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JENNIFER D. AHEARN
PRINCIPAL
DIRECTOR OF REGULATORY AND COMPLIANCE - PHARMACEUTICAL AND MEDICAL DEVICES

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Jennifer Ahearn is a Principal at Engineering Systems Inc. (ESi) and Director of Regulatory and Compliance for Pharmaceutical and Medical Devices. Ms. Ahearn specializes in FDA regulatory compliance for pharmaceutical, medical device, and food industries.

As a consultant, Ms. Ahearn has assisted pharmaceutical and medical device companies preparing for Food and Drug Administration (FDA) inspections, as well as responding to FDA 483 observations and warning letters after inspections. These responses include helping form and manage corrective and preventative action plans and assisting the quality departments in implementing the corrections. Ms. Ahearn has managed teams of consultants and scientists working on multidisciplinary efforts to improve cGMP operations to prevent and resolve compliance problems. This has included oral solid dosage form manufacturers, liquid and suspension manufacturers (sterile and non-sterile), transdermal patch manufacturers, API manufacturers, all forms of sterile drug manufacturing, and all classes of medical devices. She and her team also offer training to help shift site culture and rebuild institutional knowledge by utilizing her FDA background and network of scientists.

Prior to joining ESi, Ms. Ahearn served as a bench chemist for the Georgia Bureau of Investigation (GBI) specializing in forensic toxicology, as well as a trainer for local law enforcement and prosecuting attorneys. As an employee of the FDA, she served in a number of roles within the agency. She worked as a bench chemist testing pharmaceutical products manufactured by companies around the world, as a domestic and international investigator, as a technical liaison for FDA's Office of Criminal Investigations, and as a member of FDA's National Training Cadre.

Ms. Ahearn's goal and passion is to help industry exceed FDA regulatory compliance requirements, while maintaining practical manufacturing. She has a dedication to her clients and believes that if she is diligent and efficient then the manufacturing sites will achieve compliance, increase profitability, and have a system in place to maintain those efforts.

July 2020

Instrumentation Training

- Gas Chromatography
- LC/MS
- Immunoassays
- TLC
- FTIR
- Karl Fisher titration
- GC/MS
- IR
- HPLC
- UV
- Dissolution Techniques
- Physical Testing Techniques

Professional Training (Received)

Pharmacology, Mercer University's School of Pharmacy/GBI, 2000

Pharmacokinetics, Mercer University's School of Pharmacy/GBI, 2000

Oral Presentation Skills, Quantum Communications, GBI, 2000

Toxicology, GBI, 2001

American Academy of Forensic Science Professional Meeting, Attendee and Volunteer, 2002

Borkenstein School, "Alcohol, Drugs, and Highway Safety," IN University Center for Law in Action, 2001

Federal Courtroom Testimony, FDA, 2002 – 2003

Biological and Chemical Agents, FDA, 2002

Investigative Interviewing, FDA, 2003

ISO 17025 Auditor Training, Scott Consulting Services/FDA, Denver, CO, 2003

Food and Drug Law, FDA, Rockville, MD, 2003

Fundamentals of Regulatory Chemistry, FDA, Rockville, MD, 2003

Basic Drug School, FDA, Raleigh NC, 2004

Active Pharmaceutical Ingredients, FDA, Iselin, NJ, 2005

Pre-Approval Inspections, FDA, Rockville, MD, 2005

Verbal Judo/Situational Planning, FDA, Atlanta, GA, 2005

Industrial Sterilization, FDA, Irvine, CA, 2006

Professional Training (Given)

FDA National Training Cadre/Speaker for the following:

Basic Drug School
Pre-Approval Inspections
Introduction to Pharmaceutical Inspections for Analysts
Method Validation/Verification
Cleaning Validation
Good Documentation Practices

Georgia State Patrol Training Cadre/Speaker for the following:

Breath Alcohol Testing
Field Sobriety
Pharmacokinetics/Pharmacology of Alcohol and Drugs

Georgia Prosecuting Attorney's Council Speaker for the following:

Blood and Breath Alcohol Testing
Field Sobriety
Pharmacokinetics/Pharmacology of Alcohol and Drugs
Evidence Collection
Sample Analysis

Invited Speaker and Workshop Host for the International cGMP Conference (Athens, GA)

Invited Speaker and Workshop Host for GMP by the Sea (Cambridge, MD)

Invited Speaker and Workshop Host for CHPA Regulatory, Scientific & Quality Conference (Bethesda, MD)

Positions Held

Engineering Systems Inc., Norcross, Georgia

Director of Regulatory and Compliance, Pharmaceutical and Medical Devices
Principal
December 2015 – Present

IHL Consulting Group Inc., Atlanta, Georgia

Senior Consultant/Project Manager, November 2008 – December 2015

- Provide FDA compliance advice to the drug, medical device, and biologics industries domestically and internationally
- Perform Quality System Assessments
- Provide FDA Compliance Improvement Strategies
- Advise pharmaceutical executives on FDA compliance strategies and risk management for various regulatory issues
- Conduct mock cGMP and Pre-Approval audits of international and domestic drug manufacturer with identification of critical and major deficiencies, and recommendations for remediation
- Assist in assembling written responses to FDA inspections and Regulatory Actions
- Develop strategies for FDA preparation and readiness
- Conduct technical assessments of GMP operations
- Provide comprehensive cGMP system inspections and corrective action plans
- Provide evaluation of NDA/ANDA Pre-Approval Inspection and FDA readiness
- Provide vendor assessments and cGMP audits for pharmaceutical and medical device companies
- Provide cGMP and Pre-Approval training
- Act as liaison and provide coordination with FDA field and headquarters offices
- Provide comprehensive Quality Assurance, Quality Control, Validation and cGMP support
- Provide standard operating procedure and validation protocol development support
- Managed multiple clients on parallel project loads, performing and managing the consulting efforts
- Perform extensive retrospective review of quality records and investigations
- Review and implement cleaning validations and SOP gap assessments to increase effectiveness and decrease downtime
- Manage SOP and STP gap assessments
- Review vendor qualifications and approvals, and materials supply chain management systems
- Assess sterile systems manufacturing procedures

