Indigo Consulting Group, LLC

Beverly G. Whitaker, CQA

Experience:

Indigo Consulting Group, LLC
President - Multi-faceted consulting practice for FDA regulated industry including chemical, food, medical device and pharmaceutical manufacturing. Core business focuses on project management, operational optimization, regulatory evaluations, training and mechanical design. Provides technical expertise in sterility assurance, regulatory affairs, process validation, clinical evaluations, corrective action and external audit management - 1996 - present

National Standards Authority of Ireland
Lead Medical Device and IVDD Assessor under Canadian Medical Device Conformity Assessment System (CMDCAS) and EU Device Directives - 2002 – present

Webster University
Adjunct Faculty in Management - 1996 – 1999

Becton Dickinson & Company
Compliance Officer - Manager of regulatory compliance group including complaint handling, post market surveillance program, internal & supplier audit program, FDA liaison, strategic quality planning & continuous improvement activities - facilitated annual improvement in medical device quality in excess of 10% per year monitored by significant reduction in complaints per million manufactured - 1993-1996

Management Representative – Development and implementation of ISO 9000 Quality System for 750 employee site as a prototype for corporate implementation program. Obtained ISO 9002 registration within 9 months, EN46002 (ISO13485) registration 5 months later - 1993-1995

Division Chief Microbiologist - Manager of multi-division sterility assurance program that included seven (7) facilities (domestic and international locations), four (4) with in-house gamma or e-beam irradiators. Divisions included drug delivery devices, in-vitro diagnostic products and medical devices - 1990-1993

Chief Microbiologist – Manager of all aspects of a 3 million-curie gamma irradiation sterilization facility, contract Ethylene Oxide sterilization and supporting microbiology & tissue culture laboratories. 1984-1990

Supplier Auditor - 1984-1996

Microbiologist – Laboratory supervisor for bioburden, sterility testing, product performance testing, environmental monitoring, dose establishment and EO validation programs - 1983-1984

General Nutrition Corporation
Supervisor of Microbiology & Sampling – Supervision of pathogen screening laboratory and QA sampling program for a nutritional supplement tableting and liquid-gel manufacturing facility - 1981-1983

Education:

Masters of Business Administration - Operations Management, University of South Carolina, 1992
Bachelor of Science in Microbiology, cum laude, Clemson University, 1980
Health Canada CMDCAS Training, 2004
National Standards Authority of Ireland In Vitro Diagnostic Devices Course, 2004
National Standards Authority of Ireland ISO13485:2003, MDD 93/42/EEC and CMDCAS Course, 2003
Ninth Air Force Customer Service University, 1995
British Standards Institute Lead Assessor Training, Certificate 13476, 1992
Food & Drug Administration Facility Inspection Course, 1992
Statistical Manufacturing & Control Seminar, 1988
Radiation Protection Certification for Radiation Safety Officers, 1987
Gamma Irradiator Operator Training, 1984

Professional Licenses / Attributes:

American Society for Quality Certified Quality Auditor Certificate # 6301, 1993 - current,
American Society for Quality Biomedical Certificate # 072, 2002 - current
Certified Quality Systems Lead Auditor, 1997 – current
QSARAB Certificate # QO6156, 1997 - 2008,
IRCA #1190434, 2006 – current;
Health Canada recognized CMDR Assessor #M-1666, issued 2004

• 32 Dolphin Point Drive • Beaufort, South Carolina 29907 •
• (843) 524 -1290 • Fax: (843) 524 -1390 •
www.indigoconsultinggroupllc.com
bgwindigo@islc.net

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Project Management Skills and Attributes

General Management and Operations:

