

**Assignment Brief**

**for the position of**

**Vice President Clinical Operations  
Europe**

**Ref: PSL4010**

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## The Organisation

Founded in 1974, by Bernard Jambon and JL Menard, MAPI Group has grown both organically and through acquisition over the past 35 years. Today, MAPI Group employs over 450 people in North America, Europe and Asia.

MAPI is structured into three divisions which comprise a number of separate legal entities:

### ■ Late Phase CRO

- Phase IV Clinical Trials
- Observation and Registries studies
- Risk Management Plan
- Direct Patient Management

### ■ Strategic Consulting

- Market Access
- Patient Reported Outcomes
- Regulatory Affairs & Quality Management

### ■ Linguistic Validation

- Patient reported and clinical assessments for appropriate cross-cultural use and interpretation

A separate entity, the MAPI RESEARCH TRUST is non-profit association concerned with the promotion of PRO evaluations and worldwide distribution of information concerning these measures.

The MAPI Group consists of a number of companies, all dedicated to providing unique solutions to aid and improve drug development to meet patient and market needs.

MAPI group anticipates change and develops services and solutions designed to respond to a full range of evaluation needs. Their experience comes from extensive partnerships with industry, health authorities, investigators and patients.

MAPI Group's strength lies not only in its breadth of experience and expertise, but in the total dedication to research conducted by dynamic, specialised teams, backed up by powerful technical and logistics support.

## Late Phase CRO

### REGISTRAT-MAPI



REGISTRAT-MAPI is the industry's largest clinical research organisation dedicated solely to "real world" clinical research. Successfully drawing upon their strategic and operational expertise to design and conduct global late phase studies and to develop partnerships with biopharmaceutical and medical device company clients.

As the demand for Late Phase development grows significantly both in size and complexity, REGISTRAT-MAPI continues to lead the way through innovation in registries, safety studies and product utilisation studies.

With its head office in Lyon, France and further operations throughout Europe and United-States, REGISTRAT-MAPI specialise in:

- Phase IV Studies
- Pharmaco-epidemiological Studies
- Risk Management Programs
- Disease and Product Registries

#### Providing a complete **Spectrum of Integrated Late Phase Services** :

- Strategic Consulting Services
- Risk Evaluation and Medical Strategies
- Optimal Study Design
- Multidisciplinary Excellence in Patient Reported Outcomes
- Multi-country Regulatory Management & Ethical Submissions
- Accurate Implementation Process & Project Management
- In Fine PHARMA : network of 2000 pharmacists in France
- Remote and on-site monitoring
- Tailored integrated EDC & Call Centre solutions
- Data Management Services
- Late Phase oriented Statistical Methods
- Medical Writing, Publications
- Integrated Technologies

Evidence-based research is increasingly desired by pharmaceutical companies due to recent FDA and EMEA initiatives as well as changing requirements from health care payers (government and private insurers). The market for phase IV post-approval research is estimated at \$12 billion and growing at 23% per year<sup>1</sup>. REGISTRAT-MAPI is currently the market leader in France and a major player in Europe in Late Phase studies (Phase IV and Observational).

Given REGISTRAT-MAPI's leading position in Europe, unique range of expertise and experience already gained through its numerous key clients, the Group is well positioned to win large scale international studies, negotiate preferred provider agreements and become a leading global player in the Late Phase segment.

## Strategic Consulting

The strategic Consulting companies offer a wide range of services with recognised experts in each domain including market access, patient reported outcomes (PRO), pharmacoepidemiology, risk management, signal detection and regulatory affairs & quality management. It is comprised of six companies:

### Mapi Values:



A global leader in developing, substantiating, and communicating evidence-based value to support the successful development of pharmaceutical products Led by Patrick Marquis a member of the European Regulatory Issues on Quality of Life Assessment (ERIQa), MAPI Values employs 90 staff in the UK, The Netherlands, France, the USA and Japan. MAPI Values offers a complete range of health economics and patient reported outcomes (PRO) services across all phases of pharmaceutical, biotechnology and medical device development and commercialisation in a joint venture with the Adelphi Group.

### JNBD:



Founded in 1992 and acquired by MAPI in 2007, JNBD is a regulatory, market access and quality specialist for drugs, medical devices and diagnostic tests. Their services cover total product life and positioning, developing strategy and health care systems, including market access and regulatory and pharmaceutical affairs support.

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<sup>1</sup> Source: Cutting Edge Information 2007

## Linguistic Validation

### MAPI Institute:



Is a world leader in the field of linguistic validation, providing multilingual translation using rigorous methodology developed from many years experience. In-house knowledge of 20 languages and a worldwide network comprising 230 consultants support the delivery of a number of key services including:

- Linguistic validation of PRO and CRO instruments: 500 instruments into 110 languages
- Translational Assessment
- Preparation of manuscripts
- Formatting and printing

### Mapi Research Trust:



Is a non-profit organisation serving the information needs of research scientists, biopharmaceutical companies and governmental health agencies, on a global basis. MRT specialises in providing reliable, comprehensive and up to date information services within Patient-Reported Outcomes and Pharmaco-Epidemiology.

## Context of the Role

It is widely recognised that the demand for CRO services will continue to grow over the coming years with some predicting that this will be as much as 20% per annum<sup>2</sup>

The market for Phase IV post-approval research is estimated at \$12bn and growing by 23% per year<sup>3</sup>.

