K-One Newsflash

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Staff Training and Development ~ Understanding ISO 13485 Quality Management System for Medical Devices

In today's strategic sourcing and supply management, multinational customers are looking for supply partners who can address demand, quality, environmental concerns, human rights, innovation and provide solutions effectively. Apart from complying with the preceding pertinent requirements, supply partners are also required to meet global standards set for the particular industry. In our journey to diversify into the medical devices industry, the K-One Group has taken the initiative to embark in being ISO 13485 certified as a necessary qualification to secure medical devices businesses.

The ISO 13485:2003 certification sets to be another milestone achievement for the K-One Group

On 30 November 2015, thirty-two staff of the K-One Group attended the preliminary training for ISO 13485:2003 held in the Ibis Styles Hotel, Ipoh. Gearing for the certification of ISO 13485:2003, this training serves to provide our staff with a good understanding and knowledge of the ISO 13485:2003 requirements of the standard.

The training session was facilitated by Mr. Kenny Chong, a certified consultant with vast experience in providing consultancy for the design, development and implementation of ISO 9001, ISO 14001, Occupational Safety & Health Management System (OHSAS) 18001, ISO 13485, ISO 50001, Electronic Industry Citizenship Coalition (EICC), United States Food and Drug Administration (US FDA) and Good Distribution Practices for Medical Devices Sector (GDPMD).

Participants engaging in a fruitful session of knowledge acquisition

ISO 13485:2003, which is accepted by the world's major trading blocks including US, Canada, Europe, Japan and Australia is the best benchmark in quality and regulatory compliance certification for the design, development and manufacturing of medical devices. The Group's investment of both financial and human capital in the ISO 13485:2003 certification is testimony of our commitment to systematically design and manufacture medical devices that will consistently meet applicable regulatory compliance, customer requirements and industry safety standards.

Group exercise to gauge the participants' understanding of the topic

With the K-One Group's acquirement of ISO 13485:2003, it will enable the Group to open doors and expedites market entry into the vast untapped international markets. Succinctly, this value proposition in conjunction with its expertise learned from the consumer electronic industries gives the K-One Group a real advantage in the global marketplace.

Barring unforeseen circumstances, the Group expects to be ISO 13485:2003 certified by 1Q'16.