RUKHSANA LALANI, Ph.D.
Affiliate Scholar
Chapman University School of Pharmacy,
Irvine, California, 92618
Tel: 626-222-9462 (Mobile)
E-mail: lalani@chapman.edu

SUMMARY OF SKILLS

Protein Scientist with multiple years of experience in Pharmaceutical / Biologics and Medical Device industries, and Teaching and Research at academic institutions. Experience in protein purification and characterization, excellent team worker with strong organizational and management skills.

EDUCATION

Ph.D **Protein Chemistry (1985)**
Institution: H.E.J. Research Institute of Chemistry, University of Karachi.

M. S **Chemistry (1981)**
Institution: Western Carolina University, Cullowhee, NC, USA.

M. Sc. **Physical Chemistry (1977)**
Institution: University of Karachi.

B.Sc. (Hons.) **Chemistry, Biochemistry & Physiology (1974)**
Institution: University of Karachi.

KEY ACCOMPLISHMENTS

Teaching:

- Taught Master's level course on Medical Device quality and regulatory systems, at American University of Health Sciences (AUHS), Long Beach, CA.
- Taught Organic and Inorganic chemistry Labs to the under-grads at Western Carolina University, NC.
- Taught Quality Control in Clinical Pathology and Biochemistry Laboratories to the medical students at Aga Khan University Hospital (AKUH), Karachi, Pakistan.
- Trained sales and service engineers "Basics of biochemistry and hematology involved in the field of diagnostics" at Biomedical Corporation, Karachi, Pakistan.

Research:

- Part of the research group of scientists who identified the Human Myostatin Gene.
- Researched on Micro-gravity and Aging process and its relation with the Myostatin gene.
- Participated in NASA project on Micro Gravity and its effect on Rat muscles.
- Well acquainted in analytical and R&D techniques, such as genetic and molecular biology, immunology, histo-chemistry, tissue culture and Stem cell technology. Expertise in Genetic Mapping, PCR, SDS-PAG, CA, IEF Electrophoresis, Capillary Electrophoresis, Western and Northern Blotting, Size Exclusion, Ion Exchange, Affinity Chromatography.

Management Practices and Industry Regulations:

- Managed variety of CAPA projects, including quality, process and change control using project management standards and lean and six sigma methodologies to accomplish measurable organizational goals, coordinated with cross functional teams and outside consultants / contractors, scheduled and set up overall project milestones.

PROFESSIONAL EXPERIENCE

Affiliate Scholar **Aug 2015 – Present**
Chapman University, School of Pharmacy

- Joined the Proteomics Research group at Chapman University, School of Pharmacy. Research interest includes proteomic profiling, protein purification, characterization, including amino acid sequencing and mass spectrometry. Working on bioactive proteins and peptides from various species of plants used in folk medicines in various parts of the world.

Project Manager **July 2013 – Present**
LabDx, Orlando, FL

- Currently consulting for an international exporter of the Bio-Medical, Diagnostic and Research Laboratory equipments, managing international sales and service projects catered to the researchers or scientists at pharmaceutical companies, contract research laboratories, academic and medical institutions, and health and life sciences organizations.

Consultant Quality Engineer **Jan 2013 – May 2013**
Staar Surgical Inc., Monrovia, CA

- Collaborated with R&D, Regulatory and Manufacturing on quality and compliance issues, following the regulatory guidelines on (QSR) Quality Systems Regulations (21 CFR Part 820 and ISO 13485), Design Control (21 CFR 820.30), Risk Assessment / Management (ISO 14971), process validations, labeling and packaging following the ICH guidelines (Q7, Q8, Q9, and Q10).
- Development of the design control documentation, such as Design, Process and Use or Application FMEAs, Risk Management Reports (RMR), Design Verification and Validation protocols (DVVP), Design Traceability Matrix (DTM), Feasibility testing protocols, Manufacturing Verification and Validation of Process (MVVP) etc. Assisted in creating and compiling Device Master Records (DMR) and Device History Files (DHF). Written, Reviewed and approved several Test Methods and Equipment Validation Protocols and Reports, Sterilization Protocols, Shelf Life or Stability study protocols.

Adjunct Faculty, MSCR Program **Jan 2013 – Apr 2013**
American University of Health Sciences, Long Beach, CA

- Taught Master's level course on Introduction to Medical Device Quality and Regulatory Systems. Introducing students to understand the framework of the pharmaceutical manufacturing environment, quality system and regulatory requirements and pre-market requirements for Biologics and Drugs, like BLA, NDA, INDA, ANDA etc.

