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DRIVING CHANGE IN DTaP BATCH RELEASE TESTING

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The complexity of vaccine manufacturing has raised the need to drive standardization and quality control requirements as well as batch release of vaccines. The purpose of release testing is to ensure that efficacy and safety of the vaccine product are maintained in all batches. Classical testing includes challenge experiments in animals that provide proof of vaccine potency and identify subpotent vaccines. However, novel concepts such as “consistency testing” question the continued need for *in vivo* experiments and propose to implement rigorous QC for lot-to-lot consistency testing with other methods at an earlier stage.

In views of these developments and the recent changes in the animal legislation the Paul-Ehrlich-Institut (PEI) as OMCL (official medicines control laboratory) has substituted challenge experiments for tetanus and diphtheria by serological testing for immunogenicity. The development of a multiplex-assay using electrochemiluminescence was favored because measurements performed with this technology remain linear over broad concentration ranges and deliver robust and reliable results.

Ongoing developments at PEI further include *in vitro* methods for functional testing of DTaP bulk antigen using cell-based assays based on eliciting antigen-specific B cell responses in human peripheral blood cells and Raman spectroscopy-based approaches for identification of vaccines as a rapid, non-invasive technology.