In addition to the duties and responsibilities listed above, Ms. Ahearn has served as the Project Manager for a team of consultants working fulltime on multiple large-scale remediation projects for pharmaceutical and medical device companies. As Project Manager, Ms. Ahearn was responsible for hiring and managing multiple consultants in various areas of expertise to ensure all areas of remediation had appropriate skill level and knowledge, as well as oversight of the administration side of the business activities. Ms. Ahearn assisted client's executive management on Field Alert and recall decisions and provided periodic reports on project scope and progress.

Department of Health and Human Services – Food and Drug Administration, Atlanta, Georgia

Chemist/Investigative Analyst, June 2002 – November 2008

As an investigative analyst, Ms. Ahearn worked with the Investigations Branch of the FDA's Southeast Regional Laboratory and the Office of Criminal Investigations. As an investigator, she was responsible for assessing a firm's compliance, both domestically and internationally, with the laws that the FDA operates under, applicable regulations, guidance, and application commitments. Furthermore, Ms. Ahearn investigated complaints of injury, illness or death caused by FDA-regulated products, initiated actions against violators and advised industry, state and local officials as well as consumers on enforcement policies, methods, and interpretation of regulations. These inspections are complex, requiring the interview of various levels of corporate employees as well as the review of technical data associated with the raw material supply chain, manufacturer, distribution, and sale of products regulated by the FDA. Ms. Ahearn was required to prepare detailed investigative reports of findings and collect evidence as needed. She also served as the lead investigator, or as part of a team, during the inspection of manufacturing operations as well as chemical and microbiological laboratories.

Within FDA's Office of Criminal Investigations, Ms. Ahearn examined and provided technical investigative guidance concerning ongoing and planned criminal investigations, assisted with search warrants, interviews of potential suspects and was an advisor to the US Attorney's Office. She has also given pre-operational briefings for FDA and FBI agents. These investigations have required testimony in federal court where she has received letters of commendation for her investigative work and testimony in the litigation of cases from the FDA's Office of General Council, Department of Justice, US Attorney's Office and FDA's Center for Drug Evaluation and Research.

Laboratory duties included the analysis and interpretation of various types of material samples received from investigators throughout the country. These samples included food, cosmetics, and chemical analysis of pharmaceuticals. These samples may have been part of the drug survey programs issued each year, New Drug or Abbreviated New Drug Applications (NDA/ANDA), consumer complaints, or criminal investigations. Part of performing drug inspections included closely working with the Center for Drug Evaluation and Research (CDER) on compliance and regulatory issues such as labeling of drug products, cGMP deficiencies as they relate to currently marketed products and/or new drugs, and providing testimony in federal court on these issues. Further responsibilities included understanding the laws that the FDA operates under, maintaining laboratory equipment, entering analytical data into the computer system, collecting evidence as needed and understanding findings of regulatory significance. In addition to inspectional coverage of pre-approval applications for NDA's/ANDA's and inspections of firms with known manufacturing problems, responsibilities included training, team representation, and acting as a technical representative for the laboratory.

- Developed a solid phase extraction procedure using LC/MS/MS confirmation for an illegal antibiotic.

- Worked as the Acting Quality Assurance Manager for the Southeast Region and the Chemistry I Branch.
- Served as Acting Supervisor for the drug laboratory.
- Worked on the Counter Terrorism Analytical Chemistry team.
- Served as the Drug Survey Program Monitor for the Southeast Regional Laboratory.
- Member of the International Pharmaceutical Inspection Cadre.

Georgia Bureau of Investigation, Atlanta, Georgia

Senior Forensic Scientist – Department of Toxicology, September 1999 – June 2002

As a Senior Forensic Scientist, Ms. Ahearn's duties included the collection, analysis, and interpretation of physical evidence for officers, investigators, and district attorneys, and the presentation of those findings in the form of expert courtroom testimony. Ms. Ahearn examined and reported approximately 10,000 cases and provided expert testimony for civil and criminal trials in the state and superior courts of Georgia over 100 times. She acquired her Peace Officers Standards and Training Council post-certification to teach Georgia State Patrol and local law enforcement on the operation and theory of breath alcohol testing, field sobriety, and pharmacokinetics/pharmacology of alcohol and drugs. She was also an instructor for the State of Georgia Prosecuting Attorney's Council on procedures and protocols regarding evidence collection, sample analysis, and basic principles of alcohol and drugs in the area of toxicology.

Professional Memberships

Consumer Healthcare Products Association (CHPA)
- OTC Product Quality Manufacturing Committee
- Dietary Supplement Product Quality Manufacturing Committee

Vice Chair, Product Quality Research Institute Technical Steering Committee (PQRI)

Chair, Product Quality Research Institute Technical Steering Committee (PQRI)

Topic Leader - International Conference on Harmonization (ICH) Informal Quality Discussion Working Group

Topic Leader - International Conference on Harmonization (ICH) Informal Q9 Quality Risk Management Working Group

Parental Drug Association (PDA)

International Society of Pharmaceutical Engineering (ISPE)

Professional Awards

FDA Commissioner's Special Citation

Outstanding Service (FDA/OCI)

Publications

Rogers, CA, Ahearn JD, Bartlett MG. Data Integrity in the Pharmaceutical Industry: Analysis of Inspections and Warning Letters Issued by the Bioresearch Monitoring Program Between Fiscal Years 2007-2018. 2020