Consultant Quality Engineer **June 2012 – Nov 2012**
Abbott Medical Optics, Global Division, Santa Ana, CA

- As a member of the Business Excellence Team (BET) at AMO's Global Product Safety Department, coordinated the process improvement project for updating the software, working with cross functional teams, including IT, Manufacturing and Quality.
- Handled projects to improve the business / complaint handling processes using lean and six sigma techniques and recommended necessary process changes.
- Helped in identifying and creating Test Scenarios. Quality Test Plans, Sampling Plans and Process Validation protocols.
- Established and run CAPAs to incorporate the recommended changes to documentation and the CATSWeb Software.
- Executed the software validation protocols for the changes made to the CATSWeb software.
- Improved the overall efficiency of the complaint handling process by reducing the number of Late MDRs, ultimately reducing the cycle time of Medical Device Reporting (MDR).
- Experienced in using the Agile ERP and CATSWeb complaint handling software.

Technical Consultant **July 2010 – Oct 2011**
Nutravitplus LLC, Arcadia, CA

- Developed a dietary supplement business corporation, including the requirements for establishment, registration and licensing following the dietary supplement guidelines (21 CFR, Part 111).
- Designed the labels, labeling and packaging.
- Identified the products and the contract manufacturer.
- Established export and shipping requirements.
- Identified and qualified the overseas clients, negotiated the terms of sales and closed the deals.

Project Manager **Jan 2003 – Jul 2010**
Baxter Healthcare Corporation, Los Angeles CA

Baxter BioScience, a Pharmaceutical / Biologic, QSEAL certified Plasma product manufacturing company. I joined the company at the very inception of the state of the art automated plasma fractionating facility as Senior Quality Engineer and promoted successively with increasing responsibilities to the Principle Quality Engineer and finally to the Project Manager position. Experience includes:

- Set up quality systems, such as Deviations, CAPA, Change Control, Training, Validation, and Management Review.
- Saved a substantial amount to the company, increasing the product yield by identifying, and implementing the changes in the manufacturing processes, quality and change control.
- Identified and corrected gaps in the supplier qualification process, qualifying the chemicals, raw materials and process components, developing specifications, performing vender audits and generating quality agreements.
- Managed and coordinated the company-wide project on the physico-chemical testing and characterization of flexible hoses which resulted in scientific journal publication (Int. J Pharm. 2006 Jun 6: 315(1-2):75-92).
- Worked with a team for validating multi-segment manufacturing process including identification of Critical Process Parameters (CPP) and development of Process Ranges, and implemented those using change control procedures.
- Participated in several internal and external regulatory audits as SME, also responded appropriately to the audit observations.
- Actively monitored, analyzed and reported project progress and performance to the project management office (PMO) and senior leadership team (SLT).
- Presented quality indicators in Management Review meetings attended by quality and operation department heads.
- Generated and managed equipment, product and process related deviations including investigations, root-cause analysis, impact assessment and corrective action.
- Participated in creating the documents required for the FDA submission for Common Pathway.
- Managed and supervised team of three, one contractor and two interns.

Manager, Clinical Research Laboratory **Nov 2001 – Dec 2002**
University of Southern California, Los Angeles, CA /

- Managed the project for setting up a new research lab (core facility) to study Protein metabolism in aging process.
- Successfully managed the project on installation and qualification of Agilent GC-MS system
- Managed clinical research projects involving human subjects.
- Effectively managed the inter-departmental coordination to organize the clinical experiment.
- Optimize analytical procedure for proteins identification using GC-MS technology.

Senior Research Associate **Mar 1997 – Dec 2000**
Charles R Drew University, Los Angeles, CA

- Worked on the research project on Micro-gravity and Aging process and its relation with the Myostatin gene, which resulted in several publications in the reputable scientific Journals.
- Strong background and knowledge in R&D techniques such as genetic and molecular biology, immunology and histo-chemistry, tissue culture and stem cell technology.
- Expertise in DNA and RNA characterization, protein expression assays, well acquainted with Clontech expression arrays and Affymetrix GeneChip technologies.
- Hands on experience in RNA, DNA, Genetic Mapping using Micro-Arrays, PCR, SDS-PAGE, CAE, IEF Electrophoresis, Capillary Electrophoresis, Western and Northern Blotting, Size Exclusion, Ion Exchange, Affinity Chromatography and HPLC.
- Participated and presented the abstracts in various symposia and conferences.

Quality Control Officer **Aug 1985 – Aug 1991**
Aga Khan University Hospital, Karachi, Pakistan

- Worked in the fields of Blood Bank, Coagulation, Microbiology, Histology, Immunology and Chemistry.
- Implemented QC and QA Systems in Clinical Laboratories of a 700-bed teaching hospital.
- Participated in the External QA Programs, such as CAP, Welcome and Burrows, NEQAS and MEQAS.
- Managed the deviations and OOS, conducted failure investigations and suggested corrective actions.
- Developed formulation for quality control sera and diagnostic reagents.
- Taught the course "Introduction to the Clinical and Biochemistry Laboratories" to the medical students at Aga Khan University Hospital (AKUH).
- Participated on basic and community based research projects, resulting in the publications in scientific journals.
- Participated and presented abstracts in the national and international symposia and conferences.

