

TRUDI L. COOK

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SUMMARY OF QUALIFICATIONS

Energetic, effective Document Management Associate for GMP-compliant production facilities in the biotech and pharmaceutical industries with proficiency in:

- Document Control
- Records Management
- Customer Service
- Project Assistance
- Template and Form Creation
- Data Entry
- Proofreading, reviewing and editing materials
- Internal Quality System Audits

PROFESSIONAL EXPERIENCE

AMGEN INC., Boulder/Longmont, CO **2002–2014**
Sr. Document Management Services (DMS) Associate, QA Department (2012-2014)
DMS Coordinator II, III, QA Department (2002-2012)

DOCUMENT MANAGEMENT

- Tracked and coordinated controlled documents (ie, SOPs, forms, MPs, training materials) in the Electronic Document Management System (EDMS) to ensure proper format, accurate document properties, and timely approval.
- Published effective documents (electronic and hard copy) for site use.
- Revised department procedures.

RECORDS MANAGEMENT

- Scanned, imported, archived, and sent records (ie, validation documents, raw material specs, engineering packages, batch records) to offsite storage.
- Identified documents per the record retention policy for archive and destruction.
- Ordered, issued, reconciled, and scanned lab notebooks, logbooks, manufacturing procedures, validation packages, and controlled assay worksheets.
- Performed audits on filing systems.
- Coordinated, published, and filed job hazard assessment forms.
- Updated FileMaker Pro tracking databases for controlled documents and records.

CUSTOMER SERVICE

- MS Word and Excel support and created written instructions, retrieved documents, performed database searches, generated reports/metrics for internal clients.
- Supported inspections and audits by retrieving materials from onsite and offsite storage and updating tracking tool. Reconciled materials and returned to storage.

PROJECTS

- Completed Lab Notebook Backlog Project ahead of schedule; eliminated compliance risk.
- Created templates for standard controlled documents and macros for format conversion.
- Identified and implemented continuous improvement activities for DMS.
- Set up system for filing and archiving several years' backlog of incoming and outgoing shipping documentation.
- Eliminated records backlog: 1850 validation documents, 92 batch record archive boxes.

TEAMWORK

- Cross-trained with subject matter experts to eliminate risk of single points of failure and increase staff flexibility and efficiency.
- Cross-trained DMS staff on new offsite storage processes, developed training and reference materials and avoided risk of single-point failure during audits and inspection.
- Shared information through the company's Knowledge Marketplace.

COMPUTER SKILLS

Microsoft Office, FileMaker Pro, Outlook, Visio, SnagIt, Enterprise Imaging (EI) Scanning
Windows, Macintosh
EDMQ, EDMTeams, FileTrail

EDUCATION

BS, Elementary Education, Montana State University, Bozeman, MT
AA, Word Processing, De Anza College, Cupertino, CA
AAS, Accounting, Front Range Community College, Westminster/Longmont, CO

OTHER ACTIVITIES

ARMA International Associate Member
Kids Hope USA Mentor