

David Michael Johnson

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Professional experience

Feb 2022 – present President and Chief Scientific Officer, Tobacco Technology Inc., Eldersburg, MD 21784

- Overall management of the Tobacco Technology Group including synthetic nicotine, new product development, regulatory submissions, Quality Assurance, Quality Control, Procurement, etc. CORESTA representative and member of subgroup to develop quality and product standards for new oral products like Zyn. Lead efforts to become fully compliant with TPMP requirements. Lead efforts to develop scientific and manufacturing practices regarding cannabinoids.

Mar 2021 – Feb 2022 Sr. Director Regulatory, Tobacco Technology Inc., Eldersburg, MD 21784

- Strategic and tactical leadership of regulatory for Tobacco Technology and its Italian subsidiary to ensure compliance with FDA and TPD regulations. Generation of SDSs, submissions to FDA and other international regulatory agencies for nicotine, e-liquids, oral tobacco/nicotine products, and new initiatives. Synthetic nicotine scientific interaction with regulatory, manufacturer, and technical experts regarding characterization, manufacture, and TPMF submission.

May 2020 – Mar 2021 Consultant, Johnson Consulting, Owensboro, KY 42301

- Provide strategic and tactical support to clients in the tobacco industry in need of regulatory assistance.

April 2012 – May 2020 National Tobacco Company, Louisville, KY 40229

Sr. Director, Scientific and Regulatory Affairs

- Management of the R&D, Quality and Consumer Affairs Department, and Regulatory Affairs. Directs and leads new product development from the translation of the product concept into technical attributes to the transition to QA for on-going product monitoring post the first production run. Direct and lead all quality control, quality assurance, consumer issues management, regulatory reporting, and external vendor quality at multiple locations as these functions relate to regulatory compliance. Key contact for NTC with CORESTA, FDA, TPSAC and other scientific and regulatory entities. Responsible for new technology evaluation, development and implementation. Lead and direct electronic products (e-cigarette and vaporizer) design, development, and quality; e-liquid development, testing, and regulatory reporting. Theory of e-liquid vaporization, analysis of e-liquid vapor, hardware testing, e.g. batteries, atomizers, and new vaporization mechanisms. Scientific data generation and preparation for submission for regulatory reports for all regulated categories. Lead intellectual property management for the corporation. Responsible for the preparation of state and federal regulatory filings (MN, MA, TX, and CDC) as well as global filings as appropriate. Development of new active ingredients including cannabinoids and other functional actives including the formulation and regulatory compliance.

November 2010 – April 2012 Consultant, Johnson Consulting, Owensboro, KY 42301

Consultant

- Provide scientific input and/or testimony as required with regard to FDA regulation of tobacco products including strategic inputs, recommendations on testing methods, data analysis, and preparation of submissions to the agency to comply with the Tobacco Control Act. Presented information on tobacco product manufacturing, testing, and constituents to the FDA. Preparation and submission of regulatory filings with the Center for Tobacco Products (CTP).

November 2010 – February 2011 Senior Public Service Administrator , Manager Air Monitoring IL EPA

- Manage group of scientists responsible for air monitoring, instrument maintenance, report generation and compliance with Illinois and Federal Environmental Protection Laws. Problem solving when unknown sources of pollution were identified and work with Emergency Management to address environmental issues. Develop and maintain the remote analytical network to continuously monitor concentrations of contaminants in air for reports and environmental quality assessments, investigations, and regulatory actions as required.

September 2008 – November 2010 John J. Madden Mental Health Center, Hines, IL 60141

Manager Dietary, Engineering and Housekeeping (Public Service Administrator)

- Management of 43 support service workers and 1 engineer in the delivery of exceptional customer care in mental health environment. Development of new systems, processes, and procedures that allowed the hospital support functions to comply with all Joint Commission requirements. Sourcing and inventory management of all materials, food, equipment and services required to insure the proper functioning of the three departments. Member of the hospital management team, safety team, and union negotiating team. Evaluation and interpretation of the labor contract and administration of discipline per the tenants of the collective bargaining agreements. Successful TJC audit.

