MEDICAL DEVICE REGULATION COMPLIANCE

Roy Cowley, Managing Director of 3D-Lipo Ltd shares his journey

3D-lipo Ltd was established in 2012 as the culmination of spending over twenty years working as a distributor for other companies within the aesthetic marketplace. My personal experience and desire has always been to develop results-driven devices. Technology must perform, but must also be safe, and as a company we take pride in producing quality machines, so when changes came about in medical device regulation we knew what we had to do.

There are two major regulation changes happening which affect us, as a manufacturer of 'cosmetic' devices.

The first is the upgrading of the key ISO standard for medical device companies in Europe. This is called EN ISO 13485:2016 and companies involved in the design, manufacture or distribution of medical devices will be required to upgrade their Quality Management Systems (QMS) before 31st March 2019; as part of a 3 year transition period started in April 2016.

The second change is the upgrading of the previous Medical Device Directive (MDD 93/42/EEC) towards an enhanced new legal instrument covering medical devices called the Medical Device Regulations (MDR 2017/745). As a medical device manufacturer, you have 3 years from 25th May 2017 to transition to the MDR. Within this period, manufacturers will need to update their technical documentation and processes to meet the requirements of the new regulation. The MDR brings into scope, as a medical device, many more applications/products which were previously out of the scope of the MDD, such as products with an aesthetic or non-medical purpose, but which are like medical devices in terms of function and risk profile. This presents a disruptive change to the "near-medical and cosmetic" devices marketplace.

At 3D-lipo Ltd we have responded positively to these changes and instigated a holistic upgrade to our company operations to bring in a new ISO 13485 compliant QMS and to ensure all our products can be CE marked under the new MDR requirements as medical devices.

ISO13485 is the worldwide standard for Quality Management Systems for medical device manufacturers and is one of the major components for most global market access. Complying with this standard requires expertise and thorough understanding of the standard requirements. For most companies, the journey to compliance - having a medical device grade QMS and compiling technical files compliant with CE Marking requirements under the MDD - was a struggle. The new MDR regulations require a thorough understanding of its complexities. For us, this has been challenging and we have taken the approach of starting from the ground up, building a wholly new structure for the more rigorous MDR – effectively becoming a new medical device company.

This was a big shift in the operations within our company which required enormous investment, both monetary and from our staff, but long-term it will provide huge benefits and we will be able to support our customers seamlessly as the new MDR takes hold of the sector over the coming years. The process of compliance is an ongoing one, and never stops, but the initial process takes around 12 months.

Compared to the MDD, MDR introduces a life-cycle approach to ongoing CE Marking compliance. Conformity assessment procedures are more complex, and equivalence will be more rigorously interpreted. Our clinical data and Clinical Evaluation Report (CER) will face heavy scrutiny and require recurring updates. We must also fulfil increased Post-Market Surveillance (PMS) requirements, perform more Post-Market Clinical Follow-up (PMCF) studies, and deliver Periodic Safety Update reports. We had to create a new quality manual and quality procedures to address the requirements of both the MDR and ISO13485, ranging from PMS and PMCF, to stringent supplier controls, design history files and technical files; plus much more.

We'd be lying if we said we could do this all in-house, so this year we hired a consulting company (LUX-IEC) to provide an integrated approach to implementing the skeleton QMS, the introduction of key software to manage the QMS, and to build up the technical file content and structures to fast track us through the process. They provide us with their expertise to create procedures specific to our company and in a time frame that meets all the requirements. They are training our staff and auditing our processes to make them ready for the (CE) Notified Body audits which are necessary to prove conformity and allow us to comply with the regulations for selling medical devices in the UK and Europe.

The challenges continue, and will do throughout 2018, until compliance is achieved. The road is long, but we are moving forward and should achieve CE marking for some of our devices under the MDR within the year or early 2019. But that's not the end of it, it will continue beyond that to ensure the best possible controls and service is provided to our customers as we transition from a '*good cosmetic device supplier*' to an '*excellent medical device manufacturer*'. We believe this will make us a key supplier of products into our market with ISO 13485 compliance.

So, what does this mean for practitioners? Well, complying with regulatory requirements will provide a manufacturer with greater market access. The penalties for non-compliant devices are simply not worth risking. Our increased supplier control and post-market follow up, plus how we deal with issues when they arise, will lift our customer service to new levels, and allow us to move more quickly to bring new and improved products to market. Compliance with ISO 13485 is the only way in which we can operate once the MDR fully transitions, as all our products will be classed as medical devices from that point. Our early preparation will make sure our customer base can be assured that we will provide a seamless process over the next few years as the marketplace goes through enormous upheaval. Some cosmetic device suppliers will not be able to make the transition successfully, due to a lack of time or competence, or not being willing to make the investment. Where will they, and their devices, and more importantly their customers be then? Change like this is both disruptive and confusing, we will be able to provide purchasing checklists for our customers so they can check whether other suppliers are compliant and ask deeper questions of those who wish to sell them devices.