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RFID technology and regulations for pharmaceuticals

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Radio frequency identification (RFID) is one of the key enabler technologies which can facilitate item level serialization in the pharmaceutical supply chain especially for track-n-trace and e-pedigree applications. However, challenges exist at both regulatory and technical levels before a wide scale adoption is possible throughout the industry. In this presentation, we will provide an overview of the RFID technology, current regulations with respect to its use in the pharmaceutical supply chain, and discuss some of the limitations specifically concerning biologics. Per compliance policy guide CPG Sec.400.210, radiofrequency identification feasibility studies and pilot programs for drugs, the U.S. Food and drug administration (FDA) has excluded drugs covered under a biologics license application or protein drugs covered by a new drug application from being used in RFID pilots due to the fact that the impact of radio frequency waves on proteins is not extensively documented. We will discuss a recent research study which investigated the non-thermal effects of radio frequency waves on different biopharmaceuticals such as hormones, vaccines and immunoglobulins. Five frequencies (13.56 MHz, 433 MHz, 868 MHz, 915 MHz, and 2.4 GHz) were used to represent the most commonly used international frequency bands for RFID applications. For testing, to simulate a worst case scenario, the products were exposed to magnetic and electromagnetic fields with power levels beyond Federal communications commission (FCC) regulated commercial limits for a full 24 hour period. The *in vitro* test results on different biopharmaceuticals from eight major companies showed no non-thermal effect by radio frequency waves.

Biography

Ismail Uysal received his Ph.D. in Electrical and Computer Engineering from the University of Florida in 2008. He is currently an Assistant Professor and the Director of the RFID Lab for Applied Research as part of the Center for Wireless and Microwave Information Systems at the University of South Florida. His research concentrates on applications of radio frequency identification in cold chain and pharmaceuticals, remote environmental modeling and smart sensory data analysis. He has more than 20 peer-reviewed publications in reputable books, journals and proceedings and he was an invited speaker for numerous international conferences.

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