The spirit of ISO 13485 for 3D printing companies

Quality in medical devices encompasses more than just the (3D print) production phase (which is covered in the section about Product Realization).

Below I tried to explain the spirit or underlying intent behind the key sections of the ISO 13485 standard, specifically for a company using 3D printing to manufacture its medical devices:

1. **Scope:** The scope of ISO 13485 emphasizes that the standard applies to organizations involved in the design, development, production, installation, and servicing of medical devices. For a company utilizing 3D printing, the spirit of this section is to ensure that their activities related to 3D printing, such as design, manufacturing, and post-processing, are included within the quality management system.

2. **Quality Management System:** The spirit of this section is to establish a robust quality management system tailored to the unique considerations of 3D printing technology. It aims to ensure that the company has documented processes, procedures, and controls in place to consistently produce safe and effective medical devices using 3D printing, while adhering to applicable regulations and meeting customer requirements.

3. **Management Responsibility:** This section emphasizes the importance of leadership and management commitment. For a company using 3D printing, the spirit is to ensure that top management actively supports and drives the implementation of effective 3D printing processes, including allocating necessary resources, setting quality objectives, and ensuring continual improvement.

4. **Resource Management:** The spirit of this section is to ensure that the company has the necessary resources, both human and infrastructure, to support their 3D printing operations. It emphasizes the importance of competent personnel trained in 3D printing technologies, suitable facilities and equipment, and a conducive work environment to produce high-quality medical devices using 3D printing.

5. **Product Realization:** The spirit of this section is to ensure that the company effectively designs, develops, and produces medical devices using 3D printing. It emphasizes the need for systematic processes, including design controls, process validation, material selection, and post-

processing, to ensure the safety, effectiveness, and quality of 3D-printed medical devices.

6. **Measurement, Analysis, and Improvement:** The spirit of this section is to establish a culture of continuous improvement and data-driven decision-making. For a company using 3D printing, the spirit is to monitor and measure the effectiveness of their 3D printing processes, analyze data to identify areas for improvement, implement corrective and preventive actions, and strive for ongoing enhancement of their 3D printing capabilities.

7. **Regulatory Compliance:** While not a specific section, the spirit of ISO 13485 is to ensure that the company complies with applicable regulations and requirements specific to 3D printed medical devices. This includes understanding and adhering to regulations and standards, relevant to 3D printing in the medical device industry.

The spirit of ISO 13485 for a company using 3D printing is to establish a comprehensive and well-controlled quality management system that addresses the unique aspects and challenges associated with 3D printing technology. It aims to ensure the production of safe, effective, and reliable medical devices while meeting regulatory requirements and customer expectations.

Erik Boelen, MSc, PhD
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