- General Manager of a 3 million-curie gamma irradiator > ten (10) years. Responsibilities included employee relations, inventory control, customer service, annual and capital budgets in excess of $1.7 million, process quality assurance, commissioning and validation, preventative maintenance and major repair planning, capacity analysis production planning, process research, & employee training (GMP, process, and radiation safety).
- Long Range Strategic Goals Workshop facilitator for the South Carolina Department of Education. Workshop was dedicated to identifying key quality initiatives and trends while outlining methods of communicating success criteria to the diverse stakeholders of a state regulatory agency.
- Interim Quality and Operations Manager for contract ethylene oxide sterilization site responsible for staff development, customer relations, validation execution and compliance correction action program.
- Vice President, Medical Technology for EPA approved, FDA supported extension of ethylene oxide for use in patented decontamination of consumer goods. Responsible for the development of ethylene oxide processing strategy, validation of contract service providers, and establishment of routine operational procedures throughout supply chain. Provided regulatory feedback for business to business web-site modeling, risk evaluation and feasibility models to support initial venture capital while providing technical support for initial product marketing.
- Development and implementation of Sterility Assurance strategy and policy for Fortune 500 manufacturer of medical devices in response to the changing regulatory environment of the 1980's. Direct responsibility for seven (7) manufacturing facilities (domestic and international).
- Sterility Assurance Program Management of Radiation, Steam, and EO sterilization requalification and validation programs in accordance with ISO standards (11135, 11137, 17665) for manufacturers of Class I and Class II disposables, Class III implantable devices and sterile IVDD. Programs routinely audited by notified body and FDA inspectors with no 483's issued. Product lines have included manufacture of syringes, blood collection tubes, blood collection needles, tissue culture labware, specimen collection devices, pharmaceutical delivery devices, angiographic syringes, specialized catheter products, bandage systems, wound management products, neonate training device, endoscopic surgical supplies, sutures, absorbable orthopedic implants, Left Ventricular Assist Devices, medical textiles, custom kits, orthopedic implants, and surgical support devices.
- Microbiology Laboratory management expertise with > fifteen (15) years hands on experience within the pharmaceutical and medical device industries. Method development, validation and execution to support sterile label and product performance claims. Technology including rapid testing technology, tissue culture, traditional USP and AAMI/ ISO testing as well as personnel development, training, capacity planning, and new product introduction support.
- Personnel / staffing needs assessor for Fortune 200 device manufacturer and device service suppliers. Activities included staff development planning, evaluation of personnel performance, resource allocation evaluation and evaluation of reporting structure adequacy in accordance with organizational strategic goals.
- Y2K Readiness Project Manager for 15-site multi-national sterilization services supplier. Project included equipment and software inventory evaluation, business impact analysis, coordination of testing and / or certification of off-the-shelf and custom equipment and software, coordination of corrective action implementation program, and documentation of all project activities.
- Management consultant for European bio-absorbable implant manufacturer product line extension and capacity expansion into United States market. Project included identification of cGMP compliant suppliers, development of manufacturing implementation plan and facilitation of support process validations.
- Quality assurance, packaging standards, sterilization technology, and regulatory affairs management consultant for new product development teams including MRI / CT Scan support products, software driven radiology dosing

programs, orthopedic implants, LVAD, cardiology interventional devices, reusable medical devices and medical textiles. Development of sterility assurance standard operating procedures to support implementation of contract sterilization and laboratory services for a consortium in the Asia Pacific region.

- Project responsibilities have included:
  - Design, installation, and validation of Class 1000 HVAC systems for Laboratory operations and Class 10,000 or 100,000 HVAC for manufacturing of medical device/aseptic fill operations. Project manager roles included support for design, construction, installation, start-up and validation of four microbiology laboratory operations in the following industries: domestic pharmaceutical tableting, medical device/IVDP/Tissue Culture manufacturing - domestic and over-seas operations, and Tissue processing/preservation manufacturing. Equipment included autoclaves, laminar flow hoods, incubators, ultra low temperature freezers, dishwashers/sanitizers, and supporting utilities.
  - Design team project manager (contamination control) for validation of innovative multi-use device(s).
  - Expertise in Sterilization cost containment programs resulting from implementation of contamination control programs (personnel training, HVAC modifications, product flow re-design, and implementation of monitoring programs).
  - Expertise in the development of sterilization logistics strategy - addressing training, analysis, and strategy options for short term and long term manufacturing requirements using alternate sterilization technology. Strategy addressed implications of work in process and distribution warehouse requirements, development of supplier relationships, current and long term market trends, and in-house versus contract manufacturing options.
  - Developed impact analysis, validation program guidelines and work aids to support corporate training and implementation initiatives for a global Fortune 500 medical device company upon release of revised international standards for sterilization (ISO 11137-1:2006, 11137-2:2006, and 11137-3:2006).

