Chapter 102
Potential Impact of RFID-Based Tracing Systems on the Integrity of Pharmaceutical Products

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ABSTRACT

Radio Frequency Identification (RFID) is going to play a crucial role as auto-identification technology in a wide range of applications such as healthcare, logistics, supply chain management, ticketing, et cetera. The use of electromagnetic waves to identify, trace, and track people or goods allows solving many problems related to auto-identification devices based on optical reading (i.e. bar code). Currently, high interest is concentrated on the use of Radio Frequency (RF) solutions in healthcare and pharmaceutical supply chain, in order to improve drugs flow transparency and patients' safety. Unfortunately, there is a possibility that drug interaction with electromagnetic fields (EMFs) generated by RF devices, such as RFID readers, deteriorate the potency of bioactive compounds. This chapter proposes an experimental multidisciplinary approach to investigate potential alterations induced by EMFs on drug molecular structure and performance. To show the versatility of this approach, some experimental results obtained on two biological pharmaceuticals (peptide hormone-based) are discussed.

INTRODUCTION

The auto-identification solutions have recently seen explosive interest from a wide range of application sectors, such as manufacturing, retail, logistics, ticketing, healthcare, and pharmaceuticals, in order to improve transparency in goods flows in the international markets. These needs are substantially contributing to assert the important concept of the Internet of Things (IoT) (Thiesse et al., 2009). It represents the future vision of the Internet, a worldwide network composed of uniquely addressable interconnected objects, able

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to collect any valuable information about the same objects, using them in various applications during their life cycle. Furthermore, the growing of goods' counterfeiting imposes to the governments of many countries to define and apply effective strategies to face this serious problem. Among several scenarios, the pharmaceutical supply chain, with millions of medicines moving around the world, represents a very interesting and challenging test case. Indeed, several international institutions (e.g. Food and Drug Administration, European Medicines Agency, European Federation of Pharmaceutical Industries and Associations, GS1) are recently encouraging the use of innovative solutions for the auto-identification in healthcare and pharmaceuticals, to improve the patient safety and enhance the efficiency of the pharmaceutical supply chain, with a better worldwide drug traceability.

The Radio Frequency Identification (RFID) is an emerging auto-identification technology that promises to solve many problems related to almost obsolete optical solutions such as bar code (Finkenzeller, 2003). A communication based on the use of EMFs is able to overcome constraints as Line-of-Sight (LoS), low read rate, no bulk reading, etc. In addition, recent technological enhancements allowed realizing new types of RFID tags whose cost is very low and comparable with bar code one. These particular tags are known with the generic term "chipless" (Preradovic, 2009) because they exploit RF energy to communicate data but do not use a silicon microchip to store a serial number.

Unfortunately, there are still several obstacles that are limiting the deployment of RFID technology in healthcare organizations and in the pharmaceutical supply chain. One of these, very interesting from scientific point of view, is related to the evaluation of potential exposure effects to an EMF on drugs. It is well known that the pharmaceutical and healthcare sectors are characterized by a rich set of national and international rules (e.g. GAMP, GMP, FDA CRF21, etc.) that strictly regulate the use of new information and communication technologies.

The RF exposure effects on materials have been broadly classified into two categories: thermal effects and non-thermal effects (Uysal et al., 2010). Thermal effects are defined as those that stem from an appreciable increase in the temperature of products under RF exposure, comparable to a change in temperature caused by other heating sources. The entity of thermal effects mainly depend on the frequency of the EM source, the dielectric constant, the water content and the overall thickness of the exposed materials. Furthermore, a bulk of scientific literature focuses on the effects of temperature on drug stability.

In contrast, non-thermal effects, arising even in absence of any appreciable increase in the material temperature upon exposure to RF, are obscure. The rise of temperature generated by the high penetration power of high-frequency radiations may mask non-thermal effects, especially in liquid and metal containing samples. So, most studies in this field privileged the use of low frequency or high frequency/low power radiations, having a negligible impact on temperature (De Pomerai et al., 2003; Bismuto et al., 2003). As a turning point in this sense, Cox et al. (2006) described a tightly controlled approach to analyze non-thermal effects on drugs of RF radiation over a broad range of frequencies, at initial sample temperatures. More recently, a methodology to generate powerful RF EMFs (HF, UHF) in a temperature-controlled environment has been described (Uysal et al., 2010). The intent was to determine the impact on purity and potency of selected protein biopharmaceuticals.

The goal of this chapter is delineating an experimental framework to evaluate potential exposure effects of the EMFs generated by RFID devices working in UHF band on biological pharmaceuticals. Heterogeneous skills (engineering, chemistry and physiology) have been recruited to draw up a suitable experimental protocol for this analysis, consisting of three main steps: (i)