

Daniel B. DeOliveira, Ph.D., PMP

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SUMMARY

Senior Drug Discovery & Development Leader with extensive expertise in Project Management (PMP Certified) and in leading Internal and External (CRO/CMO) teams to achieve their goals. Effective at enabling cross-functional teams to work efficiently and collaboratively. Successful managing domestic and international teams to bring GMP manufacturing campaigns and R&D programs to successful endpoint. Experienced in peptides, small molecules, and bioconjugates R&D; especially in designing, producing, evaluating, developing and manufacturing products for use as therapeutics.

Disease Areas: Oncology, Endocrinology, Immuno-Oncology and Rare Diseases

Clinical Modalities: Classical API, Personalized Cancer Vaccines, Autologous Cell-Therapy and Radio-Theranostics

- Drug R&D Project Leadership & Management experience
- Internal & External (CRO/CMO) Project Management
- Coordinate Communication with Stakeholders / Sr. Mgmt
- Extensive personnel management (Matrix and Functional)
- Mentoring & Developing Group Members
- Leader, Influencer, Problem Solving & Negotiating skills
- Provide Cross-Functional Leadership & Alignment
- Identify, Track and Mitigate Risk
- Track Deliverables, Milestones & Budgets
- Development and Delivery of Project Strategy
- Alliance & KOL Management
- Experienced in CMC, IND and Regulatory filings

EXPERIENCE

Life Sciences Project Management; Bellingham, MA

2022 – present

Project Manager / Principal Consultant

Consulting with companies working on...

- i. an innovative means to quickly and cost-effectively manufacture peptides while meeting quality attributes to meet volume needs of current and future cell-therapy clinical trials
- ii. process development to improve quantity and quality of peptides that can be successfully utilized in a Neoantigen T-cell therapy clinical trial
- iii. radio-theragnostics to develop best in class radio-ligands that target cancer while mitigating destruction to healthy tissues

Genocea Biosciences, Cambridge, MA

2018 - 2022

Sr. Director of Tech Ops; Peptide Dev & Mfg., Pharmaceutical Science: 2020 - present

Director of Peptide Drug Substance, Pharmaceutical Sciences: 2018 - 2020

Led & manage Technical Operations team: establishing and operating within budget as well as establishing MSA and Supply Agreements with CMOs. Responsible for managing the patient Needle-to-Needle schedule with numerous CMOs in the Manufacturing Supply Chain. Responsible for coordination and shipping logistics of Drug Substance, Drug Product and Critical Raw Materials for GEN-009 and GEN-011 programs using appropriate temperature control.

Led the Drug Substance Peptide Team at Genocea Biosciences to rapidly manufacture and deliver peptide-based Neoantigen GMP Drug Substance for GEN-009 clinical trial, a personalized medicine approach to treating solid tumors; and lead a program to deliver custom critical-raw-material peptides, quickly and in high numbers for the GEN-011 Neoantigen Adoptive T-cell Therapy program.

Life Sciences Project Management; Bellingham, MA

2017 – 2018

Project Manager / Principal Consultant

Provide Project Management services to Drug Discovery organizations; from Early to Late Stage Drug Discovery (candidate validation), as well as pre-clinical to early stage clinical development; IND enabling studies and IND filings: Specializing in Personalized Medicine, Nuclear Medicine, Peptide and Peptidomimetics, Small Molecules and Biological Conjugates.

Ipsen Bioscience; Cambridge, MA

2010 – 2017

Project Manager / Group Leader – Global Drug Discovery

Managed Endocrinology and Oncology based R&D projects. Objectives: Target Identification, Novel Indications, Target Selectivity, increase in potency and longer plasma half-life. Successfully guided projects through stages of therapeutic research (Initial Assessment, Lead Identification, Lead Optimization and Candidate Selection / Validation).

