

Moving towards ISO13485:201X

(December 2014 update)

The document series 'Moving towards ISO13485:201X' has been established by Karza Pty Ltd to assist our internal consultants in considering potential change when developing clients' long-term integrated management system plans.

ISO 13485 '*Medical devices — Quality management systems — Requirements for regulatory purposes*', is the international standard relating to quality management systems (QMS) for organizations involved in the manufacture of medical devices. The current version is ISO 13485:2003.

The development of the next revision of ISO 13485 continues by the International Standards Organisation Technical Committee 210, Working Group 1 (ISOTC 210/WG1). Based on the December 2014 meetings, it appears the next final release version of ISO 13485 (currently referred to as 'ISO 13485:201X') will not be published in 2015. This will come as no surprise to those who have followed the development process.

The slow development and ongoing creep in the release timeframe will have some significant ramifications to the final product and user perception. Although the development and circulation of a final draft (FDIS) is now optional (refer ISO / IEC development rules) meaning the release timeframe could be shortened, the extent of the changes required combined with the volume, diversity and significance of comments made in regards to the last DIS (draft), would make a FDIS necessary to address the concerned stakeholders. We suggest the need for a FDIS means a replacement for ISO 13485:2003 will not be published before the first quarter of 2016 (at best).

By failing to finalise and release the standard earlier, the final release of ISO 13485:201X will now occur after the release of ISO9001:2015 (which was developed based on the newer management system structure) and unless there is a dramatic and radical change in ISOTC 210/WG1's thinking the final format of the new standard will not follow the high-level structure requirements which will (and should) be applicable to all ISO management system standards after September 2015.

With the slow development and release of ISO 13485:201X, combined with the three year (post release) transformation window open to organisation updating their management systems from 13485:2003; we strongly suggest our clients restrain (for at least 12 months) from pushing forward with their ISO 13485 evolution.

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