


SELEN STROMGREN

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CAREER PHILOSOPHY

To be a life-long learner and refine skills to perform current duties as a senior executive as effectively as possible in an increasingly digital world where extracting, filtering, and digesting information to guide decisions will be a key tenet of success.



EDUCATION

Ph.D. | Massachusetts Institute of Technology

2001

Physical Chemistry

Graduate Cumulative GPA: 4.9 (on a 5.0 scale)

B.A. | Knox College

1995

Summa Cum Laude

Majors: Chemistry, Mathematics



EMPLOYMENT

Associate Director for Research | FDA/ORA/Office of Regulatory Science (ORS)

2008 - PRESENT

Occupied positions of increasing responsibility and scope within ORA's science office since 2008. In current role, responsible for management and leadership of the diverse research portfolios of 15 ORA/ORS specialized analytical programs located at 12 laboratories distributed across the country. Also oversee the national scientific quality management program as well as the national scientific training program across the lab network.

Senior Research Scientist | Meso Scale Diagnostics, LLC

2001 - 2008

Lead scientist in development of clinical immunoassays on a point-of-care diagnostics platform. This platform consists of a reader and a disposable cartridge unit that is designed for microfluidics applications.



SKILLS

- Technical expertise in chemistry and related fields / critical technical reviewer of scientific projects and manuscripts
- Data analytics and visualization (R-Studio, PowerBI)
- Peer recognized strength in oral and written communication
- Professional mentorship
- Scientific resource management and planning



ACTIVITIES

- Proven ability to envision high-impact projects and garner diverse stakeholder support to affect organizational improvement: Among envisioned and implemented projects are Lab Optimization which increased ORA lab network capacity utilization by 40% and Operation Checkers which significantly strengthened scientific accountability within the lab network as demonstrated by a 20% reduction in deficiencies found in first-party audits.
- Ardent practitioner of organizing, cataloguing, distilling, and trending large volumes of cumulative lab operational data, such as proficiency testing results, staffing allocations, sample analysis statistics to uncover relational observations and make data-driven recommendations that identify operational gaps, bottlenecks, or better ways of doing business.
- Design and execution of technical educational workshops, partnering with FDA product centers, to upskill the ORA workforce in emerging fields:
 - Data Science Workshop - April 2021
 - Advanced Manufacturing Workshop – Sep 2018, May 2021
 - Digital Health and AI/ML Applications – Nov 2021
- Implementing expansion by 30% of methodology and instrument scope of ORA labs into new testing paradigms to be able to analyze novel and emerging products more critically.
- Over full career, was co-inventee on six US industry patents, a lead author on several scientific publications, and an invited speaker at numerous professional meetings within and outside of FDA.



SELECT AWARDS AND RECOGNITION

ACIL Public Service Award – presented to individuals from government in recognition of outstanding leadership for the advancement of independent testing industry (2024)

FDA ACRA Award of Excellence – inaugural recipient (2016)

FDA Scientific Achievement Award – outstanding inter-center scientific collaboration (2011, 2015)



CREDENTIALS IN PROGRESS

American Society of Quality: CQA (Feb 2014) CMQ/OE (Mar 2024)

Level 1 Leadership and Performance Coaching Certificate (Sep 2024)



PUBLICATIONS

Chad P. Nelson, Paul Brown, Suzanne Fitzpatrick, Kevin A. Ford, Paul C Howard, Tracy MacGill, Edward E. C. Margerrison, Donna L. Mendrick, Jacqueline O'Shaughnessy, Tucker A Patterson, Rakesh Raghuwanshi, Rodney Rouse, David G. Strauss **Selen Stromgren**, Kyung, E. Sung, Luis G. Valerio, Jr., Jeffrey L. Ward, Namandjé Bumpus, "Regulatory Considerations for New Alternative Methods: An FDA Perspective," *Science Magazine Article - Policy Forum* (submitted Apr, 2023)

Narong Chamkasem, Tiffany Harmon, LaTonya Mitchell, **Selen A. Stromgren**, "A Rapid LC/MS Method for Determination of Dicyclanil in Sheep Muscle Tissue and Fat," *FDA Laboratory Information Bulletin*, **4489** (2011)

Shaun MacMahon, Timothy Begley, Gregory Diachencko, **Selen A. Stromgren**, "A Liquid Chromatography-Tandem Mass Spectrometry Method for the Detection of High Nitrogen Adulterants," *FDA Laboratory Information Bulletin*, **4487** (2011) & *Journal of Chromatography A* **Jan13:1220**, 101 (2012)

Narong Chamkasem, Tiffany Harmon, LaTonya Mitchell, **Selen A. Stromgren**, Yi Lin, Jon W. Wong, "A Rapid LC/MS Method for Determination of Teflubenzuron in Salmon Tissue," *FDA Laboratory Information Bulletin*, **4463** (2010)

Selen Altunata, Kevin L. Cunningham, Manjula Canagaratna, Ryan Thom, and Robert W. Field, "The Mechanism of Surface Electron Ejection by Laser Excited Metastable Molecules" *Journal of Physical Chemistry A* 106, 1122 (2002)

