

JAMES G. CASE

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PROFESSIONAL EXPERIENCE

Scientist (Advanced Analytical), Cambrex, Longmont, CO, current employer. Avista Pharma Solutions was acquired by Cambrex in early 2019. Shortly thereafter the Analytical Services was subdivided into three subgroups: Drug Substance, Drug Product, and Advanced Analytical. Duties include HPLC method development for cleaning validations, chiral purity, and total impurities. I have worked extensively on evaluating impurity methods by designing forced degradation studies. These studies are used to verify that methods are stability indicating.

Associate Scientist (Analytical Services), Avista Pharma Solutions, Longmont, CO, June 2015 to January 2019. Avista Pharma Solutions acquired the Array Biopharma, Inc. CMC group (Longmont facility) as well as three out of state facilities in June 2015. Duties include method development/analysis/validations for ICP-MS, TGA/DSC, LPS (Laser Particle Size), GC-MS, MP-AES, and pXRD.

Associate Scientist, Array Biopharma, Inc., Longmont, CO, October 2010 to June 2015
Duties include providing analytical support for process and medicinal chemists, analytical and semi-preparative scale chiral method development, and preparative purification of process impurities. Extensive method development including materials characterization, purity, and GTI analysis. Isolation techniques include prep SFC, prep HPLC, and flash chromatography.

Research Associate III, Array Biopharma, Inc., Longmont, CO, August 2005 to October 2010
Duties include providing analytical support for process chemists, developing qualified methods for the release of materials and drug products, and analytical support for the filing of INDs.

Chemist II, Hauser Laboratories, Inc., Boulder, CO, November 2000 to May 2005
Duties include project management, failure/contamination analysis, method development, label claim validation, compliance support for A2LA quality assurance certification, reverse engineering, report writing/reviewing, price assessment, feasibility assessment, qualitative and quantitative analysis.

Laboratory Technician III, Hauser Laboratories, Inc., Boulder, CO, July 1998 to November 2000
Duties included physical and chemical analysis of petroleum products, thermal analysis, fungal resistance analysis, tensile sample preparation, and product testing.

Laboratory Technician, The SeaCrest Group, Broomfield, CO, 1994 to 1998
Duties included acting as chemical hygiene and safety officer, providing technical support for wastewater toxicology tests, culturing test organisms, auditing for Quality Assurance, and developing methodologies for toxicity identification on fresh and saltwater effluents.

Aquatic Toxicology Laboratory Manager, Chadwick and Associates, Littleton, CO, 1994
Managed all toxicology lab functions including safety, quality assurance, scheduling, ordering of supplies, statistical analysis, and reporting results for EPA compliance.

Analytical Chemist/Microbiologist, City of Albuquerque, NM, 1991 to 1994
Tested the chemical, microbiological, and physical properties of wastewater, drinking water, soils and sludges for local, state, and federal compliance.

SKILLS

Laboratory Instrumentation: SFC, HPLC-MS, HPLC-CAD, HPLC-CD (conductivity detection), HPLC-CD (circular dichroism detection), HSGC-FID, GC-MS, MP-AES, ICP-MS, ICP-OES, AA/GFAA, micro FT-IR & ATR FTIR, nIR, TGA & mDSC, Karl Fischer Titrations, Powder X-ray Diffraction (pXRD), and LPS (Laser Particle Size)

Method Development: Developed, qualified, transferred, and validated analytical methods for discovery, in-process, GLP, and GMP manufacturing using the laboratory instrumentation listed above.

Project Management: Prepare detailed analytical data and reports supporting legal cases, provide cost evaluations of analytical studies, provide technical support for quality assurance managers for FDA compliance, provide material identification for reverse engineering of electronic components, create custom FTIR libraries for evaluation of raw materials and possible sources of contamination from manufacturing processes. Provide custom chemical analysis for failure analysis studies.

Software: Mass Hunter, Chem Station MS, Empower III, ProNTo, OMNIC, BioRad Know it All, BioRad Have it All, JADE, MP Expert, Syngistix for ICP-MS, STARe and Diffract.Suite, Universal Analysis

Field Studies: (1) Andoas, Peru. Organized sampling and shipping of aquatic and benthic samples during ten-day water quality study that covered five major tributaries of the Amazon River in Andoas, Peru. (2) Eagle County, Colorado. Provided legal documentation of possible paint failure leading to contamination of under ground drinking water tanks in Eagle County, Colorado. (3) Arapahoe County, Colorado. Provided technical support for determining the effectiveness of a copper/silver ion generator in controlling algae and daphnid growth in Arapahoe County, Colorado.

Education Indiana University, Bloomington, IN, B.S. in Biology, May 1991

Major Courses: Experimental Chemistry, Organic Chemistry, Genetics, Molecular Biology, Cell Biology, Microbiology, Virology, Viral Tissue Culture Lab, Physics, and Calculus

Continuing Education mFTIR, Near IR, RAMAN, pXRD, HPLC, SFC, MS, GC, ICP-MS, AA, TGA/mDSC, HPLC and SFC method development and purifications, forced degradation/stability for Small Molecule Drugs, and Rheology

Publications *Protocol for Determining Major-Seawater-Ion Toxicity in Membrane-Technology Water-Treatment Concentrate*, Florida Department of Environmental Protection Bureau of Laboratories, 12/28/95.

Challenges in the Crystallization Development of a Highly Solvated Drug Substance. Poster Presentation at the 7th Annual CHI Conference on Efficient Process Chemistry, Boston, MA, May 22-23, 2014. Daniel J. Watson, Christopher M. Lindemann, Philip Anderson, Lisa Brett, Jonathan Lane, Jim Case and Donald T. Corson.