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Educating biomedical 3D printing engineers

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Abstract: Medical 3D printing is improving clinical care in many hospitals worldwide. Biomedical engineers are often highlighted as a key player in creating accurate and functional 3D prints from medical images that satisfy the needs of the clinicians. This requires multi-disciplinary knowledge in many different fields, including anatomy, medical imaging modalities, segmentation, Computer Aided Design (CAD) and additive manufacturing know-how. Consequently, we have begun teaching the necessary prerequisites at Aarhus University in a course focused on gaining a practical understanding of the necessary skills and technologies. In this work we present our framework for educating skilled medical 3D printing engineers.

I. Introduction

Medical additive manufacturing has gained wide-spread adoption in hospitals around the world allowing improved surgical outcomes, ease of communication, and reduction in costs [1]. To facilitate medical 3D printing, Point-Of-Care (POC) 3D printing facilities have been created at hospitals the world over. This allows tight cooperation between radiographers, radiologists, engineers, and surgeons since the entire workflow from images to 3D prints can be conducted in-house. Biomedical engineers form a crucial bridge between imaging the patient and creating a suitable model for the receiving surgeon since this process requires detailed knowledge of medical imaging, segmentation and morphologic enhancements thereof, computer aided design, 3D printing, post-processing, as well as quality and regulatory assurance. To educate engineers with the prerequisite skills and knowledge, we have recently begun teaching a course in medical additive manufacturing at Aarhus University, the content and structure of which is presented in this paper.

II. Course curriculum

Biomedical engineers creating medical additive manufactured devices should have comprehensive knowledge of a broad variety of fields. Thus, the curriculum depicted in Fig. 1 covers the entire process from imaging the patient to producing the 3D printed device and supporting background knowledge of regulatory requirements and quality assurance.

Per the 26th of May 2021, the Medical Device Regulation 2017/745 (MDR) regulates medical devices in Europe. Three routes for producing additive manufactured medical devices are possible through MDR: Regular CE-marking, custom-made devices, and in-house production, with different regulatory requirements (Fig. 2). The ability to choose between each route and the regulatory requirements therein warrant detailed knowledge of the structure and intent of MDR. A central requirement throughout MDR, regardless of the production route, is quality assurance from the conception of the device throughout the entire device

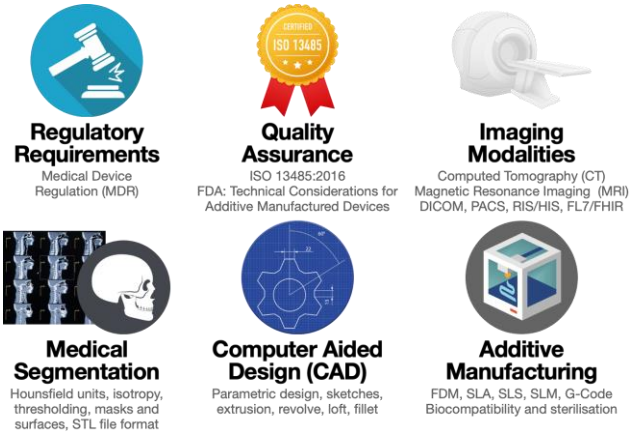

Figure 1: The main topics of the course in medical additive manufacturing cover the entire workflow from imaging to 3D print with prerequisite knowledge from regulatory requirements and quality assurance to ensure regulatory compliance.

lifecycle including post-market clinical follow-up (PMCF) with continuing monitoring of complications and side-effects. Several possible conformity routes with varying degrees of quality assurance requirements are possible. To comply with the requirements, the international standard ISO 13485:2016 is often applied. The standard describes the necessary processes and procedures to produce devices with a consistent quality. Understanding quality assurance and be able to formulate standard operating procedures governing the production of additive manufactured devices is of great importance. The ability to select the relevant parameters governing the quality of the 3D printed devices is an essential skill throughout this process. Though focused on the American market, the guidance: Technical Considerations for Additive Manufactured Medical Devices [2] is highly relevant in the European setting and together with ISO 13485:2016 forms the core of the quality assurance part of the course.

Basic understanding of the medical imaging modalities commonly employed for segmentation purposes; magnetic resonance imaging (MRI), and computed tomography (CT)

