# Quality challenges in medical 3D printing

## Research Report

### Introduction and rationale

3D printing in the medical field has a vast potential as it allows us to produce geometries and structures that are impossible to achieve with other manufacturing technologies; like **complex and organic anatomical structures** and **porous lattices** that allow tissue ingrowth and/or facilitate resorption. 3D printing has also opened up the opportunity for **mass customization**, where medical devices are matched to the (complex) anatomy of the patient.

In the medical devices industry, a Quality Management System (QMS) is a **requirement** for market access and product certification (CE marking or FDA clearance), and the main standard for quality management in medical devices is **ISO 13485**.

It does feel this standard is written with mass production in mind and as such, **requirements may be challenging to translate** to 3D printed, (mass) customized products. However, the spirit of ISO 13485 still applies and is independent of the manufacturing technology [1].

On top of that, 3D printing is a relatively **young manufacturing technology** that processes the raw material and builds the geometry of the medical device simultaneously, with the **additional risks** of sub-optimal material properties, contamination and stresses in the material and poor interlayer bonding among others.

In working with many clients in medical 3D printing, I noticed their struggles in quality management; which inspired me to conduct an (ongoing) **research study on the quality challenges** in medical 3D printing. Specifically, I am interested to find out:

- The reasons for and perceived benefits in implementing a QMS
- The hurdles and efforts made in building the QMS
- The preferred system for the QMS

I have sent a **questionnaire** to various people in medical 3D printing to learn more about these things and this revealed several interesting findings as summarized in this report.

*Included in this report are some of these boxes that contain my remarks and/or advice.*

## Reasons and benefits

For companies using 3D printing for their medical devices (incl. hospital 3D printing facilities), the **main reasons** to implement a QMS are:

- To guarantee quality (29%)
- To adhere to regulatory requirements (29%)

Interestingly, only 5% mentioned proper management of risks as a reason to implement a QMS, whereas the ISO 13485 standard preaches a risk-based approach to all processes.

*Although ISO 13485 requires "a risk based approach to the control of processes" (4.1.2), the word 'risk' can only be found 14 times in the requirements (chapters 4 – 8). There is no dedicated requirement for risk management in the standard (one could argue about 7.1), but a Risk Management procedure is definitely expected by auditors. Also the MDR is very much focused on risks. For risk management, you would be wise to adopt ISO 14971.*

It also seems that most are not implementing a QMS for the **benefit of the customer**, which was only mentioned by 14%, but more because it is a regulatory requirement.

The question about the perceived **benefits** of a QMS resulted in a wider variety of responses. The responses are summarised in the word cloud below, where the font size is related to how often that benefit was mentioned.


Both **increase quality** and **traceability** were mentioned most often, followed by **safety**.

*Personally, I see increased **efficiency** as a significant benefit of a properly implemented QMS. And also, having the **ISO 13485 certificate** builds a lot of **trust**.*

## Hurdles and efforts

The greatest **hurdles** in building a QMS are:

- The **lack of understanding** about the ISO 13485 standard
- The **unclear** regulatory requirements
- **Expensive** consultants, most of whom do **not** (fully) **understand** 3D printing

These three hurdles were indicated by more than half of all interviewees.

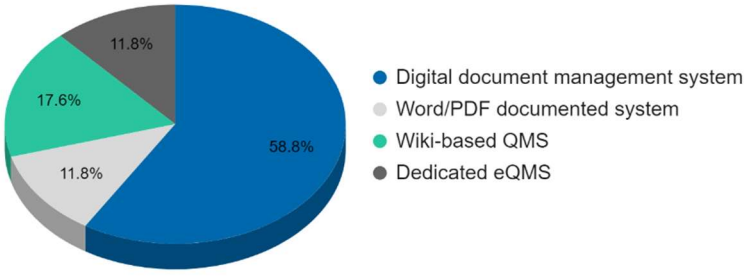
**81%**

As a result, only 19% contracts a consultant, whereas a staggering 81% starts a variety of efforts to **do it by themselves**. Most of the DIY efforts focus on the actual additive manufacturing process, whereas the requirements in ISO 13485 are far more holistic in nature and concern all company processes.

ℹ *DIY **with** a Consultant: Although consultants may seem expensive, they will help you to implement an effective, complete and compliant QMS much faster than you can achieve by doing it completely by yourself. The amount of time you have to invest to do it alone is roughly 1,5 year. DIY with the guidance of a proper consultant allows you to build your QMS in about 3-6 months, saving you the equivalent of 1 year that is better spent otherwise.*

## System

Fortunately nobody in the study population wanted their QMS system to be paper-based; the vast majority (59%) opts for a digital Document Management System.




ℹ *Consider using a Wiki-based system for your QMS; a Wiki has document control built in, is often free for small teams, completely customizable, more powerful than common document management systems, and will be used for much more than just QMS documentation [2].*

## Final remarks

The ISO 13485 standard will **seem daunting** at first, but just take some time and read it a few times. You'll notice that a lot of things that the standard requires, **you probably already do** in one way or another, it's just not documented yet. If you are like most companies, you probably have documented instructions (describing HOW you do things, which is also important), but for quality management you will also need to document WHAT you do (and the minimum of what you need to do is required by the ISO standard).

One very important thing you should do is **validation**. Do not blindly trust material and software certificates. **3D printing** is a process in which **you change the material** and its properties; so please validate that you produce what you planned and expect to produce.

Although building a QMS is not an easy task, it really helps to build confidence in your 3D printed medical devices for yourself ànd for auditors, so you can rest assured that your devices are **safe and effective**, which is also the main purpose for the regulators (both MDR and FDA).

And always ask yourself: ***"Would I use this 3D printed device for the surgery of my wife/husband or child?"***

Erik Boelen, MSc, PhD | *Quality in medical 3D printing*

# More resources

1. The spirit of ISO13485 for medical device companies using 3D printing
2. A Wiki for Quality Management; more than just document management

If you want to learn more, you can also book a Quality Meeting