GRETCHEN LEHMAN, M.S.

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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