Validation Program Management:

- Validation project management examples:
  - Ethylene oxide sterilization cycle optimization program which included development of reduced aeration time and reduced biological indicator incubation periods resulting in a reduction of WIP of 45%.
  - RF heat sealing process which included guidance on method development, research on industry standards and international guidelines for new product design and process acceptance criteria.
  - IQ/OQ/PQ execution for new cryopreservation tissue preservation production facility.
  - IQ/OQ/PQ advisor for installation of industrial irradiator for use with implantable brachytherapy devices.
  - Radiation Sterilization of Phase II and Phase III clinical combination drug delivery device requiring sterile label claim with temperature sensitivity.
  - EO sterilization program management of implantable ventricular assist device during EU and US clinical trials and regulatory reviews with continued support after market release within the EU. US PMA pending.
  - Ethylene oxide sterilization cycle optimization program achieved seven (7) day reduction in work-in-process inventory, eliminated product handling damage by $75,000 per year, and developed data for first in industry use of external process challenge device and parametric release (1998) for drug delivery device under modified NDA approval.

- Implementation of QSR compliant EO validation and sterility assurance program for product lines under FDA consent decree for sterile label claim concerns. Long standing consent decree lifted after FDA audit resulted in no 483 citations one year after program implementation.
- Sterilization technical advisor for process optimization, external biological indicator process challenge device development and parametric release programs – medical textiles, catheters, tubing sets, operating room supplies.

Regulatory:

- Pre- and Post-market clinical literature reviews for Class I, Class II (a and b) and Class III medical devices in accordance with MDD 93/42/EEC as amended by 2007/47/EC. Reports included evaluation of post market surveillance data, instructions for use, change controls, market usage, and literature review findings as an integral component of an overall risk management program. Example product lines evaluations include orthopedic implant support devices, cardiac interventional devices, and implantable radiotherapy.
- Site Audit Manager responsible for the initial (1996) FDA harmonization audit of a Fortune 500 Device facility to support GHTF audit program guidance development. Audit performed by key FDA staff with observers from the Canadian Ministry of Health, FDA headquarters, AdvaMed (formerly HIMA), a European Notified Body, United Kingdom Medical Device Agency, and the Australian Commonwealth Department of Human Services and Health in conjunction with the International Standardization Organization Global Harmonization Task Force (Study Group 4).
- Regulatory Project management examples:
  - Corrective action program development, regulatory training and Warning Letter response facilitation for Class II manufacturer of Medical Devices. Directed or edited monthly correspondence with regional compliance officer through out corrective action program implementation. Corrective action program included work instruction revision, process and purchasing specification development, validation implementation and execution, and design controls implementation in accordance with United States Quality System Regulation
  - Facilitated recall of non-conforming Class II devices (US and EU distribution) with no regulatory repercussions (FDA or Notified Body). Developed & monitored corrective action program to prevent reoccurrence. FDA recall close out inspection and QSIT inspection completed without issuance of a Form 483.
  - Medical Device Classification & 510(k) review of all product lines after client acquisition of major device manufacturer & distributor. Evaluation included elimination of 510(k) supplements based upon FDA Modernization Act, reclassification of product lines based upon target markets and indications for use, and submittal of documentation updates in support of continued market penetration.
  - Facilitated corrective action program developed to address adverse sterility assurance program results which prevented loss of market share and maintained supply chain for critical provider of non-embryonic stem cells.
  - Manufacturer's liaison for FDA inspections of domestic medical device facilities. Specialized emphasis placed on Sterility Assurance, Validation, and Complaint Handling Systems.
  - Customized training programs for sterility assurance, process validation, packaging validation, CAPA, and regulatory affairs – Class I, Class II & Class III device marketed under the European Medical Device Directives, European In Vitro Diagnostic Device Directive, Canadian Medial Device Regulation, and United States Quality System Regulations.
  - Development of sterilization strategy and validation program for steam sterilization of fully assembled drug delivery device. Project included development and execution of component interface kinetic studies and 510(k) filing to support sterile label claim.