COMPUTER SKILLS AND CERTIFICATES:

- Quality Assurance Software Testing Certificate (2012).
- Quality Assurance Management Certificate for Medical Devices, including GMP/GLP, Regulatory Affairs, Quality Auditing, Technical writing and Doc. & Database Management (2012)
- Six Sigma and Yellow Belt Certification form Baxter University.
- Project Management Methodologies and Leadership Training, 3 Day Course, offered by S2insight inc. (May 2006).
- Microsoft Project, Methods for the PMM, 1.5 Day Training Course offered by S2insight Inc. (November 2007).
- Computer Operating System: Windows.
- Application and Database Software: Microsoft Project, MS office, Visio, VMWare, Quality Test Professional, SQL. Oracle, Agile, CATSWEB, ETQ, Gene Array Analysis (Affymatrix), SPSS and Minitab.

LIST OF PUBLICATION:

Jenke DR, Story J, Lalani R.
Extractables/leachables from plastic tubing used in product manufacturing. **Int J Pharm. 2006 Jun 6; 315(1-2):75-92. Epub 2006 Mar 6.**

Magee TR, Ferrini MG, Davila HH, Zeller CB, Vernet D, Sun J, Lalani R, Burnett AL, Raifer J, Gonzalez Cadavid NE. Protein inhibitor of nitric oxide synthase (NOS) and the N-methyl-D-aspartate receptor are expressed in the rat and mouse penile nerves and colocalize with penile neuronal NOS. **Biol Reprod. 2003 Feb; 68(2):478-88.**

Taylor WE, Bhasin S, Lalani R, Datta A, Gonzalez Cadavid NE.
Alteration of gene expression profiles in skeletal muscle of rats exposed to microgravity during a spaceflight.
J Gravit Physiol. 2002 Dec; 9(2):61-70.

Lalani R, Bhasin S, Byhower F, Tarnuzer R, Grant M, Shen R, Asa S, Ezzat S, Gonzalez Cadavid NE.
Myostatin and insulin-like growth factor-I and -II expression in the muscle of rats exposed to the microgravity environment of the NeuroLab space shuttle flight. **J Endocrinol. 2000 Dec; 167(3):417-28.**

Gonzalez Cadavid NF, Taylor WE, Yarasheski K, Sinha-Hakim, I, Ma K, Ezzat S, Shen R, Lalani R, Asa S, Mamita M, Nair G, Aryer S, Bhasin S.
Organization of the human myostatin gene and expression in healthy men and HIV-infected men with muscle wasting. **ProcNatlAcadSci U S A. 1998 Dec 8; 95(25):14938-43**.

Molla A, Khurshid M, Manser WT, Lalani R, Alam A, Mohammad Z.
Suggested reference ranges in clinical chemistry for apparently healthy males and females of Pakistan.
J Pak Med Assoc. 1993 Jun; 43(6):113-5.

Badruddin SH, Khurshid M, Molla A, Manser WW, Lalani R, Vellani CW.
Factors associated with elevated serum cholesterol levels in well-to-do Pakistani schoolchildren. **J Trop Med Hyg. 1991 Apr; 94(2):123-9.**

Molla A, Manser WW, Lalani R, Badruddin SH, Mahammed Z, Khurshid M.
Blood lipids in a healthy Karachi population. **J Trop Med Hyg. 1990 Aug; 93(4):295-9.**

Molla A, Khurshid M, Lalani R, Manser WW, Alam, A.
Serum alkaline phosphatase in apparently healthy Karachi population. J **Pak Med Assoc. 1990 Aug; 40(8):182-4.**

Manser WW, Lalani R,Haider S, Khan MA.
Trace element studies on Karachi populations. Part V: Blood lead levels in normal healthy adults and grammar school children. **J Pak Med Assoc. 1990 Jul; 40(7):150-4.**

Badruddin SH, Lalani R, Khurshid M, Molla A, Qureshi R, Khan MA.
Serum cholesterol in neonates and their mothers.A pilot study. **J Pak Med Assoc. 1990 May; 40(5):108-9.**

Lalani R, molla A, Khurshid M.
Efficacy of a home-made quality control serum. **J Pak Med Assoc. 1989 Dec; 39(12):317-20.**

Manser WW, Haider S, Lalani R, Khan MA.
Trace element studies on Karachi population, Part II: Normal ranges for blood copper, zinc and magnesium for children and adolescents. **J Pak Med Assoc. 1989 Aug; 39(8):205-8.**

Lalani R, Zafar MN, Khurshid M.
Efficacy of internal and external quality control in chemical pathology. **J Pak Med Assoc. 1988 Oct; 38(10):255-9.**