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## Aderans Research

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### **Job Title & Description: Document & Records Associate/Specialist**

Implement and maintain document and record control systems in the FDA regulated biologics and medical device industry. Reports to Manager, Quality Systems.

### **Responsibilities and Duties**

- Implement record and document control plans (electronic & paper) compliant with ARI record and document systems and regulatory/standards requirements. Maintain computerized document and record systems.
- Provide expertise and input to other functional areas affecting recorded information of the organization. This applies to all recorded information regardless of medium or characteristics.
- Maintain and coordinate activities related to control of quality system and operational records including study records and specimens, manufacturing and quality records and specimens, personnel and finance files.
- Ensure security and preservation/destruction of controlled records and specimens.
- Provide expertise and input to other functional areas regarding documents and records.
- Maintain and coordinate activities related to the document system including generating, revising, obsoleting, distributing, retrieving, typing, and archiving documents to ensure compliance with regulatory/standards requirements and operational procedures, and external documents.
- Maintain electronic Training System ensuring compliance with regulatory/standards requirements and operational procedures.
- Interface electronic Document Management System with enterprise resource planning system.
- Maintain metrics for review. Perform additional duties as determined by management.

### **Work Experience**

- Working knowledge of QSR, GMP, GLP, GCP, GTP and related ISO work environment preferred.
- Must have working knowledge and experience with eDMS (Electronic Document Management System),
- eCTD (electronic common technical document) experience is a plus.
- Generally, has some independence for unreviewed action or decision.
- Ability to effectively manage time and multiple task assignments.
- Must be detail oriented with excellent organizational skills, and oral and written communication skills.
- Must be able to work independently as well as in a team environment.
- Proficiency in personal computer applications (word processing, database, spreadsheet, internet, email, PowerPoint, etc.) is required.

### **Education**

- Associate/trade degree in health science, or equivalent, with 2-3 years document and/or record control experience. Alternatively, 3-5 years experience with document and records systems, and/or similar experience within regulated industries/international standards.

### **Exposure**

- No human materials or laboratory animals (mouse, rat, pig) exposure expected.
- Limited exposure to chemicals or reagents from warehouse and incoming inspections.
- Position requires extensive use of the telephone and face-to-face communications, which requires the accurate perception of speech.
- Position requires loading and lifting of documents & records, and containers / boxes.

### **Travel**

10-15% typically between Philadelphia and Atlanta, and to suppliers and subcontractors.

### **Location**

Marietta, GA

We seek highly creative individuals with excellent written and oral communications skills, able to work in an early stage company in a multidisciplinary team with minimal supervision to achieve project goals under challenging timelines. We offer a competitive salary and an extensive benefits package.

### **Contact**

Human Resources

Aderans Research  
Fax: 678-213-1955 or Email: [hr@aderansresearch.com](mailto:hr@aderansresearch.com)  
Aderans Research. is an equal opportunity employer. M/F/D/V