Drug Delivery Trends

Edited by Ronald Swanepoel

Expectations and Realities of Multifunctional Drug Delivery Systems

Volume 3

DRUG DELIVERY TRENDS

EXPECTATIONS AND REALITIES OF MULTIFUNCTIONAL DRUG DELIVERY SYSTEMS VOLUME 3

Edited by

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Preface

The book series titled ***Expectations and Realities of Multifunctional Drug Delivery Systems*** covers several important topics on drug-delivery systems, regulatory requirements, clinical studies, intellectual properties trends, new advances, manufacturing challenges, etc. written by leading industry and academic experts. Overall, the chapters published in this series reflect the broadness of nanopharmaceuticals, microparticles, other drug carriers, and the importance of respective quality, regulatory, clinical, GMP scale-up, and regulatory registration aspects.

This series is destined to fill the knowledge gap through information sharing and with organized research compilation between diverse areas of pharma, medicine, clinical, regulatory practices, and academics.

Expectations and Realities of Multifunctional Drug Delivery Systems is divided into four volumes:

Volume 1: Nanopharmaceuticals
Volume 2: Delivery of Drugs
Volume 3: Drug Delivery Trends
Volume 4: Drug Delivery Aspects

The specific objectives of this book series are to:

1. provide a platform to discuss opportunities and challenges in development of nano medicine and other drug-delivery systems;
2. discuss current and future market trends;
3. facilitate insight sharing within various areas of expertise; and
4. establish collaborations between academic scientists, and industrial and clinical researchers.

Innovative cutting-edge developments in micro-nanotechnology offer new ways of preventing and treating diseases like cancer, malaria, HIV/AIDS, tuberculosis, and many more. The applications of micro-nanoparticles in drug delivery, diagnostics, and imaging are vast. Hence, **Volume 3: Drug Delivery Trends** in the book series mainly reviews advances in drug delivery areas via targeted therapy with improved drug efficiency at a lower dose, transportation of the drug across physiological barriers, as well as reduced drug-related toxicity.

The contribution by Fernandes et al. **(Chapter 1)** discusses new trends in drug delivery areas via bioactive hybrid nanowires. Nanowires offer multifunctionality and the prospect of biofunctionalization, thereby reducing toxicity and side effects. This synergistic approach overcomes the challenges associated with conventional nanomedicines and exhibits better performance. The authors review the potential of nanowires in this chapter.

The chapter by Procopio and Tewari **(Chapter 2)** highlights another industry trend—i.e., 3D printing. This is a fascinating topic recently adopted by industry. The Food and Drug Administration has already approved the first product: Spritam (levetiracetam), a 3D printed tablet (Aprecia Pharmaceuticals). A thorough overview of material requirements, types of

polymer, available 3D printing techniques, and regulatory aspects is provided. Finally, the authors present case studies from industry on tunable release technology and paste gel extrusion in tableting.

The contribution by Al-Hindawi **(Chapter 3)** describes marketing authorization and licensing of medicinal products in the European Union. The main aim of this chapter is to provide readers with a generalized overview of the steps and criteria while applying licenses in the European Union. The author also highlights various directives, extension requests, protection periods, and legal requirements guidance to industry and researchers. On the other hand, preclinical understanding is key to proposing products for particular indications.

The chapter by Tiwari et al. **(Chapter 4)** reviews preclinical considerations on micro- and nanodrug delivery, which will lead to the proper positioning of products for market authorization.

The work by Ghan **(Chapter 5)** is aimed at discussing synergistic delivery of nanoparticles using traditional approaches like tableting or other forms. The author reviews various nanoparticulate treatments for oral delivery to improve bioavailability, target specific regions in the gastrointestinal tract, improve physiological stability in the gut environment, and modulate release when needed. Drug delivery systems like solid lipid nanoparticles, polymeric nanoparticles, nanomicelles, and nanosuspension are also reviewed.

The chapter by Tumuluri **(Chapter 6)** highlights opportunities and challenges in formulating minitablets. This is another trend in oral drug delivery systems besides nano-oral and 3D printed dosage forms. The author describes in detail technological potential, industrial advantages, technological availability, and the limitations of minitablets.

The topic presented by Nalone et al. **(Chapter 7)** describes the potential of liquid crystalline systems in drug delivery. This chapter discusses in detail the mechanism of formation of liquid crystalline systems, types of structure formed, factors affecting formation of liquid crystalline systems, compositions, advantages, and limitations of these forms of drug delivery systems.

The chapter by Veloso et al. **(Chapter 8)** reviews opportunities and challenges in amorphous drug stabilization using mesoporous materials. The team of authors highlights key points like the role of mesoporous materials, structural characterizations of such systems, physical forms of drug loading, and physical performance of mesoporous particles. Mesoporous particles have huge potential in pharmaceuticals as a drug delivery system, in cosmetics, in nutraceuticals, and in fast-moving consumer goods (detergent, oral care), and is a highly explored trend in the market.

Quality is an important aspect in regulatory which makes sure patients receive "quality" products. Newer trends in pharmaceuticals like nanomedicines, drug device combinations, nanoparticulate-based tablets, etc. require special techniques and an understanding of quality. The chapter by Qureshi **(Chapter 9)** asks questions like "what is quality?", "do we evaluate quality as per a regulatory definition?", and "is there a need to change the definition of quality when a product is altered?" The main theme of this chapter is to underline basic concepts of "quality" and discuss them with regard to current practices. The author provides his views on further modifications of current testing methodologies to assure "real quality."

The work by Reymond and Königsrainer **(Chapter 10)** is aimed at discussing the potential of pressurized intraperitoneal aerosol chemotherapy (PIPAC). The authors review various chemotherapeutic systems currently used in vitro/ex vivo models and the success of clinical trials to date. This generalized overview of PIPAC technology provides readers with updates from another innovative trend in medical practice.

The last contribution by Türeli and Türeli **(Chapter 11)** describes industrial challenges of upscaling and good manufacturing practice in the production of pharmaceutical drug delivery systems. The authors highlight the current regulatory status of approved nanomedicines and manufacturing limitations and initiatives.

In summary, I am sure this book volume and the complete book series will provide you great insights in areas of micro-nanomedicines, drug delivery sciences, new trends, and regulatory aspects.

All the efforts of experts, scientists, and authors are highly acknowledged for sharing their knowledge, ideas, and insights about the topic.

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Editor