSAP Objectives
MDSAP目標

- Develop, manage, and oversee a single audit program that will allow a single regulatory audit to satisfy the needs of multiple regulatory jurisdictions
  開發、管理並監管單一稽核方案，以同使滿足多個法規管轄需求
- To promote greater alignment of regulatory approaches and technical requirements
  促進監管辦法與技術要求更加一致
- To promote consistency, predictability, and transparency of regulatory programs
  促進一致性，可預測性與監管程序透明度

MDSAP Benefits
MDSAP效益

- Single Audit by Auditing Organization (AO) would: AO的單一稽核將
  - minimize medical device manufacturing disruptions due to multiple regulatory audits
    最小化醫療器材製造商受多個主管機管稽核的打擾
  - leverage regulatory resources
    平衡監管資源
  - benefit patient health and patient access
    病患健康及權益的獲益
  - provide global benefit both on short term and longer term goals by IMDRF regulators – harmonization
    提供全球化的法規調和

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MSDAP Benefits for Manufacturers
MDSAP對製造商的益處

- No additional requirements for manufacturer
  對製造商而言沒有額外要求
- Single audit optimizes time and resources
  單次稽核有效地運用時間及資源
- Routine audits are scheduled/planned with AO
  例行性的稽核由AO(稽核單位, 如BSI)安排及規劃
- Expected to improve predictability
  提高稽核的可預測性
- Expected to add additional Regulatory Authorities
  預計將增加更多的法規主管機關(國家)
- MDSAP讓製造商證明其品質能力更勝ISO 13485

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MDSAP Formal Program參與國家

Health Canada Santé Canada

Canada

Health Canada

www.hc-sc.gc.ca

Français | Home | Contact Us | Help | Search | Canada.ca

Home > Drugs & Health Products > Medical Devices > Activities > International

Transition Plan

The Pilot is scheduled to conclude December 31, 2016, and as stated in Health Canada Notices dated January 2014 and January 16, 2015, Health Canada intends to implement MDSAP as the sole mechanism for manufacturers to demonstrate compliance with the quality management system requirements of the *Medical Devices Regulations* (the Regulations). MDSAP will replace the current Canadian Medical Devices Conformity Assessment System (CMDCAS) program, even in situations when a manufacturer intends to sell only in Canada. This implementation will begin at the conclusion of the Pilot on January 1, 2017, and will span a period of two years. During this two year period, Health Canada will accept certificates issued under both CMDCAS and MDSAP. As of January 1, 2019, only MDSAP certificates will be accepted. Further details will be released as the transition plan is finalized. Health Canada's transition to MDSAP is an attempt to align with the transition period for the revised version of ISO 13485, which is anticipated to be published in early 2016.

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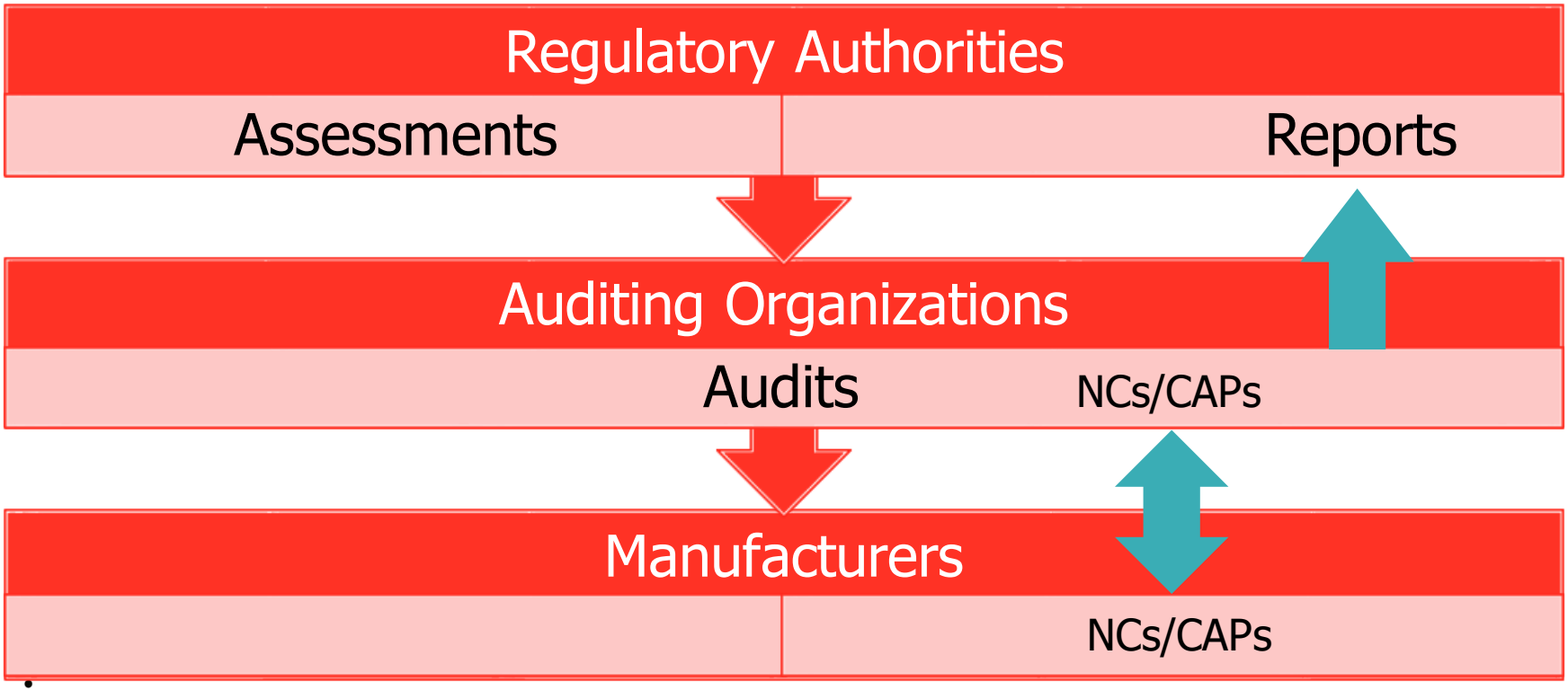
How Does MDSAP Work?
MDSAP如何運作？



