Leslie Shawn Novick

7307 W. Green Lake Dr. N. 206-861-9773 (mobile)
Seattle, WA 98103 novicksl@gmail.com

Enthusiastic, highly motivated, strategically focused leader
with extensive biotherapeutic CMC experience

Summary

- Sr. Director of Quality Control at Seattle Genetics, leading a group of 50 members including analysts, scientists, managers, and directors.
- Responsible for
    - Strategic and tactical decisions regarding release and technical review of 11 clinical and one commercial product. Comfortable working on pre-clinical to commercial stages of product lifecycle
    - Working with partners and contract manufacturing organizations to ensure clear relationship roles and responsibilities as well as regulatory compliance and quality of output
    - Providing both written and verbal communications with regulatory authorities
- Knowledge of GMP, EU, JP, and ICH guidelines and comfortable working to meet those requirements.
- Regularly write and edit reports for internal and external distribution as well as CMC portions (Module 3) of IND, IMPD, BLA and MAA submissions and amendments using the eCTD format.
- Quality Control primary representative during regulatory inspections and discussions with regulatory authorities
- Extensive experience in both development and Quality Control laboratories with 15 years in analytical development and 13 years in Quality Control.
- Commercial products I have worked on include Adcetris®, Enbrel® (an Fc-linked glycoprotein dimer), Leukine®, Bexxar®, Vectabix®.
- Clinical phase products include a number of IgG_1 and IgG_2 monoclonal antibodies ("naked" and conjugated with either aurostatins, PBDs, or I^{131}), IL1-Receptor, Flt3-Ligand, B726P breast cancer vaccine, WT-1 leukemia vaccine, and TB-72F tuberculosis vaccine.

Professional Experience

Quality Control Scientist/Manager/ Director/Sr. Director
2005-Present
Quality Control; Seattle Genetics, Bothell, WA

Coordinating and Supervising Responsibilities:

- Managing a group of 50 QC technicians, scientists, and managers responsible for performing release and stability testing as well as all QC responsibilities within a manufacturing facility, including a full microbiology and raw materials testing group.
- Working with contract organizations to perform testing in compliance with cGMPs and with a high degree of scientific integrity
- Participating in FTE and budgeting decisions
- Auditing CMOs for compliance to GMP guidelines and participating in due diligence evaluations.
- Overseeing transfer of assays between Seattle Genetics Quality Control and contract manufacturers.
- Supervising execution of assay validation for release of monoclonal antibodies and ADCs.

- Representing QC during regulatory inspections and in conferences with regulatory authorities.
- Writing CMC sections (Control of Drug Substance and Drug Product sections and Stability sections) for EU and FDA submissions.
-

Analytical Scientist 2003–2004
Analytical Biochemistry; Corixa Corporation, Seattle

Coordinating and Supervising Responsibilities:

- Lead Scientist responsible for transfer to a CMO of the Manufacturing Process and Analytics for a protein/adjuvant vaccine for breast cancer.
- Core responsibility for analytical characterization and development of QC assays needed for products in development.
- Developed work plans to assure meeting analytical development and IND filing timelines.
- Determined FTE requirements for product development activities.
- Attended internal and external scientific meetings.
- Wrote IND sections for FDA submissions and assay development reports for internal use and partner companies.
- Transferred assays to contract manufacturing organizations.

Laboratory responsibilities:

- Analyzed fusion proteins for cancer vaccines, a number of radioactive immunotherapy monoclonal antibodies, a salmonella-derived adjuvant, and a protein/adenovirus vaccine using HPLC, ELISA, MS, and other techniques.
- Developed HPLC methods for the analysis of recombinant human proteins prepared in *E. coli*, CHO, and hybridoma cell lines.
- Established stability indicating assays and protocols.
- Evaluated proteins, determining disulfide pairing, aggregation state, glycosylation sites, glycosylation profiles, and other post-translational modifications.
- Characterized protein products for presence of product-related and host cell protein impurities.

Associate Scientist 2002–2003
Analytical Sciences; Amgen Washington, Seattle

Coordinating/Management responsibilities:

- Transferred analytical assays developed at Amgen Seattle to GMP manufacturing facilities and to Amgen-Thousand Oaks.
- Audited QC departments at CMOs to determine feasibility for transfer of assays.

Laboratory Responsibilities:

- Developed methods for characterization and quality determination of monoclonal antibodies.
- Worked in teams to characterize glycoproteins in development.
- Used Capillary Electrophoresis and HPLC to help characterize post-translational modifications on an IgG2 antibody.

Research Assistant -Senior Research Associate
1990–2002
Analytical Chemistry and Formulations; Immunex Corporation, Seattle

Responsibilities:

- Developed Capillary Electrophoresis methods for use as in-process, stability, and QC methods for proteins in the Immunex pipeline.
- Characterized CE profiles, identified peaks, used CE as a characterization tool for both proteins and glycans.
- Characterized recombinant glyco-proteins and developed stability-indicating and QC methods for use in formulations and process development, as well as in QC.
- Coordinated testing of in-process samples to assure molecular equivalency when different fermentation and purification processes were explored.
- Transferred in-process and release assays to contract manufacturers.
- Wrote analytical characterization portions for IND submissions.
- Presented at internal and external scientific meetings.

