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Greg Bobrowicz

International expert in FDA GMP Compliance and Quality Assurance. Experienced in performing the most complex FDA inspections and industry audits. Expert in FDA GMP requirements for pharmaceuticals, biotechnology, and ICH Q7. Practical and systematic corrective action plans tailored to address FDA's greatest concerns about product quality. Excellent speaking and writing skills. Comprehensive and proven approach to hosting inspections. Diligent interviewer: trained in interview techniques for federal law enforcement officers. Sharp analytical skills. Ability to organize comprehensive compliance projects. Expert in inspection management techniques with unparalleled success record.

Metrics

- 142 biotech, pharmaceutical, and device clients with hundreds of sites in 20 countries.
    - 49 companies who primarily outsource
    - 25 contract manufacturers and 1 contract lab
    - 74 biotech clients, many with multiple sites, including 12 cell therapy sites
- 92% of clients in the last 7 years return to FDAReady for additional consulting projects.
- 100% of 19 clients who followed a full program of gap analyses and mock preparation have passed the inspection for which we prepared. (Program at fdaready.com.)
- 24 mock or real inspections in the last seven years.
- 2 major book chapters and 3 articles on quality and compliance.
- 24 speeches in four years on quality and compliance, mostly biotech, in the US, Canada, and Europe.
- 100% of reports delivered in fewer than 12 days, and 85% in a week or less – average is 4 days.

Areas of Expertise

Active Pharmaceutical Ingredients	Dosage Forms	Systems and Programs
• Biotechnology • Small molecule APIs • Antibiotics • Cell therapies • Vaccines • Plasma fractionators	• Parenterals • Powder & liquid inhalers • Transdermal & implantable patches • Drug-releasing implants • Modified-release oral dosages	• Quality Systems: deviations & investigations, training, audits, change control, lot release • Laboratory operations: method validation, environmental monitoring, OOS • Material management • Facility Engineering: facility design, equipment qualification, maintenance, calibration • Process: development, process validation, cleaning validation • Computer systems

Experience

Consultant to Pharmaceutical and Biotech Industry, 1998-present

Principal Consultant, FDAReady Consulting, 1999-present
Director of Biotechnology, Quintiles Consulting, 1998-1999

- Perform systematic GMP audits of pharmaceutical and biologic firms, specializing in biotechnology.
    - Audits emphasize essential points by applying risk-based evaluation of quality systems.
    - Recommendations for correction are comprehensive and systematic.
- Deliver detailed reports and corrective action plans from regulatory gap analyses.
- Improve clients' inspectional readiness with mock FDA audits.
    - Customized to a company's culture, my Inspection Management techniques have been implemented around the world – with an excellent success rate.
- Train clients in Quality and Compliance activities, including FDA Inspection Management, Failure Investigations, Laboratory Compliance, and Computer Validation.
- Report to and cooperate with executive management to manage risk and prioritize improvements.

Investigator, US Food & Drug Administration, Pacific Region, 1991-1998

- Promoted to Regional Biotechnology Specialist Investigator – a unique position in the country.
- Conducted Pre-Approval and Regulatory Inspections of scores of pharmaceutical, biologic, and medical device sites, specializing in biotechnology. Inspectional findings generally supported by FDA management leading to numerous Warning Letters, recommendations to withhold approval, and further regulatory action. Inspections frequently tracked in the trade press.
- Co-founded landmark Pacific Regional Biotechnology Team, an innovative self-directed team with expertise in biotechnology methods and techniques. Unprecedented partnerships with industry recognized with Vice Presidential award and an FDA Award of Merit.
- Managed District's Pre-Approval Inspections, Drug Quality Reporting System, and MedWatch programs.
- Managed cases and reviewed responses to 483s and Warning Letters for the Pacific Regional Biotechnology Team and my own inspections.
- Drafted inspectional guidance and compliance policy for ORA, CBER, and CDER.
- Trained other investigators in inspectional techniques in areas such as biotechnology, computer system validation, and laboratory compliance.

Education

FDA Training

- Biotechnology (organizer)
- Industrial sterilization
- Pharmaceuticals
- Pre-approval inspections
- Computer systems validation
- Team Biologics – Plasma Fractionators
- Food and Drug Law
- Evidence Development
- Investigative Interviewing and Interrogation
- Quality Systems Regulation

Joint Industry-FDA Training

- ICH Q7A for Active Pharmaceutical Ingredients
- Electronic Records & Signatures

Academic

M.S. Cellular & Developmental Biology, University of Oregon, Eugene, Oregon, 1991
B.S. Cellular & Molecular Biology, The University of Michigan, Ann Arbor, Michigan, 1986

Publications & Presentations

Publications

Quality at the Threshold of Enforcement: Perspectives from Industry and FDA. In *Pharmaceutical Quality,* R. Paincorp, Editor. 2004, Davis Horwood International Publishing.

