RESUMEDS

8888 Alvarado Street, Los Angeles, California 90026 ☎ 234.567.8888 234.567.8888
contact@resumeds.com

EXECUTIVE DIRECTOR OF MEDICAL AFFAIRS

Accomplished, seasoned, and focused professional with more than 25 years of expertise in leading medical operations in the pharmaceutical industry. Empowered with unparalleled work ethic and organizational skills to efficiently manage priorities and large-scale operations. Recognized for dynamic leadership talents and adeptness in managing group dynamics, as well as in motivating high-caliber teams of professionals. Equipped with analytical problem-solving aptitude to formulate strategic solutions to complex business and medical situations. Armed with articulate communication and interpersonal proficiencies essential in establishing positive work relationships with professionals of all levels of the business. Fluent in English and Italian languages. Proficient with Microsoft Office Suite and Adobe PageMaker.

AREAS OF EXPERTISE

Regulatory Intelligence and Compliance ~ Global Clinical Research Planning and Management
Global Medical Operations Management ~ Clinical Development ~ Marketing Support

PROFESSIONAL EXPERIENCE

RESUMEDS ▪ LOS ANGELES, CA (1999–PRESENT)

Executive Director – Medical Planning and Management ***Head of Magnetic Resonance Imaging (MRI) Product Line and Global Medical and Regulatory Affairs***	***2012–Present***
Executive Director – Corporate Medical Planning and Management, MRI Product Line, and Worldwide Medical and Regulatory Affairs	***2009–2012***
Executive Director – Head Medical Development	***2007–2009***
Senior Director – Corporate Medical Planning and Management	***2005–2007***
Director – Corporate Medical Planning and Management	***2002–2005***
Director – Clinical Development and MRI	***2001–2002***
Associate Director – Clinical Development	***2000–2001***
Associate Director – Clinical Development (Transfer)	***1999–2000***

- Examine regulatory trends and capability as well as regulatory agencies intentions related to the usage of medical imaging in clinical research to determine opportunities for new ventures and developments
- Develop and provide medical assistance during Phase I–IV clinical studies to resolve safety and efficacy issues
- Formulate strategic clinical solutions and development plans for new contrast agents
- Participate and assist with various medical education programs and initiatives
- Take charge of managing publication plans and scientific communications, including preparation of abstracts and posters, manuscripts for peer-reviewed journals, and presentations at medical symposia and congresses
- Preside over the operations of the Global Investigator Initiated Research Committee and the Extramural Research Committee, including scientific study of proposals done by academic investigators
- Supervise international clinical working groups, including clinical research personnel, data managers, statisticians, and medical writers in developing contrast agents
- Render expert oversight to all corporate medical and clinical research teams, including project delegation and management and performance evaluation
- Direct the contract research organizations operations, including clinical laboratory investigations, imaging management, and core laboratory management for electrocardiography (ECG)
- Devote efforts in overseeing marketing support operations, including medical marketing researches, product launches, and scientific material evaluation for marketing activities
- Facilitate medical evaluation of study protocols, case report forms (CRFs), blinded read methodology and training manuals, eCRF development specification document, statistical analysis plans (SAPs), tables listings and figures (TLFs), and final clinical trial reports (CTRs)

- Collaborate with international opinion leaders in Europe, the United States, and Asia to organize advisory board meetings for international imaging projects
- Function as the clinical specialist in overseeing Due Diligence teams in evaluating in-licensing candidates
- Design and provide assistance with international trials through local corporate offices, licensing partners, or contract research officers (CROs)
- Organize and facilitate presentations at more than 40 regulatory meetings with the United States Food and Drug Administration (FDA) and European agencies, such as the European Medicines Agency (EMA), Medicines and Healthcare Products Regulatory Agency (MHRA), and the Federal Institute for Drugs and Medical Devices (*Bundesinstitut für Arzneimittel und Medizinprodukte* – BfArM)
- Formulate, assess, and improve clinical development programs and protocol guidelines for core phase I–IIIA clinical studies
- Conduct more than 50 presentations at international congresses, workshops, academic institutions, and meetings
- Author/co-author of over 40 manuscripts published in peer-reviewed literature
- Evaluate non-clinical study results and pre-phase I data for inclusions to clinical trials
- Assess and present medical issues which may possibly assist with the evaluation of compounds as possible medical imaging agent candidates
- Exemplify superior scientific and medical expertise to organize observational study protocols and support investigator meetings and trainings
- Demonstrate aptitude in providing medical and scientific support with the preparation of new drug applications (NDAs), common technical document (CTD), and various regulatory submissions, such as clinical pharmacology summaries, clinical safety and efficacy summaries, and clinical overview
- Interface with regulatory units across various counties for filing MR product, including Australia, China, Indonesia, New Zealand, the Philippines, and South Korea
- Draft and evaluate clinical trial reports as well as CTD and NDA documents
- Work with Discovery teams to outline criterions to serve as basis for the new chemical compound to be considered potential medical imaging agent candidates
- Play a contributing role in product training for the Sales force and Marketing personnel
- Maintain active involvement in the oversight of major safety issues for gadolinium-based contrast agents, including various meetings with the FDA and European authorities, which gave rise to global “no product contraindication”
- Host more than 50 presentations at academic institutions in Europe, Asia, and the United States to introduce new products

EARLIER CAREER

RESUMEDS ▪ LOS ANGELES, CA

Group Leader MRI

Body Imaging Area Manager

Clinical Monitor

RESUMEDS ▪ LOS ANGELES, CA

Manager of Medical Services

EDUCATION

Degree in Medicine University of Pavia ▪ Pavia, Italy

Thesis: *Metabolism of arachidonic acid in cerebral tissue of rats undergoing experimental subarachnoid haemorrhage*

National State Board Exam for Physicians

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TRAINING

2006	42nd Annual Meeting of Drug Information Association (DIA)
2000	36th Annual Meeting of Drug Information Association (DIA) Enhancing your interviewing competencies Beyond QT Interval: Pre-Clinical, ECG and Holter Advances in New Drug R&D Presentation Skills
1999	Communication Skills for Improved Teamwork and Better Results
1998	ICH/GCP
1997	Diagnostic Imaging: Advances and International Standardization in Compound Development and Diagnostic Procedures
1993	Course: The Mechanics of Preparing INDs and NDAs and Preparation for FDA Inspections
1992	Seminar on Project Management Training Course on Project Management (1st Part) Training course on Project Management (2nd Part)
1990	International Clinical Research Clinical Trials in Pharmaceutical industry Advanced Course Clinical Trials in Pharmaceutical Industry I Course Clinical Trials in Pharmaceutical Industry II Course Good Clinical Practice Clinical Toxicology and Drug Testing Good Clinical Practice
1983	COBOL – Language for programming Diploma

PROFESSIONAL AFFILIATIONS

Member, **Drug Information Association (DIA)**
Member, **American Roentgen Ray Society (ARRS)**
Former Member, **European Society for Magnetic Resonance in Medicine and Biology /ESMRMB)**
Former Member, **Italian Society of Applied Pharmacological Sciences (SSFA)**
Member, **International Society of Magnetic Resonance in Medicine (ISMRM):**
Perfusion Study Group | Molecular and Cellular Imaging Study Group | MR of Cancer Study Group
MR in Drug Research Study Group | Cardiac MR Study Group
Former Member, **Italian Society of Radiology (SIRM):**
Section of Contrast Media | Section of Magnetic Resonance Imaging
Section of Computed Tomography | Section of Uroradiology