**Alan J. Senzel, Ph.D., 7704 Audubon Drive, Raleigh, NC 27615**

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# EXECUTIVE SUMMARY

Dr. Alan J. Senzel is a ***Manager*** and ***Consultant*** with over 35 years of diversified experience in Analytical Chemistry, Pharmaceutical Method Development and Validation, Quality Assurance, and Technical Editing and Writing. He has strong hands-on experience managing ***Publication Programs*** for scientific associations and preparing a wide variety of documentation for ***Pharmaceutical*** and ***Agricultural*** ***Chemicals*** ***Corporations*** to ensure **legal compliance** with all **government regulatory agencies**.

He has led and actively participated in successful efforts to **register and reregister many drug and pesticide products under both GMP and GLP regulations**. He can present complicated scientific data clearly and succinctly. He is an organized professional with excellent presentation, analytical, documentation, and interpersonal communication skills.

# PROFESSIONAL EXPERIENCE/ACCOMPLISHMENTS

**Validation Consultant – Alkermes, Wilmington, OH: 11/22 – Present**

* Prepare and edit **validation guidelines and other regulatory documentation** associated with the **manufacture of pharmaceutical products.**

**Technical Writer – Arcturus Therapeutics, San Diego, CA: 6/22 – 9/22**

* Prepare and edit **SOPs and regulatory documentation** associated with the **manufacture of vaccines and other pharmaceutical products.**

**Technical Writer – Hughes Engineering, Raleigh, NC: 2/22 – 4-22**

* Prepare and edit **SOPs and regulatory documentation** associated with **laboratory and production equipment used in the** **manufacture pharmaceutical products.**

**Technical Writer – CRISPR Therapeutics, Cambridge, MA: 6/21 – 12/21**

* Prepare and edit **SOPs and regulatory documentation** associated with the **manufacture of cell therapy, gene therapy, and immunotherapy pharmaceutical products.**

**Technical Writer – Sagent Pharmaceuticals, Raleigh, NC: 12/20 – 8/21**

* Prepare and edit **TrackWise documentation** associated with **nonconformances, including events and deviations that occur in the manufacture of injectable pharmaceutical products.**

**Technical Writer/Editor – Brooks Machine and Design, Zebulon, NC: 9/20 – 11/20**

* Prepare and edit **documentation** associated with **developing functional design specifications, detailed design specifications, factory acceptance tests, and site acceptance tests for robotics equipment involved in the manufacture of pharmaceutical products.**

**Technical Writer/Editor – Novo Nordisk, Durham, NC: 3/20 – 7/20**

* Prepare and edit **documentation** associated with **developing functional design specifications, validation plans and protocols, job instructions, and SOPs for equipment involved in the manufacture of pharmaceutical products**.

**Technical Writer – GSK, Research Triangle Park, NC: 3/19 – 12/19**

* Prepare **documentation and record proceedings of meetings** associated with **developing software to establish discounts from retail pricing** for **pharmaceutical products sold by prescriptions processed through Medicare and Medicaid**.

**Consultant, Pharmaceutical Chemistry and Information Technology Applications – GLG Councils, New York, New York: 8/15 – Present**

* Provide **consulting services** for **pharmaceutical companies** regarding **commissioning of manufacturing plants, method development and validation, clinical evaluation reports, regulatory submissions, and information technology applications**, as assignments occur.

**Technical Writer – Fresenius Kabi, Wilson, NC: 12/18 – 1/19**

* Prepare **IQ, OQ, and PQ documentation** for production line equipment associated with manufacture of combination product **single-use syringes** that are prefilled with **prescription opioids**.

**Senior Compliance Engineer – Ethicon/Johnson & Johnson, Athens and Cornelia, GA: 11/17 – 12/17**

* Install **Compliance Builder** software on **Ultraviolet-Visible spectrophotometer** and **Instron strength testing instruments** in **Quality Assurance Laboratory** and document installations.

**Technical Writer – Seqirus, Holly Springs, North Carolina: 6/17 – 8/17**

* Prepare, or contribute to preparation of, **Standard Operating Procedures** and **Workflow Instructions** for Seqirus maintenance documentation associated with manufacture of influenza vaccine products.

**Technical Writer – Argos Therapeutics, Durham, North Carolina: 1/17 – 2/17**

* Prepare, or contribute to preparation of, **regulatory** **clinical documents, including clinical evaluation reports,** for Argos Therapeutics products associated with ongoing clinical trials. Documentation includes **Software Development Life Cycle (SDLC) Projects, Standard Test Methods, Method Qualification Protocols, Method Development Reports, and Standard Operating Procedures**.

