



## Carlino Consulting

Joseph A. Carlino, Ph.D., Principal  
Drug Development and Project Management Consulting  
Biotechnology, Pharmaceuticals, and Devices

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### Services Provided Include:

- All aspects of project management support under time-critical circumstances such as project start-up or expansion, preparations for end-of-phase decisions, or loss of internal PM resources. Responsibilities may include: management and leadership of project teams; effective, real-time communication of project issues to senior management; corporate partner interactions; generation of timelines, budgets, and meeting minutes; timely completion of project deliverables; definition of metrics; and integration of activities across all functional areas. Extensive project management and scientific backgrounds help insure minimal “start-up” time required for effective project and team management.
- Support of corporate and project decision-making, portfolio reviews, and licensing opportunities. Guide, facilitate, and work alongside project teams and management to define, organize, write, and assemble project development plans, stage-gate documents, short-term resource requirements, and long-term project budgets, including buy-up and buy-down development options and analysis of alternative development scenarios.
- Prospective definition and implementation of project team structure(s) and development processes, as often needed with expansion of projects, based upon best-practice industry models, management interests, organizational expertise, and experience base of team. Responsibilities may include: definition and implementation of roles and responsibilities of Project Leaders, Project Managers, and functional area representatives; preparation of management committee charters and monthly project status reports; development of scientific, clinical, and corporate stage-gate criteria for portfolio decisions; linkage of corporate metrics with project team deliverables; and establishment of project-based, function-based, or top-down budgeting processes.
- All aspects of project-related corporate partner management. This may include coordination of integrated activities at both companies, oversight of contractual responsibilities, establishment of trust and cooperation, organization and leadership of joint project and management team meetings, quarterly reviews, face-to-face meetings, and annual budget reviews.
- Timely, clear, and objective communication of project-related progress and issues up to Senior Management, across to project team members, and down to bench-top scientists, technicians, and others.
- Definition and implementation of Project Management Office (PMO) systems and procedures such as those implemented in conjunction with the introduction of Enterprise Project Management Systems.
- Implementation of departmental and corporate initiatives. This may include activities such as developing the initiative from management's initial vision into an operationally effective plan, communicating the initiative's rationale to gain the input and buy-in of staff, and providing follow-up support to help insure long-term implementation and ongoing initiative development as needed.
- Facilitation of PM/PL organizational learning and professional development, such as implementation of drug development best practices, and peer discussions of project and organizational challenges.

## Joseph A. Carlino, Ph.D. – Overview of Qualifications

### **Education:**

1986 Ph.D., Columbia University, New York, NY, Pathobiology/Immunology  
1984 M.Phil., Columbia University, New York, NY, Pathobiology/Immunology  
1981 M.S. Long Island University, C. W. Post Center, Greenvale, NY. Biology  
1977 B.S., Muhlenberg College, Allentown, PA, Biology

### **Professional Experience:**

#### **Carlino Consulting, Drug Development & Project Management Consulting, 2005-present**

Independent Senior Consultant for biotech, pharma, and device clients

#### **Chiron Corporation, Emeryville, CA, 1996-2005**

From Sr. Project Manager to Sr Director, Development Management Dept.

#### **Celtrix Pharmaceuticals Inc. / Collagen Corp., Santa Clara, CA, 1987-1996**

From Research Scientist to Program Director/Sr. Scientist; Development Dept.

#### **Cetus Corporation, Emeryville, CA, 1985-1987**

Associate/Postdoctoral Scientist, Department of Cell Biology.

#### **Columbia University College of Physicians & Surgeons, New York, NY, 1981-1985**

Sr. Research Tech., Dept. of Medicine (full-time position held while in graduate school)

#### **Memorial Sloan-Kettering Cancer Center, New York, NY, 1980-1981**

Research Technician, Endocrine Biochemistry Laboratory.

#### **BioResearch Incorporated, Farmingdale, NY, 1977-1979**

Research Biochemist, Department of Biochemistry.

### **Project and Portfolio Management Responsibilities**

- Organization, leadership, and management of project teams, assignment of team responsibilities, achievement of milestones and critical go/no go decision points, and communication of project activities and issues throughout the corporate organization.
- Generation of 3-10 year development plans and TPPs for early- and late-stage projects.
- Coordination of internal & contracted project activities; use of all standard PM software
- Budget definition and management (up to \$50MM/annum); evaluation of in-licensing candidates
- Corporate partner management (e.g. GENZ, PFE, JNJ, CEPH, ROG.VX, BIIB, MLMN)
- Prep of IND and BLA sections, and participation in FDA meetings and calls.
  
- Preclinical** programs in Oncology, Restenosis, Chemoprotection, Osteogenesis, Osteoarthritis, IBD, Multiple Sclerosis, Xeno-transplantation, and Diabetes.
- Phase I & I/II** programs in Oncology (Multiple Myeloma and Solid Tumors), Psoriasis, Multiple Sclerosis, Acute Decongestive Heart Failure, Sepsis, Microvascular Surgery, Mucositis, Protein Wasting, and Peripheral Neuropathies.
- Phase II** programs in Dermal Wound Repair, MS, ALS, Diabetic Neuropathies.
- Phase III** programs in Sepsis, Migraine, Tumor-Assoc. Brain Edema, & Macular Holes
- Pre-NDA** programs in ALS and Migraine (drug-device combination).
- Registry** program in Acute Decongestive Heart Failure.
  
- Therapeutic Agents** include small molecules (CHIR-258, others), proteins (TFPI, TGF- $\beta$ , TNF, IGF-1, IGF-1/BP3, PDGF, M-CSF), peptides, ribozymes (Angiozyme), chemo-therapeutics and NCEs (cytarabine liposome, others), and mAbs (CAB2, anti-CD40, anti-IL2R).
  
- Twenty-four peer-reviewed scientific publications, six patents, and over one dozen presentations on drug development and project management.

*Full CV available upon request*