BRUCE GIRTON

Oregon, USA (+1) 425 830 8464

https://linkedin.com/brucegirton bcgirton@gmail.com https://brucegirtonconsulting.com

PHARMACEUTICAL DEVELOPMENT CONSULTANT

I have 35 years of diverse experience in small molecule pharmaceutical development, collaborating effectively with manufacturing, quality, regulatory affairs, project planning and other subject matter experts to support activities such as discovery research, non-clinical studies, process development and validation, formulation development, stability studies, clinical trial materials manufacturing, IND / NDA CMC document preparation, and commercial operations. • I have worked on a wide variety of therapeutic agents and drug product types, including antibiotics, chemotherapy agents, botanicals, psychedelics, non-opioid analgesics, as parenteral, inhalable, transdermal, and oral dosage forms. • I have worked in biotech/pharma organizations of all sizes and at all stages of organizational development; startups are particular favorites. • I offer subject matter expertise in analytical chemistry, foresight derived from experience, and creative solutions for complex drug development challenges. • My core competencies include scientific literature research, analytical method development, validation, and transfer, physical and chemical characterization of drug substances and products, impurity profiles, statistical evaluation of data, and stability studies. • I understand related topics, such as human and animal biochemistry, synthetic chemistry, drug substance and drug product manufacturing, quality, and regulatory affairs. • I provide flexible support for pre-IND studies including discovery research, target selection and validation, DMPK/tox studies, formulation development; CDMO selection and management; clinical trial materials manufacturing and testing; CMC submission preparation, review and gap analysis; and post- commercialization activities. • I have extensive experience with multi-functional teams, managing elements of diverse programs from target selection to clinical development and delivery. • I am well-versed in GLPs, GMPs, quality systems, and regulatory filings and communications. • I am passionate about applying my skills, knowledge, and experience to support the advancement of novel and effective pharmaceuticals.

PROFESSIONAL EXPERIENCE

BRUCE GIRTON CONSULTING *Oregon, USA*

Principal Consultant 2014 – present

Provided advice and assistance on a range of analytical and CMC-related topics in research, development, and commercial environments. Developed key relationships utilizing a collaborative style. Supported diverse projects, including:

- Pre-IND development program for an electrospun oral solid dosage form with unique applications, overcoming unusual formulation and analytical challenges. (confidential client, Apr 2024 – Nov 2024)
- Pre-IND development program for a botanical psychoplastogen drug product, including literature research into biosynthesis pathways, human pharmacodynamics and pharmacokinetics, and mechanisms of action. Provided guidance for complex materials characterization, multi-drug pharmacology, analytical methods development, stability study planning, reference standard sourcing, and program strategy. (Empyrean, Mar 2023 – Dec 2023)
- Pre-IND development program for a unique, high-potency non-opiate analgesic drug product, including activities and clinical trial materials manufacture planning and development. Assisted with CDMO engagement and management. (confidential client, Feb 2021 – Dec 2021)
- CTD preparation for COVID-19 vaccine (Novavax, Aug 2021 – Nov 2021)
- CDMO selection and data review related to clinical trial materials testing for a protein drug product. (Vaxxinity, Apr 2022 – Nov 2022)
- Drug development programs for mid-sized biotechs, including analytical data review for global CDMOs, evaluation of stability data, and resolution of interlaboratory reproducibility issues. (Kronos Bio, May 2021 – Apr 2022; Mirati Therapeutics, Feb 2021 – Feb 2022)
- Establishment of GMP controls in a research laboratory supplying DNA sequences to a biological manufacturing process. (Vir Biotechnology, May 2019 – Feb 2022)
- CTD preparation for a novel taxane oncological drug product, including gap analysis involving reorganization of large, chaotic libraries of documents. (Odonate Therapeutics, Jun 2019 – Mar 2021)

- Advancement of a discovery research program, investigating issues with the identity or purity of key intermediates; the results led to significant research program modifications. (Revolution Medicines, 2016)
- CTD preparation for an orphan drug product, performing evaluation of stability data. (Hyperion Therapeutics, 2015)
- Investigated significant manufacturing and analytical issues for a commercial drug product. (Raptor Pharmaceuticals, Sep 2014 – Mar 2015)
- Advanced method validation gap analysis for a large library of analytical methods. (Gilead Sciences, Mar 2014 – Sep 2014)
- Advanced process validation program for drug product containing live genetically modified herpes virus. (Amgen, Jan – Mar 2014)

SENTIER THERAPEUTICS *San Diego, CA, USA*

Senior Director, Technical Operations February 2018 – November 2018

Supported analytical development, process development, quality and compliance optimization, and regulatory activities for a unique animal-derived drug product. Developed a novel procedure to identify and release or reject incoming raw materials in real time, using a handheld instrument to inspect shipments on the loading dock with minimal user training and no sample preparation.