MDSAP Information – Official Sources (USA-FDA)
MDSAP資訊 – 官方資源(FDA官方網站)

Pilot Program Announcement (brief description)	http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM372066.pdf
Program Announcement (including benefits)	http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM429958.pdf
MDSAP FAQs	http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM430563.pdf
Eligible Auditing Organizations	http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM429978.pdf
MDSAP Audit Procedures & Forms	http://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/ucm377580.htm
Website	www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/

MDSAP

MEDICAL DEVICE SINGLE AUDIT PROGRAM

Companion Document

Medical Device Single Audit Program

Chapter 1

Process: Management

The intent of the **Management process** is to provide adequate resources for device design, manufacturing, quality assurance, distribution, installation, and servicing activities; to assure the quality management system is functioning properly and effectively; and to monitor the quality management system and make necessary adjustments. A quality management system that has been implemented effectively and is monitored to identify and address existing and potential problems is more likely to produce medical devices that function as intended.

The **management representative** is responsible for ensuring that the requirements of the quality management system have been effectively defined, documented, implemented, and maintained. Prior to the review of any process, interview the management representative (or designee) to obtain an overview of the process and a feel for management's knowledge and understanding of the process.

The Management process is the first process to be audited per the MDSAP audit sequence.

Auditing the Management Process

Purpose: The purpose of auditing the Management process is to verify top management ensures an adequate and effective quality management system has been established and maintained. The management processes should be re-evaluated at the end of the audit to determine whether top management has demonstrated the necessary commitment for an effective quality management system that has been communicated to personnel.

Outcomes: As a result of the audit of the Management process, objective evidence will show whether the organization has:

A) Identified processes needed for the quality management system, their application throughout the organization, and their sequence and interaction

B) Defined, documented, and implemented procedures and instructions to ensure the development and maintenance of an effective quality management system

C) Established quality objectives at relevant functions and levels within the organization consistent with the quality policy and ensured that these are periodically reviewed for continued suitability

D) Determined the criteria and methods needed to ensure the operation and control of quality management system processes, including the identification and management of interrelated processes

E) Committed the appropriate personnel and resources for infrastructure to the quality management system

F) Assigned responsibility and authority to personnel and established the organizational structure to ensure processes assuring quality are not compromised

G) Performed risk management planning and ongoing review of the effectiveness of risk management activities to ensure that policies, procedures and practices are established for analyzing, evaluating and controlling risk

H) Ensured the continued effectiveness of the quality management system and its processes

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Medical Device Single Audit Program (MDSAP)

MDSAP Documents

MDSAP International Regulations [English] (Australia, Brazil, Canada, Japan, and USA)

SHARE TWEET LINKEDIN PIN IT EMAIL PRINT

Australia

- Therapeutic Goods (Medical Devices) Regulations 2002

Brazil

- Brazilian Health Surveillance Agency
- Resolution RDC 16 2013 (PDF - 141KB)
- Resolution RDC 23 2012 (PDF - 26KB)
- Resolution RDC 67 2009 (PDF - 41KB)

Adobe Acrobat Document

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Auditing Organization Availability to Conduct MDSAP Audits

The organizations listed below submitted an application to the Medical Device Single Audit Program (MDSAP). The table specifies their status regarding their application, their authorization to conduct MDSAP audits, and their recognition.

