Quality-by-Design for the safe development of medical devices containing nanomaterials. A study case in photodynamic therapy

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Abstract title:

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Abstract body:

Background. According to the new medical device regulation (MDR 2017/745), devices employing advanced materials containing nanomaterials will be classified as class III and will have to undergo

(re-)assessment of risks. To that aim, the Quality-by-Design approach, as defined in ICH Q8-Q11 (QbD), is indisputably accepted and strongly recommended by the FDA and EMA for risk assessment during drug development. Some papers have emphasized the possible implementation of QbD in the medical device industry [1]. Nevertheless, to date no real and effective adaptation of this risk-based quality management approach has been adapted to biomedical devices manufacturing [2].

Objectives. Our goal is to develop both a new QbD paradigm and a web-based tool devoted to the safe development of class-III medical devices containing nanomaterials. This objective is pursued in the context of the European H2020 project TBMED (An Open Innovation test bed for the development of high-risk medical devices).

Methods. A six-step QbD approach is proposed. The first four stages are devoted to the preclinical development while the next two steps concern the industrial implementation. Three categories of risk-assessment methods are used at different development steps: failure mode and effects analysis based on prior knowledge, statistical designs of experiments and Bayesian inference. To assess its applicability, we applied the integrated QbD approach to the development of a new medical device devoted to the realtime control of light during photodynamic therapy using nanoparticle-based photosensitizers.

Results. The new SaaS platform, entitled “Nanologic”, is available at: (www.i-nano.eu). Four key documents for regulatory agencies are established during the preclinical study: the target product profile, the list of critical quality attributes (quality/safety descriptors), the list of critical material attributes and process parameters (risk factors associated with the design and production phases) and the design space: a key concept of risk assessment in QbD.

Conclusion. We show how the QbD best practices can be adapted to the development of medical devices containing nanomaterials. Moreover, new questions still have to be investigated such as the solutions to be developed to better predict risks associated with the clinical proof of concept.

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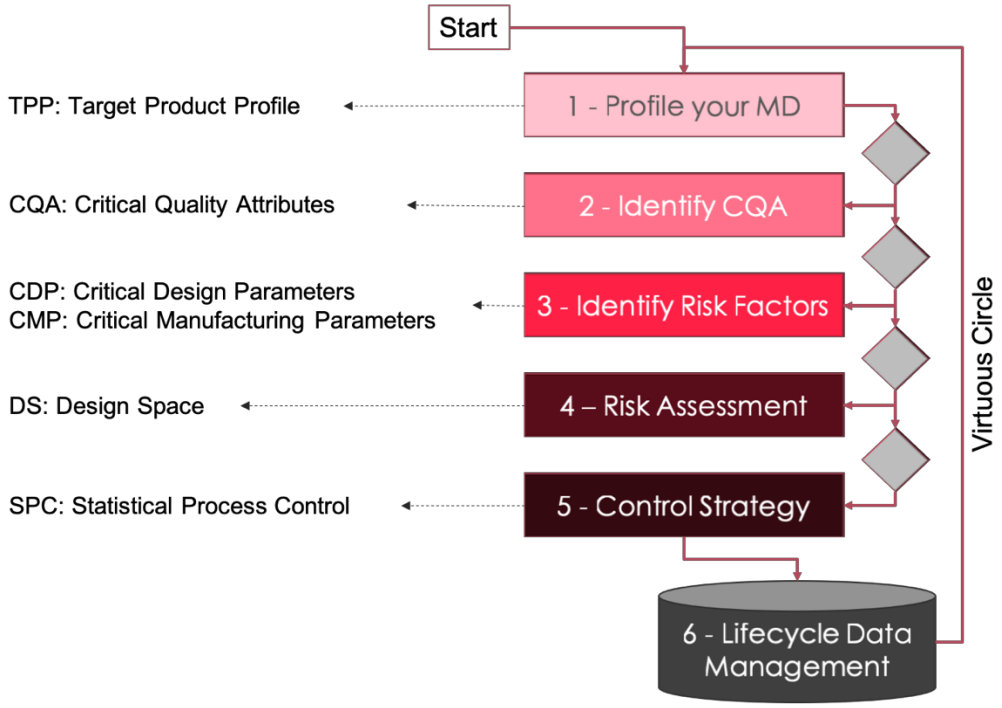

Fig. 1 A Quality-by-Design best practices approach for the safe development of biomedical devices containing nanomaterials.

References:

[1] D Martinez-Marquez, et al. PloS one, vol 13, no 4, (2018).
[2] T Bastogne. Nanomed: Nanotech, Bio and Med, 13(7):2151–2157, 2017.

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