REATA PHARMACEUTICALS *Irving, TX*

Director, Analytical and Quality Control July 2017 – February 2018

Managed analytical and quality control activities for multiple ongoing clinical-phase drug development projects.

RETROTOPE *Los Altos, CA*

Director, Analytical and CMC July 2015 – July 2017

Managed complex bioanalytical, manufacturing, and analytical activities for a novel drug platform in clinical development. Conducted extensive literature research into free radical oxidation, proposed mechanism of action of deuterated lipids, and orphan indications such as Friedreich's ataxia.

SAREPTA THERAPEUTICS *Corvallis, OR*

Senior Scientist 2010 – 2012

Managed control account within Earned Value Management project planning environment, and supported Department of Defense audit. Applied oligonucleotide analytical chemistry, including implementation of analytical method development, validation and transfer. Liaised with contract research organizations, assisting with resolution of laboratory events and systems development.

PONIARD PHARMACEUTICALS *Seattle, WA*

Quality Control Manager 2007 – 2010

Participated in development of a platinum-based chemotherapeutic agent, overseeing quality control release and stability testing, supporting drug substance and product manufacturing process development. Prepared documents for FDA New Drug Application submission, including detection and resolution support, addressing technical and regulatory compliance risks and issues. Collaborated in progressing process development, recognizing raw material impurity as ligand exchange catalyst, stabilizing yields and reaction rates of key intermediate synthesis step. Directed optimization and validation of new and improved High Performance Liquid Chromatography (HPLC) methods for analyzing platinum-based synthetic intermediates, drug substances and products. Built and sustained effective working relationships with diverse contract manufacturing and research organization staff, improving product quality work efficiency. Prepared CMC elements, including analytical and characterization components of the CTD, for FDA and EMA regulatory submissions including an NDA, IND annual updates, and an IMPD.

GILEAD SCIENCES *Seattle, WA*

Research Scientist 2003 – 2007

Provided analytical chemistry and formulation support for drug discovery/medicinal chemistry laboratory. Developed Liquid Chromatography/Mass Spectrometry (LCMS) methods for wide variety of sample types. Developed *in vitro* enzymatic pro-drug characterization protocols, validating concepts, comparing drug release rates, confirming expected reaction products, and predicting potential metabolites. Co-invented international patent application WO 2006/138212. Identified reaction products of 2 incompatible drugs, developing a 2-part formulation scheme for inhaled liquid drug product, optimizing strength, stability, and biocompatibility. (Corus Pharma was purchased by Gilead in 2006.)

QLT *Vancouver, BC, Canada*

Senior Research Scientist / Consultant 1999 – 2003

Directed optimization and re-validation of 4 problematic analytical methods and development including HPLC and LCMS methods. Authored United States Pharmacopeia monographs for drug substance and drug product. Averted urgent threat to principal commercial drug product, initiating corrective and preventive actions (CAPAs). Conducted out-of-trend investigation to discover a defect in previously applied method and instrument. Collaborated with technical experts and corporate partners in United Kingdom and Switzerland. Developed and validated analytical method with selection of alternative instruments, producing reliable results. Authored resolution justifications for annual report submission, ensuring uninterrupted marketability of drug product. Designed unique, novel analytical instrument to quickly and accurately measure dissolution rate of lyophilized cakes in viscous, visually opaque liquid medium. Supervised up to 3 laboratory scientists, and Laboratory Information Management System (LIMS) personnel.

CTI BIOPHARMA *Seattle, WA*

Systems Coordinator / Research Scientist 1996 – 1999

Supported process scale-up and technology transfer at multiple international sites, fostering constructive inter-organizational relationships and open communication. Identified novel trace impurity, highly insoluble in water and almost all common organic solvents, discovered in final stages of drug manufacturing process validation. Devised HPLC methods for control of impurity and supported process improvements to resolve the issue. Heightened inter-departmental communication by creating forms and designing a system to store information, and track samples and data flow using MS Outlook/Exchange. Originated automated systems enabling analysts to consolidate data from individual spreadsheets into single file, eliminating transcription errors.

PAR PHARMACEUTICALS *Spring Valley, NY*

Senior Analytical Chemist 1993 – 1996

NOVARTIS *Suffern, NY*

Analytical Chemist 1989 – 1993

EDUCATION

MS, Physical Chemistry, North Dakota State University, Fargo, ND

BS, Chemistry State University of New York at Albany, Albany, NY