Eligible Auditing Organization	Location	Contact	Application Received	Authorized to Conduct MDSAP Audits	Recognition
bsi.	**BSI Group America Inc.** 12950 Worldgate Drive, Suite 800, Herndon, VA 20170 USA http://www.bsigroup.com/en-US/ **Critical Location** Milton Keynes, UK	**Patricia Murphy** patricia.murphy@bsigroup.com +1 571 291 5726	Yes	Yes	Yes
DEKRA	**DEKRA Certification B.V.** Meander 1051 Arnhem, 6825 MJ Netherlands http://www.dekra.com/en/home	**Brent Anderson** Brent.Anderson@dekra.com +1 925 283 7535	Yes	Yes	Yes

Audit Cycle 稽核循環

- Three Year Audit Cycle(與ISO 13485相同)
  - Initial Audit (Stage One & Stage Two)
  - Surveillance Audits (Years 1 and 2)
  - Re-audit (Recertification Audit)

- Other Possible Audits
  - Special Audits
    - changes, nonconformances, suppliers, post-market issue follow-up
  - Audits by Regulatory Authorities
  - Unannounced Audits無預警現場稽核(與ISO 13485不同)

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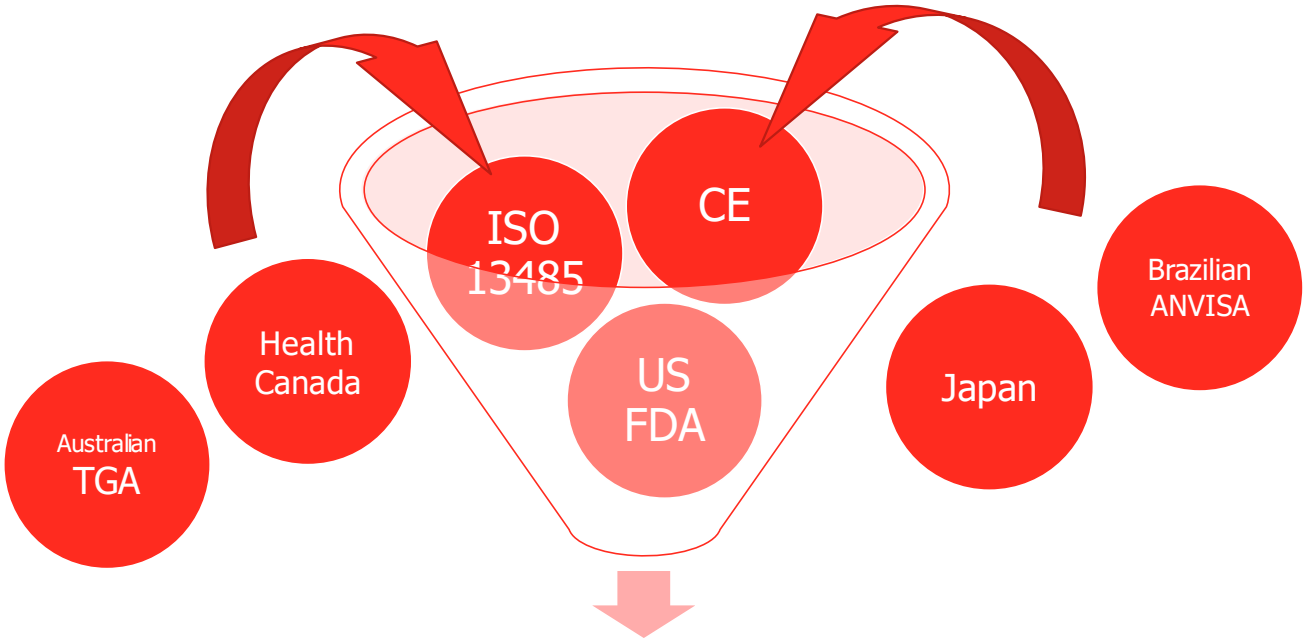
Requirements 要求



