Michael Wehmöller*, Michael Utz, Valentine Gesche

Digital process chains for patient specific medical devices

Digitale Prozessketten für patientenindividuelle Medizinprodukte

Abstract: The Medical Technology Advisory Committee of the VDI Society develops a guideline for the implementation of digital process chains for patient-specific medical devices. The underlying medical device constitutes the basis for each individualized medical device. It serves as the development framework for manufacturing.

Keywords: digitization, regulatory affairs, custom orders, custom-made, patient matched, patient individualized, underlying medical device

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1 Introduction

As part of digitization, customers are increasingly being involved in designing their desired product. For example, customers can configure their chosen vehicle, plan their own kitchen or design an individual T-shirt. To meet healthcare needs, health workers cooperate with manufacturers to develop innovative, patient-specific medical devices. For patient-specific medical devices, healthcare professionals are involved, via online services, in the design of patient matched and custom-made products. Digital process chains are the key.

The requirements for digital process chains of standardized products in medical technology are described in the quality management [1] and software systems [2] standards. In addition, requirements from the General Data Protection Regulation (GDPR) [3] must be observed. Structurally, high level digital process chains differ from low-level digital process chains in the degree of automation, the use of software tools and digital platforms. From the point of view of quality management, the development of digital processes must be attached to the development file.

***Corresponding author: Michael Wehmöller:** University of Applied Sciences Osnabrück, Albrechtstraße 30, Osnabrück, Germany, e-mail: m.wehmoeller@hs-osnabrueck.de
Michael Utz: Aesculap AG, Am Aesculap-Platz, 78532 Tuttlingen, Germany
Valentine Gesche: Institute for Textile Technology at RWTH Aachen University, Otto-Blumenthal-Straße 1, 52074 Aachen, Germany

In the case of custom-made products, it is also necessary for the treating healthcare professional to specify the custom-made product. Digitalization makes it possible to integrate the medical expertise of the health worker and thus his specification for the design and modeling of patient specific products into the process workflows.

1.1 Patient matched Product

For patient matched medical devices, the manufacturer is responsible for ensuring that the product fulfils its intended purpose, the development process has been documented and the associated conformity procedure has been certified, if necessary. In accordance with the manufacturer's design rules, a medical device, which can be manufactured as standard product, is matched to the geometry or anatomy of a designated patient. No technical design by the health worker is required; when ordering, he communicates anatomical characteristics, geometries or key figures (comparison: selection of a shoe size or manufacture of a medicine according to a recipe). The essential aspect is that the product can be matched to the patient without further medical evaluation by the healthcare professional [4].

1.2 Custom-made Product

For custom-made products ([5] Article 2 (3)), the practitioner takes part in the design of the custom-made product (material, etc.) and its geometrical modelling (design). He is responsible for the medical evaluation of the device for the designated patient. The Medical Device Regulation (MDR) exempts custom-made products from many regulations. For example, the manufacturer does not have to create a new product development file for each custom-made product and have the development process re-certified ([5] Article 10 (4)). He is obliged to document the manufacturing facilities, design, manufacturing and performance of the product ([5] Section 2 of Annex XIII, and additionally Annex IX and XI for Class III products). A reduced declaration of conformity must be issued. No CE marking may be affixed.

Taking these aspects into account, a digital process chain for patient matched products and custom-made products is set up below.

2 Digital process chain for the manufacture of patient-specific medical devices

The Medical Technology Advisory Committee of the VDI Society for Technologies of Life Sciences is currently developing a guideline on digital process chains in industrial medical technology [6]. In the first step, four patient-specific medical devices, from different medical areas, were used to analyze the processes, starting with the patient examination and ending with market observation. Subsequently, four process areas were identified, a digital process chain was described (Figure 1) and assistance for implementation was developed, as well as references to regulations given.

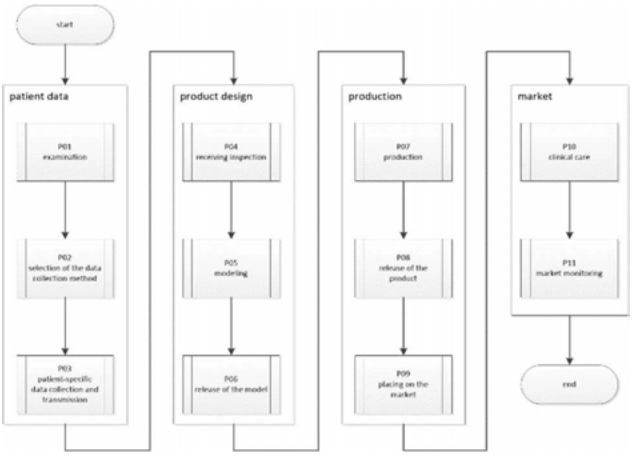

Figure 1: Digital process chain in industrial medical technology

For the development process ([1] Chapter 7.3), the product development file of the underlying medical device was identified as a central element. The underlying medical device contains all permitted variants of geometries, materials, manufacturing processes, etc.. This underlying medical device is abstract and while going through the described process chain it is complemented by specific designs, geometries, materials, manufacturing methods, and so forth to become an actual patient specific medical device (Figure 2).

The development file of the underlying medical device is created during the development process and is validated including all permitted variants. After successful validation of the underlying medical device, the individual medical device can be manufactured within the limits of the permitted variants without having to re-validate or re-evaluate the design.

3 Design documentation

The product development file is prepared for the permitted variants and is referred to as the underlying medical device. Together with the manufacturing documentation, the required design documents of the digital process chain for patient-specific medical devices are therefore available.

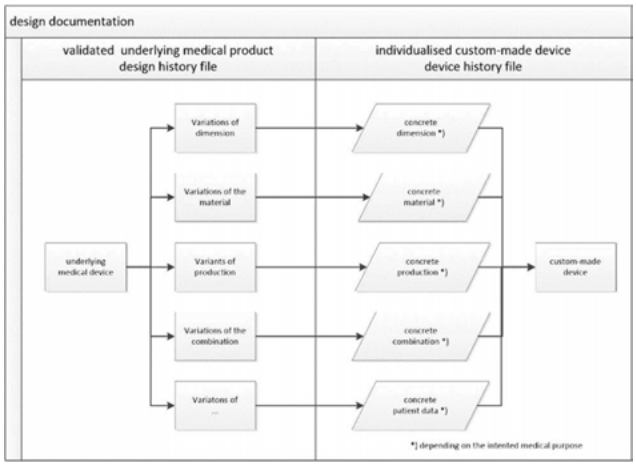

Figure 2: The design documentation contains the Design History File and the Device History File

Online services allow the health worker to order medical devices according to key figures (patient matched medical devices) as well as to design custom-made devices.

Selected references to regulations

MDR: Annex XIII lists the procedure for custom-made products.

DIN EN ISO 13485: Chapter 7.3 covers the design and development plan. The digital process chain must be considered in the development process.

GDPR: The patient must consent to the health worker processing his/her personal data. The manufacturer must provide information and, if necessary, erase personal data upon request, provided that the erasure does not conflict with the retention periods of the MDR.

Author Statement

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[2] IEC 62304 AMD 1:2015-06: Medical Device Software - Software Lifecycle Processes

[3] REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)

[4] C.M. Ling, 'Personal Medical Devices - Regulatory Pathways, IMDRF International Medical Device Regulators Forum, 18.3.2020

[5] REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

[6] VDI 5705: Digital process chains in industrial medical technology - manufacturing of custom-made products – in progress in 2020