

**Gary Dykstra**
Integrated Material Sciences LLC (Principal)

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**Professional Summary**

Highly experienced Validation Chemist and Analytical Consultant with over two decades of expertise in method development, validation, regulatory compliance, and laboratory operations. A proven leader in chromatography (HPLC, GC-MS, AA), formulation chemistry, and GMP documentation. Adept at transitioning companies to in-house analytical testing and optimizing laboratory workflows for efficiency and compliance. Extensive background in the pharmaceutical, nutraceutical, petrochemical, and materials science industries.

**Core Competencies**

* Equipment Acquisition and Qualification
* Method Development & Validation
* Process Design, Qualification and Verification
* High-Performance Liquid Chromatography (HPLC)
* Gas Chromatography (GC-MS, GC-FID)
* FAAS/ICP/UV/IR Spectroscopy
* Titrations
* GMP, FDA, ISO Compliance
* OOS, Root cause, CAPA, Revision Change
* Organic, Kosher, and Halal Certification
* SOP Development & Laboratory Documentation
* Equipment Acquisition & Laboratory Setup
* R&D, Pilot Formulation
* Product Stability
* Environmental Monitoring
* Compounding API, USP, And Inactive Ingredients
* Vendor Qualification
* Project Management
* Agilent OpenLab, ChemStation, and MassHunter Waters Empower and Perkin elmer totalchrom
* Empower (Waters) & LIMS Systems
* Inventory Management Systems Excel, JMP, Minitab and Access
* Sample Preparation & Extraction Techniques
* Thermal Decomposition & Metal Digestion
* CFR ISO OSHA EPA FDA USDA USP European Pharmacopoeia Compliance
* Quality by Design (QbD) – CQAs, risk, process control, improvement
* Phase 1-4 FDA Clinical trials

**Key Qualifications**

**Multidisciplinary Troubleshooting & Technical Skills** — Proficient in diagnosing and resolving complex issues across laboratory, industrial, and facility systems. Practical expertise spans **plumbing, electrical, carpentry, and structural engineering principles**, with working knowledge of **code compliance** to ensure safe and regulatory-aligned modifications. Skilled in **welding, fabrication, and CNC design**, related to tooling fabrication and troubleshooting bridging hands-on craftsmanship with technical precision. This breadth enables rapid response to mechanical failures, infrastructure challenges, and equipment design needs, reducing downtime and enhancing operational resilience.

* Food Safety & Quality Systems Leadership – GMP, FDA, FSMA, HACCP, FSSC 22000, ISO 9001/14001/45001
* Regulatory Compliance & Audit Management – FDA, EPA, ISO, Kosher/Halal, internal & external audits
* Budget & Capital Planning – laboratory buildouts, equipment acquisition, cost control, continuous improvement savings ($150K+ /yr perpetuity scaling annually)
* Environmental Health & Safety – EPA compliance, ISO 14001 monitoring, environmental controls in chemical, Pharma & nutraceutical operations
* Team Leadership & Development – built and managed high-performing QC and R&D teams; trained and mentored scientists and engineers
* Continuous Improvement – transitioned outsourcing to in-house labs, optimized workflows, GMP process enhancements
* ERP & Data Integrity Systems – LIMS, Empower, OpenLab, documentation control, master data governance transferable to SAP
* Cross-Functional & Executive Communication – direct liaison with regulators, C-suite, and external auditors on compliance and technical operations

**Leadership & Cross Functional Oversight**

* Hired, supervised, trained, and qualified multidisciplinary teams across **Manufacturing, Quality Control, Quality Assurance, and Raw Material Purchasing**, ensuring alignment with GMP, ISO, and corporate standards.
* Built a culture of compliance and continuous improvement by developing staff capabilities, standardizing qualification processes, and leading audit-ready operations.

**Technical & Creative Systems Support**

* 20+ Years of graphic arts design, product packaging and Adobe creative could applications
* Applied a **minor in Liberal Arts** to enhance professional roles beyond chemistry, including **document control, technical writing, marketing collateral, and incident (INCI) design**.
* Designed and supported **web hosting and digital documentation systems** for laboratory operations, improving accessibility, regulatory compliance, and cross-departmental communication.

