



Assignment Brief
for the position
of
Associate Director,
Clinical Operations Europe
Ref: AQ1675

Prepared by:

Astralis Group Plc
New Barnes Mill
Cotton Mill Lane
St Albans
Herts.
AL1 2HA

Tel: + 44 (0) 1727 86 70 70

Dr Grant R Coren
grant.coren@astralisgroup.com
June 2008

The Organisation

Committed to Improving the Lives of Patients Worldwide

Celgene Corporation, a uniquely positioned entrepreneurial biopharmaceutical company, and its employees are working relentlessly to provide novel solutions for unmet medical needs in cancer and debilitating inflammatory diseases. Their goal is to provide next-generation innovative therapies that deliver quality outcomes for better healthcare. Celgene is dedicated to improving healthcare by delivering more disease-altering therapies to patients in need. In fact, there are more than 200 ongoing clinical trials at major medical centres worldwide using innovative compounds from Celgene. These promising drugs include many high-potential compounds in their rich and diverse regulatory pipeline. These investigational compounds may address immediate medical needs of patients with incurable haematological and solid tumour cancers, including multiple myeloma, myelodysplastic syndromes, chronic lymphocytic leukaemia (CLL), non-Hodgkin's lymphoma, glioblastoma, ovarian, pancreatic and prostate cancer.

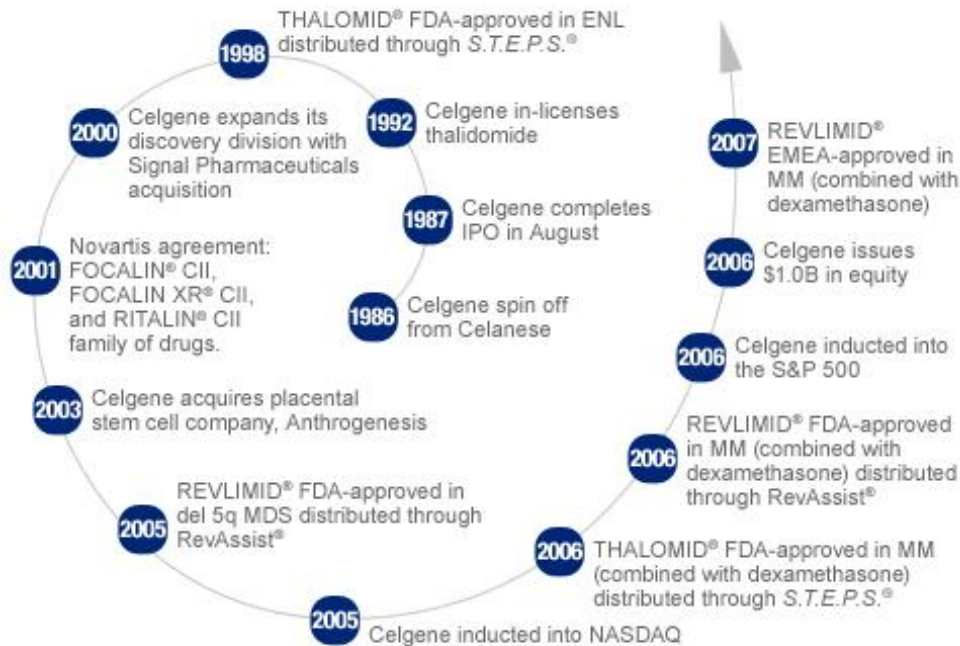
Celgene is committed to improving the lives of patients worldwide. By utilising the latest advances in molecular and cellular research to develop novel therapies that target the mechanisms of disease at their source, Celgene is making potentially life-saving treatments a reality for the millions of patients around the world fighting cancer and other debilitating diseases.

Celgene has built a commercialisation, development, and discovery platform for drug and cell-based therapies that allows them to both create and retain significant value within their therapeutic areas of cancer and inflammatory diseases. This target-to-therapeutic platform integrates both small molecule and cell-based therapies and spans the key functions required to generate a broad, deep and diverse pipeline of new drugs and cell therapy candidates, including:

- cell biology, genomics, proteomics and informatics technologies for identifying and validating clinically important therapeutic targets;
- high throughput screening systems combined with diverse and focused compound libraries for discovering new drug leads;
- computational and medicinal chemistry for optimizing drug candidates;
- in vitro and in vivo models of disease for preclinical evaluation of drug efficacy and safety; and
- a clinical and regulatory organisation highly experienced in the successful development of pharmaceutical agents.

The ongoing development of immunomodulatory agents, cell-signalling inhibitors, as well as cellular and tissue therapeutics may allow us to provide physicians/clinicians with a more comprehensive and integrated set of therapeutic solutions for managing complex human diseases such as cancer and inflammatory-related diseases.

Celgene History



- Celgene was initially founded as a unit of the Celanese Corporation in 1980. However, following the 1986 merger of Celanese Corporation with American Hoechst Corporation, Celgene was spun off as an independent biopharmaceutical company.
- In July 1998, the company received approval from the FDA to market [THALOMID®](#) (thalidomide) for the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL). [THALOMID](#) is not indicated as monotherapy for such ENL treatment in the presence of moderate to severe neuritis. [THALOMID](#) is also indicated as maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence. In May 2006, Celgene received approval for THALOMID in combination with dexamethasone for the treatment of patients with newly diagnosed multiple myeloma.
- Over 145,000 patients have been prescribed the innovative product, [THALOMID](#) (thalidomide), through Celgene's patented S.T.E.P.S.® (System for Thalidomide Education and Prescribing Safety) delivery program. Designed in collaboration with the FDA for the restricted distribution of [THALOMID](#), S.T.E.P.S. involves four of the 830 pending and issued patents in our expanding intellectual property estate.
- In April 2000 an agreement was reached with Novartis Pharma AG to license d-MPH our chirally pure version of RITALIN®. The FDA subsequently granted approval to market d-MPH or [FOCALIN®](#) in November 2001.

