

# GRETCHEN LEHMAN, M.S.

4512 North 10<sup>th</sup> Avenue, Boston, Massachusetts 13553  
909.555.1133 ~ grlehman@gmail.com

## PROGRAM LEADER – GLOBAL PHARMA & BIOTECH

*Leading Clinical Research Programs That Enhance Profits, Promote Quality, & Build Client Satisfaction*

**Big-picture leader and clinical project executive who drives on-time, cost-controlled programs in alignment with SOP/budget restrictions.**

**Turnaround expert** who ensures stakeholder satisfaction through constant communications and relationship-building—producing consistent, quality results and tightening cost controls of multimillion-dollar impact to research programs.

**Lab-to-approval expertise** for biologic/molecular pharmaceutical compounds, building top-performance therapeutic business unit/CRO teams and instilling stringent quality throughout drug development.

*Consistently Meet 100% of Fiscal Goals, While Guiding Teams of 100+*

### AREAS OF EXPERTISE

- Compound Development
- Program Planning
- Financial Controls
- Global Oversight
- Business Unit Leadership
- Remote Team Management
- CRO & Vendor Oversight
- Risk Assessment & Reporting
- Matrix Management

### Clinical Research Studies:

*Oncology, Musculoskeletal, Hematology, Cardiovascular, Nervous System*

## PROGRAM LEADERSHIP HISTORY

PPD, Boston, Massachusetts, 2007 - Present

**SENIOR PROJECT MANAGER, 2008–PRESENT / PROJECT MANAGER, 2007–2008**

Phase III HRPC & Phase II Basal Cell Carcinoma Trials | Project & Clinical Team Manager Direction

**As Global Program Manager**, coordinated deliverables from Data Management, Biostatistics, Quality Assurance, and PVG. Direct full-phase financial/contract compliance, logistics, and operations. Administer Master Action, Audit Readiness, Monitoring, and Safety Medical Monitoring plans. Handle client relations.

- **Client Relations:** Preserved \$50M relationship and gained additional \$3.5M (7%) bottom-line profit, turning around challenged project within 6 months by rebuilding trust among client and team members.
- **Rapid Promotion:** Rose to Senior-level role in 6 months based on previous Senior Director experience to tighten controls and improve Oncology program profits (renal, breast, lung cancer protocols).
- **Cost Savings:** Brought project in \$7M (9-10%) under budget, consistently delivering 8%+ savings through precise monitoring of program costs and rapid action on expected vs. actual metrics.
- **Margin Improvement:** Boosted profits \$4M, strengthening budget analyses and monitoring staff spend.
- **Compliance Standards:** Pushed quality past FDA requirements with closely managed performance to SOPs; audited team knowledge with specific training and mentoring in global trial practices.
- **Client Satisfaction:** Raised feedback ratings 45% through constant communication; *commended for vigilant cross-functional oversight* affecting billable hours and strategic, aerial view of project purpose.

XY BIOTECH & WILSON PHARMACEUTICALS, Washington, D.C., 1998–2007

**GLOBAL PROGRAM DIRECTOR, 2004–2007**

Global Oncology Trials | 40+ Countries | \$150-\$200M Budget

**Oversaw global trials with authority for up to 10 simultaneous projects** and matrix management across numerous geographic regions for phase I-III pivotal/non-pivotal trials.

## GLOBAL PROGRAM DIRECTOR, *Continued...*

- **Financial Oversight:** Held high-level fiduciary responsibility as contract leader for major pharmaceutical and biotechnology firms, meeting/exceeding 100% of financial goals for multi-phase global programs.
- **Expense Reductions:** Saved \$38.5M from original \$250M budget after launching 7 projects worldwide and building 200-member global team to implement trials for specific compound under development. Negotiated contract savings with vendors and eliminated costs through efficiency improvements.
- **Staff Leadership:** Guided up to 100 functional/direct reports: Global Program Managers, Clinical Research Associates (CRAs), Project Managers, clinical/cross-functional leaders (DM, Biostats, Medical Writing).
- **Vendor & Delivery Management:** Monitored results from CROs, ensuring quality and alignment with internal procedures. Negotiated vendor contracts; minimized charges by monitoring CRO practices.

## GLOBAL PROJECT MANAGER / GLOBAL PROGRAM MANAGER, 2001–2004

19 Countries | Global Program Planning | 450-900+ Subjects | 6 Project Managers

*Initiated worldwide, multiple-phase (I-III) clinical trials for pharmaceutical and biotech companies*, leading startup-to-close activities and taking oversight of strategic analysis, budget management, regulatory risk/reward assessment, CRO procurement, and NDA preparation/submission, with 100-150+ sites. Held authority for decisions on CRO and ancillary partner outsourcing.

- **Program Oversight :** Led program deliverables of 3-7 protocols (global/non-global clinical trials), logistical management, budget controls, and risk variables.
- **Reporting:** Instituted stringent standards for Project Manager feedback, delivered executive status/risk reporting, and orchestrated project team meetings that included all internal/external program members.
- **RFP Processes:** Took influential role in bid defense meetings with CRO partners; administered CRO relationships, ensuring integration and collaboration among sponsor-CRO teams.

## SENIOR CLINICAL RESEARCH ASSOCIATE, 1998–2001

Phase I-III Global & Non-Global Trials | Pharmaceutical, Biotech, & CRO Firms

*Handled study requirements according to SOPs*, and managed 2-15 investigative sites. Mentored and trained junior clinical team members in monitoring tasks, and supplied detailed reporting to Project Manager.

### Additional Experience:

**PHARMA RESEARCH** (Managed 25 Canadian investigative sites with multiple protocols/therapeutic indications)

### Therapeutic Experience:

Head/Neck, Pancreatic/Breast/Solid Tumor/Advanced/Brain, Rheumatoid Arthritis, Lupus; Non-Hodgkin's Lymphoma/Lymphoma, Colorectal/Non-Small Cell Lung/Renal/Basal Cell Carcinoma; Adult/Pediatric Epilepsy; Stroke, Acute Myocardial Infarction, Congestive Heart Failure/Angina

## EDUCATIONAL BACKGROUND

**MASTER OF SCIENCE IN MEDICAL SCIENCES**, Medical College of Columbia School of Medicine, Dayton, Ohio

**BACHELOR OF SCIENCE IN BIOLOGY**, University of Minnesota, Minneapolis, Minnesota

## PROFESSIONAL AFFILIATIONS

American Society of Clinical Oncology – Association of Clinical Research Professionals