

Marian Boardley

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Summary

20+ years of diverse management consulting experience in regulatory, laboratory, and computer quality systems

- Advise clients in the food, drug, and dietary supplement industries in good manufacturing practices
- Conduct audits for compliance with applicable legal and regulatory requirements for manufacturing, labeling etc.
- Establish procedures and policies for all aspects of quality assurance and manufacturing operations
- Provide expertise on identity testing for dietary ingredients, raw materials, and selection of lab instrumentation
- Write specifications, manufacturing records, SOP's, technical, laboratory, and process documentation
- Assess internal and contract laboratories for compliance with GMP's and FDA guidance for laboratory testing

FDA Compliance Group LLC, Littleton, CO

Senior Consultant, April 2010 – present

Providing regulatory and quality system consultants to regulated industries, *FDA Compliance Group* is dedicated to helping companies attain and maintain compliance with all FDA requirements. My engagements with FDACG include:

Aug 2010 – present: Client is a multi-national dietary supplement company, and the UK's oldest and largest manufacturer of homeopathic remedies. Audited firm's UK dietary supplement manufacturing, packaging, and laboratory operations for compliance with US regulations. Wrote SOP's for the US import and distribution of homeopathic medicines and dietary supplements, including compliance with applicable GMP's (21 CFR 111 & 211) and adverse event reporting.

April 2010 – Nov 2011: Implemented and managed compliance with dietary supplement GMP regulations for this manufacturer and supplier of ayurvedic supplements and health products, based in New Mexico. Assessed, wrote, and implemented the entire dietary supplement quality control system. Wrote manufacturing and quality control SOP's, compiled and generated component and product specifications, implemented master manufacturing and batch records. Conducted a pilot study to assess raw ingredients and reference materials and to determine suitability of FTIR for identity testing. Advised management on equipment purchase and strategy for testing, verification, and identification of incoming botanical materials. Worked with both PerkinElmer and Bruker mid-IR instrumentation and software, incl. PCA analysis.

May – July 2011: For a fitness company based in California, audited several contract manufacturers for compliance with dietary supplement and food GMP's.

Jan – May 2011: At a large 1.5 billion dollar multi-level marketing dietary supplement distributor, based in N. Utah. Enabled and documented an independent project (the Product Qualification Program) which involved auditing, assessing, and remediating product qualification requirements including product and component specifications and testing, to conform with 21 CFR 111 Subpart E. Liaison between QA, R&D, and other departments was required. Performed several laboratory audits to assess contract manufacturer's identity testing methods for raw materials.

Jan 2011: Large contract manufacturer, Vancouver, Canada – Audited facility and quality system for compliance with US dietary supplement and food GMP's.

Nov 2010: Contract manufacturer, Nebraska. Audited facility for compliance with dietary supplement and food GMP's.

Synergy Production Laboratories, Moab, UT

Consultant, April 2008 – Dec 2010

Managed Synergy's compliance program and implemented current GMP's for dietary supplement manufacturing. Advised management and trained quality assurance and production staff on legal requirements for current GMP's (21 CFR 111 & 115). During this engagement I accomplished the following projects:

- Developed written policies and wrote SOP's for quality assurance, manufacturing, holding, and distribution.
- Wrote technical and process documentation, created raw material and finished product specifications.
- Recommended methods of analysis for botanicals including FTIR spectroscopy and HPTLC for identification of botanicals and other materials used in dietary supplement manufacturing.
- Established an identity testing program for all raw materials.
- Trained QC technicians in laboratory procedures, including use of the PerkinElmer Spectrum 100 IR spectrometer, lab analytical reporting, and OOS investigations.

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Moab Art Works, Moab, UT 2006 – 2010

Co-owner of a retail gallery of art and photography in Moab, UT. Set up film laboratory for traditional color and B&W development, processing, and printing all formats. Involved in marketing and promoting artists and group exhibitions.

Siebel Systems, Inc. San Mateo, CA Group Director, Engineering, 2003 - 2004

Managed software development for *Siebel Test Automation*, an application for testing Siebel sales management software, integrated and launched this application with *Mercury Quick Test Pro* software. Oversaw Siebel's localization team and custom applications supporting the globalization and translation of Siebel CRM applications into 14 languages.

Independent Consultant, San Francisco and Los Angeles, CA 1999 – 2002

Independent software development manager and technical consultant for start-up companies. Assisted several firms and early-stage internet ventures with technical recruiting and sourcing. Clients included eToys.com and Riffage.com.

C|NET (BuyDirect.com) San Francisco, CA Vice President, Technology Development, 1997 – 1998

Managed development of web applications and oversaw site technical operations for *BuyDirect.com*, a software download and e-commerce web site. Recruited and managed a team of ~15 programmers during the successful spin-off from C|NET. As *Director, Content Technology*, managed content management software development for *Computers.com*, the original C|NET consumer electronics and hardware information web site.

Oracle Corporation, Redwood Shores, CA Product Director, Oracle Financials, 1989 – 1997

Managed engineering and product development for Oracle Accounts Receivable and Oracle Assets. Led development teams consisting of 15-30 software engineers, product managers, quality assurance. Collaborated with Oracle's global development teams to write requirements for localizing accounting applications for markets in Asia, Europe and South America. Led team with Oracle Japan to provide new depreciation and tax features used by companies implementing Oracle Assets in Japan. Implemented regression testing. Responsible for product manuals and user documentation. Taught classes in SQL and the Oracle database for Oracle UK customers (transferred to Oracle Corp. USA in 1991).

