

Christopher C. Hardwick, M.S.

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EXPERIENCE

Laboratory Scientist – Navigant Biotechnologies Inc. (May 2000 – Present)



- * Assisted in start up chemistry GLP compliance program
- * Study director of chemistry GLP studies
- * Developed and validated analytical techniques.
- * Familiar with GMP/GLP/FDA and international regulations relevant to project work.
- * Analytical support of the Pathogen Inactivation project (HPLC/IC/UV-Vis).
- * Designed and performed project work and experiments.
- * Directed work to other technical resources and technicians.
- * Participated in project leadership responsibilities such as report writing, planning, scheduling, and cost control.

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

- * Instruction of General Chemistry I and II (Thermodynamics, Equilibrium, etc.)

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

- * Managed entire operation of store while owner was in state legislature.

Graduate Chemistry Instructor – USC, Pueblo, CO (Aug. 1994 – May 1997)

- * Instruction of General Chemistry Labs.

Graduate Organic Chemistry Research – USC, Pueblo, CO (Aug. 1994 – Oct 1998)

- * Synthesis, isolation, and characterization of novel fluorinated compounds.

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

- * Analytical support (GC) of R&D – Syngas Technology.

Squad Leader – U.S. Army 101st Airborne, Fort Campbell, KY (Aug. 1984 – May 1988)

- * Honorable Discharge.

EDUCATION

M.S. - Organic Chemistry USC, Pueblo, CO (May 1999)

B.S. - Chemistry/Biology (Double Major) USC, Pueblo, CO (May 1994)

INSTRUMENTATION

NMR - ¹⁹F, ¹H, AND ¹³C, Radial Chromatotron, HPLC – DAD, FLD, 2-D Electrophoresis, Ion Chromatography, GC-FID/TCD/MS, IR/FTIR, TLC/Column/Flash Chromatography

COMPUTER SKILLS

Office 2000

Outlook/MS Project

DOS/Windows 3.1/95/98/2000/XP

OTHER INTERESTS

2004: President of the Colorado Mycological Society

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" Submitted to <i>Photochemistry and Photobiology</i> , April 2004 .
Publications (Internal)
Method Verification of High Performance Liquid Chromatography (HPLC) Determination of Caffeine and Theophylline Concentrations in Saline Solutions.
Method Verification of High Performance Liquid Chromatography (HPLC) Determination of Aminophylline Concentration in Saline Solutions.
Method Verification of High Performance Liquid Chromatography (HPLC) Determination of Alprostadil Concentrations in Ethanol Solutions.
Standard Operating Procedure for Analysis of Chloride, Acetate and Phosphate Anions by Ion Chromatography SOP P/N 300054-095
Standard Operating Procedure for Analysis of Vitamin E Acetate ([+/-]-alpha-Tocopherol Acetate), DEHP and Citroflex by High Performance Liquid Chromatography SOP P/N 300054-102
Standard Operating Procedure for Analysis of Riboflavin and Lumichrome by High Performance Liquid Chromatography SOP P/N 300054-094
Validation of High Performance Liquid Chromatography (HPLC) Instrument Method for Determination of Riboflavin and Lumichrome R/N 01-0051
Validation of Ultra-Violet/Visible Spectroscopy Instrument Method for Determination of Riboflavin in Saline Solutions R/N 00-0058
Validation of High Performance Liquid Chromatography (HPLC) Method for Determination of Purity of Vitamin E Acetate ([+/-]-alpha-Tocopherol Acetate), and Concentration of DEHP and Citroflex in Vitamin E Acetate. R/N 01-0054
Validation of High Performance Liquid Chromatography (HPLC) Instrument Method for Determination of Riboflavin and Lumichrome R/N 01-0051
Validation of Ion Chromatography method for Determination of Chloride, Acetate and Phosphate Anions in Aqueous Solutions R/N 00-0133

