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Abstract

Regulatory considerations on physical anatomical models

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This presentation serves as an introduction to regulatory issues regarding physical anatomical models in the medical field. Application areas such as product development, operation planning and diagnostic purposes will be reviewed.

Currently, there is no clear guidance regarding the regulatory qualification and risk classification of such physical anatomical models in the EU. According to the Regulation (EU) 2017/745 ("MDR"), such anatomical models might be classified as class I devices [1]. In the USA, they are classified as class II devices according to a software related rule which has been adapted in 2021 [2]. The FDA pursued the approach that a physical anatomical model that was produced by using a picture and communication system according to this rule will be classified correspondingly as class II device [2]. In Australia, an individual rule was introduced in 2021 classifying anatomical models as class IIa devices [3]. According to this rule, a physical anatomical model itself is classified like the classification of radiology related products that are considered as class IIa device.

Another interesting aspect is how to handle in-house manufacturing of the anatomical models by a health facility for such purposes. From a logistic and medical point of view, manufacturing anatomical models at the point-of-care has several advantages. However, regulatory challenges regarding the responsibilities and accountabilities of the different parties for the various steps from the design and development to the production and use of medical device production systems ("MDPS") must be resolved [4].

Potential regulatory concepts will be discussed from an international and EU perspective. The presentation will focus on the current regulatory discussion regarding personalized and simulated patient diagnostics and treatment.

AUTHOR'S STATEMENT

Alberto Di Benedetto is the founder and CEO of the company QMB Qualint Gesellschaft für Qualitäts- und Businessmanagement mbH, Munich. and collaborates with the Centre for Regulatory Affairs in Biomedical Sciences – CRABS, Technische Hochschule Lübeck on scientific projects. All other authors state no conflict of interest.

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