- Technical writer - conversion of Instructions For Use to target United States market for European / Asian manufacturers.
- Coordinator of clinical trial testing to support risk analysis of off-label institutional re-use of disposable vascular devices for documentation within risk mitigation plans.
- Technical consultant for risk management programs with emphasis on central sterile supply and operating room flow and contamination control processes. Sites range from ambulatory care and surgical centers to 250 bed hospital.
- Active member of MDMA lobbying team for implementation of the FDA Modernization Act of 1997. Provided comment and evaluation to the Food and Drug Administration on preliminary guidance documents and initiatives resulting from the FDA Modernization Act of 1997 as a member of the Regulatory Affairs committee of the Medical Device Manufacturers Association.

Quality Assurance / CE Mark / ISO 9001 / Canadian MDR / ISO 13485

- Twenty nine (29) years audit experience for regulated manufacturers, distributors, critical device components, services and suppliers. Extensive auditing experience in contract sterilization and laboratory services as well as raw materials utilized to support plastic injection molding, plastic extrusion, rubber compression molding, glass forming, packaging, and high speed assembly operations. Emphasis placed on optimization of Manufacturing, Distribution, Regulatory Affairs, Validation, Complaint Handling, Sterilization, and Total Quality Systems.
- IRCA and ASQ certified auditor with experience conducting assessments under the following standards: cGMP, Quality System Regulation, ISO 9001 (1994, 2000, 2008), ISO 13485 (1996, 2003(R)2009 & Canadian requirements), AAMI/ISO Sterility Assurance Standards, Medical Device Directive, & In Vitro Diagnostic Directive, ISO 14971 – Risk Management.

  - commodity food,
  - coffee and tea,
  - bakery mixes,
  - paper and paper products,
  - printing - flexographic and screen printing,
  - toll chemicals,
  - corrugated containers,
  - calibration services,
  - medical devices,
  - medical electronics,
  - injection molding,
  - plastic extrusion,
  - rubber compression molding,
  - glass forming,
  - CNC machining & stamping,
  - biomaterials
  - surgical drapes and textiles,
  - petroleum products,
  - implantable orthopedic products
  - software development (mainframe, PC, and Internet based programs),
  - insurance services,
  - engineered minerals,
  - wound care products,
  - Rx / OTC liquids
  - Rx / OTC tableting
  - dose imaging software
  - design control processes
  - laboratory services (microbiology, chemistry, general testing, LAL reagents)
  - cardiac interventional therapy devices
  - sterile solutions
  - sterilization services – gamma and EO
  - In Vitro Diagnostic test kits - *Limulus* Amebocyte Lysate, pregnancy testing, drugs of abuse, ELISA, EIA, hematology reagents, controls, & calibrators
  - organ perfusion devices
  - cardiac care devices
  - pharmaceutical packaging
  - hospital central supply services
  - filtration and separation products
  - contract design / engineering services
  - mechanical seal design & distribution
  - bioprocessing containers
  - biomedical instrumentation
  - catheter assembly
  - product development

Publications

- "*Achieving Continuous Improvement through Internal Auditing*", 1994 Small Manufacturer Technology Center Conference.
- "*Effective Complaint Handling: Your Key to a Smooth FDA Visit*", November 1996 -- The Validation Consultant.
- "*Supplier Auditing, What to Do When Things Go Wrong! Effective Crisis Auditing Techniques*", 1997 ASQC Quality Auditing Division Conference
- "*What Is A Recall And When Is It Required*", November 1998 -- The Validation Consultant.
- Commonwealth of Penn. Trade Mission Briefing Session -- "*Manufacturers, are you prepared for the CE Mark? What you need to know to get started in the European Union",* 1999.
- Course Development Team member (1999) and approved faculty for the Association for the Advancement of Medical Instrumentation Course titled "*Process Validation – Requirements and Industry Practice".*
- Course Development Team member (2002) for the Association for the Advancement of Medical Instrumentation Course titled "*Corrective and Preventive Action Requirements and Industry Practice*".