Job Specific Training	
Document Number	Document Description
038400-415	SOP GLP Equip: Water Baths
038400-417	SOP Corning Megapure Distiller
038400-419	SOP IEC Centrifuges
038400-420	SOP Sartorius 2357 Balance
038400-769	SOP Operation of Lab Balances
038400-772	SOP Calibration and Use of pH Meter
038400-862	SOP Balance Checkweight Log Sheet
038400-874	SOP pH Determination
038400-875	SOP Anion Analysis by IC
038400-876	SOP Reagent Grade Water
038400-931	SOP Printing Specs F/GLL Training Checklist
038400-932	SOP Printing Spec F/Curriculum Vitae
038400-947	SOP Beckman 125 HPLC
038400-951	SOP Sulfite Analysis by Ion Chromatography
038400-978	SOP Cleaning Laboratory Glassware
300054-009	SOP for pH Determination of Sodium Bicarbonate
300054-016	SOP HP 1100 Series HPLC
300054-033	SOP GLL Reports
300054-035	SOP Damon/IEC Centrifuge Model HN-S and HN-SII
300054-036	SOP Sartorius A200S Analytical Balance
300054-037	SOP Thermolyne Type F62735 Furnace
300054-040	SOP Sartorius U3600 Balance
300054-045	SOP Laboratory Refrigerators
300054-056	SOP GLL Audit Program
300054-058	SOP UV Bench Lamp
300054-060	SOP Fisher Isotemp Waterbath
300054-094	SOP Riboflavin & Lumichrome Analysis by HPLC
300094-095	SOP Chloride, Acetate and Phosphate Analysis by IC
300054-101	SOP Dionex DX600 Ion Chromatograph
300054-102	SOP Vitamin E Acetate, DEHP & Citroflex Analysis by HPLC
300100-000	SOP Non GMP Documents
376200-030	SOP Chemical Management Awareness Training
503080-000	SOP Dionex 2010i Ion Chromatograph
503201-000	SOP Spectronic Unicam UV300 Spectrometer
509233-000	SOP Measurement of Conductance
LPS-0021	Hypotonic Stress Response (HSR)

Job Specific Training	
LPS-0023	Platelet Morphology (K-Score)
LPS-0025	Fixation for GMP-140 Analysis
LPS-0027	Beckman-Coulter AcT-diff Operation
LPS-0028	Ciba-Corning 238 Analyzer, Operation
LPS-0032	Platelet Swirl
LPS-0035	Platelet Extent of Shape Change (ESC)
LPS-0040	BioSafety Cabinet, Operation & MQC
LPS-0045	Manual Hematocrit Determination
LPS-0049	Osmotic Fragility Assay
LPS-0056	Beckman-Coulter AcT-diff, MQC
LPS-0060	General Laboratory Equipment, Operation
LPS-0061	General laboratory Equipment, MQC
LPS-0062	Incubator Log Sheet
LPS-0063	Refrigerator Log Sheet
LPS-0064	Freezer Log Sheet
LPS-0065	Dual Compartment Refrigerator Log Sheet
LPS-0070	ELIX water system, Operation & MQC
LPS-0073	Mettler Toledo AG balance, MQC
LPS-0074	Harvey Sterile -max Sterilizer, Operation and MQC
LPS-0075	pH meter, Operation & MQC
LPS-0076	Radiometer ABL725 BGA, MQC
LPS-0082	CIBA-Corning 238 Analyzer, MQC
LPS-0092	2,3 Diphosphoglyceric Acid Assay
LPS-0093	Luminescence-based ATP Assay
LPS-0095	Definition of Apheresis Platelet Process to be used in PET Platelet Process Development and Testing
LPS-0096	CO2 Incubator Log Sheet
LPS-0097	Platelet Incubator Log Sheet
LPS-0109	Plasma Hemoglobin via Hemocue
LPS-0110	Cross-Match Compatibility of RBCs
LPS-0116	Lactate Dehydrogenase Assay with Human Platelet Samples
LPS-0117	Operation of HPLC
LPS-0118	Eye wash
LPS-0121	Riboflavin and Lumichrome via HPLC
LPS-0127	Preparation of Buffy Coat Platelets from Whole Blood
LPS-0128	Procedure for Maintenance, Calibration, and Quality Control of the Fresenius Compomat G4
LPS-0133	Riboflavin Analysis by UV-Vis

Job Specific Training	
LPS-0134	Cleaning Laboratory Glassware for Chemistry
LPS-0135	Purification of Lumichrome for Analytical Standard
LPS-0136	HPLC GLP Testing Schedule
LPS-0137	Bayer 248 Analyzer, Operation
LPS-0138	Bayer 248 Analyzer, MQC
SOP-0002	Product Support Studies
SOP-0017	Requirements for GLP Studies
SOP-0022	Quality Assurance Unit
SOP-0023	Laboratory Facilities
SOP-0024	Control of Laboratory Reagents, Solutions and Chemicals
SOP-0025	Research Studies
SOP-0026	Test and Control Articles
SOP-0031	Safety Requirements

