JOHN BOTHOS, PHD

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Raritan, NJ 08869

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SUMMARY

Experienced and driven Clinical Scientist with a strong scientific background. Brings operational excellence and a proven track record of success in the pharmaceutical and biotech industries. Extensive strengths in all facets of the clinical development of small molecules, large molecules, and medical devices in the Phase I/II clinical setting (design, operations, data collection, analysis and reporting). Expertise in the design and execution of global clinical trials in CV, Urology, Oncology, Neurology and Cartilage Repair. Professional, conscientious, focused and highly motivated leader delivering scientific research excellence with results-oriented intensity.

PROFESSIONAL EXPERIENCE

JOHNSON & JOHNSON, Somerville, NJ **2011 – Present**

Senior Manager, Clinical Sciences and Operations
Supervises 5 professionals within the clinical operations, data management and biostatistics groups; responsible for all aspects of trial design and conduct, as well as collection, analysis and reporting of clinical trial data for 2 clinical programs (pain management, cartilage repair).

- Generated and managed the execution of the clinical development program of a growth factor for the treatment of degenerative disc disease.
- Organized a national advisory board meeting and presented the clinical development plan of a cell-based therapy in ALS.
- Led the Clinical Data Repository (CDR) Initiative, which significantly improved medical review of clinical data as well as enhanced the forecasting capabilities of the Clinical Operations group.
- Managed budget and contracting requirements as well as oversaw the services of CROs and vendors utilized for the execution of the 2 clinical programs.
- Fostered relationships with key opinion leaders and academic institutions improving project communications.
- Created the publication plans for 2 clinical programs.

GENENTECH, South San Francisco, CA **2008 – 2011**

Clinical Scientist, Exploratory Clinical Development, Oncology 2009 – 2011
Accountable for all Clinical Sciences deliverables for clinical programs (Phase I-II), including authoring clinical trial protocols/ICFs/Investigator Brochures, developing clinical sections of IND applications/IND annual reports and contributing in interactions with regulatory agencies (FDA, MHRA, EU regulatory agencies), KOLs and cooperative groups.

- Developed protocol and oversaw execution of a PhII clinical study of a large molecule in NSCLC; enrolled 120 patients in 4 countries in ~1 year and achieved proof of concept within 18 months of protocol completion. Awarded by company for scientific contributions and leadership.
- Authored protocol and oversaw execution of a PhII study of a large molecule in 3N Breast Cancer; 120 patients in 4 countries.
- Filled an IND of a small molecule.
- Developed protocol and oversaw execution of a PhIb study of a combination of 2 new molecular entities (NME).
- Created the Imaging Charter, oversaw execution and analyzed data from the imaging sub-studies (FDG-PET) of 3 clinical trials.

Associate Clinical Scientist, Exploratory Clinical Development, Oncology 2008 – 2009
Accountable for all Clinical Sciences deliverables for clinical studies (Phase I-II), including authoring clinical trial protocols/ ICFs/Investigator Brochures as well as developing clinical sections of IND applications/IND annual reports; performed clinical review of data listings; organized and presented at Investigator meetings. Facilitated protocol training to sites/ monitors.

- Authored protocol and oversaw execution of 2 Phase I, dose-escalation clinical studies.
- Participated as the clinical representative in the Clinical Data Review (CDR) process development initiative; initiative created a process map that allowed a more efficient and effective collection and analysis of clinical data.

GLAXOSMITHKLINE, Philadelphia, PA **2005 – 2008**

Principal Clinical Research Scientist, Clinical Sciences and Study Operations (CSSO), 2007 – 2008
Clinical Pharmacology and Discovery Medicine (CPDM), CV/Urology
Led the operational management of clinical programs within the CV/Urology Pharmacology department. Secured and negotiated budget and resources for the implementation of clinical trials (PhI/II). Accountable for decision making during the progress of the clinical trials.

- Developed protocol and executed a Phase IIa, 120-patient, proof of concept international study of a small molecule in Dyslipidemia receiving company sponsored Silver Award for excellence.
- Authored and executed Phase I, healthy volunteer, pharmacology studies (first-in-human, drug-drug interaction, food effect, dose-finding, bridging studies).

Senior Clinical Research Scientist, Clinical Sciences and Study Operations (CSSO), 2005 – 2007
Clinical Pharmacology and Discovery Medicine (CPDM), CV/Urology
Managed the operations for clinical trials within the CV/Urology Pharmacology department; secured and negotiated budget and resources for the implementation of clinical trials (PhI/II); adjudicated the scientific and technical contributions of all relevant disciplines of a study (e.g., data management, pharmacokinetics, statistics). Reviewed and analyzed resultant data; oversaw and guided CRAs; project management of studies from initiation to completion.

- Created and executed Phase I, healthy volunteer, pharmacology studies (first-in-human, drug-drug interaction, food effect, dose-finding, QTc, bioavailability, bridging studies).
- Key member of an important initiative to execute clinical studies in developing countries (Latin America, Central Europe, Asia). Awarded by company for exceptional performance.
  - Studied the operational requirements to perform studies in these countries (e.g., regulatory environment, issues with drug importation/exportation of clinical samples, Ethics Boards).
  - Developed protocol and executed a Phase I, bioavailability study in Mexico as part of this initiative.

UNIVERSITY OF PENNSYLVANIA / THE WISTAR INSTITUTE, Philadelphia, PA **1998 – 2005**

Post-doctoral Fellow 2004 – 2005

- Investigated the molecular mechanisms of the LATS1 tumor suppressor gene in cancer development.
- Received NIH Radiation Biology Cancer Grant CA09677.

