MS-based host cell protein testing strategy for a vaccine manufactured in a novel cell line

Annemiek Verwilligen, Saskia Crowe, Jonathan Knibbe, Eveline Sneekes-Vriese, Shariteé Bouthisma, Arjen Scholten

Janssen Vaccines & Prevention, Analytical Development, Newtonweg 1, 2333 CP Leiden, The Netherlands

The recombinant viral vectors employed in Janssen's AdVac® vaccine platform are harmless adenoviruses that are modified to genetically encode for proteins of viral origin so-called transgenes. Upon vaccination, these transgenes are expressed in the host cell and presented to the immune system, thereby expectedly eliciting a protective immune response against the virus. The AdVac® vaccines are manufactured in cell culture, on the novel human retinal PER.C6® cell line. The purified viral vectors contain, besides the viral proteins, a small portion of residual host cell proteins (HCPs). Analysis of these HCPs is traditionally performed by immunoassays, as ELISAs. However, this approach is restrained by absence of information on individual proteins. Recently, this hurdle has been lowered by the introduction of mass spectrometry in the field of HCP analysis by which information on protein identity and abundance can be obtained.

The improved HCP testing strategy of Janssen Vaccines and Prevention for the PER.C6® cell line consisting of traditional immunoassays strengthened by mass spectrometric data will be presented. It demonstrates that product and process understanding of HCP composition relies on the use of mass spectrometry from cell to final drug product, with techniques varying from full cell lysate proteomics to semi-quantitative peptide mapping in all stages of the AdVac® production process. The focus of this presentation will be on the benefits and challenges that the use of mass spectrometry brings to the field of HCP analysis.