May 2004 – Feb. 2008 Swedish Match North America, Owensboro, KY *Director, Scientific and Regulatory Affairs*

- Responsible for strategic and tactical functions related to scientific research and regulation of tobacco by the U. S. Food and Drug Administration, state and local agencies, and foreign governments. Responsible for all regulatory submissions and insuring permission to sell. Design, support, and monitor toxicological testing and clinical trials for submissions under NDAs with FDA. Regulatory expert for Swedish Match North America. Scientific liaison with investigators, media, and public for dissemination of scientific information. Scientific expert for SMNA with responsibility to guide the R&D organization to more creative and innovative products and solutions and to manage all intellectual property. Division representative to the global Swedish Match Scientific Affairs Committee with significant interaction and cooperation with other divisions. Primary resource for communication of scientific issues to legislators regarding tax issues and harm reduction. Lean Sigma implementation resulting in savings in excess of \$500,000 in first year. Toxicological and epidemiological assessment of literature related to tobacco issues. Development of business process optimization plan for Operations.

June 2001 – May 2004 Swedish Match North America, Owensboro, KY *Director, Analytical Section, Research and Development*

- Responsible for the strategic and routine functions of the laboratory, regulatory submissions, and research projects. This laboratory supports production, regulatory data submissions, and customer compliant handling. The director is responsible for the development of new technology as well as improvements in existing methods and capabilities. Also responsible for providing support to litigation efforts and responsible for the submissions to regulatory authorities at all levels, state, federal and international. Additionally the director is responsible for developing the science basis for the future direction of the business. Member of the global Swedish Match Scientific Affairs Committee.

September 2002 – 2007 Kentucky Wesleyan College, Owensboro, KY *Adjunct Professor*;

School of Business

- Taught the following courses: Business Statistics (2 years), Java Programming, and Operating Systems.

May 1999 – June 2001 E. I. du Pont de Nemours and Co., Wilmington, DE *Six Sigma Deployment Champion - Agricultural Products Research and Development*

- Responsible for the successful deployment of Six Sigma in DuPont Agricultural Products Research and Development. Member of the management team responsible for the deployment of Six Sigma throughout Ag Products. Responsible for the selection of Black Belts and Master Black Belts, coordination of training, selection and assignment of projects, monitoring of project progress, signoff on completed projects, and full managerial responsibility for R&D Black Belts and Master Black Belts. Delivered total recurring annual savings in excess of \$12 million.

May 1997 - May 1999 E. I. du Pont de Nemours and Co., Inc. Wilmington, DE *Manager, Research and Development - Cereal and Specialty Herbicides*

- Responsible for the R&D programs in DuPont Agricultural Products for Cereal and Specialty Herbicides. As the interface between the business and R&D the incumbent is required to insure that the targets of the R&D effort are aligned with business opportunity. In addition, the incumbent provides guidance to the biologists, chemists, engineers, regulatory affairs personnel, and other regarding the discovery of compounds of interest consistent with the business defined targets. Responsible for the renewal of two portfolios with annual sales of approximately \$800 million total. Responsible for providing input into the strategic direction of the entire R&D community. Managed intellectual property for the cereal and specialty herbicide businesses. Evaluated new technology, from internal and external sources, for VP of R&D and made decision to acquire or not. Negotiated contract with 3DP to conduct contract research.

May 1995 – May 1997 E. I. du Pont de Nemours and Co., Inc. Wilmington, DE *District Sales Manager*

- Full managerial and profit and loss responsibility for a sales district with a technical sales force of 17 field representatives in 4 states (NY,PA,OH, and IN). Full budgetary and asset management responsibility for the sales force with an operating budget of approximately \$1,200,000 and assets of approximately \$1,000,000. Achieved the sales required (approximately \$68,000,000 and \$78,000,000 in the respective years) to grow the business each year. Only district of twelve to meet objectives for growth in both years. Provided career guidance to the sales force and negotiated contracts with customers to insure growth of the business. Required to understand the chemistry and biology, including biochemistry of action, of all of DuPont's Agricultural Products in order to convey this information as necessary to customers.