法規資訊

食品藥品相關

印尼-食品進口法規簡介

保健食品及中西藥輸銷東南亞國家貿易障礙檢核表

醫療器材相關

醫材業者赴新南向國家參加醫療展相關規定及附件 1 2 3 4 5 6

印尼-醫材法規簡介

印度-醫材法規簡介

菲律賓-醫材法規簡介與附件 1 2 3

泰國-醫材法規簡介

越南-醫材法規簡介

馬來西亞-醫材法規簡介

緬甸-醫材法規簡介

澳洲-醫材法規簡介

新加坡-醫材法規簡介

柬埔寨-醫材法規簡介

Support from BSI

BSI - 值得信賴的國際認證品牌

51% of Fortune 500

75% of FTSE 100

68% of Nikkei Index

全球佈局

全球服務據點

30 國家

全球員工人數

4,000

全球客戶分佈

81,000 客戶

128,382 驗證地點數

182 國家

51 淨推薦值 Net Promoter Score

Best in class NPS is a score over 50

成果展現

標準發表數量

2,893

培訓學員

113,000

delegates trained

Kitemark

3,395

Licences issued

管理系統驗證

195,000

Number of days spent with clients last year

醫療器材

24/25

的全球醫療器材製造商選擇BSI作為其符合歐盟指令CE標誌的認可機構

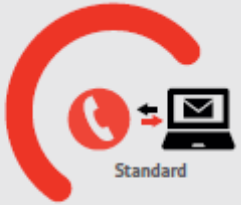
CE marking

7,063

CE 0086

BSI CE marking 歐盟醫材法規-快速審核解決方案

BSI 承諾會提供全球市場最有經驗與有效的途徑。如果您想要保持競爭力或是處於市場領先地位，以下提供您所需要的**『醫療器材快速審核解決方案』**



CE-Standard

The CE-Standard review service allows you to work closely with your assigned BSI Product Expert on your product certification. These reviews are conducted remotely, with communication between you and your BSI Product Expert via phone and email, as required.

CE-Dedicated FastTrack

The CE-Dedicated FastTrack review service allows you to book your technical documentation review in advance. The service is conducted remotely with your BSI Product Expert, who uses the time allocated to your company to conduct a focused review of your technical documentation. This allows you to interact with your BSI expert, providing them information during the review. The CE-Dedicated FastTrack service improves the efficiency of the process, and provides predictability in your planning of the review.

CE-Onsite FastTrack

The CE-Onsite FastTrack review service is conducted at your premises; a BSI Product Expert visits the facility for a period of time. CE-Onsite FastTrack reviews allow for dynamic communications and opportunities for immediate responses to questions raised by the reviewer. Planning a CE-Onsite FastTrack review in advance provides you with more predictability and the reassurance of knowing when your BSI Product Expert will be at your premises.

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BSI 專業醫材法規訓練課程規劃

Training Topics

CE marking 訓練課程

- Introduction to CE marking
- Medical Device CE marking
- Introduction to CE marking for In Vitro Diagnostics
- Application of the In Vitro Diagnostics Directive

ISO 13485 訓練課程

- Introduction to ISO 13485
- ISO 13485: Clause by Clause
- Implementing ISO 13485
- Internal Auditor ISO 13485
- Lead Auditor ISO 13485

ISO 13485 轉版課程

- ISO 13485:2016 Transition
- ISO 13485:2016 Auditor Refresher

BSI 專業醫材法規訓練課程規劃

Training Topics

Specialist Training
客製化課程

- MDSAP醫療器材單一稽核方案
- 醫療器材上市後監督和警戒系統
- ISO 14971風險管理應用
- ISO 14971 醫療器材風險管理 /FMEA 失效模式分析
- 醫療器材製程確效
- Creating and Maintaining Compliant Technical Files and Design Dossiers
- Technical Files and Design Dossiers for In Vitro Diagnostics
- Performance Evaluation and Clinical Files for IVD
- Utilising Materials of Animal Origins
- CE marking with Medical Device Software
- Device-Drug Combinations

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BSOL醫療器材標準法規資料庫

醫療器材相關標準共有4,100份(持續更新)

- 醫材通用標準
- 生物相容性標準
- 塑膠/橡膠類醫材標準
- 牙科類醫材標準
- 滅菌相關標準
- 機械/系統類醫材標準
- IMD相關標準
- AIMD相關標準
- 電子類醫材標準
- IVD相關標準
- 輔具類標準
- 醫材軟體標準