The Quality Agreement: Compliance Considerations in Selecting a Contract Manufacturer**,** *Biopharm,* February 2001.

Biotechnology Manufacturing Issues: A Field Investigator's Perspective. In *Biotechnology: Quality Assurance and Validation*, K.E. Avis, C.M. Wagner, and V.L. Wu, Editors. 1999, Interpharm Press.

The Compliance Costs of Hasty Product Development, *BioPharm*, August 1999.

The History and Origin of Team Biologics, *Regulatory Affairs Focus Volume 4,* Issue 1, January 1999.

Speeches

After 2002, I voluntarily reduced public appearances.

Working with Contract Manufacturers. Featured meeting workshop, Barnett Conferences. March 2003, Boston, MA.

FDA Inspections of Drug Manufacturers. Invited Lecturer, University of California, Berkeley (BioEngineering 190), in partnership with ISPE. April 2002 and February 2003, Berkeley, CA.

Planning for Success: PAIs and CMOs. *Scaling Up from Bench to Clinic & Beyond*, IBC Conferences. August 2002, San Diego, CA.

Working with Contract Manufacturers. Dinner Meeting, American Society for Quality, San Francisco Chapter. May 2002, Oakland, CA.

The Costs of GMP Non-Compliance for Clinical Trial Materials (CTM). PARCS (Pacific Regional Clinical Supplies). October 2001, South San Francisco, CA.

Discussion Leader, CMOs and outsourcing companies. Roundtable Panel Discussions at *Transitions from Bench To Clinic,* IBC Conferences. August 2001, Boston, MA.

Quality Assurance and Facility Engineering: Resolving the Conflict. Dinner Meeting, ISPE-San Diego Chapter. April 2001, San Diego, CA.

Quality Assurance and Facility Engineering: Resolving the Conflict. Dinner Meeting, ISPE-San Diego Chapter. April 2001, San Diego, CA.

Diagnosing Your Problems: What are the FDA Showstoppers? Dinner Meeting, American Society of Quality-San Francisco/Bay Area Chapter. March 2001, Oakland, CA.

Quality Assurance and Facility Engineering: Resolving the Conflict. Dinner Meeting, ISPE-San Francisco/Bay Area Chapter. December 2000, Berkeley, CA.

When Things Go Wrong: FDA Inspections of OOS, Deviations, and Corrective Action Programs. Workshop at *Well Characterized Biologicals,* IBC Conferences. September 2000, Washington, DC, and December 2000, San Diego, CA.

Compliance Considerations in Selecting a Contract Manufacturer. *From Bench to Clinic,* IBC Conferences. September 2000, San Francisco, CA

FDA Inspections of a Transferred Process. *Production Site Transfer,* IBC Conferences. September 2000, San Francisco, CA

FDA's "New" Expectations for Validation of Biologics. *Validation of Biologics,* Institute for International Research. May 2000, Seattle WA.

A Biotech Experience of preparing for and passing a PAI. *Surviving and Passing FDA Inspections,* Vision in Business. December 1999, London, England.

Conducting software validation and electronic data management in line with the FDA requirements. *Surviving and Passing FDA Inspections,* Vision in Business. December 1999, London, England.

A Successful FDA Site Inspection. *Production Site Transfer,* IBC Conferences. December 1999, London, England.

Regulatory Perspective on Facility Design and Engineering. *ISPE Vendor Night,* San Diego Chapter ISPE. November 1999, San Diego, CA.

Meeting FDA's Expectations for Compliance in Purification. *Biotherapeutics '99*, IBC Conferences. October 1999, Washington, DC.

Team Biologics: An Insider's Perspective. *11th Annual Technical Conference,* Pharmaceutical Sciences Group. September 1999, Niagara-on-the-Lake, Ontario, Canada.

FDA's "New" Expectations for Validation of Biologics. *Validation of Biologics,* Institute for International Research. September 1999, San Francisco, CA.

Lessons from the Field: Regulatory Perspective on Process Validation. *FDA Team Biologics Field Inspections,* IBC Conferences. September 1999, Boston, MA.

Comparability and Validation. *BioPharm Conference*, BioPharm. June 1999, Burlingame, CA.

Process Development and Process Validation. *West Coast Meeting,* PDA. April 1999, San Francisco, CA.

Vendor Audits: A Regulatory Perspective. *Chapter Meeting,* ISPE San Diego Chapter. January 1999, San Diego, CA.