

Topic: Rare Diseases: Regulatory landscape and market access

Dr. Oxana Iliach, PhD, Senior Director, Regulatory Strategy. Certara

Dr. Iliach has about 20 years of experience in the healthcare industry including the last 15+ years in regulatory affairs. In the last 8 years she supported at least 25 rare disease drug developments by providing regulatory strategies with a focus on Chemistry, Manufacturing and Control (CMC). Oxana's specialty is global regulatory strategy for biologics, including cell and gene therapy products. Oxana has experience working with the FDA, EMA, Health Canada, and other smaller agencies.

She has a MSc in Chemistry and PhD in Pharmaceutical Science.

Oxana Iliach is a member of Canadian Organization for Rare Disorders (CORD). She is a vice-chair of Regulatory Scientific Committee at International Rare Disease Research Consortium (IRDiRC). She is also a part-time faculty at Northeastern University, Toronto Campus and a professor at Seneca College, Toronto, Canada



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TUESDAY, JUNE 17, 2025 8:00 am to 4:00 pm EDT **capra.ca**

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