**Technical Writer/Documentation Specialist – Biogen, Research Triangle Park, North Carolina: 3/15 – 8/15**

* Provide **regulatory** documentation support for **TrackWise applications,** including **user requirements, design, and functional specifications (software development life cycle products); data migration, system project, and test plans; and traceability matrices.** Assist with **TrackWise administration, Crystal reports,** and **validation documentation**, as required.

**Medical Writer – Quintiles/Expression Analysis, Durham, North Carolina: 9/14 – 3/15**

* Prepare, or contribute to preparation of, straightforward **regulatory** **clinical documents**, for either internal Quintiles customers or external clients, for **investigational drugs, biologicals, or medical devices**, under guidance of senior staff, in accordance with American Medical Writers Association (AMWA) and European Medical Writers Association (EMWA) standards. Participate in project teams and may lead specific tasks, consulting senior staff as necessary. Document workflow for Next Generation Sequencing operations using Boolean logic diagrams developed from Microsoft Visio and freeware alternative programs. Prepare **Software Development Life Cycle (SDLC) Products**.

**Senior Technical Writer – Novartis, Holly Springs, North Carolina: 4/14 – 6/14**

* Adapt and update Holly Springs automation SOPs to correspond with **regulatory** procedures for **Delta V automation equipment** at sister **vaccines manufacturing plant** under construction in Recife, Brazil.

**Delta V Automation Consultant – Merck, Durham, North Carolina: 5/13 – 8/13**

* Update **Regulatory** Requirements Traceability Matrices to correspond with **Regulatory** Requirements Specifications for **Delta V automation equipment** at **vaccines manufacturing plant**.

**Technical Writer – HGS/GSK, Rockville, Maryland: 10/12 – 3/13**

* Prepare supporting **regulatory** documentation associated with transition of **IT Application Services** from Human Genome Sciences (HGS) to GSK. Effort required familiarity with MEDLINE and CANCERLIT databases.

**Technical Writer – Becton Dickinson Diagnostics, Mebane, North Carolina: 4/12– 9/12**

* Prepare and update **service manuals** for field service engineers and technical service engineers to use in maintaining and repairing **automated robotic instruments** designed to prepare and analyze patient cytology specimens (principally pap smears) associated with women’s health testing.

**Senior Compliance Associate – Hospira, Rocky Mount, North Carolina: 1/12– 3/12**

* Prepare **regulatory** investigation reports in the **Hospira Trackwise system** to identify **root cause and corrective action/preventive action (CAPA)** for manufacturing and laboratory analysis aberrations associated with **manufacture of injectable and intravenous generic drug products**.

**Technical Writer – LensAR, Orlando, Florida: 8/11– 11/11**

* Prepare user guide to elucidate **graphical user interface (GUI)** for equipment designed to aid ophthalmologists in performing **laser-assisted cataract surgery**.

**Technical Author – GSK, Research Triangle Park, North Carolina: 5/10 – 10/10**

* Prepare supporting **regulatory** documentation associated with user interface modifications for two key **drug synthesis software projects (using Agile technology team approach)**, **CRO Request Approval Workflow (CRAW)** and **Electronic Laboratory Notebook (eLNB)**.

**Technical Editor – Telecommute Pros, Phoenix, Arizona and ELSS, Tsukuba, Ibaraki, Japan: 12/08 – 5/10**

* Edit English-language research manuscripts in the fields of **biology, chemistry, engineering, mathematics, medicine, and physics** authored by professors and researchers from China, Korea, Germany, Japan, and Taiwan for publication in American and British scientific journals.

**Technical Consultant – GSK, Research Triangle Park, North Carolina: 6/07 – 12/08**

* Prepare all documentation associated with user interface for two key **drug discovery software projects (using Agile technology team approach)**, **Operational Reporting and Metrics (OR&M)** and **Encoded Library Technology (ELT)**.

**Technical Consultant – Patterson, Dilthey, Wilmington, North Carolina: 3/06 - 10/06**

* Provide scientific expertise to law firm defending contractors in a case involving alleged **harmful exposure via HVAC system to toxic compounds** affecting residents of a beach condominium. Case was settled to my client’s satisfaction out of court.

**Quality Assurance Associate – ENTHALPY ANALYTICAL, INC., Durham, North Carolina: 1/06 – 3/06**

* Review and audit **analytical data packages (LC-MS)** for testing **of animal tissues** (including rat brain and blood) dosed with **developmental pharmaceutical products**.