- Successfully led a RadioTheranostics (Nuclear Medicine) program from Concept through early stage Candidate Validation; targeting Neuroendocrine tumors utilizing a small-molecule / peptide combination approach
 - Successfully led a project team comprised of twelve R&D function representatives
 - Delivered programs within-budget and met Key Project Deliverables (KPI) within pre-specified criteria
 - Successfully managed multiple CROs via communication, working collaboratively and performance tracking
 - Identified, Managed and Mitigated Key Project Risks
 - Managed Communications among Key Stakeholders and KOLs (internal and external)
 - Successfully developed, tracked and met aggressive timelines
- Developed cost-effective, non-PET based *in-vivo* screening tools to evaluate biodistribution of radio-theranostics.
- Developed a successful, novel approach to solve the kidney rate limiting effects of radio-theranostics
- Successfully validated a small molecule / peptide combo to target Neuroendocrine tumors via non-SSTR approach
- Led teams;
 - to develop an antagonist/agonist of Growth Hormone Receptor
 - to investigate cytotoxic conjugates aimed at designing potent cancer therapeutics with improved safety profiles
 - to investigate cyclotides as a peptide drug delivery platform
 - initiated a peptide-RNAi project to explore feasibility of using peptides to deliver siRNA

Ipsen Bioscience/Biomeasure, Inc.; Milford, MA

2005 – 2010

Senior Scientist - Discovery and Innovation

- Contributed to the discovery & development of Ghrelin agonist (out-licensed to Allergan; Relamorelin, BIM-28131) for cachexia and post-operative ileus (POI) therapeutic indications. Coordinated technology transfer for internal and external (CRO) API scale-up operations for IND enabling and Phase-I studies.
- Contributed to the discovery & development of high affinity Melanocortin-receptor (MC4R) specific analogs (out-licensed to Rhythm): an agonist for obesity (Setmelanotide, BIM-22943); and an antagonist for cachexia. Coordinated technology transfer for internal and external (CRO) API scale-up operations for IND enabling and Phase-I studies.

Biomeasure Inc.; Milford, MA

2001 – 2005

Scientist - Chemistry Group

- Designed, synthesized and characterized Melanocortin and Ghrelin based analogs to target obesity and cachexia indications.
- Contributed to numerous programs utilizing designed peptide analogs based on LHRH, GHRH, GIP, NPY, SST, Urotensin and others natural ligands

Dyax Corp; Cambridge, MA

2000 – 2001

Senior Scientist - Peptide Chemistry Group

Established and managed research group to meet the needs of peptide-based projects, including design of peptide based therapeutics, imaging agents, and peptido-mimetics with increased plasma half-life.

- Directly participated in the development of phage-display derived peptide products: Blys (HGS) and Refacto (Genetics Institute)

Massachusetts Institute of Technology; Cambridge, MA
Director - Combinatorial Peptide Synthesis Core Facility

1998 - 2000

Managed all aspects of the facility; Staffing, Training, Purchasing, Budgeting, and Equipment Operations & Maintenance, as well as directed research efforts;

- Designed tight binding MHC peptide analogues that function as synthetic T-cell antigens with improved properties
- Identified and determined the mode of binding of “non-conforming” HIV-derived antigenic peptides

EDUCATION

Ph.D., Medicinal/Organic Chemistry, Boston University

M.S., Organic Chemistry, Boston University,

B.S., Chemistry/Biochemistry, University of Massachusetts Dartmouth

CERTIFICATIONS

PMP (Project Management Professional), Project Management Institute, Jan 2014:

Certification Number: 1692464

PATENTS

WO/2010/096186A1	Analogues of Neuropeptide Y Having At Least One Synthetic Amino Acid Substitution
WO/2010/096175A1	Cytotoxic Conjugates Having Neuropeptide Y Receptor Binding Compound
WO/2010/016935A2	Truncated Analogues of Glucose-Dependent Insulinotropic Polypeptide
WO/2009/108364A2	Antagonistic Analogues Of GHRH
WO/2008/147556A2	Melanocortin Receptor Ligands Modified With Hydantoin

ADDENDUM

PUBLICATIONS

Hubert Lam¹, Lisa K. McNeil, Hanna Starobinets, Victoria L. DeVault, Roger B. Cohen, Przemyslaw Twardowski, Melissa L. Johnson, Maura L. Gillison, Mark N. Stein, Ulka N. Vaishampayan, Arthur P. DeCillis, James J. Foti, Vijetha Vemulapalli, Emily Tjon, Kyle Ferber, **Daniel B. DeOliveira**, Wendy Broom, Parul Agnihotri, Elizabeth M. Jaffee, Kwok-Kin Wong, Charles G. Drake, Pamela M. Carroll, Thomas A. Davis, and Jessica Baker Flechtner; **(2021)** An Empirical Antigen Selection Method Identifies Neoantigens That Either Elicit Broad Antitumor T-cell Responses or Drive Tumor Growth, *Cancer Discovery*, **11**, 696-713