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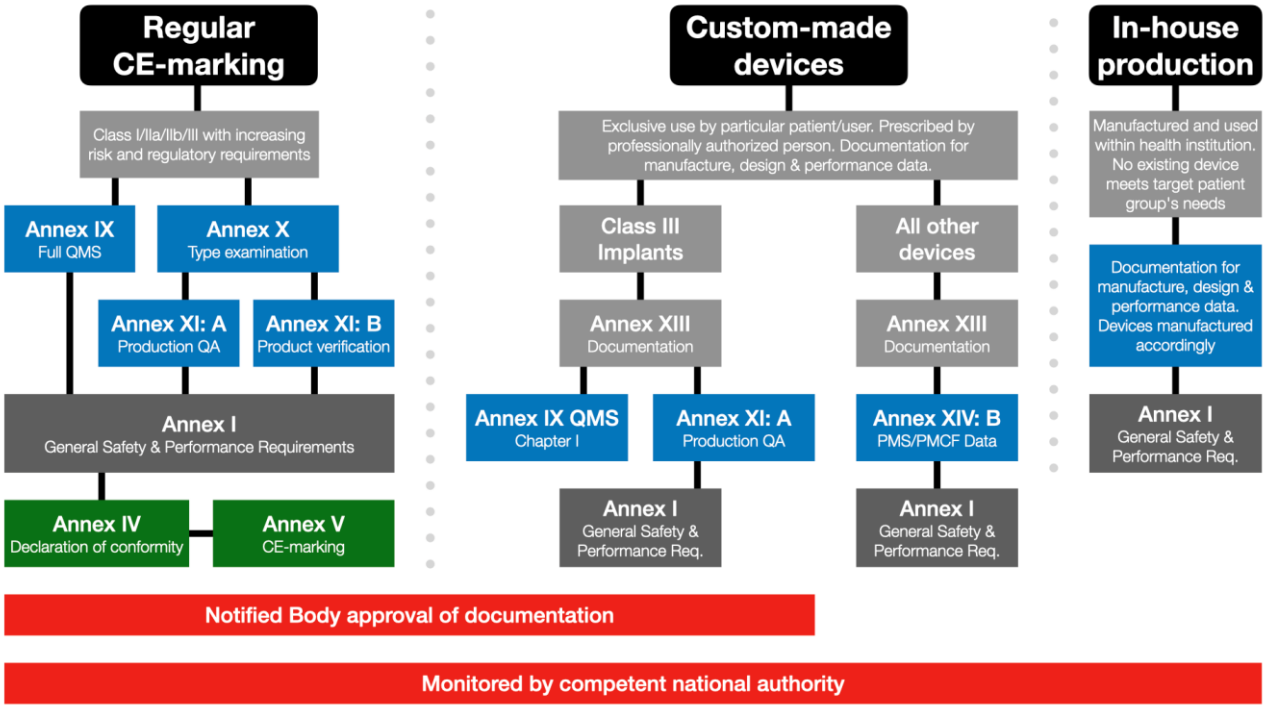

Figure 2: Illustration of the different production and conformity routes possible through the Medical Device Regulation 2017/745 for individualized additive manufactured medical devices. Note that every route contains requirements pertaining to quality assurance (blue boxes) and compliance with the general safety and performance requirements from annex I (dark gray). QA = Quality Assurance, QMS = Quality Management System, PMS = Post Market Surveillance, PMCF = Post-Market Clinical Follow-up

allows qualified dialogue with the radiographers to select appropriate settings for producing medical images suitable for segmentation. For instance, knowledge of CT metal artefacts and how to alleviate them can vastly improve the quality of the final model. Knowledge of common MRI sequences allows choosing appropriate contrast weightings to image the organs of interest, e.g., T1/T2 weighted scans, fat suppression, fluid attenuation, and contrast enhancement. Understanding the infrastructure of medical imaging in the hospital setting is essential for integrating 3D printed services. Thus, the students are introduced to the DICOM file format, PACS, HIS/RIS systems, and FL7/FHIR communication protocols.

To create individualized devices, models of the individual patient structures must be created through segmenting DICOM images. Common methods include thresholding, morphologic operations, and smoothing, the adjustment of which can have major impact on the dimensional accuracy of the final device. Skills in performing the operations and the quality impact of each is essential.

To create cutting guides and other 3D printed devices medical segmentation are often be combined with computer generated geometry. Therefore, cases are presented through which the students gain experience generating parametric geometry suitable for combining with patient segmentations to generate individualized devices.

A thorough understanding of available additive manufacturing technologies, their respective qualities and requirements, the available materials and their biocompatibility, possible sterilization methods, post-processing requirements, and the essential parameters to monitor to quality assure the production of medical 3D printed parts form a central part of the course. Through practical exercises and design challenges, the students learn how to design and produce quality parts using common 3D print technologies including FDM, SLA, SLS, and SLM additive manufacturing.

III. Discussion

Initial experience with the course suggests a high degree of student satisfaction with the course and its content. Collaborating healthcare institutions appreciate the scope of the students' knowledge and breadth of competences, which is continually aligned to the state of the art presented at medical 3D printing conferences and workshops.

IV. Conclusions

In this paper, we have presented a framework for educating biomedical 3D printing engineers with the requisite knowledge to be a key player in producing quality medical additive manufactured devices in compliance with regulatory requirements.

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Author's statement

Conflict of interest: Author states no conflict of interest.

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