- With products on the market, Celgene completed a merger with Signal Pharmaceuticals, Inc., a privately held biopharmaceutical company focusing on the discovery and development of drugs that regulate genes associated with disease.
- On December 31, 2002, Celgene acquired Anthrogenesis Corporation, a privately held New Jersey based biotherapeutics company and cord blood banking business, which has also pioneered the recovery of stem cells from human placental tissue following the completion of a full-term, successful pregnancy.
- In December 2005, Celgene received approval from the FDA to market [REVLIMID](#)[®] (lenalidomide) for the treatment of patients with transfusion-dependent anaemia due to Low- or Intermediate-1-risk MDS associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.
- In June 2006, the FDA approved [REVLIMID](#) in combination with dexamethasone for the treatment of multiple myeloma patients who have received at least one prior therapy. [REVLIMID](#) is only available through a restricted distribution program called RevAssist[®].
- Celgene is now an integrated biopharmaceutical company focused on discovering developing and commercialising innovative therapies to treat cancer and inflammation through gene and protein regulation.
- In March 7, 2008 Celgene announced the completed acquisition of Pharmion Corporation, setting the stage for Celgene as a global leader in hematology/oncology and brings together three medically meaningful therapies, Revlimid(R), Thalomid(R) and Vidaza(R), treating patients worldwide. These products are expected to generate multiple global revenue streams for accelerated financial growth as Celgene plans to move into nearly 100 countries over the next five years and beyond.”

Driving the commercial success and profitability of the company are marketed products, which include Thalomid[®] (thalidomide), Alkeran[®] (melphalan), Focalin[™] (dexmethylphenidate HCl), cellular and tissue therapeutics, as well as the Ritalin[®] family of drugs. The company's strong, growing revenue base will provide the financial strength to propel the successful development of new products for multiple indications that Celgene is committed to introduce over the next several years.

Celgene invests over 40% of its total revenue in the R&D that is essential to its future success. This significant investment clearly demonstrates its commitment to successfully expand the company's profitable commercial franchises, advance its development pipeline, and discover new classes of compounds with meaningful medical benefit. The company's broad, deep and proprietary pipeline of seventeen product development programs spans all phases from preclinical to Phase III and will soon extend to Phase IIIb. Celgene's growth and success is being driven by continued R&D investment and recent extremely positive results with their lead investigational development compound, Revlimid[®].

Job Description

Primary Purpose of the Role

Celgene have recently established their International headquarters in Neuchâtel, Switzerland and are seeking to further develop clinical operations capability.

Having enjoyed tremendous success commercially and from a research perspective their pipeline is extremely healthy. As an organisation, a significant proportion of Celgene's clinical research is outsourced. We are currently seeking to recruit clinical research professionals with the experience, vision, drive and determination to add value to these research programmes and enhance Celgene's product development success.

The position calls for a team player with well developed clinical operations and project management experience, strong cultural awareness, confidence in your own position and able to manage internal and external resources.

Critical to success of this role, therefore, will be the ability of the selected candidate to further enhance the reputation of the European business and the value of Europe's contribution, through both internal and external relationships.

In return, Celgene can offer the right individual a growing environment, with a positive culture where you will be able to take a highly visible role with the opportunity for personal development and growth coupled to the ability to assist in influencing, shaping and developing the clinical research expertise in line with the continued expansion of the Celgene business.

Core Responsibilities

Responsibilities will include, but are not limited to, the following:

- Overall strategic management for the planning, execution and reporting of multiple clinical programs (phases I – III) needed to support INDs, SNDAs, NDAs with focus on execution, administration and organization.
- Draft protocols in cooperation with medical staff and statistics group. Set project goals, develop feasibility assessments to plan for accurate number qualified of investigators for study conduct to support clinical development plans.
- Oversee Clinical Operations Managers and assure adherence to high quality GCP standards for studies. Must participate directly in all study activities as necessary.
- Participate in drafting/review of integrated clinical study reports, annual reports, Investigator Brochure updates.

- Develop, track and administer budgets, FTE requirements, and schedules with responsibility for cost, time and quality of clinical operations activities. Must be able to anticipate deviations, and inform management with proposed corrective actions.
- Prepare RFPs, and participate in the identification, selection and oversight of Contract Research Organizations, central laboratories, IVRS vendors for outsourced programs.
- Participate on project and clinical teams serving as key liaison to project managers.
- Interface with all drug development personnel to ensure timelines are met, conflicts resolved and projects are on time and on budget.
- Provide guidance and expert advice in the areas of SOP development and clinical research regulations

Person Specification and Competencies

- Advanced degree (or equivalent experience) in a relevant scientific discipline, with significant clinical operations and clinical research management experience.
- Demonstrated management skills and experience, with success in executing clinical research projects
- Excellent written and verbal communication skills and interpersonal skills. Must be able to relate effectively to people at all levels of the organization.
- Computer literate; familiarity with Microsoft Office programs, in particular, Microsoft Project (or similar planning/tracking software).
- Clinical project management skills
- Knowledge of clinical trial design, basic statistics and pharmacokinetics a plus
- Familiarity with all other aspects of the drug development a plus
- Demonstrate commitment, dedication, co-operation, positive behaviour, adaptability and flexibility with changes in responsibilities and duties

Experience

- Degree and advanced degree in Life Sciences
- Significant clinical operations experience, clinical research management experience and expertise within the Oncology therapeutic area

Package

An attractive salary and benefits package will be offered, commensurate with experience, for the right candidates.

This will include relocation costs, where appropriate.

The package is negotiable, based upon the level of experience of the individual.