



Medical Device Expert adds new focus to Quality Division

Establishing and Auditing Quality Systems

In today's challenging times it is no longer sufficient to produce products at the cheapest rate. In order to be competitive in any industry, quality is as important as price. Having an appropriate quality system in place will ensure products are produced to specification and any failures will result in appropriate corrective and preventive actions.

Through CDAMC's new Medical Device Expert, **Donal Clancy**, we now offer a complete package to establish quality systems across all sectors. Donal is an IRCA approved ISO 9001 Lead Auditor and IEMA approved ISO 14001 Auditor.

CDAMC has a background in conducting quality system audits of suppliers and internal audits to ensure compliance with regulatory standards in the Medical Device Sector. This includes ISO 9001, ISO 13485 & FDA standards as well as standards relating to the Automotive Sector.

HOW WE CAN HELP YOU

CDAMC has extensive experience in developing and testing manufacturing solutions and implementing them in full scale production, whilst ensuring the process is validated and complies to all relevant quality requirements.

We can establish a Quality System, and train staff in all aspects of maintaining the system. In addition, where a quality system is established, we can conduct internal audits or supplier audits on behalf of the client, specialising in areas of primary interest to the client.

CDAMC can assist with outsourcing of production. Where the need to outsource production has been identified, we can conduct quality system audits to determine the suitability of the supplier for the manufacture of the product. This along with our expertise in manufacturing processes, provides an ideal solution for clients who wish to outsource.

WHAT WE DO

- **Establish Quality Systems** – the basis of any quality system is determining the accept / reject criteria. We have expertise in establishing quality systems in the highly regulated medical device industry.
- **Quality System Auditing / Inspection** – we can help you achieve the most from your quality system by conducting internal audits or supplier audits. All audits follow a practical format, and focus on the areas of concern identified with the client.
- **Risk Based Approach** - we provide practical risk based solutions by focusing on the most critical areas for the client. This begins with incoming inspection and continues through validation and product release.
- **Environmental Management Systems Assessment** – we have trained personnel to audit for compliance to Environmental Management System ISO 14001 and can assist in establishing certification to the standard.

SPECIALISTS IN MEDICAL DEVICE INDUSTRY

Donal Clancy has many years experience in the medical industry, having worked on quality projects for leading medical device manufacturers such as Boston Scientific, Hospira and Medisize. Projects included areas of risk based incoming inspection, internal auditing, supplier quality system auditing, and problem solving within FDA regulated industries.

BENEFITS OF WORKING WITH CDAMC

- **Best Practice Advice** – we'll help you establish and maintain your Quality or Environmental Management System with the benefit of experience from several major Medical Device, Automotive and Aerospace manufacturers.
- **Better Products** – we will work with you to improve the key characteristics of your product, looking at aspects ranging from product performance to production time.
- **Reduced Costs** – we can conduct Quality System and manufacturing process inspections on your behalf, and through our Lean expertise highlight areas where you can reduce costs.



PROFESSIONAL PROJECT EXECUTION

We bring strong project management disciplines to all of our engagements, meaning you can relax in the knowledge that you have a professional team working on your behalf. We use a clearly defined methodology to understand the scope of a project, identify all tasks, develop accurate estimates of effort and costs, identify the key project risks and define deliverables and milestone dates.

Once we have agreed the plan with you we report back regularly on progress against that plan, ensuring that problems are identified and resolved early and that the project is delivered on schedule and to budget. We can take a risk based approach to implement CAPA's, draft or revise existing FMEA's and manage or implement supplier and internal audit schedules.

CASE STUDY - Risk Based Receiving Inspection

This involved working with one of the world's leading medical device manufacturers to implement Risk Based Receiving Inspection. This covered inspecting all components based on the level of risk associated with the component in the finished device. This is the first step in preventing component related defects during the manufacturing process or use of the finished device. A review of the manufacturing process and all possible defects associated with the component, enabled inspection to be conducted based on the associated risk. This also involved working with the supplier to eliminate or minimise the risk through the implementation of appropriate engineering solutions. This is considered best practice in many sectors including the Medical Device Sector.

CASE STUDY - Implementing a Supplier Quality System

This involved implementing and maintaining all aspects of the Supplier Quality System in a Class III Medical Device Manufacturer to comply with corporate, site level and regulatory requirements and demonstrating compliance to internal and external auditors. This also involved management of all Supplier Quality Records, maintaining agreements, conducting reviews of all suppliers and resolving any issues through the quality system as appropriate.

CASE STUDY - Implementing a Liquid Silicone Moulding Capability

This involved leading a knowledge transfer project between a University and a Medical Device Manufacturer. The project involved installing and validating the equipment and process, and transferring the knowledge and expertise from the University to the company to ensure all staff were trained in the use of the equipment. This was a Fusion project which is part funded by Intertrade Ireland. Fusion projects can help companies improve their technical knowledge and recruit high caliber, highly educated staff. Through our experience we can support you in such funded projects.



INNOVATION AWARD

News & Events

- IMDA and Applied Optics/NUIG Seminar, Galway, Ireland. 24th February 2010
- Medical Devices Summit 2010, Boston, USA. 1-3rd March 2010
- Demand Generation B2B Digital Marketing, Galway, Ireland. 11th March 2010
- MEDTEC Europe, Stuttgart, Germany. 23-25th March 2010

Contact us now on:

Tel: +353 87 672 9703
+ 353 86 354 0300

Web: www.cdadc.ie

Email: donal.clancy@cdadc.ie