Nancy Sajjadi, M.Sc.
Founder and Principal
Life Quality by Design, LLC, registered in Virginia
DBA Sajjadi Consulting
www.sajjadiconsulting.com
sajjadiconsulting@gmail.com

703-727-9195

Summary Client Profile (2000-Present)

Biotech/gene therapy start-ups
Biopharmaceutical companies
Contract service facilities
Large pharmaceutical companies
Consulting groups
Academic institutions
Standard setting organizations
Community hospitals

Services Provided

Technical Consulting

Quality systems

- Assay design, development, qualification and validation
- QC laboratory and documentation management
- Review of manufacturing and lot release testing records
- Out of specification (OOS) investigations
- Internal and external audits
- Contract manufacture and test data management
- Design, development and implementation of assay standards
- Stability program development
- Interface with biostatisticians

Regulatory

- Strategy and scientific feasibility assessments
- Product lot release specification development
- Investigational new drug application preparation and review
- Development of responses to FDA queries
- Technical standard operating procedures, test methods, protocols and reports review
- Preparation for successful California Food and Drug Branch inspection

Training

- Regulatory compliance
- Assay development and validation
- Fundamentals in biostatistics
- General biology/biotech for non-scientists

Professional Development- Select Topics for Workshops, Retreats and Coaching Sessions

For Physicians, Nurses, Psychologists, Clinical Social Workers, and Scientists in Leadership Roles

- Creating a Culture of Quality
- Synergy, Psychological Safety, Conflict Resolution and Quality in the Context of Human Evolution
- Understanding Empathy and Empathic Attunement and Its Role in Leadership
- Assessing Your Team for Psychological Safety and Synergy
- Aspects of Just Culture and Servant Leadership That Promote Quality in Healthcare

For VA Dept. of Small Business and Supplier Diversity

- Healthy Work-Life Integration and Self-Care Strategies for Small Business Owners

For Conference of Minority Transportation Officials

- Engineering Well-Being: An Introduction to Life Quality by Design

Professional Leadership Volunteer Activities

- United States Pharmacopeia (USP) *ad hoc* advisory panel member for revision USP<111>/<1034>, new chapter development USP <1032> and <1033> covering design and validation of bioassays and <1098> validation of research test kits (*ad hoc* panels dissolved August 2010)
- USP panel member for <1046> Cell and Gene Therapy chapter (completed)

Chiron Technologies Center for Gene Therapy

Director, Quality Control 1998-2000

General Responsibilities

- *Developed departmental goals and managed budgets for three departments- quality control, assay development and clinical testing*
- *Contributed to leadership position for corporation in gene therapy community through participation in NIH/FDA gene therapy conferences, RAC meetings, and relevant scientific meetings*

Departmental Responsibilities

Quality Control

- Managed in house quality control laboratory and contract laboratories responsible for raw materials, in process, bulk and final container product testing
- Conducted testing review and dispositioning of raw materials and gene therapy products for use in preclinical and clinical studies
- Developed raw material, cell bank and product specifications
- Developed and implemented bulk and final container product stability program
- Developed and managed assay validation studies

Assay Development

- Directed project to assess the probability of germline transduction after a high dose retroviral vector encoding human FVIII was administered intravenously in a rabbit model
- Directed activities in the design, development, and transfer of molecular and bioassays to support retroviral and plasmid based vectors
- Managed polymerase chain reaction (PCR)- based biodistribution analyses as part of pharmacology and toxicology preclinical research studies

Clinical testing

- Developed testing plans to support phase I, phase II and lifetime monitoring of gene therapy trial subjects for product specific assays
- Directed activities necessary to receive samples, conduct in house tests and report results for clinical specimens

Associate Director, Testing Services 1995-1997

- Assumed responsibility for quality control and clinical trials testing function after acquisition of Viagene, Inc. by Chiron Corporation
- Continued management of ongoing and newly initiated preclinical studies and assay development
- Led investigation into the detection of replication competent retrovirus (RCR) in vector producing cell line and rejected product lots

Manager, Pharmaceutical Analysis 1994-1995 (Viagene, Inc.)

- Conducted PCR based biolocalization studies for directly administered retroviral vector encoding HIV *env/rev*
- Developed strategy to monitor clinical trial subjects for RCR that was accepted by FDA
- Managed development and extensive characterization of RCR detection and product titering methods for transfer to quality control
- Managed PCR core facility

Research Scientist I 1992-1994 (Viagene, Inc.)

- Evaluated existing methods to detect RCR for sensitivity, specificity and suitability as release tests for transduced cell and recombinant retroviral products
- Developed panel of assays to measure potency of a retroviral vector encoding HIV *env/rev* proteins
- Evaluated molecular and cell based assays for titering recombinant retroviral vectors
- Developed panel of PCR assays for use in research, clinical trials testing, product characterization and OOS investigations
- Developed methods for identity of biological raw materials for vector production

Research Associate III 1990-1992 (Viagene, Inc.)

- Designed PCR assays and conducted analyses to support overall toxicology and pharmacology studies for recombinant retroviral vector
- Developed PCR based end point dilution assay for monitoring HIV viral load in peripheral blood mononuclear cells from clinical trial subjects enrolled in a phase I study

Research Associate II 1989-1990 (Viagene, Inc.)

