



> THERE'S SOMETHING **GREATER** AT WORK HERE™



Associate Director, Regulatory Affairs – CMC (Home or office based in US or Canada)

Our team has an exciting opportunity for an Associate Director, Regulatory Affairs – CMC. If you have 8 - 10 years regulatory experience, including minimum three years managerial experience, expert knowledge in regulatory agency submission requirements, and experience in multiple jurisdictions (especially, US, Canada, Europe), we would like to speak with you! This key role would manage and ensure maintenance of a positive and productive liaison with internal and external contacts, including regulatory agencies, clients, and related institutions. They would also manage consulting group responsible for CMC, insuring the output meets appropriate quality standards, lead multiple CMC projects and manage CMC associates.

Other requirements include:

- Expert knowledge of legislation, regulations and guidelines pertaining to CMC submissions.
- In-depth knowledge of the practices of FDA, Health Canada, multiple European agencies and International Conference on Harmonization requirements.
- Ability to effectively negotiate with regulatory agencies (especially FDA, Health Canada and European agencies) in order to obtain desired outcomes.
- Excellent project management skills.
- Ability to interact with clients and to adapt to their priorities is essential.
- Minimum B.Sc. in Life Sciences; M.Sc. preferred. RAC Certification preferred.

OptumInsight is part of the family of companies that make UnitedHealth Group one of the leaders across most major segments of the US health care system.

OptumInsight is one of the largest and fastest growing health information companies. We specialize in improving the performance of the health system by providing analytics, technology and consulting services that enable better decisions and results.

Diversity creates a healthier atmosphere: equal opportunity employer M/F/D/V
UnitedHealth Group is a drug-free workplace.

Interested individuals, please email your MS Word resume to jennifer_schaible@uhc.com and reference "Associate Director, Regulatory Affairs-CMC" in the subject line.