

QNET BV - Authorized Representative Notice: Transition Planning For ISO13485:201X - 3rd revision and ISO/DIS9001:2014

Dear Authorized Representative client,

Both Quality Management Standards are under revision, the present situation is as follows:

ISO/DIS 9001:2014

DIS (draft international standard) published for comment - May 2014.

FDIS (Final draft international standard) – proposed publication – March 2015

Proposed ISO 9001:2015 publication in Official Journal (OJ) – September 2015.

Transition period is 3 years from OJ publication date.

You can find the standard here: <http://www.techstreet.com/searches/6477619>

ISO/DIS 13485:201X

DIS ISO Technical Committee 210 Working Group will meet for a second time to review all comments received on the DIS version of this standard in December of 2014.

A second DIS review to take place first quarter 2015

Anticipated publication - 4th quarter 2015.

No transition period has been announced as yet.

You can find the standard here: http://www.iso.org/iso/catalogue_detail?csnumber=59752

We recommend that you carefully plan implementation of the changes to these standards in order to avoid having to implement the changes of the upcoming IVDD/Medical Device Regulations at the same time.

Keeping you up-to-date as a good Authorized Representative should.

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