Jennifer Wilhelm

DIRECTOR, REGULATORY AFFAIRS
AT MERCK CANADA

Jennifer (JJ) Wilhelm is a regulatory affairs professional in the biopharmaceutical industry as Director of Regulatory Affairs at Merck Canada Inc (Merck). She started in the industry at a toxicology consulting firm, working for companies mainly at the initial/FIH clinical trial stage. She then worked for Canadian biotech companies at the clinical trial stage and has been with Merck since 2011. JJ holds an Honours BSc in Biomedical Sciences from the University of Guelph, an MSc in Pharmacology and Toxicology from McGill University, and an eMBA from JMSB at Concordia University, as well as the RAC (US) credential from RAPS.

JJ is currently focused on CMC aspects of regulatory applications in Canada, pre-approval to post-market, as well as related areas such as Drug Establishment Licensing (DEL), Drug Shortages, New Substances Notifications for Organisms [NSN(O)], and Medical Device requirements. She has worked on innovative biologic medicines throughout her career. She is actively involved in several Health Canada policy activities, with the Innovative Medicines Canada (Quality group) and BIOTECanada (Biologics Regulatory Affairs Group).