

Nancy Sajjadi, M.Sc.
Founder and Principal
Life Quality by Design, LLC, registered in Virginia
DBA Sajjadi Consulting
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Summary Client Profile (2000-Present)

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

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| — Regulatory compliance | — Fundamentals in biostatistics |
| — Assay development and validation | — 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. Using an Equivalence Approach to Establish Lot Release Limits for Vector Dose During Pre-Clinical Studies and Early Phase Clinical Trials. *Manuscript in preparation. Preview of article distributed at ISBiotech Viral Vectors and Vaccines Conference March 2023 by BioProcessing Journal.*
2. **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/J190A.Sajjadi>
3. 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.
4. **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>
5. 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.
6. 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.
7. 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.

8. 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.
9. 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. Respass, 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.
10. 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.
11. 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.
12. 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
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“A TALE OF TWO READOUTS”

CaSSS Bioassay 2023- Gaithersburg, MD April 18, 2023

Podium Presentation-Invited Speaker

“USING AN EQUIVALENCE APPROACH TO ESTABLISH LOT RELEASE LIMITS FOR VECTOR DOSE DURING PRE-CLINICAL STUDIES AND EARLY PHASE CLINICAL TRIALS”

ISBiotech Viral Vectors and Vaccines- Norfolk, VA, March 22, 2023

Podium Presentation

“STATISTICS AND BIOASSAYS: FROM FAQs TO FACTS”

Cambridge Healthtech Institute- Arlington, VA, October 3-6, 2022

Immunogenicity and Bioassay Summit; Optimizing for Biologics track- Session Co-Chair

“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

“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)

Also presented at:

- BEBPA’s 3rd Annual US Bioassay Conference - San Pedro CA, March 2019
- 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)

TEACHING AND COURSE DEVELOPMENT
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“BIostatISTICS FOR BEGINNERS”

Cambridge Healthtech Institute: Immunogenicity and Bioassay Summit Pre-conference Workshop
Arlington VA, October 2019

Alexandria, VA October 2022

(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 ONLY

Technical

- CASSS Bioassay July 2022 (Gaithersburg, MD)
- 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