Fraser Williams Laboratory Systems Twyford, England Programmer, 1987 – 1989

Developed and maintained laboratory information management systems (LIMS) for use in environmental monitoring and water pollution quality control laboratories by water authorities in England and Wales using Oracle, SQL, and COBOL.

Tate and Lyle R & D, Reading, England Research Analyst, 1985 – 1986

Investigated the long-term stability of sucralose in food products and drinks with high-performance liquid chromatography.

University of Reading, Plant Sciences Laboratory, England Research Technician, 1980 – 1985

Researched into links between plant taxonomy and flavonoid biochemistry with Prof. J. B. Harborne's group in the Department of Botany. Used methods incl. chromatography (HPLC and TLC) for separation and analysis of phenolic plant pigments, and to identify novel compounds and/or develop new methods of analysis. See *Publications* below.

Esso (Exxon) Research, Milton, England Laboratory Technician, 1978 – 1979

Analyzed crude oil, refinery and petroleum samples using traditional wet-chemical analysis and gas chromatography.

Pavlova Co. Ltd. Abingdon, England Quality Control Laboratory Manager, 1976 – 1978

Managed the tannery quality control laboratory for factory processes, including physical and chemical testing of leather products, chromium analysis, and performed water monitoring and testing for heavy metals, biological activity etc.

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Education

TEC Certificate in Chemistry (1979) Oxford College of Further Education, England

Computer Programming and Systems Analysis (1986) Training Opportunities Program, Slough, England

Publications

- Identification of two Gossypetin Monomethyl Ethers as Yellow Flower Pigments in the Rutaceae – Jeffrey B. Harborne and Marian Boardley, *Z. Naturforsch.* 38c, 148-150 (1983)
- Trisubstituted Flavonol Glycosides in *Coronilla Emerus* Flowers – Jeffrey B. Harborne and Marian Boardley, *Phytochemistry* Vol. 22 No. 2, 622-625 (1983)
- Use of High-Performance Liquid Chromatography (HPLC) in the Separation of Flavonol Glycosides and Flavonol Sulphates – J. B. Harborne and M. Boardley, *Journal of Chromatography* 299, 377-385 (1984)
- The Widespread Occurrence in Nature of Anthocyanins as Zwitterions – Jeffrey B. Harborne and Marian Boardley, *Z. Naturforsch.* 40c, 305-308 (1985)
- Variations in Flavonoid Patterns Within the Genus *Chondropetalum* (Restionaceae) – Jeffrey B. Harborne and Marian Boardley, *Phytochemistry* Vol. 24 No. 2, 273-278 (1985)
- A Chemotaxonomic Survey of the Tribe Psoraleeae in Africa – Marian Boardley, Charles H. Stirton, and Jeffrey B. Harborne, *Biochemical Systematics and Ecology* Vol. 14 No. 6, 603-613 (1986)
- The Flavonoids in Leaves of Diploid *Triticum* Species (Gramineae) – Jeffrey B. Harborne, Marian Boardley, Sune Frost, and Gerhard Holm, *Plant Systematics and Evolution* 154, 251-257 (1986)

I am the published and collator of several widely distributed charts based on data I routinely collect from Warning Letters and cGMP inspections by FDA under the Dietary Supplement regulations (specifically 21 CFR 111 violations) since the regulations became effective. The latest version of these charts is found at <http://www.marianboardley.com/charts>

Memberships and Affiliations

- American Herbal Products Association (AHPA) – Member, Analytical Laboratory Committee
- Member of UNPA NDI working group (to comment on FDA Draft Guidance for New Dietary Ingredients)
- AOAC International
- American Herbal Pharmacopoeia (AHP)
- American Botanical Council (ABC)

Training and Seminars

- Introduction to FT-IR and AssureID™ Software – PerkinElmer Inc. (on-site instrument training, 2011)
- Batch Production Records - Do's and Don't's – NSF-DBA Specialty Class (SupplySide West, 2011)
- NDI GUIDANCE - Understanding The New Safety Paradigm – United Natural Products Alliance (UNPA, 2011)
- FDA's New Dietary Ingredient Guidance – American Herbal Products Association (AHPA, 2011)
- Risk in Dietary Supplements (Guest Speaker) – Intermountain Biomedical Association Annual Workshop 2010
- Microscopic Identification of Popular Botanical Materials – AHPA / USC, 2010
- Establishing Identity & Quality Testing Programs for Compliance with Dietary Supplement cGMP's - NPI/Bruker, 2010
- Meeting Specifications: Identity Testing and Vendor Qualification – AHPA cGMP Compliance Series, 2010
- Expanding Your Dietary Supplement Business into Canada [Canadian GMP's] – Dicentra Inc., 2010
- GMP V: Inspections, Enforcement, Compliance – UNPA, 2010
- How to Conduct & Manage an FDA Inspection – AHPA cGMP Compliance Series, 2009
- Botanical Identification for GMP Compliance – UNPA with Dr Ikhlas Khan (Univ. Mississippi, School of Pharm.), 2009
- Mock FDA GMP Inspection for Dietary Supplements – UNPA, 2009
- Introduction to FT-IR and Spectrum™ Software – PerkinElmer Inc. on-site instrument training, 2009
- Setting and Meeting Specifications for Contaminants in Finished Products Under cGMP – AHPA, 2009
- GMP's for Dietary Supplements II – UNPA, 2008