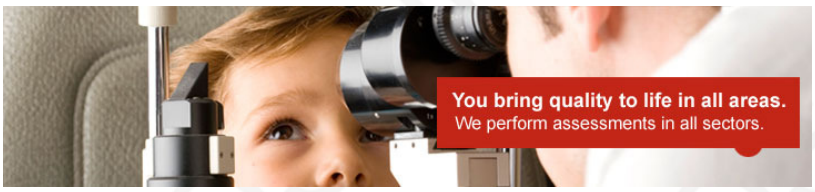
2016 年 3 月 14 日

尊敬的客戶，

ISO13485:2016 新標準正式頒佈

ISO13485 於 2016 年 2 月 25 日發佈自 2003 年以來的第一新版本，這是國際標準化組織的 TC210 技術委員會的 WG1 工作組的工作成果。這是該標準的第三個版本，考慮了監管機構和其他用戶的反饋。

ISO13485 是國際標準，它定義了醫療設備的設計和開發、製造、安裝和服務組織的質量管理體系的要求，其中包括了在醫療設備使用的材料或零部件製造商的設計和開發、製造、安裝及服務。ISO13485 建基於 ISO 9001，但更多的重點放在文件管理、風險管理、設計控制、工作環境、監管部門的批准和報告。



2016 版的主要變化和改善在於以下幾點：

- 適用範圍擴大到與醫療設備製造商有關聯的組織；
- 風險導向的質量管理體系過程；
- 更加強調最高管理層的責任和承諾；
- 更加強調對符合法規要求的承諾；
- 與法規協調一致(美國 CFR, 巴西 ANVISA, 加拿大 CMDR, 歐盟 MDD, 日本 JPAL 和澳洲 TGA) – MDSAP 醫療設備單一審核方案；
- 強化的設計過程控制；
- 軟件應用的驗證要求的協調一致；
- 涵蓋整個產品生命週期的風險管理；
- 增加了對供應商和外包活動的控制；
- 強調合適的基礎設施；及
- 強化的投訴和監管通報要求。

ISO9001:2015 遵從 SL 附件的共通文本和高階結構，但修訂後的 ISO13485 標準是以 ISO9001:2008 為基礎並保持了 ISO 指南 83 格式。一個重要原因是現在很多監管機構還將 ISO 13485:2003 的架構作爲他們的法規要求。目前沒有具體計劃 ISO13485 何時將採用高階結構進行修訂，不過其定期檢討將被提前到 2019 年 3 月。然而，組織可以建立一個管理體系同時滿足 ISO9001:2015 和 ISO13485:2016 的要求。

本次發行的 2016 版有一個為期 3 年的過渡期，未升級的 ISO 13485 認證將在 2019 年 2 月 25 日被撤銷。如果您的 ISO13485 認證包括 ISO9001，請同時考慮 ISO9001:2015 的升級過渡期將於 2018 年 9 月截止。

現有的證書可以在認證週期期間的任何時間升級到 ISO13485:2016。它可以在再認證審核、監督審核、或組織認爲合適的日期進行特別審核來完成。

DQS 期待協助您做好標準升級的準備。如果您有培訓尋求、在審核策劃或證書轉換上有疑問，歡迎聯絡我們。

敬頌 商祺！

DQS Management Systems Solutions (HK) Limited

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Dear Valued Clients,

Release of ISO 13485:2016

For the first time since 2003, there is a new revision of the ISO 13485 standard, as of February 25, 2016, with the efforts by Working Group 1 (WG1) of Technical Committee 210 (TC210) in ISO. This is the 3rd edition of this standard, addressing the feedbacks from regulators and other users.

ISO 13485 is the international standard that defines quality management system requirements for organizations that design and develop, manufacture, install and service of medical devices and design, develop, and provide related services, including manufacturers of materials or component parts that are used in medical devices. It is based on ISO 9001, but with additional emphasis on documentation, risk management, design control, work environment, regulatory approval and reporting.

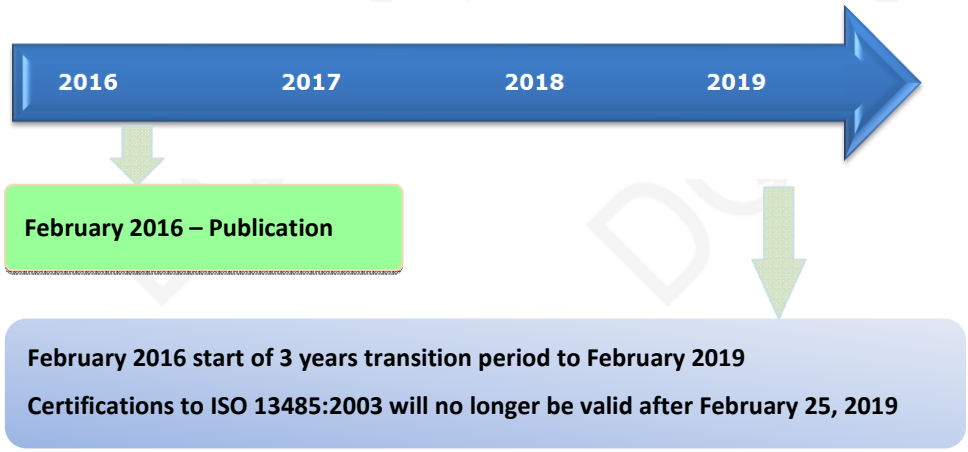
The primary changes and enhancements in 2016 version include:

- Broadened application to organizations interacting with medical devices manufacturers;
- Risk-based approach to QMS processes;
- Greater emphasis on responsibilities and commitment of top management;
- Greater emphasis on commitment to applicable regulatory requirements;
- Harmonization with US CFR, ANVISA (Brazil), CMDR (Canada), MDD, JPAL, and TGA – MDSAP；
- Increased controls on design process;
- Harmonization of validation requirements for software applications;
- Risk management throughout product life cycle; and
- Increased controls over supplier and outsourced activities,
- Emphasis on appropriate infrastructure; and
- Enhanced requirements on complaint handling and regulatory reporting.

ISO 9001:2015 follows the Annex SL – the common text and high level structure, but the revised ISO 13485 standard maintains the ISO Guide 83 format, with ISO 9001:2008 as its basis. A primary reason is that many regulators have the ISO 13485:2003 as their regulatory model.
There is no specific plan at the moment when ISO 13485 will be revised to follow the high level structure, whereas a periodic review has been accelerated to March 2019. Nevertheless, a management system can be established to comply with both ISO 9001:2015 and ISO 13485:2016 in the meantime.

A three year window from the issuance of the standard is allowed for upgrade to the 2016 revision. Any ISO 13485 certificate that is not upgraded to 2016 version will be withdrawn on February 25, 2019. If your ISO 13485 certification also includes ISO 9001, the deadline, September 2018, for update to ISO 9001:2015 should be considered.

Current certifications may be upgraded to ISO 13485:2016 at any time during the certification cycle. It may be done as part of the Re-certification Audit, regularly Surveillance Audits, or by a Special Audit done at the organization's preferred time.



DQS looks forward to helping you prepare for the 2016 revisions. Contact us if you have need for training, questions on audit planning, or certificate transfer to DQS.

Thank you for your attention.

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