Diane E. Carrera

ADDRESS

Bolt Biotherapeutics
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Summary

Experienced process chemist adept at designing and developing phase appropriate syntheses of small molecule APIs for preclinical, clinical and commercial supplies. Extensive experience working with CMO/CRO organizations to perform process development, supply starting materials, intermediates, and GLP/GMP APIs in support of clinical programs. Established scientific leader in the field with a strong track record of publications and external presentations. Effective people manager and recruiter with an extensive network across the pharmaceutical industry and academia.

PROFESSIONAL EXPERIENCE

Associate Director, Process Chemistry **Nov 2019-present**
Bolt Biotherapeutics

- Responsible for all small molecule development activities in support of the Boltbody® platform including evaluation and selection of CDMO partner for GMP manufacturing.
- Established internal small molecule development capabilities at Bolt through strategic hiring, design of process laboratory space and capital improvements to enable process chemistry and QC activities.
- Leading external research activities through management of FTEs and fee for service research programs.
- Responsible for authoring small molecule CMC sections for regulatory filings including the IND for Bolt's first clinical candidate BDC-1001.

Scientist, Process Chemistry **2013-2019**
Genentech

- Served as lead chemist on numerous development projects ranging from the pre-clinical to Ph 2 clinical trials. Responsible for designing and developing new synthetic strategies for GMP syntheses as well as GMP starting materials at external CROs.
- Extensive experience authoring CMC sections of regulatory documents such as INDs, IMPDs and rBA applications. Skilled at working with colleagues from other CMC functions to respond in a timely fashion to health authority questions.
- Responsible for developing GTI control strategies for ED, Ph 1 and Ph 2 projects including obtaining in silico screening results, preparing compounds for Ames mutagenicity assay testing and establishing a purging rationale with Mirabilis software.
- Directly manage a team of chemists (Ph. D. & M.S./B.S. levels) and multiple interns, contractors and apprentices.
- Founding member of the Genentech Graduate Symposium committee. Responsible for reviewing application materials, organizing the multi-day event and hosting the graduate student winners.
- As the founding member of the SMPC recruiting committee, responsible for identifying top talent via on-campus recruiting and phone interviews.
- Reviewer for chemistry journals Organic Letters and Organic Process Research and Development. Member of Organic Process Research and Development Editorial Advisory Board.

Associate Scientist, Process Chemistry **Oct 2009-May 2013**
Genentech

- Early and late stage process research and development for numerous programs at the ED, Ph 1 and Ph2 stages. Activities include route scouting and developing processes for chemical transformations and API recrystallizations. Delivered API to support IND enabling toxicology studies, Ph 1 and Ph 2 clinical trials.
- Experience operating in a GMP environment including writing, reviewing and executing batch records, recording incidents with the Trackwise system and setting material specifications.
- Extensive experience with cross-functional teams to support Discovery Chemistry SAR, final target selection and preliminary toxicology studies. Provided material to support pre-ED go toxicology studies for multiple programs to enable decision making for ED candidates.
- Served as lead on ImmunoPET project to provide a clinical imaging tool for the Genentech ADC and AAC programs.
- Managed numerous B.S. level contractors, research associates and summer interns.
- Member of the Roche Technical Working Group on Green Chemistry for three years. Responsibilities included designing and distributing a Roche/Genentech solvent guide for chemists, organizing a Green Chemistry Speaker Series, established the REACT award in Green Chemistry and increasing awareness of green chemistry principles in the Genentech process chemistry group.

Graduate Research with Professor David W. C. MacMillan **2004-2009**
California Institute of Technology, Pasadena, California

- Development of an organocatalytic, enantioselective reductive amination of ketones with a mild reductant
- Investigation of the mechanism and reaction kinetics of the organocatalytic reductive amination of ketones
- Designed and implemented a novel organocatalytic Petasis reaction of unactivated imines and enamines with potassium trifluoro(organoborate) salts

Researcher at Johnson & Johnson, Medicinal Chemistry **2002-2003**
Johnson & Johnson, La Jolla, California

- Developed synthetic route towards a Neuromedin A receptor antagonist
- Designed and synthesized a parallel library of related analogs for biological testing

Undergraduate Research with Professor Paul A. Wender **2000-2002**
Stanford University, Palo Alto, California

- Designed and performed multiple step syntheses to access a key intermediate in the total synthesis of a Bryostatin analog
- Subsequent analysis of intermediates to define the absolute stereochemistry of the biologically active compound.