REGISTRAT-MAPI is uniquely positioned to take advantage of this growth for several reasons:

- They have an established infrastructure which is required to perform large, multinational observational studies and registries.
- They have more than two hundred specialist employees in ten locations and have successfully conducted studies in over 32 countries.
- Having completed the acquisition of a U.S late phase company will mean significantly increased resources and late phase expertise globally, and specifically within the US market place.
- MAPI Group has pursued an acquisition strategy and partnered with companies that have enabled them to incorporate many ancillary services to their product and service offering without compromising their quality.
- REGISTRAT-MAPI has an enviable track record in the design conduct and analysis of late phase studies which provides an excellent platform for further new business generation.
- Access to other MAPI Group company expertise provides a rich source of complementary capabilities

For further information please review the company and group websites at:

- [www.registratmapi.com](http://www.registratmapi.com)
- [www.mapigroup.com](http://www.mapigroup.com)

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<sup>2</sup> Tufts Center for the Study of Drug Development Outlook 2008

<sup>3</sup> Cutting Edge Information 2007

## Job Description

- Working closely as a key member of the organisation's Executive Leadership Team and reporting to the CEO Europe, the Vice President Clinical Operations, Europe is responsible for operations in Europe and affiliated territories outside of North America.
- Responsibilities include the strategic development, implementation and oversight of international Operations to ensure growth, profitability, quality and customer service goals are achieved. The position also ensures appropriate standards, policies, systems and procedures are in place to drive the required levels of performance, continual improvement and compliance throughout operations.
- The VP European Operations works in partnership with other functional leadership at regional and global levels to support the worldwide harmonisation of operations consistent with the direction of a global, integrated CRO.
- The position provides management and direction for all planning and control of European Operations activities, including employment, promotion, performance management, training and counselling of Operations staff.

## Primary Purpose of the Job

### Leadership (General)

- Drives international project/operations strategy and oversight and participate as part of the senior management team in both short and long-term strategic planning for Operations.
- Provides regional management and operations staff with leadership, support and guidance on operational issues (internal and external).
- Fosters a supportive and inclusive working environment through individual leadership and effective teamwork.
- Drives local and international growth for the business and individuals within the business, creating shared best practices whilst recognising international differences.

### Customer facing/Sales

- Interacts with senior client management to provide senior point of contact to promote relationship health and resolution of operational issues.
- Participates in sales and marketing activities including attendance at customer meetings to ensure Operations and the broader REGISTRAT MAPI business are represented and presented well.
- Provides input to, and review/approval of, bid proposals and contracts.

## Operations Management

- Works with the CEO Europe and Finance staff, in preparing, implementing, and managing budgets and staffing for Clinical Operations.
- Engages appropriate internal and external resources to support project strategy and operations plan development.
- Maximizes profitability through superior customer service, effective and prompt communication, and follow-up/resolution of customer issues.
- Coaches, trains and mentors operations staff .
- Supports and/or conducts annual performance reviews for appropriate staff.
- Utilizes superior communications skills to reinforce REGISTRAT MAPI values and culture, motivate staff and develop effective working relationships with customers, within functions, project teams, and across the region.
- Ensures compliance of Operations with company policies and procedures as well as other applicable rules, guidelines and codes of practice required by regulators or law.
- Reviews analysis of activities, costs, operations, and forecast data to determine progress toward business and functional goals and objectives. Initiates action as required to ensure success.
- Implements a philosophy and practice of continual improvement
- Maintains and improves structures and systems by which third party relationships are managed to ensure quality of sub-contracted services.

## Profile

### Education & Experience:

- A degree level qualification in the life sciences, nursing, or equivalent, plus demonstrable operations leadership experience (10+ years) in clinical trials including previous CRO experience. The candidate must be able to demonstrate experience which has been specifically gained in relation to the Late Phase trial environment.
- A solid understanding of strategic planning, management and financial fundamentals.
- Excellent leadership and decision making skills are required, along with the ability to understand, organise and supervise staff to work concurrently on several projects with differing requirements.
- Business development and customer relationship management experience
- Proven track record of successfully leading and line managing reports and teams on a distributed/international basis.
- A solid understanding of all aspects of clinical development, including applicable regulations, guidelines and practices (including the late phase setting)
- Good intercultural sensitivity and previous experience of working internationally, ideally including integration experience.
- A team player with excellent communication skills and with a track record of success in building effective internal and external (customer & third party) relationships.
- Well developed analysis, planning and tracking skills with a demonstrable understanding of the importance of effective planning and tracking in resource management.
- Requires presentation, documentation, technical and interpersonal skills commensurate with senior leadership position
- Requires a willingness to travel domestically and internationally.

## Skills

- **Conceptual and Execution Skills:** Proven ability to design and grow a successful business model on a multi-country basis.
- **Analytical skills:** Experience in dealing with ill-defined, ambiguous or evolving information to reach sound conclusions and decisions.
- **Organizational skills:** Can demonstrate prior success in effectively organizing people and responsibilities to achieve growth and/or profitability.
- **Communication skills:** Demonstrates excellent communication written and verbal skills.
- **Leadership:** Effectively communicates goals, principles and values to inspire & guide people in attainment of individual and team goals.
- **Integrity:** Demonstrates ethical business practices and holds people accountable for ethical action.
- **Team Player:** Demonstrates successful, positive participation on teams, as a team player and as a leader.
- **Communicator:** Is observed to share information positively, accurately and effectively with others. Naturally keeps others informed. Ensures best practices are transferred beyond their point of origin.
- **Mentor/Teacher:** Demonstrates an ability to listen and impart knowledge effectively. Helps others grow and develop.
- **Facilitator:** Has history of helping diverse groups accomplish goals in a positive manner. Effectively removes barriers impeding progress or success
- **Problem Management:** Can effectively handle difficult internal and external issues and bring to satisfactory resolution or closure
- **Language Skills:** ability to communicate, both written and spoken, in English and French will be critical to your success.

## Package

- Salary package commensurate with experience.
- Bonus plan
- Contributory pension
- Health insurance
- Life Assurance
- Holiday