Avyron Pharma
JOB DESCRIPTION

September 2026
Montreal Area, QC
Full-Time

Job Title	**Senior Regulatory Affairs Associate**
Department	Regulatory Affairs
Reports To	Director, Regulatory Affairs
Position Type	Permanent, Full-Time
Location	Montreal Area, QC
Schedule	Monday to Friday, 9 a.m. to 5 p.m.

Position Summary

Avyron Pharma is an early-stage Canadian generic pharmaceutical company. With a substantial product portfolio, the company is actively building out its corporate functions.

We are seeking a motivated and experienced **Senior Regulatory Affairs Associate** to join our regulatory team. Reporting to the Director, Regulatory Affairs, this role supports all regulatory activities with Health Canada. The successful candidate will play a pivotal role in coordinating regulatory submissions, managing regulatory documents and ensuring compliance with Canadian regulatory requirements.

Key Responsibilities

- Prepare, compile, and submit regulatory filings to Health Canada for a range of dosage forms, including NDS, S/NDS, ANDS, and S/ANDS.
- Collaborate with the Director, Regulatory Affairs to develop and implement regulatory strategies for product registration, labelling and post-market compliance in Canada.
- Review development documentation, identify gaps or weaknesses ahead of submission and work with stakeholders to resolve them in line with Canadian requirements.
- Prepare and provide expert guidance on product labelling, including Product Monographs and coordinate French translation.
- Maintain regulatory documents and submissions in accordance with company procedures and Health Canada regulations, ensuring accuracy, completeness and timeliness.
- Manage post-approval activities and filings to keep products in continuous regulatory compliance.
- Interpret Canadian regulations, guidelines, and policies, and provide clear regulatory guidance to internal stakeholders.
- Support interactions with Health Canada, including responding to queries, facilitating meetings, and assisting with inspections and audits.
- Work with internal and external stakeholders to obtain the documentation needed for submissions, represent the company's position, and remove obstacles to timely filing.
- Monitor changes to Canadian regulations and guidance affecting Avyron's product portfolio and advise the organization on their potential impact and required actions.
- Perform other duties as assigned by the Director, Regulatory Affairs.

Candidate Profile

Education & Credentials

- Bachelor's degree in life sciences, pharmacy, chemistry, or a related health sciences field; an advanced degree (e.g., MSc) is preferred.
- Graduate Certificate in Pharmaceutical Regulatory Affairs.

Experience

- Minimum of 8 to 10 years of experience filing regulatory submissions with Health Canada.
- Proven ability to manage multiple projects and prioritize workload in a fast-paced, results-oriented environment to ensure all deadlines are met.

Technical Knowledge

- Strong technical knowledge of CMC requirements and the ability to critically analyze and draw conclusions from scientific data.
- Expert knowledge of the Canadian Food and Drugs Act and Food and Drug Regulations, GMPs, ICH Guidelines, and Health Canada policies and guidelines.

Personal Skills & Attributes

- Strong interpersonal skills and the ability to independently build strong working relationships with key internal and external stakeholders.
- Excellent organizational, written and verbal communication skills.
- Strong commitment to quality, accuracy and attention to detail.
- Strong problem-solving, analytical and issue-resolution skills.
- Ability to work well under pressure in a team-based environment.

Language Requirements

- Proficiency in English.
- Knowledge of French is an asset.

What We Offer

- The opportunity to play a pivotal role in a growing Canadian pharmaceutical company.
- Competitive compensation, including a base salary and performance bonus.
- A flexible hybrid work environment based in Montreal.
- Competitive group insurance and benefits.

How to Apply.

Interested candidates are invited to submit their resume along with a cover letter describing their relevant experience to:

> **Sandeep Shrivastava**
> Director, Regulatory Affairs
> Avyron Pharma
> Subject: Senior Regulatory Affairs Associate Position
> hr@avyronpharma.com

Avyron Pharma is committed to the principles of employment equity and welcomes applications from all qualified individuals, regardless of gender, ethnic origin, disability, or any other ground protected by law.