Roubert, P., Dubern, B., Plas, P., Lubrano-Berthelie, C., Alihi, R., Auger, F., **DeOliveira D.B.**, Dong, J. Basdevant, A., Thuriereau C., and Clemént K., **(2010)** Novel pharmacological MC4R agonists can efficiently activate mutated-MC4R from obese patients with impaired endogenous agonist response. *Journal of Endocrinology*, **207**, 177-183

Dong Jesse Z; **DeOliveira Daniel B**; Halem Heather A; Taylor John E; Roubert Pierre; Plas Pascale; Culler Michael D; Zhang Jundong., **(2009)** Novel melanocortin-4 receptor agonists that decrease food intake and body weight. *Advances Experimental Medicine and Biology*, **611**, 485-6.

Shrivastava A, von Wronski MA, Sato AK, Dransfield DT, Sexton D, Bogdan N, Pillai R, Nanjappan P, Song B, Marinelli E, **DeOliveira DB**, Luneau C, Devlin M, Muruganandam A, Abujoub A, Connelly G, Wu QL, Conley G, Chang Q, Tweedle MF, Ladner RC, Swenson RE, Nunn AD. **(2005)** A distinct strategy to generate high-affinity peptide binders to receptor tyrosine kinases. *Protein Eng Des Sel.*, **18**, 417-424.

Rubinfeld H, Hadani M, Taylor JE, Dong JZ, Comstock J, Shen Y, **DeOliveira DB**, Datta R, Culler MD, Shimon I. (2004) Novel ghrelin analogs with improved affinity for the GH secretagogue receptor stimulate GH and prolactin release from human pituitary cells. *Eur J Endocrinol.* **151**,787-795.

Zavala-Ruiz Z, Sundberg EJ, Stone JD, **DeOliveira DB**, Chan IC, Svendsen J, Mariuzza RA, Stern LJ. (2003) Exploration of the P6/P7 region of the peptide-binding site of the human class II major histocompatibility complex protein HLA-DR1. *J Biol Chem.*, **278**,44904-44912.

Huang L, Sexton DJ, Skogerson K, Devlin M, Smith R, Sanyal I, Parry T, Kent R, Enright J, Wu QL, Conley G, **DeOliveira DB**, Morganelli L, Ducar M, Wescott CR, Ladner RC. (2003) Novel peptide inhibitors of angiotensin-converting enzyme 2. *J Biol Chem.*, **278**, 15532-15540.

Sato AK, Sexton DJ, Morganelli LA, Cohen EH, Wu QL, Conley GP, Streltsova Z, Lee SW, Devlin M, **DeOliveira DB**, Enright J, Kent RB, Wescott CR, Ransohoff TC, Ley AC, Ladner RC. (2002) Development of mammalian serum albumin affinity purification media by peptide phage display. *Biotechnol. Prog.*, **18**, 182-192.

De Oliveira DB, Harfouch-Hammoud E, Otto H, Papandreou NA, Stern LJ, Cohen H, Boehm BO, Bach J, Caillat-Zucman S, Walk T, Jung G, Eliopoulos E, Papadopoulos GK, van Endert PM. (2000) Structural analysis of two HLA-DR-presented autoantigenic epitopes: crucial role of peripheral but not central peptide residues for T-cell receptor recognition. *Molecular Immunology*, **37**, 813-825.

Le protéins, architectes des coquillages (1998) *Science et Vie*, **966**, 13.

Las proteínas para controlar las conchas (1998) *Ciencia & Vida*, **2**, April, 1998.

DeOliveira, D. B.; Laursen, R. A.; (1997) Control of Calcite Crystal Morphology by a Peptide Designed to Bind to a Specific Surface, *J. Am. Chem. Soc.*, **119**,10627-10631.

Protein shells out guidance to crystals (1997) *Science News*, **152**, 327.

Fu F-N, **DeOliveira DB**, Trumble WR, Sarkar HK, Singh B-R. (1994), Secondary structure estimation of proteins using the Amide III region of Fourier Transform infrared spectroscopy: Application to analyze calcium binding induced structural changes in calsequestrin. *Applied Spectroscopy*, **48**, 1432-1441.

