



*The Source of BioProcess Efficiency*

Great opportunity to work for a market leader in the fast growing single-use bioprocessing industry. Our products include single-use mixing, storage, and bioreactor technology, fluoropolymer-based products, and custom engineered, flexible packaging solutions that maximize product integrity and enhance process efficiency for our biopharmaceutical customers worldwide.

ATMI promotes a culture that engages employees and fosters growth and development, while offering compensation programs that reward outstanding performance.

ATMI LifeSciences, a division of ATMI Inc, has manufacturing facilities in Hoegaarden, Belgium and Bloomington, Minnesota, USA.

Based in Hoegaarden, Belgium, we are looking for a

## SITE COMPLIANCE MANAGER

### **Job Overview:**

ATMI is seeking a Site Compliance Manager for our LifeSciences Quality Team. This is an excellent opportunity for a regulatory affairs professional to further develop the quality compliance and RA function in our cGMP manufacturing environment. In this role, you will have the opportunity to share your knowledge, be part of a dynamic team and experience and implement throughout the organization. You will report to the Quality Director

### **Primary responsibilities:**

- Provide scientific support and follow-up evolutions in the regulatory domain and compliance field in order to design, implement and manage company and manufacturing processes and procedures. This results in the assurance of consistent quality, provides competitive advantages and meets customer expectations.
- Representation of ATMI quality in all regulatory affairs matters with customers and authorities and/or notified bodies in close cooperation with operations and product management.
- Full management of all product specifications: change coordination both internally with product and manufacturing engineering teams and change notification to customers in conjunction with the sales team and product managers
- Lead shelf life & stability studies for raw materials, work in progress and finished products
- Take lead in creating, evaluating and approving of ATMI-quality agreements, closely working with the legal department

### **Education/experience:**

- Master Degree in Engineering or Pharmacy (ir, bio, biomedical, scientific, ...)
- Minimal 3 to 5 years experience in Regulatory Affairs or Quality in a cGMP environment
- Working experience in the pharmaceutical industry, work experience in a manufacturing environment is a plus.
- Flexible in working hours and the ability/willingness to travel on occasion.
- Perfect MS Office-skills, ERP knowledge is a plus.
- Experience with lean manufacturing and 6-Sigma methodology is a plus.
- Fluent in English and Dutch.



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**To be successful in this role and at ATMI you will need:**

- Ability to manage change through cross-functional partnering in an international work environment;
- Active listening and structured problem solving skills (written and verbal);
- Finding solutions, you combine creative and critical thinking;
- Able to develop relationships within a matrix and international organization;
- Strategic mindset and detail orientation;

***ATMI's Core Values revolve around its employee's ability to ACT IT:***

Be **Accountable** for your work and responsibilities.

Always works towards **Continuous Process Improvement**.

Be prepared to **Teach** and lead the organization to achieve new levels of success.

Always act with **Integrity**.

Maximize the value of **Teamwork**

**Interested?**

Please apply online through the "Careers" section of our website [www.atmi.com](http://www.atmi.com).

Questions can be send to [hr\\_belgium@atmi.com](mailto:hr_belgium@atmi.com) .

Please always indicate the job title, followed by your name as the reference.

*Essential functions are the primary job responsibilities which an employee must be able to perform with or without reasonable accommodation. The list of requirements, duties and responsibilities is not exhaustive, but is the most accurate list for the current job. ATMI reserves the right to revise the job description as well as to require that other task be performed when the circumstances of the job changes.*

*Please only apply if you are authorized to work in Belgium.*