Journal of Nanotoxicology and Nanomedicine
Volume 2 • Issue 2 • July-December 2017

Nanomaterials in Medical Devices: Regulations' Review and Future Perspectives

Karolina Jagiello, QSAR Lab Ltd, Gdansk, Poland & Laboratory of Environmental Chemometrics, Faculty of Chemistry, University of Gdansk, Poland

Anita Sosnowska, QSAR Lab Ltd, Gdansk, Poland & Laboratory of Environmental Chemometrics, Faculty of Chemistry, University of Gdansk, Poland

Alicja Mikolajczyk, Laboratory of Environmental Chemometrics, Faculty of Chemistry, University of Gdansk, Gdansk, Poland

Tomasz Puzyn, QSAR Lab Ltd, Gdansk, Poland & Laboratory of Environmental Chemometrics, Faculty of Chemistry, University of Gdansk, Poland

ABSTRACT

This article gives a brief description of the existing regulations related to biomaterials safety that need to be considered before it is introduced into EU market. According to these regulations, the risk analysis should include two characteristics: probability of occurrence of harm, and severity. Identified user-related harm should be reduced by managing the risk. Additionally, the review presents an overview of engineered biomaterials (EBMs), which in combination with nanoscale components (NPs) have shown promises in Advanced Therapy Medicinal Products (ATMP) and Medical Devices (MD). In this article, recent challenges, objectives and perspectives in risk assessment and risk management of ATMP and MD composed of nanobiomaterials were also highlighted.

KEYWORDS

Advanced Therapy Medicinal Products, Engineering Nanomaterials, EU Regulations, Medical Devices, Nano-Bio-Materials, Risk Assessment, Risk Management, Safety Assessment

DOI: 10.4018/JNN.2017070101

Copyright © 2017, IGI Global. Copying or distributing in print or electronic forms without written permission of IGI Global is prohibited.

INTRODUCTION

Medical Devices (MD) and Advanced Therapy Medicinal Products (ATMP) play a crucial and still growing role in improving human healthcare. The market size related to biomaterials applied in MD and ATMP development, commercialization, manufacturing and distribution was about $330 billion in 2013 and is growing at ~6% per year through 2017 in consequence contributes significantly to the European economy (http://ec.europa.eu/growth/sectors/medical-devices_en)

Due to that biomaterials inevitably come in contact with the patient's tissue and/or circulatory system their application should be always accompanied with a comprehensive risk assessment and risk management (Hollinger, 2011). Managing and reducing risk is necessary to ensure the safety of the designed devices (Palanichamy, 2002). The risk analysis should include probability of occurrence of harm and severity. According to these two characteristics, there were three risk zones defined: i) risk zone 1 that consists medical devices with generally acceptable risk (low severity and low probability); ii) risk zone 2 – conditionally acceptable risk (medium severity and probability); and iii) risk zone 3 – generally unacceptable risk, Figure1 (Palanichamy, 2002). In consequence, medical devices will be defined as 'unacceptable' only in case, if its application provides to catastrophic effects (e.g. to death), and this effect occurs frequently.

There are existing regulations related to biomaterials safety that need to be considered before their introduction into European (EU) market (EU Communities 1990, 1993, 1998). The three main directives are: directive 90/385/EEC regarding active implantable medical devices (EU Communities 1990); directive 93/42/EEC regarding medical devices (EU Communities 1993) and directive 98/79/EC regarding *in vitro* diagnostic medical devices (EU Communities 1998). The European Commission also adopted a series of implementation measures and guidelines, of which the most known are the Medical Devices Directive series, also known as MEDDEV (MEDDEV, 1994, 2010). Currently, the ISO 10993-1:2009 (ISO, 2009) is in practice for the safety testing and risk assessment of medical devices including biomaterials. This guideline provides the information on how to perform the biological safety assessment for biomaterials considering the body contact and duration of this contact (ISO, 2009).

The goal of the risk management analysis is to provide tools to minimize user-related hazards that are identified within risk assessment analysis. The risk management process for biological evaluation of medical devices is described in ISO 10993-1:2010 (ISO, 2010), Annex B and follows the wording of ISO 14971:2012 (ISO, 2012) and the guidance document ISO/TR 15499:2016 (ISO/TR, 2016). Further, in ISO 10993-1, Annex B the risk analysis is extended and also comprises risk evaluation and risk control. ISO/TR 15499:2016 provides more detailed advice on carrying out biological risk evaluations within a risk management process than ISO 10993-1.

Biological safety assessment approaches dedicated to medical devices proposed so far have serious limitations. Firstly, most of these assays are based on the *in vivo* tests that need to be performed for each material separately (extrapolation from one

9 more pages are available in the full version of this document, which may be purchased using the "Add to Cart" button on the publisher's webpage: www.igi-global.com/article/nanomaterials-in-medical-devices-regulations-review-and-future-perspectives/201030

Related Content

Fabrication of Metal@SnO2 Core-Shell Nanocomposites for Gas Sensing Applications

Sanjay K. Suar, Sayantan Sinha, Amrita Mishraand Suraj K. Tripathy (2015). *Handbook of Research on Diverse Applications of Nanotechnology in Biomedicine, Chemistry, and Engineering (pp. 438-451).*

www.irma-international.org/chapter/fabrication-of-metalsno2-core-shell-nanocomposites-for-gas-sensing-applications/116857

Single-Electron Devices and Circuits Utilizing Stochastic Operation for Intelligent Information Processing

Takashi Morie (2009). *International Journal of Nanotechnology and Molecular Computation (pp. 1-28).*

www.irma-international.org/article/single-electron-devices-circuits-utilizing/4075

Artificial Organs

Gerardo Catapanoand Gijsbertus Jacob Verkerke (2011). *International Journal of Biomaterials Research and Engineering (pp. 41-76).*

www.irma-international.org/article/artificial-organs/104503

Einstein-Podolsky-Rosen Paradox and Certain Aspects of Quantum Cryptology with Some Applications

Narayanankutty Karuppathand P. Achuthan (2014). *Nanotechnology: Concepts, Methodologies, Tools, and Applications (pp. 1579-1587).*

www.irma-international.org/chapter/einstein-podolsky-rosen-paradox-and-certain-aspects-of-quantum-cryptology-with-some-applications/102085

Artificial Organs

Gerardo Catapanoand Gijsbertus Jacob Verkerke (2011). *International Journal of Biomaterials Research and Engineering (pp. 41-76).*

www.irma-international.org/article/artificial-organs/104503