

## Christopher C. Hardwick, M.S.

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### SUMMARY OF QUALIFICATIONS

Chemist with fifteen years experience using various analytical instrumentation including LCMS (Agilent Ion Trap and QTOF), HPLC (Agilent 1100, 1200), GC/MS (HP 5890, 6890), FTIR, NMR, and UV-Vis analysis in a research/cGLP/cGMP environment, including extensive method development and optimization as well as compound synthesis, isolation, and characterization. Experience in a lead role in a fast paced environment, with five years professional supervisory experience including coordinating work of employees, hiring, training, evaluating work performance, ensuring all training is current, including participating in work of subordinates to facilitate productivity and to overcome difficult aspects of the work.

### EDUCATION

M.S. - Organic Chemistry (Applied Natural Science)	CSU - Pueblo, CO	(May 1999)
B.S. - Chemistry/Biology (Double Major)	CSU - Pueblo, CO	(May 1994)

### EXPERIENCE

**Senior Scientist** (Chromadex Analytical, Boulder CO.)  
(Oct. 2009 – Present)

- Analysis of dietary supplements and natural products using Agilent 1100 HPLCs, Agilent Ion Trap SL Mass Spectrometer, Agilent Q-TOF, HP 5890/6890 GC/FID and GC/MS.
- Assigned special projects / R&D of significant technical challenge.
- Developed and optimized analytical methods including solid phase / liquid phase extraction, sample preparations, and optimizing LC/MS and GC/MS parameters.
- Composed and edited reports, methods, and SOPs per ISO 17025, GLP, and cGMP.
- Worked under strict timelines.

**Lead Scientist** - (XTENT, Inc., Menlo Park CA)  
(Nov. 2007 – Feb. 2009)

- Lead scientist on XTENT's Forced Degradation Program for their Active Pharmaceutical Ingredient (API), Biolimus A9 (BA9).
- Interpreted analytical results from CROs ensuring the quality of analytical results from chemical analysis, protocol design, and project reporting.
- Provided data management and analysis in support of XTENT's regulatory filings in the United States (FDA) and Europe (NSAI, MEB)
- Provided scientific support for animal pharmacokinetic and toxicokinetic studies.
- Designed and performed experiments based on cGMP, cGLP, ICH, and FDA regulations.
- Developed protocols in accordance with the ICH guidelines for the development of stability programs for both Drug Substance and Drug Product (Drug Eluting Stents).
- Performed isolation and structural identification of drug impurities and degradation products using HPLC (LCUVMS Ion trap, LCMSMS, and QTOF spectroscopy).
- Investigated the effects of heat, light, oxidation, and pH on BA9 drug substance.
  - This work was used in support of XTENT's regulatory filings including an IND, DMF and MAF.
- Developed and validated LCUV-Ion Trap/LCUV/UV-Vis assays.
- Performed HPLC method transfers and method optimization.
- Authored and compiled informal and formal reports.
- Contributed to general laboratory upkeep, including instrument preventative maintenance, coordination of maintenance work, management of supplies, and ordering.
- Attended online 'webinars' and 'e-seminars' relating to various analytical techniques.

**Laboratory Scientist** - Navigant Biotechnologies, Inc., Lakewood, CO  
(May 2000 - Jan. 2007)

- Assisted in development of chemistry GLP compliance program.
- Acted as study director for chemistry GLP studies.
- Provided expertise on GMP, GLP, FDA, ISO, ICH, and international regulations.
- Managed and supervised other technical resources and technicians.
- Provided pharmaceutical support for Navigants' Pathogen Reduction Technology (PRT) including the photochemical inactivation of selected viruses and bacteria in platelet concentrates, plasma and red blood cells using riboflavin and light (UV and/or visible).
- Developed analytical methods for the separation, identification and quantification of Riboflavin and its photoproducts in blood products using HPLC with Fluorescence detection.
- Developed and validated analytical techniques in accordance with ICH guidelines.

**Chemistry Instructor** - Community College of Aurora, Aurora, CO  
(Fall 1999)

- Instructed General Chemistry I and II (Thermodynamics, Equilibrium, Kinetics).
- Presented six 3-hour lectures per week.
- Prepared, instructed, and cleaned up lab experiments.

**Graduate Chemistry Instructor** - CSU - Pueblo, CO  
(Aug. 1994 - May 1997)

- Instruction of General Chemistry Labs (60 students).
- Monitored laboratory safety.
- Organized and participated in 'Chemistry Magic Shows' for Chemistry Day.