標 準 訓 練 驗 證

BSOL
線上標準資料庫

- 訂閱BSOL是運用標準快速簡便的方法
- 降低追蹤及保留文件檔案的成本
- 降低使用過期文件的風險

訂閱 BSI 醫療器材電子報

BSI 官網首頁
bsigroup.tw

轉版進度 | 白皮書 | 標準新知 | 活動&課程訊息

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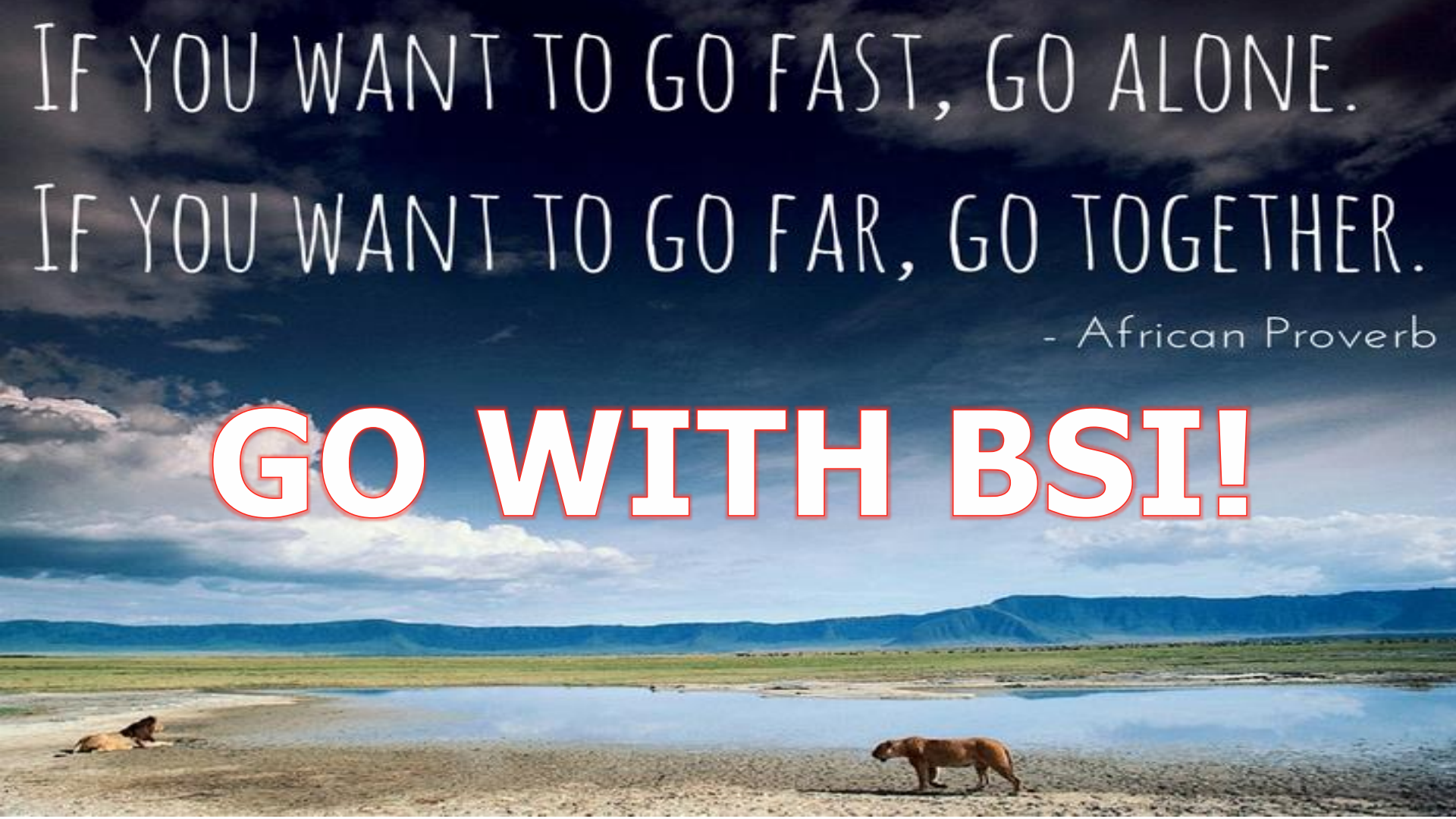
What you can do now?
現在您能夠做什麼?

- Study the regulation and standard 研讀法規及標準
- Prepare a budget for the next 3-5 years 規劃三至五年預算
- Determine training required 員工教育訓練
- Perform the gap analysis 進行差距分析
- Look out for additional help 尋求外部顧問, 公會及協會協助
- Working closely with your NB 與驗證單位緊密合作


IF YOU WANT TO GO FAST, GO ALONE.
IF YOU WANT TO GO FAR, GO TOGETHER.
- African Proverb
GO WITH BSI!

...making excellence a habit.™

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