May 1994 – May 1995 E. I. du Pont de Nemours and Co., Inc. Wilmington, DE *Product Manager - Insecticides*

- Responsible for the insecticide portfolio of DuPont Agricultural Products approximately \$200 million in annual sales. Provided technical information and product positioning to field sales reps to insure that objectives were met. Provided supply

forecast information, developed competitive strategies, managed product supply and distribution, and created a unique custom software model to facilitate distribution of products with long supply chains. Lead a multi-functional effort involving marketing, manufacturing, customer service, data processing and accounting, to establish two remote product refill sites in a manner that met all environmental and product quality concerns.

January 1993 – May 1994 E. I. du Pont de Nemours and Co., Inc Wilmington, DE *Research Supervisor - Special Assignment*

- Research Supervisor assigned to provide technical assistance and training to attorneys involved in litigation to defend DuPont. Required to train lawyers in the fundamentals of the science, analyze data, provide expert testimony, assist in the preparation of cross examinations of suspect science, and interpretation of spectrometric data.

January 1991 – January 1993 E. I. du Pont de Nemours and Co., Inc Wilmington, DE *Research Supervisor*

- Supervision of 17 Ph.D and 30 B.S. level scientists involved in the development of new analytical methods and technology. Full managerial responsibility for these personnel including their day-to-day activities, professional growth and development, training and conflict resolution. The methods generated by this group were used in the collection of data from environmental samples to support EPA registration of agricultural products. In addition, participated on the leadership team responsible for 300 individuals supporting the registration process. Managed annual administrative budget of \$5 million as well as \$2 million in capital. Responsible for identifying and hiring new scientists to maintain and expand the competency of the group. Led a group of 100 analytical scientists in the investigation of the largest toxic tort case in the U.S. to that time.

May 1990 – January 1991 E. I. du Pont de Nemours and Co., Inc Wilmington, DE *Section Research Chemist*

- Responsible for a research program to develop new environmental analysis methods including methods for water, soil and plant tissue. The objective was to analyze for small organic molecules in these matrices and to quantitate the levels of the originally applied molecule as well as environmental and plant metabolites. Developed high speed separation methods that were utilized in a patent application (co-inventor) for a portable HPLC . Developed quantitative particle beam MS methods for agricultural chemicals. Also develop SFE and SFC methods for the determination of organic compounds in soil, water, plant tissue, and animal tissue.

1989 – May 1990 Lee Scientific Gray, TN *Regional Technical Specialist*

- Provided technical assistance to variety of industries in the use of Supercritical Fluid Chromatography (SFC) and Supercritical Fluid Extraction (SFE) for industrial, pharmaceutical , and environmental applications. Developed novel methods and participated in instrument design. Routinely presented seminars and short courses on the technology at universities or industrial/governmental research sites.

1987 - 1989 Nuclear Fuel Services Erwin, TN *Process Engineer*

- Responsible for in-line instrumentation to monitor and control operations related to manufacturing process. Developed laser spectroscopic methods for the analysis of inorganic molecules. Developed environmental methods for the monitoring of inorganic materials.

1986 - 1987 Oklahoma State University Stillwater, OK *Visiting Assistant Professor*

- Designed course offerings in instrumental analysis, quantitative analysis, general chemistry, and a graduate course in separation science. Prepared grant to build a MS facility with external funding. This was funded and the center established.

1981 - 1983 United States Navy *Officer in the US Navy Nuclear Power Program*

- Officer in the Naval nuclear Power Program attached to the submarine force. Received training in nuclear engineering.

1977 – 1978 Magee Chemical Company Des Plaines, IL *Technical Specialist*

- Technical Specialist responsible for analysis, formulation, and quality control of all wax, floor finish, detergent, and personal care products. Prepared manufacturing recipes, analyzed color and other physical and chemical properties to insure production to specification. New product development responsibilities included formulation, testing, and final formula confirmation.

Education

1985 - 1986 University of North Carolina Chapel Hill, NC *Post Doctoral Training in Organic Mass Spectrometry*

- Post-doctoral training in Organic Mass Spectrometry (MS) with Dr. Maurice M. Bursey. This work involved assisting the graduate students with their projects as well as utilization of thermospray HPLC/MS and MS/MS to elucidate the ionization mechanism in filament off thermospray HPLC/MS and the ion-molecule reactions that occur in the gas phase in MS/MS. The ion-molecule reaction work involved the determination of reaction energetics and reaction products.