**Graduate Organic Chemistry Research** - CSU - Pueblo, CO  
(Aug. 1994 - Oct 1998)

- Masters Thesis: Electrophilic Fluorination of Aryl Alkenes using F-TEDA.
- Synthesized, isolated, and characterized novel fluorinated compounds.
- Characterized novel compounds using:
  - $^{19}\text{F}$ ,  $^1\text{H}$ , and  $^{13}\text{C}$  Nuclear Magnetic Resonance Spectroscopy (NMR)
  - Gas Chromatograph Mass Spectrometer (GC-MS)
  - Infrared Spectrometer (IR)
- Isolated novel compounds using:
  - Radial Chromatotron
  - Shimadzu Gas Chromatograph (GC)
  - Thin Layer Chromatography, Column Chromatography, and Flash Chromatography

**Laboratory Technician** - Rentech, Pueblo, CO  
(April 1995 - Jan. 1996)

- Provided analytical support for R&D Syngas Technology.
- Operated Gas Chromatograph (GC).
- Performed hydrocarbon / aqueous separations.
- Assayed wax for solid catalysts using a muffle furnace.

**Store Manager** - Waterbed Palace, Colorado Springs, CO  
(Oct. 1998 - Nov. 1999)

- Managed entire operation of store while owner was in state legislature
- Responsible for sales, bookkeeping, taxes, inventory, and hiring
- Constructed store web site using Hypertext Markup Language (HTML)
- Supervised four employees

**Squad Leader** – U.S. Army 101<sup>st</sup> Airborne, Fort Campbell, KY  
(Aug. 1984 - May 1988)

- Received an Honorable Discharge
- Attained the rank of Squad Leader (SP4)
- Provided support primarily as a driver (Humvee, Jeep, ITV)
- Specialized in Anti-tank weapons (Infantryman, MOS = 11H)

#### **INSTRUMENTATION**

- Agilent 1100 HPLC System with LC/MS-MS Ion Trap Mass Spectrometer
- Agilent 1200 HPLC System with QTOF Mass Spectrometer
- Agilent 1100 High Performance Liquid Chromatography (HPLC) with Chemstation Software, Diode Array, Fluorescence Detector, Fraction Collector, Column Switching.
- Hewlett Packard 5890/6890 GC/MS Gas Chromatograph Mass Spectrometer / FID
- Ultraviolet-Visible Spectroscopy (UV-Vis)
- Shimadzu GC-9A (GC) Gas Chromatograph
- Varian 300MHz NMR Spectrometer <sup>19</sup>F, <sup>1</sup>H, and <sup>13</sup>C
- HR7924T Radial Chromatotron
- Infrared Spectrometer (IR)
- 2-Dimensional Electrophoresis
- Ion Chromatography (IC)
- Gas Chromatography using Flame Ionization Detector, Thermal Conductivity Detector, and Mass Spectrometer (GC-FID/TCD/MS)
- Fourier Transform Infrared Spectroscopy (IR/FTIR)
- Thin Layer Chromatography (TLC), Column Chromatography, and Flash Chromatography

#### **COMPUTER SKILLS**

- Microsoft Office: Word, Excel, PowerPoint, Access, Outlook, MS Project
- Various Operating Systems (Linux, DOS, Windows 3.1, Win 95, Win 98, Win 2000, Win XP, Vista)
- Agilent ChemStation Software
- Chemdraw Pro
- HTML Web Page Construction, including JavaScript and Hypertext Markup Language (HTML)
- ACD Software: <sup>13</sup>C NMR Predictor 3.0, <sup>1</sup>H NMR Predictor 3.0, ChemSketch

#### **PRESENTATIONS:**

- *Electrophilic Fluorination of Aryl Alkenes using F-TEDA (Selectfluor<sup>TM</sup>)* M.L. Druelinger and C.C. Hardwick, 14<sup>th</sup> Winter Fluorine Conference (ACS), St. Petersburg, Fla., Jan. 1999 (p.18)

#### **OTHER INTERESTS:**

- 2004 and 2007: President of the Colorado Mycological Society
- Web page design and construction (<http://www.capsandstems.com>)

#### **PUBLICATIONS (EXTERNAL)**

- Hardwick, CC, Ruane, PH, Herivel, TR, Hernandez SC, Goodrich, RP. “*Separation Identification and Quantification of Unbound Riboflavin and Lumichrome in Apheresis Platelets using High Performance Liquid Chromatography Fluorescence Detection: A Method to Support Pathogen Reduction Technology*” Photochemistry and Photobiology, **2004**, 80: 609–615.

**REFERENCES:**

Dr. Patrick H. Ruane	Director of Drug Eluting Stent Chemistry XTENT, Inc., 125 Constitution Drive Menlo Park, CA 94025 Tel: (650) 862-5397 E-mail: <a href="mailto:patrickhruane@yahoo.com">patrickhruane@yahoo.com</a>
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