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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

Director, Office of Science and Laboratory Advancement | FDA/OC/Office of the Chief Scientist
2008 - PRESENT
Occupied positions of increasing responsibility and scope within FDA's science offices since 2008. In current role, responsible for: A) advancing regulatory laboratory science by implementing and refining a framework of operational risk management and safety, as well as ensuring regulatory laboratories function within a quality management system to produce defensible, actionable results; B) designing and delivering data solutions to extract key information from voluminous laboratory data to assist agency decision makers; C) coordinating with agency Centers and stakeholders on laboratory science activities to facilitate a cohesive approach to public health protection by cultivating scientific connectivity and fostering analytical cross-collaboration.

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 FDA regulatory 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 workforce in emerging fields:
    - Data Science Workshop
    - Advanced Manufacturing Workshop
    - Digital Health and AI/ML Applications

- Implementing expansion by 30% of methodology and instrument scope of regulatory 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

American Society of Quality:

Certified Quality Auditor (CQA)

Certified Manager of Quality/Operational Excellence (CMQ/OE)

Level 1 Leadership and Performance Coaching Certificate from ACT/Brown University

PUBLICATIONS

Chad P. Nelson, Paul Brown, Suzanne Fitzpatrick, Kevin A. Ford, Paul C Howard, Tracy MacGill, Edward E. C. Margerrison, Jacqueline O'Shaughnessy, Tucker A Patterson, Rakesh Raghuwanshi, Rodney Rouse, **Selen Stromgren**, Kyung, E. Sung, Luis G. Valerio, Jr., Jeffrey L. Ward, Namandjé Bumpus, "Advancing alternative methods to reduce animal testing," *Science,* **Vol 386***, No 6723, pp 724-726* (2024)

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

R Conference – Government and Public Sector (October 2024)

"Harnessing NLP in R to Create the Concept of Operations for a Large Organization," **Selen A. Stromgren**, Evgeny Kiselev and Danielle Larese Washington DC

University of Arkansas Medical Sciences/College of Pharmacy (April 2024)

"Where Rubber Hits the Road: FDA's Field Mission and Laboratories," **Selen A. Stromgren**

Little Rock, AR

R Conference – Government and Public Sector (October 2023)

"Deterministic Extraction vs Probabilistic Extrapolation: A Pilot for R-Enabled Augmentation of Information Retrieval by Humans," **Selen A. Stromgren** & Danielle Larese Washington DC

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 S_1 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 C_2H_2," 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, Examplar 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)