- Designed, constructed and tested vector producing cell lines
- Designed and tested culture conditions for stimulating retrovirus replication/expression in peripheral blood mononuclear cells from rheumatoid arthritis patients

ACADEMIC RESEARCH EXPERIENCE
Agouron Research Institute -Dr. Robert Reese, Principal Investigator

Research Technician January 1988- December 1988

- Provided technical support to PI and postdoctoral fellows conducting research on *Plasmodium falciparum* malaria vaccine development. Responsibilities included malaria cell culture maintenance, amino acid analysis, gene cloning, gene sequencing and western blot analysis.

PEER REVIEWED PUBLICATIONS

1. **Sajjadi N,** Callahan J. Defining therapeutic window for viral vectors: A statistical framework to improve consistency in assigning product dose values. *BioProcess J,* 2020; 19. https://doi.org/10.12665/J19OA.Sajjadi

2. W. Hauck, R. Capen, J. Callahan, J. DeMuth, H. Hsu, D. Lansky, **N. Sajjadi**, S. Seaver, R. Singer, and D. Weisman. Assessing parallelism prior to determining relative potency. 2005 *PDA Journal of Pharmaceutical Science and Technology* 59 (2), 127-137.

3. **N. Sajjadi** and J. Callahan. Detailing an approach to using the adenovirus reference material (ARM). 2003 *BioProcess J,* 2 (5), 83-87. https://www.bioprocessingjournal.com/index.php/article-downloads/279-j25-defining-a-detailed-approach-to-using-the-adenovirus-reference-material-arm

4. J.Powell, M. Ragni, G. White, J. Lusher, C. Hillman-Wiseman, T. Moon, V. Cole, S. Ramanathan-Girish, H. Roehl, **N. Sajjadi**, D. Jolly and D.Hurst. Phase I trial of FVIII gene transfer for severe hemophilia A using a retroviral construct administered by peripheral intravenous injection. 2003 *Blood* 102 (6), 2038-2045.

5. J. Callahan and **N. Sajjadi**. Testing the null hypothesis for a specified difference—The right way to test for parallelism. 2003 *BioProcess J,* 2 (2).; 71-77.

6. B. Hutchins, **N.Sajjadi**, S. Seaver, A. Sheperd, S. Bauer, S. Simek, K. Carson, E. Aguilar-Cordova. Working Toward and Adenoviral Vector Testing Standard. 2000 *Mol. Ther.* 2 (6) 532-534.

7. H. Roehl, M. Leibbrandt, J. Greengard, E. Kamantigue, W. Glass, K. Boekelheide, D. Johnson, D. Jolly, and **N. Sajjadi** Analysis of testes and semen samples from rabbits that received intravenous administration of a retroviral vector encoding the human factor VIII gene- No evidence for germline transduction. 2000 *Hu. Gen. Ther.* 11: 2529-2540.

8. P. Sheridan, M. Bodner, A. Lynn, T. Phuong, N. DePolo, D. DeLaVega, J. O'Dea, K. Nguyen, J. McCormack, D. Driver, K. Townsend, C. Ibanez, **N. Sajjadi**, J. Greengard, M. Moore, J. Respess, S. Chang, T. Dubensky, D. Jolly and S. Sauter Generation of retroviral packaging and producer cell lines for large scale vector production and clinical application: Improved safety and high titer. 2000, *Mol. Ther*. 2 (3): 223-232.

9. McCormack, J.E., D. Martineau, N. DePolo, S. Maifert, L.Akbarian, K. Townsend, W. Lee, M. Irwin, **N. Sajjadi,** D.J. Jolly and J. Warner Anti-vector immunoglobulin induced by retroviral vectors. 1997 *Hu. Gene Ther.* ; 8(10): 1263-1273.

10. D. Martineau, W.M. Klump, J.E. McCormack, N. DePolo, E. Kamantigue, M. Petrowski, J. Hanlon, D.J. Jolly**,** S.J Mento and **N. Sajjadi** Evaluation of PCR and ELISA assays for screening clinical trial subjects for replication-competent retrovirus. *Hu. Gene Ther.* 1997; 8(10): 1231-1241.

11. Printz M, Reynolds J, Mento SJ, Jolly D, Kowal K, Sajjadi N. Recombinant retroviral vector interferes with the detection of amphotropic replication competent retrovirus in standard culture assays. Gene Ther. 1995 Mar;2(2):143-50. PMID: 7719931.

