Person Responsible for Regulatory Compliance

Under the EU's MDR and IVD, manufacturers and authorized representatives must have Person Responsible for Regulatory Compliance. This term replaces the Qualified Person in an early draft.

Qualifications
The qualifications are:

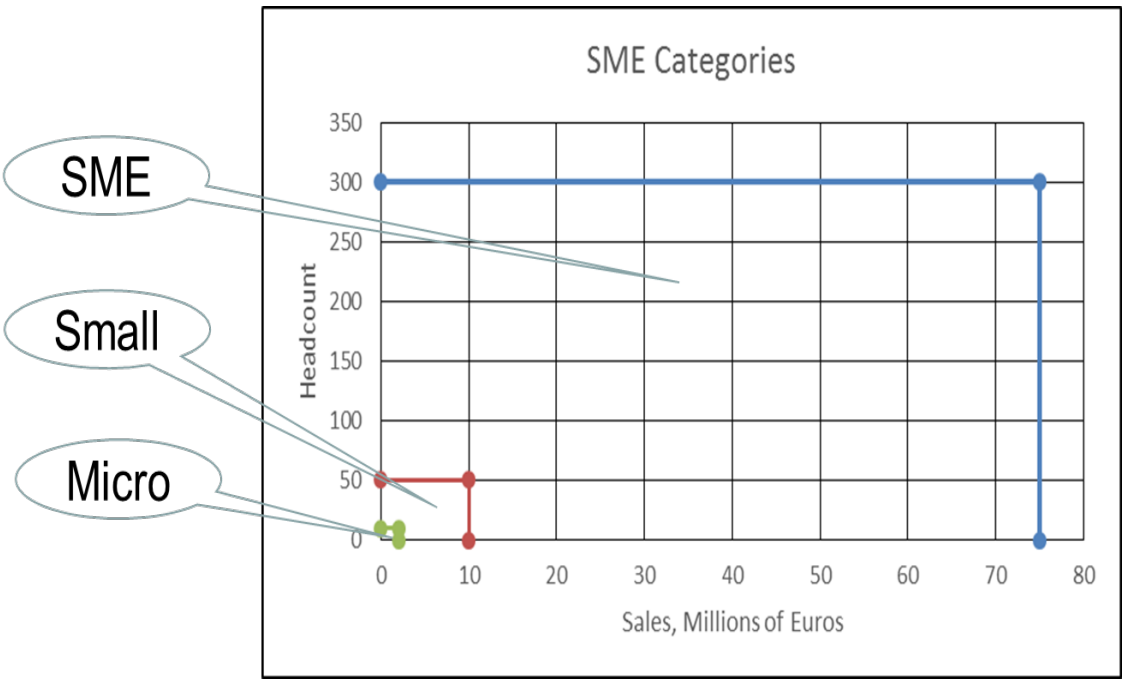
- A degree or equivalent in law, medicine, pharmacy, engineering, or another scientific discipline, PLUS at least one year of professional experience OR
- Four years of professional experience

The Person Responsible for Regulatory Compliance must be available within the organization unless the enterprise is a small or micro enterprise (SME). These enterprises may not need a person available within the organization, but that person must be permanently and continuously at their disposal.

In the EU system, an SME is a micro, small, or medium sized enterprise as defined in Commission Recommendation 2003/361/EC. See also the EU's SME Guide.

- An SME employs fewer than 250 people and has annual sales less than €50 million.
- A small enterprise employs fewer than 50 people and has annual sales less than €10 million.
- A microenterprise employs fewer than 10 people and has annual sales less than €2 million.

The recommendation and the guide explain how to determine and document the status of an enterprise.



Responsibilities

The Person Responsible for Regulatory Compliance ensures:

- Device conformity is checked before release
- The technical documentation is up-to-date
- The Declaration of Conformity is up-to-date
- The company meets the PMS requirements
- The company meets the reporting requirements:
    - Serious incidents
    - Field safety corrective actions
    - Trend reporting
    - Analysis of serious incidents
    - Analysis of field safety corrective actions
    - Analysis of vigilance data

Recommendations for Manufacturers

- Identify the people in your organization who meet the qualifications for a Person Responsible
    - It would be best to have at least two people (to provide "bench strength")
- Determine if your organization qualifies as an SME
- If your company is an SME and needs to use an outside person, start to identify contractors or consultants who can provide the service
    - Start working on contracts and quality agreements
    - EN ISO 13485:2016 requires controls on providers of outsourced processes that include written quality agreements