Professional Associations / Awards

- International Register of Certificated Auditors (IRCA), Lead Auditor Certificate #1190434 – 2006 - present
- American Society for Quality (ASQ) Certified Quality Auditor, Certificate # 6301, 1993 – current
- ASQ Certified Quality Auditor-Biomedical, Certificate # 72, 2002 - current
- RABQSA Certified Lead Quality System Auditor, Certificate # QO6156, 1997 – 2008, transferred to IRCA.
- Health Canada recognized Medical Device Assessor, Certificate # M-1666, 2004 - current
- S. C. Department of Health and Environmental Control licensed Radiation Safety Officer, 1983 - 1996.
- American Quality Assessors, an ANAB (formerly RAB) accredited ISO/QS 9000 Registrar
    - Chairman, Governing Board, 1994 - 1998.
    - Member, Advisory Board - regulated industry (pharmaceutical, device and food), 1998 - 2003.
    - Member, Registration Committee for ISO 13485 certification, 2008 – 2011.
    - Note: AQA International merged with NSF-ISR in 2011.
- South Carolina Governor's Quality Award examiner (1996) & senior examiner (1997). Award utilizes Malcolm Baldrige National Quality Award Criteria for the evaluation of service, education, manufacturing and government organizations.
- Becton Dickinson Worldwide Sterilization Capacity & Transportation Logistics Task-force, 1991-1994
- Member, American Society for Quality, 1992 - present
- Member, Parenteral Drug Association, Inc., 2000 – present
- Member, PDA Combination Products Task Force, 2008 – present
- Member, PDA Combination Products Regulatory Affairs Sub-committee, 2009 – present
- Member, Regulatory Affairs Professionals Society, 1993 - present
- Member, Association for the Advancement of Medical Instrumentation, 1998 - present
- Member, PDA Packaging Supplier Auditing and Qualification Task Group, 2002 – 2004
- Member, American Society for Microbiology, 1977-1993,
    - Secretary/Treasurer – South Carolina Branch, 1988-1992
- Awarded Tribute to Women in Industry Award, 1986

- Awarded Becton Dickinson Diagnostic Sector Manufacturing Excellence Award for substantial achievements in technology transfer, process improvements, or effective execution of programs that provide significant competitive advantage through manufacturing, 1994
- Awarded BD Special Achievement Recognition Award, 1986, 1990, & 1994
- Awarded St. Peter Church Catholic Woman of the Year, 2010

Community Relations

- YWCA - Sumter, Board of Directors & Vice President of Finance, 1987-1990
- Greater Beaufort Chamber of Commerce -- Education Committee and Governmental Affairs Committee -- 1997 - 1999. Community representative for the Legislative Issues committee of the Beaufort County School Board. Evaluated key legislative initiatives such as Charter Schools, School Accountability and Standards of Excellence. Focus was the implementation, funding, and impact of legislative initiatives on public education (1997 - 1999).
- Managed non-profit fund raising programs as PTO President with net proceeds in excess of $45,000 in 1999 and $100,000 in 2001.
- Beaufort Designer Show House Guidebook Editor, 2000 & 2003
- "Full Moon – High Tide" Management consultant for book sales and distribution office, 2001 – 2003
- St. Peter's Catholic Church Women's Club President, 2004 – 2006
- The Beaufort Academy, Inc. Board of Trustees, 2001 – 2010
    - Member, Student Life, Finance and Executive Committee
    - Secretary, Board of Trustees, 2002 – 2009
    - Chair, ad hoc Compensation Committee, Beaufort Academy Board of Trustees, 2004 – responsible for establishing employee benefit guidelines and procuring affordable health insurance programs for non-profit organization with under 100 employees.
- Dolphin Point Property Owners Association Treasurer, 2009 – present
- St. Peter Catholic Church and School Finance Council, 2010 - present
    - Secretary, 2011 - present

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