Tuesday, April 23, 2019

WHITE PAPERS
& APPLICATION NOTES

PHOTONICS MEDIA

DOWNLOAD FREE WHITE PAPERS & APPLICATION NOTES


WHITE PAPER

www.baslerweb.com

Camera-based Products in Medical & Life Sciences - What Are the Benefits of a ISO13485:2016-Certified Supplier?

Contents

1. Introduction 1
2. The ISO13485: Medical products standard 2
3. ISO13485:2016 - What specific concerns does it introduce for manufacturers that use cameras in their products? 3
4. Requirements for suppliers with the new ISO13485:2016 4
   4.1 Medical product manufacturer transfers its QM system to suppliers 4
   4.2 Suppliers with QM system according to ISO 9001 4
   4.3 Suppliers with QM system according to ISO 13485 5
5. Summary 6
6. What is the advantage of Basler AG's ISO13485:2016 certification? 6

1. Introduction

The market for medical products is growing rapidly. Point-of-care, personalized medicine, health 4.0, artificial intelligence – never before has there been so much potential for manufacturers to take an active role in the digitization of medicine. Vision-based systems in particular assist doctors in diagnosis and therapy, and help document the procedures. Vision-based systems even make it possible to develop new generations of medical products.

But this growth is accompanied by another trend. For years, the regulatory hurdles for medical product manufacturers have been steadily rising. Companies in this sector must work according to specific, legally-mandated quality management systems that result in high costs, for example by stringent procedures in the selection and quality assurance of suppliers.

It is rare for medical product manufacturers to develop and manufacture all components of a medical product themselves. Individual components that require high technological expertise and whose in-house development involves too many resources are often procured from external suppliers. In many cases this also applies to cameras.

In other words, the medical device which the medical product manufacturer is launching on the market incorporates components which it doesn't develop or produce itself. Ultimately, however, it is the responsibility of the medical product manufacturer as the product's distributor to ensure that the device is safe for the patients and users and fulfils its designated purpose. The medical product manufacturer bears this responsibility for the product and its components not just for the development and production but during the entire product lifecycle. When the product is on the market, the medical product manufacturer is responsible for communicating known malfunctions of the device and its components to the appropriate authorities according to criticality, in the form of a risk report. Due to the growing complexity of the devices and components, the number of risk reports submitted to the Federal Institute for Drugs and Medical Devices (BfArM) has more than doubled from 2010 to 2016. It increased from 5,687 to 11,976 during this period.

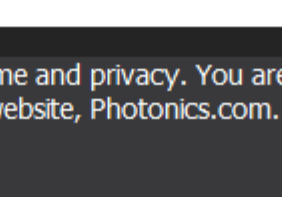

Fig. 1: Number of risk reports regarding medical products at the Federal Institute for Drugs and Medical Devices (BfArM).

Medical product manufacturers are thus caught between their responsibility for patient security and the necessity to procure individual components from suppliers whose safety practices they can only indirectly influence.

The medical technology supplier thus plays a central and responsible role. But how can a medical product manufacturer recognize which suppliers it can trust in such a situation? What are the reliable indicators to tell whether a component supplier meets the high demands of medical technology?

Camera-based Products - Benefits of an ISO13485:2016-Certified Supplier

What advantages does a supplier certified according to the medical device standard ISO 13485:2016 offer to a manufacturer of camera-based medical products? Our White Paper describes the requirements of this standard, presents various ways in which the manufacturer and supplier could cooperate in quality management and explains the advantages and disadvantages of these scenarios.

DOWNLOAD NOW

Sponsored by

BASLER

More White Papers from this Sponsor

- CoaXPress 2.0 – The Standard in Industrial Image Processing for Demanding Applications
- Modern CMOS Sensors and Their Use in Fluorescence-Based Applications
- How Machine Vision Cameras Help Medicine

PHOTONICS MEDIA

Visit Photonics Media to download other white papers and learn more about the latest developments in lasers, imaging, optics, biophotonics, machine vision, spectroscopy, microscopy, photovoltaics and more.

www.photonics.com/WhitePapers.aspx