Disphar International is looking for a

(CMC) Manager Regulatory Affairs (full time, 0.8 FTE possible)

You will work in a team of RA colleagues and you will work closely with other departments within Disphar: QA, Supply, R&D. We are interested in candidates that either have a strong background in procedures, managing a lot of activities at the same time or candidates that have a strong background in CMC.

Disphar is a developer of generic products, which are licensed out to clients worldwide. The RA department takes care of the contacts with clients: dossier audits, initial applications, life cycle maintenance.

Next to the Disphar RA activities, the central RA function for Nordic Group is also part of the RA department at Disphar. Nordic Group is an ambitious, innovative and fast-growing European pharmaceutical group, its headquarters are located in Paris. Nordic focuses on niche products for the hospital market in several therapeutic areas (oncology, hematology, critical care, GI and gynecology).

The Regulatory Affairs Department consists of 13 people and is responsible for all regulatory activities to register and launch Nordic and Disphar's products.

Position
You will be reporting to the Director Regulatory Affairs.

The CMC Manager Regulatory Affairs:
- takes part in the product development project teams for regulatory scientific support on CMC
- works on CMC strategic aspects for new product developments and existing products
- compiles or supervises the compilation of the CMC dossier (Module 3, Quality Overall Summary, IMPD)
- answers questions from health authorities

The Manager Regulatory Affairs:
- supervises submissions of initial MAAs, duplicates, variations, renewals, PSUR submissions, etc by our clients
- supports our clients in all these activities and is their contact person
- works on regulatory strategy for new product developments and existing products
- answers questions from health authorities

For both functions we expect
- BSc or MSc (Chemistry, Physics, Pharmacy, Analytical Chemistry or Life Science) preferred.
- Several years of experience in RA
- Good command of the English language, both spoken and written.
- Good writing/editing skills
- Good communication skills
- Out of the box thinking
- Enthusiastic and flexible personality and a real team player
- Good organization skills, accurate, hands on mentality

Response
Interested? Please send your Curriculum Vitae and letter of motivation to Disphar International BV, f.a.o. Marcella Brouwer-Davidis, Director Regulatory Affairs, Postbus 17, 3740 AA Baarn or per e-mail to brouwer@disphar.com.

For further information, please contact Marcella (035-5280400). More information on Disphar International B.V. and Nordic Group can be found at www.disphar.com and www.nordicpharmagroup.com.