Medicinal Chemistry Intern at Tularik **2000**
Tularik, South San Francisco, California

- Prepared a library of small molecules in the course of designing novel antibacterial agents
- Optimization of a novel Cu-catalyzed Suzuki reaction with aryl boronates

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EDUCATION

California Institute of Technology, Pasadena, California **2004-2009**
Ph. D., Organic Chemistry
Advisor: Prof. David W. C. MacMillan

Stanford University, Palo Alto, California **1998-2002**
B.S. with Honors, Chemistry
Advisor: Prof. Paul A. Wender

PUBLICATIONS AND PATENTS

1. "Manufacture of the PI3K β-Sparing Inhibitor Taselisib: Part 2. Development of a Highly Efficient and Regioselective Late-Stage Process" St-Jean, F.; Remarchuk, T.; **Carrera, D.E.**; Beaudry, D.; Malhotra, S.; McClory, A.; Kumar, A.; Angelaud, R.; Gosselin, F. *Organic Process Research & Development,* **2019**, *23*, 783.

2. "Synthesis of IDO Inhibitor" Angelaud, R.; Bachmann, S.; Beyeler, A.; **Carrera, D.**; Fischer, R.; Guillemot-Plass, M.; Hou, H.; Iding, H.; Kraft, A.; Manns, A.; Meier, R.; Niedermann, K. M.; Olbrich, M.; Piechowicz, K.; Rege, P.; Remarchuk, T. P.; Sirois, L.; St-Jean, F.; Xu, J. PCT 2018, US2018/024127.

3. "Magnesium Ethoxide Promoted Conversion of Nitriles to Amidines and Its Application in 5,6-Dihydroimidazobenzoxazepine Synthesis" Dalziel, M.E.*; Deichert, J. A.; **Carrera, D. E**.*; Beaudry, D.; Han, C.; Zhang, H.; Angelaud, R. *Organic Letters* **2018**, *20*, 2624.

4. "The Acid Promoted Petasis Reaction of Organotrifluoroborates with Imines and Enamines" **Carrera, D. E.** *Chemical Communications* **2017**, *53*, 11185.

5. "Analytical Methodology for Characterization of Reactive Starting Materials and Intermediates Commonly Used in the Synthesis of Small Molecule Pharmaceuticals" Stowers, S.; Kumar, A.; **Carrera, D. E.**, Gu, C.; Patel, P.; Venkatramani, C.; Stoianov, D.; Wigman, L. *American Pharmaceutical Review* **2017**, *20* (2).

6. "Highly Diastereoselective *a*-Arylation of Cyclic Nitriles" Dalziel, M.E.*; Chen, P.; **Carrera, D. E**.*; Zhang, H.; Gosselin, F. *Organic Letters* **2017**, *19*, 3446.

7. "Process Development of the Synthesis and Purification of a Reactive Immuno-PET Conjugate Intermediate" **Carrera, D. E**.; Nguyen, T.; Medley, C.D.; Li, Y.; Angelaud, R.; Gosselin, F. *Organic Process Research & Development* **2016**, *20*, 312.

8. "Process for Making Benzoxazepin Compounds" Angelaud, R.; Beaudry, D.; **Carrera, D. E**.; Malhotra, S.; Remarchuk, T.; St-Jean, F. Application# 14/205,634; Docket# P4974R1(2014)

9. "Synthesis of Akt Inhibitor Ipatasertib. Part 2. Total Synthesis and First Kilogram Scale-up" Remarchuk, T.; St-Jean, F.; **Carrera, D. E**.; Savage, S.; Yajima, H.; Wong, B.; Babu, S.; Deese, A.; Stults, J.; Dong, M. W.; Askin, D.; Lane, J. W.; Spencer, K. L. *Organic Process Research & Development* **2014**, *18*, 1652.

