EU-MDR Economic Operators

The European Council released the final text of the Medical Device Regulation (MDR) and scheduled the vote for March 7, 2017. If passed, the MDR will go to the European Parliament in April.

If both bodies approve, the Official Journal could publish the MDR in May 2017, and it would enter into force in either May or June. Because there is a three-year transition period for the MDR, it would apply in 2020.

Device manufacturers have a lot of work to understand the new regulations, implement them, and apply the CE Mark. The final draft is 566 pages, available from http://data.consilium.europa.eu/doc/document/ST-10728-2016-INIT/en/pdf

Economic Operators
Article 2 defines the Economic Operators identified in the MDR.

- *Manufacturer* means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark

- *Authorized Representative* means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Regulation

- *Importer* means any natural or legal person established within the Union that places a device from a third country on the Union market

- *Distributor* means any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service

Each economic operator has a responsibilities and obligations defined by MDR articles.

Manufacturers
Article 10 General Obligations of Manufacturers provides information for manufacturers. While there is a lot of information in the article, the highlights are:

- Establish, document, implement, and maintain a system for risk management
- Conduct a clinical evaluation including Post-market Clinical Follow-up, PMCF
- Establish and maintain technical documentation that includes the elements set out in Annexes II and III
- Draw up an EU declaration of conformity in accordance with Article 19, and affix the CE marking of conformity in accordance with Article 20
- Comply with the obligations relating to the UDI system referred to in Article 27
- Comply with the registration obligations referred to in Articles 29 and 31

- Establish, document, implement, maintain, keep up to date, and continually improve a quality management system
- Implement and keep up to date the post-market surveillance system in accordance with Article 83
- Ensure that the device is accompanied by the information in Annex I, Section 23 in an official Union language determined by the Member State in which the device is made available to the user or patient
- Have a system for recording and reporting of incidents and field safety corrective actions as described in Articles 87 and 88

Authorized Representative

Article 11 Authorized Representative provides information for authorized representatives. The highlights are:

- For a manufacturer not established in the EU, designate a sole authorized representative
- Verify that the EU declaration of conformity and technical documentation have been drawn up
- Keep available a copy of the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate
- Comply with the registration obligations in Article 31
- Verify that the manufacturer has complied with the registration obligations in Articles 27 and 29
- Immediately inform the manufacturer about complaints and reports from healthcare professionals, patients, and users about suspected incidents related to a device for which they have been designated
- Where the manufacturer is not established in a Member State and has not complied with the obligations laid down in Article 10, the authorized representative shall be legally liable for defective devices

Importers

Article 13 General Obligations of Importers includes the following verifications:

- The device has been CE marked and that the EU declaration of conformity of the device has been drawn up
- A manufacturer is identified and designated an authorized representative
- The device is properly labelled and accompanied by the required instructions for use
- The manufacturer assigned a UDI
- The importer keeps a register of complaints, of non-conforming devices, and of recalls and withdrawals, and provide the information to the manufacturer, authorized representative, and distributors

Distributors

Article 14 General Obligations of Distributors includes the following verifications:

- The device has been CE marked and that the EU declaration of conformity of the device has been drawn up
- The device is accompanied by the information to be supplied by the manufacturer
- For imported devices, the importer has complied with Article 13

- The manufacturer assigned a UDI
- Distributors that have received complaints or reports from healthcare professionals, patients, or users forward the information to the manufacturer, the authorized representative, and the importer

EN ISO 13485:2016
Clause 4.1.1 requires the organization to document any roles it undertakes under the applicable regulatory requirements. A note says that the roles can include manufacturer, authorized representative, importer, or distributor.

The standard defines each role, but the definitions are not the same as those in the MDR.

Recommendations for Manufacturers
Obtain a copy of the draft MDR and start to understand it. If there were any changes because of the voting, they would be minor and have little effect on any work you would do. The draft is 566 pages; there is a lot of work and little time – only three years.

Determine the economic operators in your current distribution channels

Read the MDR requirements for each kind of economic operator

Start an information sheet for each of your economic operators so they will know to expect such as registration, technical documentation, *etc*.

Start working on contracts and quality agreements. EN ISO 13485:2016 requires controls on providers of outsourced processes that include written quality agreements. This will include the economic operators in your distribution chain.