QC Analyst 1989 –1990
Quality Control; Immunex

Responsibilities:

- Followed GMP and GLP guidelines for testing recombinant proteins per S.O.P.s using many of the above techniques.
- Responsible for training new employees, maintaining the lab and scheduling assays to meet release deadlines for clinical and marketed products.
- Participated in assay transfer and optimization.
- Wrote S.O.P.s for analytical Q.C. methods.

Education

B.A.	New York University
Graduate Biochemistry Coursework	University of Washington

Professional Associations

CASSS: Associate Director

CASSS is the global premier, non-profit scientific society facilitating the interaction among industry, academic and regulatory professionals

ECA: Member

The European Compliance Academy (ECA) is the leading European association with regard to GMP and regulatory compliance.

PDA: Member
IQ Consortium

IABS (International Alliance for Bioanalytics Standardization): Member
Committee member on the Biotherapeutics Committee

Presentations

Antibody Drug Conjugates
Shawn Novick, Nathan Ihle, Damon Meyer, Carol Krantz, Oscar Salas
Oral presentation: *FDA OBP Training, 2018*

Proteomics; Modern Methods of Protein Analysis (1)
Shawn Novick
Invited lecture for Lehigh University Graduate Chemistry (class # CHM475-D10) through their distance education program. Included in their Spring, 2008 catalogue.

Characterization of Charge Isoforms of a Monoclonal Antibody Using C-IEF
Shawn Novick, Amy Guo, Robert Bailey, Claudia Jochheim
Oral presentation at *CE in Biotechnology and Pharmaceutical Industry, 2002*

Analysis of Glycosylated Proteins Using LabChip Technology
Shawn Novick
Oral presentation at *CE in Biotechnology and Pharmaceutical Industry, 2001*

Characterization of CE-SDS and C-IEF profiles of Glycoproteins
Shawn Novick, Claudia Jochheim, Mei Han, Wayne Gombotz,
Oral presentation at the *14th International Symposium on Microscale Separations and Analysis, 2001*

Characterization and Monitoring of C-Terminal Heterogeneity in rhuFlt3 Ligand Derived From CHO Cells
Shawn Novick, Claudia Jochheim, Wayne Gombotz
Poster presented at the *3rd Well Characterized Biological Pharmaceutical conference, 1/99*

Separation of rhuTNFR:Fc Isoforms by C-IEF
Shawn Novick, Claudia Jochheim, Wesley Wang, Wayne Gombotz.
Poster presented at the *Ninth International Symposium on High Performance Capillary Electrophoresis and Related Microscale Techniques.3/98*

Purification of Recombinant Human IL-1R by Displacement Chromatography
Clayton Brooks, Galina Blum, Kay Stremler, **Shawn Novick,** Joe Dunn
Oral presentation at *Recovery of Biological Products VII, 1997*

Characterization of a Recombinant Human Interleukin-1 Receptor
J. L. McGourty, **S. Novick**, K. Brasher, K. Stremler, A. Balland, S. Srinivasan, S. Waugh, H. Sassenfeld
Poster presented at *Recovery of Biological Products VI, 1996*

Characterization of CHO Cell Derived Interleukin-1 Receptor Glycoforms
K. Stremler, **S. Novick**, C. Brooks, C. Jochheim, K. Hoch, C. Blosch, C. Jacobs, H. Sassenfeld
Oral presentation at the *Third International Glycobiology Symposium 1995*

Publications:

Expectations for Phase-Appropriate Drug Substance and Drug Product Specifications for Early-Stage Protein Therapeutics
Kretsinger, Juliana; Frantz, Neha; Hart, Scott A; Kelley, Wayne P; Kitchen, Bob; **Novick, Shawn**; Rellahan, Barbara; Stranges, Daniela ; Stroop, Corné J.M.;Yin, Ping^{0} and Gastens, Martin H. *Journal of Pharmaceutical Sciences,* TBD

Electrophoretic Evidence for the Presence of Structural Isoforms specific to IgG_2 isotype
Amy Guo, Mei Han, Theresa Martinez, Randal Ketchem, **Shawn Novick**, Claudia Jochheim, Alain Balland. *Electrophoresis*, vol. 29, 2008

Evaluation of pI Marker Sources for cIEF Characterization of a Therapeutic Antibody
Charlie Meert, Amy Guo, **Shawn Novick**, Dean Petit, Alain Balland

Chromatographia, vol. 66, no. 11-12, December 2007

Separation of Enbrel (rhuTNFR:Fc) Isoforms by Capillary Isoelectric Focusing
Book chapter in *Methods of Capillary Electrophoresis*
Claudia Jochheim; **Shawn Novick;** Alain Balland; Julia Mahan; Wei-Chun Wang; Andrew Goetze; Wayne Gombotz

Separation and Characterization of Monoclonal Immunoglobulin IgG_2 Antibody by Cation Exchange Chromatography (CEX)
Yuling Zhang, Andrew Goetze, **Shawn Novick**, Claudia Jochheim, Julia Boyce, Mary Gerhart, Xiaochun Qin, and Wayne Gombotz
Bioprocessing Journal, vol. 2 (12), 2003.