PRESENTATIONS /CONFERENCE PARTICIPATION

"DOSE ESCALATION STUDIES: *HOW TO DEAL WITH VARIABILITY IN VECTOR DOSE MEASUREMENTS"*
Cambridge Healthtech Institute – Virtual, March 23,2021
Best of Biotherapeutic Analytics Summit Virtual Series- Cell and Gene Therapy Analytics- Speaker

"OPTIMIZING BIOASSAYS FOR BIOLOGICS ANNUAL CONFERENCE-CASE STUDIES DEMONSTRATING SUCCESSFUL BIOASSAY DEVELOPMENT"
Cambridge Healthtech Institute – Virtual, October 8,2020
Invited Session Chair and Panel Moderator- INNOVATIVE STRATEGIES TO DESIGN BIOASSAYS track

"CREATING A CULTURE OF SYNERGY-AN EVOLUTION INSPIRED APPROACH TO ACHIEVING OPTIMAL OUTCOMES FOR ALL"
Chesapeake Bay Chapter American Biosafety Association (ChABSA) - Virtual June 3, 2020

Annual Scientific Symposium
"UNDERSTANDING CRITICAL FOLD DIFFERENCE AND ITS APPLICATION IN REPORTING ASSAY PRECISION"
Cell Therapy Working Group Forum--US FDA White Oak Campus
Silver Spring MD, March 2019
(**Invited speaker**)

"UNDERSTANDING CRITICAL FOLD DIFFERENCE AND ITS APPLICATION IN REPORTING ASSAY PRECISION"

1. -BEBPA's 3rd Annual US Bioassay Conference - San Pedro CA, March 2019
2. Immunogenicity and Bioassay Summit - Washington DC, October 2018 (**Invited speaker**)

"BIOASSAYS FOR CELL AND GENE THERAPIES- WHAT KIND OF ASSAYS ARE RELEVANT? WHAT ARE THE ANALYTICAL CHALLENGES"
Well Characterized Biologics and Biological Assays
Rockville MD, October 2018
(Invited Panelist)

"ACHIEVING SUCCESS BY CREATING A CULTURE OF COOPERATIVE ADAPTABILITY"
Women and Children's Service Quality and Education Forum
Anne Arundel Medical Center
Annapolis MD, May 2018

(Invited Speaker/Panelist)
DESIGN, DEVELOPMENT AND VALIDATION OF ASSAYS TO SUPPORT ADVANCEMENT OF EXPERIMENTAL THERAPIES
UCLA California Institute for Regenerative Medicine
Los Angeles CA, March 2018
(Departmental Seminar; Invited Speaker)

"APPLYING QUALITY BY DESIGN PRINCIPLES TO ASSAYS- LESSONS FROM THE DEVELOPMENT OF UNCONVENTIONAL VACCINES"
New Technologies, New Vaccines
Wilmington DE ,March 2014
(**Invited speaker**)

"ASSAY VALIDATION 101- *GOOD SCIENCE MEETS FEDERAL COMPLIANCE"*
UCLA California Institute for Regenerative Medicine
Los Angeles CA ,October 2012
(Departmental Seminar; Invited Speaker)

TEACHING AND COURSE DEVELOPMENT

"BIOSTATISTICS FOR BEGINNERS"
Cambridge Healthtech Institute: Immunogenicity and Bioassay Summit Pre-conference Workshop
Alexandria, VA October 2019
(**Course Developer/Instructor**)

"CONSIDERATIONS IN THE DEVELOPMENT AND QUALIFICATION OF CLINICAL ENDPOINT ASSAYS"
Clinical Trials Training Course: Lab to Licensure
American Society for Cell and Gene Therapy Conference
Washington DC May 2014
(**Invited speaker**)

BIOLOGY 101: General Biology I and Lab (Annandale campus; 3 semesters)
BIOLOGY 165: Principles in Regulatory and Quality Environments for Biotechnology (Manassas campus; developed course and taught first offering)
Adjunct Professor, Northern Virginia Community College 2011-2012

CONTINUING EDUCATION THROUGH CONFERENCE ATTENDANCE

Technical

- CASSS Cell & Gene Therapy Products July 2018 (Bethesda, MD)
- 29th CMC Strategy Forum- Bridging Analytical Methods for Release and Stability Testing: Technical, Quality and Regulatory Considerations (Renaissance Mayflower, Washington DC)
- PQRI Workshop on Nanomaterial Drug Products: Current Experience and Management of Potential Risks (USP HQ, Rockville, MD)
- Suitability and Compatibility for Packaging and Delivery Systems Workshop Co-sponsored by PQRI and USP (USP HQ, Rockville, MD)
- Co-sponsored Workshop on Cell and Tissue-based Regenerative Medicine Products: From Characterization to Compendial Assays (USP HQ, Rockville, MD)

CONTINUING EDUCATION THROUGH CONFERENCE ATTENDANCE

Culture of Quality

- Healthy Aging Summit (July 2018, Washington, DC).
- Uniting Women in Cyber Symposium (March 2018, McLean, VA)
- 2nd Annual Annapolis Physician Wellbeing Conference (Annapolis, MD March 2018)
- 9th Employer Healthcare and Benefits Congress (Los Angeles, CA, October 2017)
- Gallup Course- Women: Work and Life Well-Lived; How to Attract, Engage and Retain a Gender Diverse Workforce (Washington DC, June 2017)
- George Mason University Leading to Well-Being Conference (Fairfax VA, April 2017)

COLLEGE EDUCATION

1985 - 1987 **M. Sc. Microbiology** University of British Columbia
Thesis: Cloning and characterization of a cellobiase gene from *Cellulomonas fimi*

1981 - 1985 **B. Sc. (Honours) Microbiology** University of British Columbia