Upper Level Training	
Document Number	Document Description
300100-000	SOP Non GMP Documents
377500-000	POL COBE BCT Quality
377500-001	SOP Writing Standard Operating Procedures
377500-002	SOP Writing Policies and Guidelines
377500-003	SOP Auditing the BCT Quality System
377500-004	SOP FDA Inspections
377500-006	SOP Writing Manufacturing Operating Procedures
377500-007	SOP New of Significantly Modified Products
377500-009	POL Manufacturing Environment
377500-010	SOP Measuring Equipment Control and Calibration
377500-012	POL, Cleanroom Access
377500-013	POL Record Retention
377500-016	POL BCT GMP Training
377500-017	BCT Index
377500-021	POL Complaint Handling
377500-033	SOP Engineering Change Order
377500-036	SOP Removal From Quarantine
377500-038	SOP Device History Record
377500-040	POL Design Controls
377500-042	SOP Plant Tests and Engineering Documentation
377500-045	POL Device Master Record

377500-046	POL Documentation Structure
377500-068	POL Management Responsibilities
377500-070	SOP Supplier Approval
377500-080	SOP BCT Production Disposition

General Training	
Document Number	Document Description
038400-410	SOP Control of Instruments
038400-850	SOP CLG Records Retention
038400-868	SOP Reagents and Chemicals
038400-878	SOP Method Validation Protocols
038400-930	SOP CLG Training
038400-978	SOP Cleaning Laboratory Glassware
038400-984	SOP Approved Supplier List Used by CLG
079494-101	CLG Index
200054-033	SOP CLG Reports
300080-000	SOP CLG Safety Policy
300081-000	SOP CLG Notebook Policy
377500-400	Business Services Index
777092-736	SOP Business Services Complaint Handling System

External Seminars/Training		
Date	Organization	Description
06/02-04/04	Gambro BCT	Project Management Workshop
11/14/02	Gambro	(Brown Bag): Red Gold, Episode Four
11/12/02	Gambro	(Brown Bag): Red Gold, Episode Three
11/07/02	Gambro	(Brown Bag): Red Gold, Episode Two
11/05/02	Gambro	(Brown Bag): Red Gold, Episode One: Magic to Medicine
10/24/02	Agilent - Thomas J. Waeghe	Validated HPLC Methods - To Tweak or Not to Tweak
8/25/02	Agilent	E-Seminar: HPLC Method Optimization III: When All Else Fails: Gradient Elution, Normal Phase
8/08/02	Agilent	E-Seminar: HPLC Method Development by the Numbers
07/30/02	Gambro	(Brown Bag): Dendritic Cells in Cancer Vaccine Therapy
06/26/02	Gambro – Dennis Caddigan	(Brown Bag) RF Welding
06/18/02	Gambro - Cheresse Montgomery	MS Project Advanced Training
06/11/02	Gambro - Cheresse Montgomery	MS Project Intermediate Training
05/22/02	Gambro – Joe Fenn	MS Outlook web access
05/21/02	Gambro - Cheresse Montgomery	MS Project Introductory Training
05/02/02	Gambro – Kathy Kimmens	Communication styles
01/22/02	Gambro – Maureen Detine	Marketing training
10/16/01	Gambro – Terri Salankey	Quality System Big 7
09/24/01	Gambro – Kathy Kimmens	Team Development
09/21/01	Gambro – Kathy Kimmens	Apples & Oranges Finance and Marketing
07/25/01	Gambro – Outside Trainer	(Brown Bag) 401K
06/05/01	Gambro – Tuane Young	Security Brief of Facility
12/07/00	Gambro – Outside Trainer	Rethinking Stress
12/04/00	Gambro – Dennis Hlavinka	Pathogen Eradication Technology
10/17/00	Gambro – Maureen Detine	QA Manual Update 3 rd QTR 2000
8/29/00	Agilent	E-seminar: Separating Peptides and Proteins in RP-HPLC and RP-HPLC/MS
08/22/00	Gambro – Jennifer Rhamy	(Brown Bag) Blood Basics
8/16/00	Agilent	E-seminar: HPLC Column and System Troubleshooting

8/2/00	Agilent	E-seminar: HPLC Separation Robustness and Ruggedness - Evaluating the Variable
06/07/00	Gambro – Betty Hearty	Bloodborne Pathogen Training

References available upon request