



International Alliance for  
Biological Standardization



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Advisor to the Director and Sr. Evaluator in the Center for Vaccines, Clinical Trials and Biostatistics at Health Canada. He has over 25-years of experience in research and regulatory science in support of innovation for vaccine development, manufacturing and quality control. He is active in the development / implementation of related guidance, and has a wide range of biologics-based scientific and regulatory experience from his Sr. Scientific Evaluator and management roles in Centre Divisions including Viral and Bacterial Vaccines, Hemostatic Agents & Blood Substitutes, as well as the Clinical Evaluation Division-COVID.

Representing Health Canada, he has contributed to WHO's smallpox and rabies vaccine guidance, the Extended Controlled Temperature Conditions (ECTC) guidance in support of innovative vaccine stability assessment for vaccination campaigns over the "last mile" with limited cold chain. Additionally, he contributed to WHO's R&D Blueprint International COVID-19 vaccine consultations during the pandemic, and since 2018 has been engaged in the regulatory / industry patient-centric harmonized specification exchanges in line with an assumed intent of ICH Q6B.

Smith is Health Canada's representative to the European Directorate of Quality of Medicines (EDQM) Group 15 (Vaccines and Sera) of the European Pharmacopeia. He has served on the Science and Ethics Advisory Committee for VAC2VAC under the European Vaccines Initiative to substitute more appropriate *in vitro* QC methods for existing *in vivo* vaccine QC methods, on the Regulatory Advisory Group to WHO and CEPI (Coalition for Epidemic Preparedness Innovations) during the COVID-19 pandemic, and most recently on the current EDQM mRNAC-Working Party.

Smith's Ph.D. in Immunology is from the University of Alberta, Canada, where his research dealt with vaccine antigen discovery, autoimmunity and viral vector-based gene therapy. He was a Research Associate at the National Research Council's Institute of Biological Science, Vaccine Design Group in Ottawa, prior to joining Health Canada.

