Hugo Hamel

ASSOCIATE DIRECTOR, CBBB, BRDD,
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Hugo Hamel graduated from the University of Montreal with a B.Sc. in Biochemistry, an M.Sc. in Molecular Biology, and an M.Sc. in Pharmaceutical Sciences. He also graduated with an MBA in 2015.

Mr. Hamel spent the last 24 years working with the Biologic and Radiopharmaceutical Drugs Directorate (BRDD) at Health Canada as a Senior Evaluator in the Monoclonal Antibodies Division and Division Manager in the Radiopharmaceuticals and Monoclonal Antibodies (Inflammation) Division. He is currently an Associate Director with the Center for Blood, Blood Products, and Biotherapeutics at BRDD.

During his career with BRDD, Mr. Hamel was involved with reviewing the Chemistry, Manufacturing and Controls information pertaining to Clinical Trial Applications (CTAs), New Drug Submissions (NDSs) and Post-Marketing changes associated with Biotherapeutics. He also acted from 2005-2022 as the BRDD lead of the working group in charge of developing and updating the Canadian Post-NOC changes quality guidance and represented Health Canada on the WHO drafting group in charge of developing the WHO Guidelines on procedures and data requirements for changes to approved biotherapeutic products.

He is a member of the ICH Q12 IWG and leads its implementation in Canada. Mr. Hamel is also a member of the ICH M4Q EWG and led the implementation of the CTD guidance document for biotherapeutic and blood products at Health Canada. He is pleased to share his perspective on implementing these two important guidelines in Canada.