10. "Identification of GNE-293, a Potent and Selective PI3Kδ Inhibitor: Navigating in vitro Genotoxicity while Improving Potency and Selectivity" Safina, B. S.; Sweeney, Z. K.; Li, J.; Chan, B. K.; Bisconte, A.; **Carrera, D. E.** *et al Bioorg. & Med. Chem. Lett.* **2013**, *23*, 4953.

11. "A Safe Synthesis of 1,5-Disubstituted 3-Amino-1H-1,2,4-triazoles from 1,3,4-Oxadiazolium Hexafluorophosphates" Wong, B.; Stumpf, A.; **Carrera, D. E.**; Gu, C.; Zhang, H. *Synthesis* **2013**, *45(8)*, 1083.

12. "Development of a Scalable Strategy for the Synthesis of PI3Kδ Inibitors: Selective and Efficient Functionalization of Purine Derivatives." **Carrera, D. E.**; Sheng, P-J.; Safina, B. S.; Li, J.; Angelaud, R. *Organic Process Research & Development* **2013**, *17*, 138.

13. "Development of a General, Enantioselective Organocatalytic Mukaiyama-Michael Reaction with α,β-Unsaturated Aldehydes" Borths, C. J.; **Carrera, D. E.**; MacMillan, D. W. C. *Tetrahedron* **2009**, *65*, 6746. Special Issue in Honor of the 2009 Tetrahedron Prize for Creativity in Organic Chemistry, Larry Overman.

14. "Enantioselective Organocatalytic Reductive Amination." Storer, R. I.; **Carrera, D. E**.; Ni, Y.; MacMillan, D. W. C. *J. Am. Chem. Soc.* **2006**, *128*, 84-86.

INVITED PRESENTATIONS AND POSTERS

1. "Development of a Crystallization-Induced Dynamic Resolution to Access IDO Inhibitor Navoximod" Carrera, D. E. 257^{h} Meeting of the American Chemical Society, Orlando, Fl, April 2, 2019

2. "Heterocycle Synthesis in the Manufacturing Route of Taselisib" Carrera, D. E. Emory University, Atlanta, GA, March 26, 2019

3. "Process Development for the Reactive ImmunoPET Intermediate GNE-605" Carrera, D. E. 256^{h} Meeting of the American Chemical Society, Boston, MA, August 26, 2018

4. Poster presentation: "Highly Diastereoselective *a*-Arylation of Cyclic Nitriles" Carrera, D. E. Gordon Research Conference on Stereochemistry, Newport, RI August, 2016.

5. Poster presentation: "New Platforms to Enable Delivery of the ImmunoPET Small Molecule GNE-605" Carrera, D. E. Pacifichem, Honolulu, HI Dec 2015

6. "RORc LSR Program: A Tale of Two Series" Carrera, D. E. PTDCA gRED Collaboration Exchange, Basel, Switzerland November 2015.

7. "Early Process Research: Developing a Synthetic Strategy for PI3Kδ Inhibitors" Carrera, D. E. The 27th International Conference and Exhibition on Organic Process Research and Development, Clearwater, FL March 2013.

8. "Early Process Research: Developing a Synthetic Strategy for PI3Kδ Inhibitors" Carrera, D. E. 11th Winter Conference on Medicinal and Bioorganic Chemistry, Steamboat Springs, CO January 2013.

9. Poster presentation: "Early Process Research: Developing a Synthetic Strategy for PI3kd Inhibitors", Gordon Research Conference on Heterocycles, Newport, RI June 2012.

AWARDS AND HONORS

- Roche REACT Award in Green Chemistry – GDC-0919 commercial process 2018
- Roche REACT Award in Green Chemistry – GDC-0032 commercial process 2015
- Zechmeister Fellowship – California Institute of Technology 2004-2005
- Summer Student Fellowship – Johnson & Johnson 2002
- University Chemistry Fellowship – Stanford University 1999-2002
- Bing Summer Research Fellowship – Stanford University 2001
- Boeing National Merit Scholarship 1998-2002
- National Hispanic Scholar 1998