Graduate Student, Graduate Thesis Research, Cell Cycle and Cancer 1998 – 2004

- Studied the mechanism of action of 2 newly identified mitotic checkpoint genes.
- Received NIH Cancer Training Grant CA09171, 2000 – 2004.

ROWAN UNIVERSITY, Glassboro, NJ **1996 – 1998**

Research Technician, Department of Chemistry

- Biochemically investigated the physiological role of the Prostate Specific Antigen (PSA)

BIOTECHONOLOGY CONSULTING EXPERIENCE

- **PENN BIOTECHNOLOGY GROUP**: **Consultant / Project Manager**, 2004
  - Marketing consulting project for a medical information technology company, Hx Technologies Inc.
- **Consultant**, 2003
  - Provided external marketing analysis and evaluated the business plan and portfolio of an international biotechnology company, Cytorex Biosciences
- **Consultant**, 2001
  - Marketing analysis for a private biotechnology company, Integral Molecular

EDUCATION

- **PhD**, Cell and Molecular Biology, University of Pennsylvania, Philadelphia, PA, 2004
  - Concentration: Oncology and Cell Cycle Regulation
- **BS**, Biology, Minor: Chemistry, Rowan University, Glassboro, NJ, 1998
  - Graduated Summa Cum Laude; GPA 3.92
  - Rowan University Undergraduate Scholarships (1996, 1997); Dean's list for 6 consecutive semesters (1995 – 1998)

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ADDENDUM

PUBLICATIONS

- **Bothos, J.**, Tuttle R.L., Ottey M., Luca F.C., and Halazonetis T.D., "Human LATS1 is a Mitotic Exit Network kinase", Cancer Research, 2005, 65, 6568-6575.
- **Bothos, J.**, Summers, M., Venere, M., Scolnick, D.M. and Halazonetis, T.D., "Ubc13-Mms2 is the preferred ubiquitin-conjugating enzyme for the ubiquitin ligase activity of the Chfr mitotic checkpoint protein", Oncogene, 2003, 22, 7101-7107.
- Tuttle R.L., **Bothos, J.**, Summers, MK., Luca, FC, and Halazonetis T.D., "Defective in mitotic arrest 1/Ring Finger 8 is a checkpoint protein that antagonizes the human mitotic exit network", Molecular Cancer Research, 2007, 5 (12), 1304-1311.
- Summers, M., **Bothos, J.**, and Halazonetis, T.D., "The Chfr mitotic checkpoint protein delays cell cycle progression by excluding Cyclin B1 from the nucleus", Oncogene, 2005, 24, 2589-2598.
- Mariatos, G., **Bothos, J.**, Summers, M., Scolnick, D.M., Kittas, C., Halazonetis, T.D. and Gorgoulis, V.G., "Inactivating mutations targeting the Chfr mitotic checkpoint gene in human cancer", Cancer Research, 2003, 63, 7185-7189.
- Stavridi, E.S., Harris, K.G., Huyen, Y., **Bothos, J.**, Stayrook, S.E., Luca, F.C., Pavletich, N.P., and Jeffrey, P.D., "Crystal structure of a human Mob1 protein: toward understanding Mob-regulated cell cycle pathways", Structure, 2003, 11, 1163-1170.
- Yang, C. F., Porter, E. Kanyi, D., **Bothos, J.**, Hsieh, M-C and Cooperman, B.S., "Design of Synthetic Hexapeptide Substrates for the Prostate Specific Antigen Using Combinatory Library", Journal of Peptide Research, 1999, 54 (5), 444-448.

SCIENTIFIC MEETINGS

- Poster at the European Society of Molecular Oncology (ESMO) Annual Meeting, Milan, Italy, October 2010
- Poster at the American Association for Cancer Research (AACR) Conference, Washington, DC, April 2010 **– Blue Ribbon Award**
- Poster at the 20th European Organization for Research and Treatment of Cancer (EOR NCI-AACR) Symposium, Geneva, Switzerland, October 2008
- Poster at the Cell Cycle meeting, Cold Spring Harbor Laboratory, NY, May 2002
- Poster at the Cell Cycle meeting, Keystone Symposia, Taos, NM, January 2001

INVITED LECTURES

- Oral presentation at the Cell Cycle Meeting, Cold Spring Harbor Laboratory, NY, May 2000

CONFERENCES

- European Society of Molecular Oncology (ESMO) Annual Meeting, Milan, Italy, October 2010
- American Society of Clinical Oncology (ASCO) Annual Meeting, Chicago, June 2010
- American Association of Cancer Research (AACR) Annual Meeting, Washington, DC, April 2010
- San Antonio Breast Cancer Symposium (SABC), San Antonio, December 2009
- American Society of Clinical Oncology (ASCO) Annual Meeting, Orlando, May 2009
- American Society of Clinical Oncology (ASCO) Annual Meeting, Chicago, May 2008
- American Heart Association (AHA), Orlando, November 2007
- Drug Information Association Annual meeting (DIA), Philadelphia, June 2006
- Thorough ECG Trials and The Evolving Role of Cardiac Safety in Clinical Development, eResearch Technologies, Philadelphia, May, 2006
- The FDA, ECG and your future: Bringing the pieces together – Successful approaches to regulatory, technology and trial management within electrophysiology, MDS Pharma, Philadelphia, February 2006

ACTIVITIES

- Member of the American Society of Clinical Oncology (ASCO)
- Member of the American Association of Cancer Research (AACR)
- Member of the Upenn Tae Kwon Do team, 2000 – 2005
- Member of the Penn Biotechnology Group, 2000 – 2005