THE MDR JOURNEY

NEWSLETTER No. 10 – January 2020

«Let's make transparency a standard requirement»

Subject: The Role of the Person Responsible For Regulatory Compliance

Where did it all start?

Previous drafts of the MDR/IVDR used the term: **QUALIFIED PERSON (QP) as in the "pharma world".**

Then, the wording changed to: **PERSON RESPONSIBLE FOR REGULATORY COMPLIANCE (PRRC).**

The MD Regulation has Adapted the QP concept to Medical Devices

Whereas at point (34) of MDR states

It should be ensured that supervision and control of the manufacture of devices, and the post-market surveillance and vigilance activities concerning them, are carried out within the manufacturer's organisation by a person responsible for regulatory compliance who fulfils minimum conditions of qualification

The MDR Article 15 states:

Manufacturers shall have available within their organisation at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of medical devices. The requisite expertise shall be demonstrated by either of the following qualifications:

- *a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognised as equivalent by the Member State concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices;*
- *four years of professional experience in regulatory affairs or in quality management systems relating to medical devices.*

Without prejudice to national provisions regarding professional qualifications, manufacturers of custom-made devices may demonstrate the requisite expertise referred to in the first subparagraph by having at least two years of professional experience within a relevant field of manufacturing.

Micro and small enterprises within the meaning of Commission Recommendation 2003/361/EC (1) shall not be required to have the person responsible for regulatory compliance within their organisation but shall have such person permanently and continuously at their disposal.

2003/361/EC defines small and micro entreprises categories as follows:

- Small entreprise: < 50 employees, annual turnover < 10 M €
- Micro entreprise: < 10 employees, annual turnover < 2 M €

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The person responsible for regulatory compliance shall at least be responsible for ensuring that:

- **the conformity of the devices**
- **the technical documentation and the EU declaration of conformity**
- **the post-market surveillance obligations**
- **the reporting obligations referred to in Articles 87 to 91 are fulfilled;**
- **in the case of investigational devices, the statement referred to in Section 4.1 of Chapter II of Annex XV is issued.**

If a number of persons are jointly responsible for regulatory compliance in accordance with paragraphs 1, 2 and 3, their respective areas of responsibility shall be stipulated in writing.

In practice…

- Areas of responsibilities should be defined and documented
- The person responsible for regulatory compliance should "suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his duties"
- Qualification and expertise should be documented and maintained

The PRRC is responsible for ensuring: (a)

✓ **the conformity of the devices is appropriately checked in accordance with the quality management system under which these devices are manufactured before a product is released.**

EN ISO 13485 applicable revision and Requirements of MDR

The PRRC is responsible for ensuring: (b)

✓ **the technical documentation and the declaration of conformity are drawn up and kept up-to-date;**

MDR Annex II: Technical Documentation

- that the technical documentation and the declaration of conformity are drawn up and kept up-to-date;

MDR Annex III: Technical Documentation on PMS

- PMS plan
- PMS report
- PSUR – Periodic safety update report

MDR Annex IV: Declaration of Conformity provides details on information required on the DoC

The PRRC is responsible for ensuring: (c)

- ✓ **the post-market surveillance obligations in accordance with Article 10(10) are complied with Article 10 General Obligations of the manufacturer.**
  Manufacturers of devices shall implement and keep up to date the post-market surveillance system referred to in Article 83.

The PRRC is responsible for ensuring: (d)

- ✓ **the reporting obligations referred to in Articles 87 to 91 are fulfilled;**

The PRRC is responsible for ensuring: (e)

- ✓ **in the case of investigational devices, the statement referred to in Section 4.1 of Chapter II of Annex XV is issued.**

"Example:

The device in question conforms to the general safety and performance requirements apart from the aspects covered by the clinical investigation. Every precaution has been taken to protect the health and safety of the subject.

Person Responsible For Regulatory Compliance"

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This newsletter is part of our campaign to increase the sensitivity and the awareness of all our business partners, to bring more clarity around the MDR journey and challenges and opportunities around the MDR Art.22 "Systems and Procedure Packs".

We are already today all dependent on an effective cooperation. For the MDR implementation, we require even a closer collaboration in order to ensure we all can deliver safe supply to hospitals and patients in the future.

We are confident we'll be able to continue to supply health care competently on customized surgical procedure sets and small kits.

You want to know more about specific topics? Do you have any questions or comments?
Please send an email to **MDR2020@stsmedicalgroup.com**

The next issue of the MDR Newsletter will be issued in February 2020

We wish everybody pleasant days.

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