

Landes Highlights

Biosimilars enter Europe

Biosimilars are copies of already authorized biological drugs, which are referred to as reference products. Biosimilars are known as follow-on biologics in the United States and as subsequent entry biologics in Canada.

Drs Beck and Reichert, the Associate Editor and Editor-in-Chief of the Landes Journal *mAbs*, consider this to be a significant landmark for the European biopharmaceutical industry. The positive opinion issued on Celltrion's Remsima and Hospira's Inflectra represents validation of the process established in the EU for approval of biosimilar antibodies, and paves the way for approval of other products with patents

that have expired or are close to expiration, including rituximab (Rituxan®, MabThera®), bevacizumab (Avastin®), trastuzumab (Herceptin®), and adalimumab (Humira®), as well as the Fc fusion protein etanercept (Enbrel®). Global sales for these products were between \$6.1 billion (infliximab) and \$9.3 billion (adalimumab) in 2012.

Reference

Beck A, Reichert JM. Approval of the first biosimilar antibodies in Europe: a major landmark for the biopharmaceutical industry. *MABs* 2013; 5:621-3; PMID:23924791; <http://dx.doi.org/10.4161/mabs.25864>.



Broad spectrum biosensors

Four scientists from Ibis Biosciences, an Abbot company, have contributed a special focus review on broad spectrum biosensors in *Virulence*. The issue focuses on the potential of broad spectrum biosensors to revolutionize both medical diagnostics and public health/biothreat surveillance. These technologies allow clinical laboratories, surveillance agencies, and researchers to query single samples for hundreds of organisms simultaneously. The universal nature of such assays means that routine diagnostics, epidemiological tracking, biothreat surveillance, and pathogen discovery work

could occur simultaneously in near real-time at the point of care. The authors provide arguments that a simple linear extension of the current models for validation does not provide a feasible path toward acceptance of technologies with hundreds of potential analytes. A strategy for validation of broad spectrum biosensors is proposed.

Reference

Metzgar D, Sampath R, Rounds MA, Ecker DJ. The value and validation of broad spectrum biosensors for diagnosis and biodefense. *Virulence* 2013; 4:752-8; PMID:24128433; <http://dx.doi.org/10.4161/viru.26652>



Mobile Genetic Elements: Class 1 integrons

In their review titled “Vehicles and pathways for horizontal dissemination in bacteria,” Sara Domingues, Gabriela da Silva, and Kaare Nielsen examine how different vehicles and mechanisms of horizontal gene transfer enable the dissemination of integrons. This review focuses on the main type of integron involved in the spread of antibiotic resistance, the class 1 (C1) integron. Although most integrons were initially described in human clinical isolates, they have now been identified in many non-clinical environments, such as water and soil. Integrons are present in ~10% of sequenced bacterial genomes and are

frequently linked to mobile genetic elements (MGEs). Integrons can incorporate one or more gene cassettes, though usually less than five in clinical isolates. C1 integrons are usually found linked to various types of MGEs, and will therefore move within and between bacterial genomes as part of the MGE(s) they reside in.

Reference

Domingues S, da Silva GJ, Nielsen KM. Integrons: Vehicles and pathways for horizontal dissemination in bacteria. *Mob Genet Elements* 2012; 2:211-23; PMID:23550063; <http://dx.doi.org/10.4161/mge.22967>

Mobile Genetic Elements

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