**Multiplex assays in quality control of multivalent vaccines: Challenges and Oppurtunities**

Manish Gautam, PhD and Sunil Gairola, PhD, Laxmikant Kadam, M.Sc. and Krunal Patel

Immunoassay Development Group, Serum Institute of India Pvt Ltd, Pune, Maharashtra, India-411028

[m.gautam@seruminstitute.com](mailto:m.gautam@seruminstitute.com), [sunil.gairola@seruminstitute.com](mailto:sunil.gairola@seruminstitute.com)

**Background**

Multiplex assays that allow the simultaneous measurement of multiple analytes in small sample quantities have developed into a widely used technology. Their implementation spans across multiple assay systems and provides readouts of similar quality as the respective single-plex measures, albeit at far higher throughput. Multiplex assays will have an important role to play in quality control of vaccines and especially multi-valent or combination vaccines. Nonetheless, to date, relatively antigen content based multiplex immunoassays have been validated or included in testing of vaccines. At Serum Institite of India Ltd, we have developed and introduced multiplex assays for quality testing of multivalent polysaccharide conjugate vaccines.

**Methods**

Luminex technology was used to develop an indirect immune-assay for monitoring and stability testing of antigen content in polysaccharide conjugate vaccines.

**Results**

The challenges of implementation of such assays in quality control settings is challenging. A good quality control program involving reagents control, antibody control and assay monitoring is required for its implementation. Our presentation will outline the challenges: that must be ameliorated prior to the widespread integration of multiplex immunoassays in quality control testing of vaccines. The presentation will include some case studies to show challenges and oppurtunities for integration of these technologies in quality assessment of vaccines.

**Conclusion**

Luminex technology offers oppurtunities in quality testing of vaccines. A global collaborative effort is required for harmonizing the testing metholodologies and assay procedures. Luminex users meet will be an ideal platform to discuss these possibilities with potential users.