**Professional Experience**

**Founder & Principal**
*Integrated Material Sciences LLC | 2024 – Present* Daytona Beach, Florida

* Provide consulting services for method development, validation, and regulatory compliance for pharmaceutical, Industrial and Research in a diverse portfolio of consumer Healthcare and manufacturing services.
* Assist companies in transitioning from outsourced testing to in-house analytical capabilities, optimizing workflows, and acquiring appropriate laboratory equipment.
* Develop GMP-compliant documentation, including SOPs, validation reports, and regulatory compliance
* Specialize in chromatography and elemental analysis techniques, troubleshooting complex analytical challenges.

**Validation Chemist & Scientific Consultant**
*Redacted NDA | 2022 – 2025* Holly Hill, FL

* Designed and validated analytical methods for pharmaceutical products, including sunscreens, vitamins, and formulations containing zinc oxide and titanium dioxide.
* Performed instrument qualifications (IQ/OQ/PQ) and preventive maintenance for Agilent HPLC systems.
* Assisted laboratories with compliance documentation and data integrity improvements.
* Provided statistical analysis and research support for method optimization.

**Analytical Consultant R&D Chemist**

Beach Grove Technologies | 2015 – 2019 Hopewell Junction, NY

* Perform proprietary extractions and reactions on raw materials
* Create Pilot batch formulations and encapsulations
* HPLC and UV-VIS Testing Carotenoids on Shimadzu HPLC and UV-VIS
* Perform supercritical CO2 Extractions on raw materials, Formulate, encapsulate and package products

**Senior Chemist II**
*Watson Pharmaceuticals (Teva) | 2008 - 2014*

* Conducted HPLC, GC-MS, and GC-FID assays for raw materials, in-process, and finished pharmaceutical products.
* Managed analytical method validation and verification for prescription (RX) and OTC drug products.
* Led quality control initiatives, authored Certificates of Analysis, and ensured regulatory compliance.
* Trained junior chemists in advanced analytical techniques and GMP regulations.

**Quality Control Manager**
*Pharmline Inc. (Stauber) | 2001 - 2008*

* Hired managed trained 10+ Technicians and Quality Assurance Personal
* Developed and validated new analytical assays for pharmaceutical and nutraceutical products.
* Authored and revised SOPs, ensuring full compliance with FDA and CGMP standards.
* Led research and development projects for new formulations and product enhancements.
* Served as the QC department representative during regulatory audits and compliance reviews.

**Analytical Chemist I**
*Revere Smelting and Refining | 2000 - 2001 - Contract Position* Middletown, NY

* Analyzed and processed metal samples using ICP and XRF
* Conducted environmental compliance testing and ensured adherence to EPA regulations.
* Assisted in battery recycling and smelting operations, analyzing lead and heavy metal content.

**R&D Chemist**

Pfizer Global Research and Development | 1999-2000 Contract Position Morris Plains, NJ

* R&D formulation for Drug discovery
* Phase I and II clinical trial support for Geodon®
* Disolution bioavailability testing
* MIC / Micro testing for new API anti microbials

**Synthetic Chemist / Formulation Chemist**
*Westwood Chemical Corporation | 1998 - 1999*

* Performed synthesis and formulation research for specialty chemicals.
* Conducted wet chemistry analysis, including gravimetric, volumetric, and titration methods.
* Utilized analytical instrumentation such as IR spectroscopy, HPLC, and GC.

**Education & Certifications**

**State University of New York at New Paltz**
*Bachelor’s Degree in Chemistry | 1997 - 2002*

**Professional Training & Certifications:**

* American Chemical Society (ACS) approved Bachelors Program
* Liberal Arts minor

**Additional Information**

* Extensive experience with method development for sunscreens, vitamins, and formulations containing metallic oxides.
* Special expertise in regulatory compliance and forensic documentation for legal and audit purposes.
* Passionate about mentoring and training professionals in advanced analytical techniques.