**Delta V Validation Engineer – OXFORD GLOBAL RESOURCES, INC., Cordis Johnson & Johnson Site, Miami Lakes, Florida: 11/05 - 01/06**

* Prepared **Delta V** **regulatory** **validation protocols and execution reports** for testing **of cardiac medical devices** including hydraulic burst leak tester, linear and lateral stiffness tester, and syringe tester.

Contract Editor – ENVIRONMENTAL HEALTH PERSPECTIVES, National Institute of Environmental Health Sciences, Research Triangle Park, North Carolina: 06/05 - 11/05

* Edited **toxicogenomics monographs** for publication in **ENVIRONMENTAL HEALTH PERSPECTIVES**, a monthly journal published by the **National Institute of Environmental Health Sciences**.

**Documentation Development Specialist – ROVISYS, INC., Wyeth Site, Sanford, North Carolina: 12/04 - 05/05**

* Prepared **DeltaV automation controls documentation** for **regulatory** commissioning **of 13-valent pneumonia vaccine manufacturing plant**.

###### Senior Technical Writer/Scientist – CARDINAL HEALTH, Morrisville, North Carolina: 06/02 - 11/04

* Prepared **method development and method validation regulatory reports** for **drug development studies** sponsored by **major pharmaceutical companies,** including **Astra Zeneca, Bausch & Lomb, Boehringer Ingelheim, Eon Pharmaceuticals, Glaxo Smith Kline, Pfizer, Schering-Plough, Skye Pharma, and West Pharmaceuticals,** among others.
* Integrated **raw data** from **gas chromatography, high performance liquid chromatography, and mass spectrometry experiments** into **templates** that had to be continually refined to meet customer needs as required.
* Prepared **Requests for Proposals (RFPs)** to solicit new business.

Publications Manager – INTERNATIONAL UNION OF PURE AND APPLIED CHEMISTRY (IUPAC), Research Triangle Park, North Carolina: 02/99 - 05/02

* Managed **editing, production, and publication** of a **monthly research journal** and a **bimonthly scientific newsmagazine**.
* Directed **technical liaison** from headquarters office for **25 international chemistry conferences** that **IUPAC** sponsored each year.
* Supervised **editing, production, and publication** of **35 issues** of **Pure and Applied Chemistry** and **18 issues** of **Chemistry International** (**winner** of an **Excellence Award** from the **Society for Technical Communication**).
* Successfully **administered 75 international chemistry conferences**.
* Directed **additional IUPAC business**, **including reprint orders, permissions, publications inventory, and web-based correspondence**.
* **Supervised 3-5 employees**.

Consultant, Pharmaceutical Documentation and Validation – ALAN J. SENZEL, Ph.D., Raleigh, North Carolina: 06/96 - 02/99

* Prepared software documentation and test plans for a biotech instrument manufacturer (Tecan U.S., RTP, NC). This project included documenting and testing the graphical user interface (GUI) for Tecan’s Genesis series of automated pipetting instruments.
* Developed 60 SOPs for a plasma testing laboratory (Bayer Pharmaceuticals PCR Lab, Raleigh, NC)
* Prepared 50 SOPs for an analytical testing laboratory (Enthalpy, Inc., RTP, NC)
* Created 35 GMP validation documents (IQ, OQ, PQ) for temperature and humidity stability chambers for a pharmaceutical company (Glaxo Wellcome, RTP, NC).
* Prepared Requests for Proposals (RFPs) to solicit new business.

###### Analytical Contract Laboratory Manager – ENTROPY, INC., Raleigh, North Carolina: 05/95 - 07/96

* Led team that provided **complete analytical support services for air emissions tests conducted in field**.
* Duties included **stocking mobile testing vehicles, custody of samples, selection of and shipment to analytical laboratories for testing, and interpretation of analytical results**.
* Team successfully completed approximately **500 air emissions tests** in continental United States and Puerto Rico.
* Prepared **Requests for Proposals (RFPs)** to solicit new business.
* **Supervised 3-5 employees**.

Consultant, Agricultural Chemical Field Crop Trial Documentation and Data Review – ALAN J. SENZEL, Ph.D., Raleigh, North Carolina: 05/93 - 05/95

* Reviewed analytical field crop data from residue chemistry studies and prepared final regulatory reports for registration and reregistration of fungicide, herbicide, and insecticide products for Ciba Plant Protection (Greensboro, NC), American Agricultural Research, Inc. (Cary, NC), Stewart Pesticide Registration Associates, Inc. (Columbia, MO), and the Spray Drift Task Force (Cockeysville, MD) under GLP regulations.
* Prepared Requests for Proposals (RFPs) to solicit new business.

