



Curriculum Vitae

Kerin L. Ablashi
kablashi@bcg-usa.com
Consultant
Biologics Consulting Group, Inc.
Derwood, MD

EDUCATION

M.S. *Environmental Biology*, Hood College, Frederick, MD (2000)

B.S. *General Biological Science*, Emphasis in Zoology, The University of Maryland, College Park, Maryland (1989)

EXPERIENCE

Biologics Consulting Group, Inc., Consultant

Derwood, MD (May 2005 to present)

- Serve as Project Manager for client product development, manufacturing, and clinical trial programs, either on-site or off-site as required by clients. Coordinate teleconferences, facilitate communication between parties especially in situations with multiple client groups and/or vendors involved with a project, manage schedules, track progress of all tasks to ensure none are forgotten, and monitor budgets
- Perform vendor qualification and in-process quality audits
- Generate SOPs, study worksheets, and other project-specific documents ranging from general facility/management policies and training forms to clinical endpoint testing worksheets
- Assist in establishing quality practices in academic laboratory settings, working with the staff to ensure that the proscribed procedures are both “user friendly” and compliant with regulatory requirements
- Perform quality review of completed laboratory worksheets, GMP manufacturing records, equipment records, and other project-specific primary documentation
- Write, review, and revise technical documents including white papers, Investigator’s Brochures, clinical study protocols, and informed consent forms
- Conduct Good Documentation Practices training, primarily for academic laboratory personnel



Biosynexus, Incorporated, Project Manager, Manufacturing
Gaithersburg, MD (Oct. 2001 – Apr. 2005)

- Managed Process Development, Technology Transfer, Manufacturing, Distribution, and Analytical Testing for two separate clinical products: one monoclonal antibody and one recombinant protein produced through bacterial fermentation and ultimately formulated into a cream
- Identified potential contractors, perform due diligence and quality audits at vendor sites
- Participated in review of vendor contracts, batch records, technical reports, IND submissions, and SOPs
- Managed contract resources (contract API manufacturers, formulation & filling CMOs, testing labs, and others) to ensure deadlines and budgets are met
- Served as IND Coordinator, including FDA correspondence and personal interaction
- Ensured that manufacturing and testing programs comply with appropriate regulations, working directly with consultants as needed
- Interfaced with the Biosynexus clinical team to ensure that their needs are met

BioReliance Corporation, Client Services Group Project Manager, Manufacturing
Rockville, MD (Mar. 2000 – Oct. 2001)

- Managed projects for multiple clients concurrently
- Worked with Manufacturing Department staff (Process Development, Manufacturing, Quality Control), Quality Assurance personnel, and clients through all phases of contract manufacturing projects to ensure that timeline commitments were met and that the project was performed to meet each client's needs
- Scheduled testing for all Manufacturing projects, including Cell Banking and Process Development
- Communicated regularly with clients and Account Managers to provide project updates
- Participated on project teams, schedule and lead project team meetings to enhance communication both within BioReliance and with the clients
- Provided technical and regulatory advice to clients regarding their projects and associated safety testing
- Scheduled and participated in client site visits, delivered the Manufacturing Services presentation, traveled with Account Managers to visit clients

BioReliance Corporation, Manufacturing Division, Process Development Group, Laboratory Manager II, Technology Transfer
Rockville, MD (June 1999 – Mar. 2000)

- Worked with Manufacturing Department to adapt client processes and new technologies to production suites in a contract manufacturing facility
- Participated in client site visits and conference calls as technical representative
- Assessed the feasibility of client manufacturing plans and developed appropriate documentation
- Wrote and reviewed proposals and project reports for Process Development studies



- Developed documentation (SOPs, Production Records, Technical Specifications) for new processes

BioReliance Corporation, Manufacturing Division, *Laboratory Manager II*, Rockville, MD (July 1998 – May 1999)

- Participated in the manufacturing of retroviruses, adenoviruses, herpesviruses, cell-associated products, and cell banks for a contract manufacturing facility and in accordance with current Good Manufacturing Practices (cGMP) following client specifications
- Scheduled all BioReliance manufacturing, cell banking, and pilot projects
- Worked with Process Development Department and clients to design pilot runs
- Worked with Technology Transfer Group to implement the use of new technologies in manufacturing
- Wrote and reviewed Standard Operating Procedures (SOPs) and Production Records, audited completed production records and cell bank reports
- Participated in client site visits and conference calls, including conducting facility tours for clients

MAGENTA Corporation (A BioReliance Company), *Production Supervisor II* Rockville, Maryland (Apr. 1994 – July 1998)

- Prepared SOPs, production records and training modules for use in cGMP laboratories and production suites; wrote and revised Technical Specifications detailing client production requirements
- Worked directly with clients, Quality Assurance auditors, and production staff to ensure that the client's needs were met
- Trained new employees in cGMP-compliant cell culture and associated techniques
- Designed and ran feasibility studies to develop new production procedures and maximize product yield
- Planned Production Staff daily schedule and supervised up to 10 staff members (5 direct reports)

Microbiological Associates, Inc. (now BioReliance, Corp.), *Senior Biologist* Rockville, MD (Jan. 1991 – Apr. 1994)

- Worked under GLPs and cGMPs
- Wrote production records to comply with FDA guidelines
- Produced adenovirus for gene therapy clinical trials
- Worked in Biosafety Level 3 laboratory
- Performed various cell culture and molecular biology assays

Universal Biotechnologies, Inc. (formerly Pan Data Systems, Inc.), *Laboratory Technician* (Jan. 1990 – Jan. 1991)

- Performed DNA sequencing, tissue culture, assorted virus detection assays
- Produced materials for diagnostic kits (research)
- Tested clinical specimens for chlamydia, syphilis, and glucose level



ADDITIONAL TRAINING

May 2004	Auditing for GMP, The GMP Institute
April 2004	Good Clinical Practices, the Center for Professional Innovation & Education
Aug. 2001	Fundamentals of Finance and Accounting for Non-financial Managers, SkillPath Seminars
Mar. - June 1998	Management Seminar, The Learning Group (at BioReliance) Management Training, American Management Association, Washington, DC
Oct. 1996	Conflict Management for Technical Professionals
July 1996	Management and Development Program, DCM and Associates and KMB and Associates
Oct. 1995	Successfully Managing People
May 1994	Management Skills and Techniques for New Supervisors