

## 4<sup>th</sup> International Conference and Exhibition on **Pharmacovigilance & Clinical Trials** August 10-12, 2015 London, UK



### *Subodh Bhardwaj*

Arable Corporation, USA

#### Vaccine vigilance: Towards strengthening pharmacovigilance

Vaccines pharmacovigilance is of utmost importance and necessary today, as millions of subjects are being immunized globally in the platinum era of vaccines with the introduction of 13 new vaccines in this century. New vaccines with safety profiles emanating from clinical trials on a small sample size would need active monitoring globally to assess newer reactions post-licensure. Vaccines differ from drugs as they are preventive while drugs are curative. Vaccine related adverse events are immunologic and indicate immune response while drug reactions are undesirable effects. This has bearing on prevention, analysis, intervention and data interpretation. The vigilance gap between developed and developing countries needs to be improved. As newer vaccines are produced using sophisticated technologies with novel adjuvants and unique routes of administration (like nasal) for LAIV, new challenges emerge for adverse events detection, analysis and management. This workshop aims to provide better insights, discuss methods for AE detection and management with real time case reports on rare adverse events to commonly administered bacterial and viral vaccines. To make the researchers and managers be better prepared to manage AEs as per international guidelines. In conclusion, vaccine vigilance is the need of the hour as children are an extremely sensitive young group receiving up to 37 shots from birth to 6years. Clearly, vaccine safety has a narrow margin for error.

#### Biography

Subodh Bhardwaj is a Qualified Physician and Clinical Pharmacologist with 3 decades of experience in the pharmaceutical Industry leading research and development of Vaccines and Biopharmaceuticals. He qualified the MBBS from Medical College Jammu, India in 1981 and worked in Internal Medicine for 7 years, before qualifying MD Pharmacology from the prestigious AMU in India in 1990. He was associated with research on Hypertension, diabetes and trace elements till 1993. He joined as Medical Director of Serum Institute of India in 1993 which is the largest exporter of vaccines globally and conducted research on bacterial & viral vaccines licensing DTPwHB, HB, Hib, DTPwHB Hib, MMR, MR, R, HDC Rabies Vaccines, Infertility drugs, Somatostatin, Somatropin & Onco BCG for Superficial Bladder Cancer as adjunctive therapy. His experience blends special skills in Pharmacovigilance of drugs & pharmaceuticals across broad therapeutic groups including Monoclonals for rabies. He has managed Pharmacovigilance, as Director Medical, Regulatory & Public Policy of Sanofi Pasteur India during 2008-2011, when notable products licensed were Acellular Pentavalent IPV containing Vaccines, Pandemic and Seasonal Influenza Vaccines, Boosters, Yellow fever vaccine, Meningococcal vaccines among others. Well versed with Marketing and Distribution of anticancers, biologicals in Uganda, he worked as the Director Medical Affairs, Surgipharm Uganda & Rwanda during 2013-2015. Leading Clinical Research & Pharmacovigilance in Vaccines & Pharma, he has organized large sample size trials from preclinical to licensure and post marketing surveillance in India and abroad. He is a Member of BRAPP, European Society of Pharmacovigilance, with 60 National & International publications in reputed journals. He currently works as Biopharmaceutical Consultant & Vice President, Arable Corporation, besides consulting for international organizations on topics of public health importance.

[bhardwajsubodh@yahoo.co.in](mailto:bhardwajsubodh@yahoo.co.in)

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