1983 - 1985 University of Mississippi Oxford, MS *Ph.D in Chemistry (Physical/Analytical)*

- Use of Mass Spectrometric Tracer Pulse Chromatography (MSTPC) to study the interactions of gas phase molecules with surfaces. Theoretical and practical investigation of the interactions between various molecules in the gas phase, these molecules and the surface, and their interaction with each other in the adsorbed phase. Adsorption isotherms and other physicochemical properties were measured for single and multicomponent systems. The thermodynamics of the processes were quantified. Subsequently, a model was found for these interactions and a predictive model was developed that corresponded with actual observations. Thus paving the way for *a priori* determination of these interactions based on some fundamental experimentation. This methodology finds application in the areas of chromatographic separations, catalysis, environmental remediation, enhanced petroleum recovery, and others.

1978 - 1981 University of Mississippi Oxford, MS *M.S in Chemistry (Physical/Analytical)*

- Development of methods for determining the dead-time in chromatographic

separations using both experimental and mathematical techniques. This work paved the way for the development of Mass Spectrometric Tracer Pulse Chromatography.

1976 - 1977 University of Mississippi Medical Center Jackson, MS *Graduate Studies in Biochemistry*

- 37 hours of graduate courses and research in biochemistry. Research involved the synthesis and utilization of affinity columns for the separation of heme binding proteins from complex matrices. Subsequent purification and assay of the heme binding proteins was also performed. Isolation, purification, and assay of a peptide from rabbit reticulocyte ribosomes that inhibited protein synthesis by binding to the physical terminus of the messenger RNA.

1972 - 1975 Millsaps College Jackson, MS *B.S. in Chemistry*

- Undergraduate studies leading to a Bachelor of Science degree in Chemistry.

Professional memberships

- Sigma Xi
- American Chemical Society
- American Association for the Advancement of Science
- Advisory Board Member -Analytical Laboratory Exposition and Conference 1992-1994

Interests and activities

- Avid computer programmer for the modeling of chemical processes
- Extensive experience with utilization of computer hardware to design custom systems

Patents and publications

T. M. Fahmy, M.E. Paulaitis, D. M. Johnson, and M. E. P. McNally, "Modifier Effects in the SFE of Solutes from Clay, Soil, and Plant Materials", **Anal. Chem.**, **65(10)**, (1993) 1462-1469.

R.W. Smith, C.E. Parker, D.M. Johnson, and M.M. Bursey, "Eluant pH and Thermospray Spectra: Does the Charge on the Ion in Solution Influence the Spectrum?", **J. Chromatogr.**, **394**, (1987) 261-270.

J. F. Parcher and D. M. Johnson, "Chromatography on Monolayers", **J. Chromatogr. Sci.**, **23**, (1985),459-464.

K.J. Hyver, J.F. Parcher, D.M. Johnson, and P. J. Lin, "Adsorption of Mixtures of Acetone and Benzene Vapors on Graphitized Carbon Black", **J. Chromatogr.**, **328**, (1985) 63-72.

Jon F. Parcher, Ping J. Lin and David M. Johnson, "Physical Model for Gas-Solid Chromatography with Volatile and Non-Volatile Modifiers", **Anal. Chem.**, **58**, (1986) 2207-2212.

J. F. Parcher and D. M. Johnson, "Methane Retention Time versus Mathematical Dead Time", **J. Chromatogr. Sci.**, **18**, (1980) 262-272.

R.W. Smith, C.E. Parker, D.M. Johnson, and M.M. Bursey, "Eluant pH and Thermospray Spectra: Does the Charge on the Ion in Solution Influence the Spectrum?", American Society

for Mass Spectrometry, 34th Annual Conference (poster).

David M. Johnson and Ken W. Olsen “Synthesis of Affinity Resins for Heme Binding Proteins” paper presented at the Mississippi Academy of Science, 1977.

David M. Johnson and Charles L. Woodley “F_x a Protein Isolated from Rabbit Reticulocyte Ribosomes that Inhibits Protein Synthesis” paper presented at the Mississippi Academy of Science, 1977.

PRESENTATIONS

Numerous presentations as a consultant to CITMA

Numerous presentations as an invited speaker and as a regional technical specialist for Lee Scientific (Dionex). The total number exceeds 200

References available upon request.