Singh B-R, **DeOliveira DB**, Fu F-N, Fuller MP. (1993), Fourier Transform infrared analysis of Amide III bands of proteins for the secondary structure estimation. *Proceedings of Society of Photo-Optical Instrumentation Engineers: Biomolecular Spectroscopy III*, **1890**, 47-55.

INVITED SPEAKER

- 2022 *TIDEtalks* East-Coast Inaugural Symposium, Mass Biotechnology Council
Neoantigens: What are they; and why are they so important for next-generation cancer immuno-therapy.
- 2021 Biologics Europe; London, England, UK (virtual)
GEN-009: The Complexities of Manufacturing Personalized Neoantigen Cancer Vaccines
- 2020 Peptide Therapeutics Symposium; La Jolla, CA (virtual)
Peptide Neoantigen Cancer Vaccines and T Cell Therapy
- 2020 TIDES: Oligonucleotide and Peptide Therapeutics, Boston, MA (virtual)
Peptides for Neoantigen Cancer Vaccines and T Cell Therapy

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- 2019 Boulder Peptide Symposium, Boulder, CO
Pioneering NeoAntigen Immunotherapies via ATLAS: GEN-009 a NeoAntigen vaccine based on autologous Peptide Immune Responses
 - 2019 TIDES: Oligonucleotide and Peptide Therapeutics, San Diego, CA
Pioneering NeoAntigen Immunotherapies: via ATLAS & Re-thinking Peptide NeoAntigens
 - 2018 Peptide Science Colloquium of New England, Cambridge, MA
Pioneering NeoAntigen Immunotherapies
 - 2017 Univ. Massachusetts Dartmouth Commencement, Xfinity Comcast Center, Mansfield, MA
Alumni Commencement Address, Graduate Student Ceremony
 - 2016 Ipsen Innovation Day, Baveno, Italy
"Strategies to Reduce Nephrotoxicity of Radiopeptides: Developing a Competitive Edge in PRRT"
 - 2016 Univ. Massachusetts Dartmouth Commencement, UMass Dartmouth Campus, N. Dartmouth, MA
Alumni Commencement Address, Undergraduate Student Ceremony
 - 2009 21st American Peptide Symposium, Indiana University, Bloomington, IN
Microwave Peptide Synthesis Workshop; Panel Member
 - 2008 6th International Microwaves in Chemistry Conference, Cambridge, MA
Microwave-Assisted Solid-Phase Peptide Synthesis Workshop; Panel Member
 - 2001 ACS Young Investigator Symposium: Career Workshop, Brookline, MA
"Employment Prospects for new Ph.D. Graduates: the Good and the Bad"
 - 1998 University of Massachusetts, Department of Chemistry, North Dartmouth, MA
"Control of Calcite Crystal Morphology via a novel Calcite Binding Peptide"

CONFERENCE ORGANIZER

Cambridge Peptide Showcase East; March 14-15, 2016, Microsoft *NERD* (New England Research and Development) Center; Co-organizer of a 2-day conference with a focus on engaging with peptide-based companies to connect with investors and strategic partners through presentations, one-on-one meetings and informal discussions.

Pep-Talks (Peptide Science Colloquium of New England; PSCNE, quarterly seminars, 2015-2017; co-organizer of peptide and protein therapeutics seminar series for academic and industry scientists in the New England area.

AWARDS

- 2016 IPSEN Innovation Award
- 2013 UMASS Legacy of Leadership: UMass Dartmouth Accomplished Alumni & Leader in Science & Research
- 2011 IPSEN Innovation Award
- 2010 IPSEN Innovator Award
- 1993 University of Massachusetts Citation for Academic Performance
- 1993 American Association for the Advancement of Science Student Poster Winner
- 1992 American Chemical Society's Student Internship Program Award
- 1992 American Chemical Society's Analytical Division Award

AFFILIATIONS

Society for Nuclear Medicine and Molecular Imaging; 2014- present
Project Management Institute; 2013 – present
American Peptide Society; 1998 - Present
American Chemical Society; 1993 – present

VOLUNTEER

University of Massachusetts Dartmouth Alumni Association, Board of Directors.

President: 2016 – 2018

Vice President: 2015–2016

Member, Board of Directors: 2014 – 2020