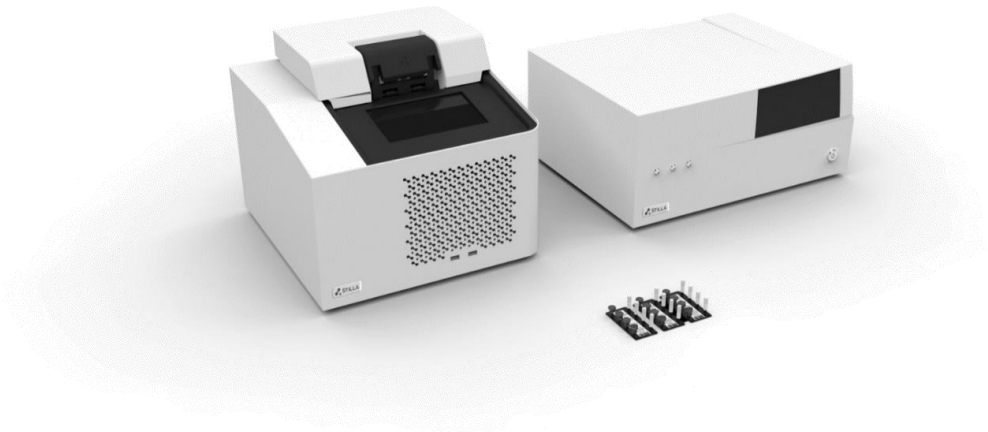
Stilla is hiring a Quality & Regulatory Manager

Who we are?

Stilla Technologies is a Paris-based "tools for Life Sciences" company that helps scientists to build the future of medicine.

Since 2016, Stilla Technologies has been providing research organizations specialized in molecular biology and genetic analysis with its Naica™ System, a ground-breaking digital PCR solution that enables scientists to detect and quantify DNA mutations with unrivalled precision.

With the Naica System, researchers worldwide are developing a new generation of high-precision genetic tests, in various fields of applications such as liquid biopsy tests for cancer diagnostics, non-invasive prenatal testing or GMO detection.



After closing a 16 M€ Series A funding round in November 2018, Stilla is scaling its operations worldwide and prepares to enter the clinical market.

Stilla's talented and multidisciplinary team shares a passion for building successful Life Science products based on deep technological innovations. We are pursuing a huge potential market and aim to become the new leader in the exciting field of precision genetic analysis. If you are interested in knowing more about the company & the team, go on our Welcome Page !

Stilla is hiring a Quality & Regulatory Manager to drive the transition of the company toward the clinical market.

Our ideal candidate:

- Has 10+ years of experience in an industry with strong regulatory constraints, ideally in IVD
- Has one or more successful experiences implementing Quality Management Systems (QMS) compliant with ISO 13485 and compatible with continuous improvement of products and processes
- Has ideally built a QMS from scratch
- Has a deep knowledge of ISO 14971, Directive 98/79/EC and/or Directive 93/42/EEC, including the imminent regulatory changes (Regulation 2017/746) and ideally their equivalent FDA standards
- Has one or more successful experiences getting products CE-IVD certified and/or FDA cleared and/or China-FDA cleared
- Has successful experiences negotiating Quality Agreements with key suppliers
- Has experience managing and coordinating teams
- Must speak French and English fluently

Missions for the Quality Manager

The Quality & Regulatory Manager ensures Stilla's transition toward the clinical market. He/she drives the implementation of the Quality Management System and coordinates with external partners for regulatory compliance. He/she is responsible for the certification of the Naica system for diagnostic use in Europe, the USA, and Asia.

1. Put in place a Quality Management System compliant with ISO 13485

   - Define and maintain Stilla's Quality Policies and Quality Manual in collaboration with the Management
   - Identify and prioritize actions to put in place a QMS, more particularly:
     - Design processes structure and key performance indicators with identified pilots
     - Organize and optimizin document management, non-conformities and CAPAs
     - Record and coordinate the resolution of quality issues (complaints, non-conformities) with CAPAs follow-up
     - Plan, perform and coordinate internal audits (including suppliers') as well as external audits (from customers, notified bodies or regulatory authorities)
     - Ensure regulatory and standards watch
     - Evaluate suppliers in collaboration with Purchasing and R&D department
     - Prepare and coordinate the management review of the QMS
   - Make all existing processes, methods and tools compliant
   - Coordinate and train teams to put in place and comply with the QMS
   - Monitor and report progresses

2. Ensure regulatory approval for the Naica system

   - Coordinate with external partners for quality and regulatory assurance
   - Provide expertise and training to the teams regarding the regulatory requirements
   - Participate in the definition of product intended use, positioning and claims from RUO to IVD, and ensure its consistency with product risk analysis
   - Put in place Product Life Cycle management tools and Change Management tools
   - Coordinate and train teams to perform product risk analysis including change control
   - Source and manage external partners to help certify the Naica system
   - Negotiate quality agreements with key suppliers
   - Prepare and collect all documents required for CE-IVD certification of instruments, consumables, software and assays/kits
   - Maintain technical documentation to regulatory and standards state-of-the-art, as well as change management

Why join us?

- Drive the company toward the clinical market and derisk its operations in a challenging environment!
- Join a young and dynamic Life Science company growing at a 3-digit pace!
- Work with a team who shares a passion for building successful Life Science Products based on deep technological innovations.

Location:
Main office: Paris
This position involves physical activity such as travel

How to apply?
Send your resumé and cover letter to **:** jobs@stilla.fr

All qualified applicants will receive consideration for employment without regard to race, sex, color, religion, sexual orientation, gender identity, national origin, protected veteran status, or on the basis of disability.