###### Project Scientist – CIBA-GEIGY CORPORATION, Greensboro, North Carolina: 07/88 - 05/93

* Managed a group that **prepared samples from residue chemistry field crop trials under GLP regulations**.
* Provided **regulatory** **documentation** in support of **registration and reregistration of agricultural chemicals under GLP regulations**.
* Administered all **archival information** for **residue chemistry and metabolism departments** in biochemistry division under GLP regulations.
* Successfully supported scientific efforts associated with **dozens of registrations that involved hundreds of field crop trials under GLP regulations**.
* **Supervised 5-8 employees**.

Consultant, Regulatory and Quality Assurance Issues – ALAN J. SENZEL, Ph.D., Raleigh, North Carolina: 05/84 - 07/88

* Developed air emissions standards, waste analysis plan guidance manuals, regulatory impact analysis for 200 hazardous chemicals, and exposure assessment guidelines.
* Clients included Research Triangle Institute (RTP, NC), Technical Resources, Inc. (Rockville, MD), American Petroleum Institute (Washington, DC), Becton Dickinson, Inc. (RTP, NC), Integrated Laboratory Systems (Durham, NC), and Environmental Resources Management (Exton, PA).
* Prepared Requests for Proposals (RFPs) to solicit new business.

###### Senior Chemist – DEL GREEN ASSOCIATES, INC., Foster City, California: 05/81 - 05/84

* Provided **technical support and liaison** **for EPA's Stationary Source Compliance Division** to contractor who developed **modifications and enforcement of visible emissions methodology**.
* Continually **updated documentation** to ensure that **enforceable visible emissions methodology** was available to **EPA's Stationary Source Compliance Division**.
* Prepared **Requests for Proposals (RFPs)** to solicit new business.

Consultant, Preventive Maintenance Documentation for Electronic Manufacturing Equipment – ALAN J. SENZEL, Ph.D., Raleigh, North Carolina: 12/78 - 05/84

* Prepared more than 100 operation, maintenance, and troubleshooting SOPs for a capacitor manufacturing plant (Corning Glass Works, Raleigh, NC)

###### Methods Editor – AOAC INTERNATIONAL, Washington, DC: 01/74 - 12/78

* Managed **development, validation, editing, publication**, and continual updating **of regulatory laboratory methods** for **analysis of foods, drugs, pesticides, cosmetics, fertilizers, feeds, disinfectants,** **hazardous substances**, and other materials related to **agriculture and public health**.
* Directed publication of **compendia, supplements, and monographs** used in **U.S. and international regulatory laboratories**.
* **Supervised 2-4 employees**.

###### Associate Editor – ANALYTICAL CHEMISTRY, American Chemical Society, Washington, DC: 06/70 – 01/74

* Reviewed and edited **feature articles, technical manuscripts, and books** on **analytical chemistry**.
* Also authored **column** on **instrumentation** **every month**.
* Participated in publication of about **50 issues** of **journal** containing **thousands of scientific manuscripts**, as well as **assembly and production of numerous review compilations, books, and monographs on analytical chemistry**.
* Authored **column on instrumentation** every month.

### EDUCATIONAL / TECHNICAL BACKGROUND

* Ph.D., Analytical Chemistry, UCLA, Los Angeles, California, 1970
* M.S., Analytical Chemistry, UCLA, Los Angeles, California, 1969
* B.S., Chemistry (Summa cum Laude), CSULB, Long Beach, California, 1967

**CERTIFICATIONS**

* Certified Junior College Chemistry Teacher, California State Junior College System, 1969

**ACHIEVEMENTS**

* Recipient of **Society for Technical Communication Excellence Award** for **Chemistry International (IUPAC), 2002**
* Successfully completed **FIFRA 88 Registration** for all **Ciba Plant Protection** active ingredients, **1993**
* Recipient of **Society for Technical Communication Achievement Award** for **Safety in the Laboratory (Becton Dickinson), 1984**
* Recipient of **FDA Commendation Award** for **Manual of Cosmetic Analysis, 1978**

**SIGNIFICANT PUBLICATIONS**

* **Instrumentation in Analytical Chemistry, American Chemical Society, 1973**
* **Newburger’s Manual of Cosmetic Analysis, Association of Official Analytical Chemists, 1977**
* **Safety in the Laboratory, Becton Dickinson, 1984**
* **Chemistry International, Editor, International Union of Pure and Applied Chemistry, 1999-2001**
* **Pure and Applied Chemistry, Editor, International Union of Pure and Applied Chemistry, 1999-2001**