Adya P. Mishra, Ryan L. Thom, **Selen Altunata**, Robert W. Field, "Study of Intramolecular Dynamics of Highly Energies Small Molecules Using Laser Spectroscopic Techniques," In Book: Current Developments in Atomic, Molecular, and Chemical Physics with Applications (pp. 49-56) (2002)

Selen Altunata and Robert W. Field, "An Assumption-Violating Application of the Lawrance – Knight Deconvolution Procedure: A Retrieval of Electronic Coupling Mechanisms Underlying Complex Spectra," *Journal of Chemical Physics* **114**, 6557 (2001)

Selen Altunata, "Chemistry and Humanity: Challenges Our Profession Faces as We Advance Towards the Third Millenium," *HYLE International Journal of Philosophy of Chemistry* **7**, 51 (2001)

Selen Altunata and Robert W. Field, "A Statistical Approach for the Study of Singlet-Triplet Interactions in Small Polyatomic Molecules," *Journal of Chemical Physics* **113**, No.16 (Oct. 2000)

Co-author of Instructor's Solution Manual of Probability and Statistics: A Multivariate Approach by Kevin J. Hastings, Addison_Wesley Longman, MA, 1997

Selen Altunata, Rosa L. Earley, Daniel M. Mossman and Lawrance E Welch, "Pulsed Electrochemical Detection of Penicillins Using Three and Four Step Waveforms," *Talanta* **42**, 17 (1994)



INVITED TALKS

American Association of Pharmaceutical Scientists Pharmsci 360 Conference

(October 2023) “Achieving Scientific Agility in a Rigid Matrix,” **Selen A. Stromgren**
Orlando, FL

R Conference – Government and Public Sector (December 2022)

“R Supported Transformation of Unwieldy Data into Information,” **Selen A. Stromgren** & Danielle
Larese Washington DC

AOAC, 2019 Analytical Solutions Forum (March 2019)

“Emerging Issues Round Table Discussion,” **Selen A. Stromgren** Gaithersburg, MD

CHPA, 2016 Regulatory, Scientific & Quality Conference (May 2016) “Post-Market Pharmaceutical
Testing at ORA Labs,” **Selen A. Stromgren** North Bethesda, MD

US FDA, Commissioner’s Fellows Seminar Series (June/July 2011, 2013, 2014, 2015, 2016)

“Science Supporting Regulatory Mission,” **Selen A. Stromgren** Rockville, MD

US FDA, Council on Pharmaceutical Quality (December 2013)

“Establishment of the ORA/CDER Strategic and Scientific Compliance Steering Committee” **Selen
A. Stromgren**, Rick Friedman, Cindy Buhse Silver Spring, MD

US FDA, ORA Method Development and Validation Program Seminar Series (January 2012)

“FDA Response to the 2011 Phthalate Contamination in Products from Taiwan: An Account of
Intra- and Inter-Agency Collaboration,” **Selen A. Stromgren** Rockville, MD

US FDA, CFSAN Field IQ Seminar Series (October 2011)

“Introduction to ORA Laboratory Procedures and Operations: Overview,” **Selen A. Stromgren**,
Rockville, MD

Wesleyan University, Chemical Physics Seminar Series, Invited Talk (October 2000)

“Long-Lived, Energetic States of Small Molecules,” **Selen Altunata** Middletown, CT

MIT Physical Chemistry Graduate Seminar Series (November 1999)

“Acetylene – Simple System That Brings Molecular Complexity Within Spectroscopists’ Grasp,”
Selen Altunata Cambridge, MA

54th Ohio State University International Symposium on Molecular Spectroscopy (June 1999)

“Investigation of the Mechanism of Intersystem Crossing in S₁ Acetylene,” Abstract number TG11,
Selen Altunata, Kevin L. Cunningham, and Robert W. Field Columbus, OH

53rd Ohio State University International Symposium on Molecular Spectroscopy (June 1998)

“Surface Electron Ejection by Laser-Excited Metastable Spectroscopy of C₂H₂,” Abstract number
TG12, **Selen Altunata**, Kevin L. Cunningham, Stephen Drucker, and Robert W. Field Columbus, OH



PATENTS

Co-inventee on **U.S. Patents 6,919,173 (issued July 2005), 7,288,410 (issued October 2007) and 7,491,540 (issued February 2009)** filed on behalf of Meso Scale Diagnostics, L.L.C. that outline methods to improve the chemical reaction that gives rise to the electrochemiluminescence technology commercialized by the company.

One of two inventees (Eli N. Glezer, Selen A. Stromgren) on **U.S. Patents 7,704,730 (issued April 2010), 8,236,555 (issued August 2012) and 8,530,230 (issued September 2013)** filed on behalf of Meso Scale Diagnostics, L.L.C. entitled “Multiplexed Assays for Analytes of Different Abundance.” These patents outline approaches that enable measurement of analytes of widely varying abundance in the same well of a multi-array plate.



INVITED PROFESSIONAL MEMBERSHIP

- Advisor for Pharmaceutical Quality Control Analysis Certification Program Committee, Exemplar Global (2017-2018)
- Member, AOAC INTERNATIONAL Analytical Solutions Forum Steering Committee (2019-2021)
- Member, Harvard – MIT Center for Regulatory Science, Regulatory Sciences Advisory Forum (2018 – present)
- Contributor, Trustworthy AI Forum, IBM Center for the Business of Government and Innovation (2023)