

SUNNY DAY

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QUALIFICATIONS

Document Management professional with broad pharmaceutical industry experience. Acknowledged throughout career for abilities to organize and administer information to meet business objectives, lead and work effectively in cross-functional teams, and communicate and recommend system improvements.

- ◆ Knowledge and experience across all aspects of Document Management including archiving, document control, and records management.
- ◆ Proven expertise in developing, implementing and administering document management system processes and identifying areas for improvement within existing systems.
- ◆ Strong technical aptitude and knowledge of electronic document management systems.

EXPERIENCE

Mid-Size Biopharmaceutical Company, Big City, State (2002 – 2009)

Develops and commercializes antiviral, cardiovascular, and respiratory drug products to advance the care of patients suffering from life threatening diseases.

Manager, Regulatory Operations (2009)

- ◆ Site Records Administrator responsible for over all implementation of records management policies and procedures for the site including education and training, developing retention schedules, coordinating with internal departments and external vendors, managing off-site records contract and off-site storage database, and leading annual records review activities.
- ◆ Site lead for global Documentum installation allowing creation, review, approval and archive of all documents intended for regulatory submission.
- ◆ Provide first point of contact for end-user assistance and training, work with IT technical staff to resolve issues. Perform user acceptance testing and assist with validation of system upgrades.
- ◆ Perform advanced document processing on a variety of submission documents using MS Word and Acrobat/ISI tools. Provide style guide and word processing assistance to authors.
- ◆ Publish eCTD submissions electronically using Insight Publisher.
- ◆ Administer and update central Endnote reference library, provide training and assistance as needed.

Manager, Document Management/Information Technology (2002 – 2008)

- ◆ Site Records Administrator (see above.)
- ◆ Developed, implemented and maintained hardcopy and electronic document management storage and retrieval systems for central archives. Responsibilities included classification, indexing, archiving, tracking and disseminating records.
- ◆ Developed procedures to ensure the integrity and completeness of files in a secure, service-oriented environment. Ensured systems and documentation adhered to applicable regulatory requirements.
- ◆ Developed and implemented lab notebooks tracking and scanning procedures, clinical contracts and patents tracking and scanning procedures.
- ◆ Performed system administration activities for Documentum including user, group and security account management, global permission changes, and monthly log reviews.
- ◆ Managed library services including Endnote reference database; managed library contracts and account management for Sci-Finder and Nerac search services.

Mid-Size Pharmaceutical Company, City, State (1995-2001)

Pharmaceutical company that develops aerosolized drugs and antibiotics.

Manager, Document Management/Regulatory Operations

- ◆ Drafted records management policies, procedures and retention schedules for records management program. Led record tracking activities ensuring successful acquisition of products from other companies.
- ◆ Managed and administered the central archives including CMC documentation intended for regulatory submissions, clinical trial master file, nonclinical documentation, and regulatory submissions.
- ◆ Led the coordination of regulatory records document production efforts including pre-INDs, INDs, annual reports, study reports and NDA.
- ◆ Managed contract for NDA e-submission of case report forms and case report form tabulations, including scanning, pdf conversion, bookmarking and compilation.
- ◆ Led electronic document management system committee resulting in acquisition and smooth transition to FileNet electronic document management/imaging system.
- ◆ Performed scientific laboratory notebook tracking and microfilm activities.

3RD Party Contractor/Government Agency (1990-1995)

Records Information Manager II/Librarian I

Maintained administrative records and site files for hazardous waste sites in Washington, Idaho, Oregon and Alaska, at both central and off-site repository locations.

- ◆ Compiled record files according to guidance documents. Developed file structures and indexing/classification documents ensuring consistency and improved access to records.
- ◆ Provided references services to EPA staff members and the general public.
- ◆ Conducted training sessions for EPA staff.
- ◆ Audited in-house and off-site record repositories.
- ◆ Developed and documented records center policies and procedures.

EDUCATION

University of Washington, Seattle, WA, Graduate School of Library and Information Science
Master of Library and Information Science
Bachelor of Arts
National Championship Rowing Team
Husky Hall of Fame

ADDITIONAL PROFESSIONAL TRAINING – Attended classes and conferences regarding document management, GxP regulations, clinical archiving, legal requirements for record keeping, retention schedules and disaster recovery, and regulatory submissions.

TECHNICAL SKILLS - Proficient in MS Office applications, Insight Manager. Advanced knowledge of MS Word 2003, ISI Toolbox, Adobe Acrobat, Endnote X, FileNet, Documentum.