

TRANSFERRING METHODS FOR VACCINE RELEASE BETWEEN THE INDUSTRY, ACADEMY AND A REGULATORY AGENCY: LESSONS LEARNED

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Flublok, developed and manufactured by Protein Sciences Corporation (PSC), is the first recombinant influenza vaccine in the market, which was approved by the FDA in 2013.. In August 2014, Flublok was licensed to Laboratorios Liomont for the Mexican market and, potentially, other Latin American countries. In order to obtain approval in Mexico and begin commercialization, a joint team of PSC, Liomont and LAMMB formed an alliance for registering Flublok in Mexico and transferring the analytical methods needed for vaccine testing and release by CCAYAC and COFEPRIS, respectively,, which are the Mexican agencies responsible for vaccine commercialization control. Flublok was approved in Mexico in October 2015, and method transfers from PSC to LAMMB and CCAYAC began soon afterwards.. Several analytical methods are compendial methods or are routinely performed by CCAYAC, who also releases the traditional influenza vaccines for the Mexican market, but two methods -SRID and DNA- were identified as critical for vaccine release, and thus method transfer protocols were set in place. In this work, an account of the challenges and lessons learned during method and technology transfer between institutions from distinct fields -industry, academy and regulatory- , will be presented. After intense multi-institutional and multidisciplinary team work, method transfer was successfully performed between PSC and both Mexican organizations. This work set the basis for the commercialization of Flublok in Mexico for the 2016-2017 winter season.