

Teresa Mancusi

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Professional Profile

Flexible and resourceful professional with years of cross-industry experience focusing on **project management support** in the following areas:

- Editing/Proofreading
- Writing/Composition
- Correspondence Management
- Quality Control
- Internet Research
- Regulatory Submissions
- Process Development
- Records Management
- Report Preparation
- SOP Development
- Database Maintenance
- Operations Support
- Training Administration
- Human Resources
- Contract Support
- Vendor Approval & Monitoring
- Customer Service
- Compliance

A trusted team member and independent thinker who skillfully works behind the scenes to ensure processes and procedures are followed and operations run smoothly. Methodical and organized in planning and managing complex project details while effectively responding to shifting priorities and multiple overlapping tasks.

Computer competencies: Microsoft Word, Microsoft Outlook, Excel, PowerPoint, Access and JD Edwards; website maintenance and internet research

Education

B.S., Liberal Arts, University of Maryland, College Park, MD

Professional Experience

ROY JORGENSEN ASSOCIATES, INC., Buckeystown, MD 2006 to 2011
A nationally recognized leader in providing outsourced facilities management services Jorgensen has a diverse client base, which includes auto manufacturers, banks, hospitals, and software companies.

Compliance Administrator, Facilities Services Division

Ensured Jorgensen's compliance with contract terms and specification pertaining to employees and vendors providing facilities maintenance services for Toyota's customer service centers, parts distribution centers, and vehicle financing facilities throughout the United States and Puerto Rico.

- Functioning as HR generalist, managed employee screening and personnel records for five field managers and more than 200 Jorgensen employees assigned to contract.
- Reviewed, processed and approved submission from new and recurring third-party building and grounds maintenance firms/subcontractors (HVAC, electrical, plumbing and landscaping).
- Tracked and monitored vendor status and eligibility, insurance, and other regulatory documents for more than 900 vendors resulting in considerable reduction of out-of-compliance exceptions.
- Managed computerized database of vendor and employee records and generate reports to apprise senior managers of contract issues and performance.
- Supported division managers and regional office staff in developing or improving working documents, operating procedures, and processes maximizing optimal contract performance.
- Effectively managed multiple overlapping and shifting priorities and maintain daily communication with employees, subcontractors and senior managers via phone and email.

Select Contributions

- Accelerated vendor approval process and reduced paperwork by implementing electronic transmission of application materials and correspondence.
- Streamlined system to track and monitor vendors' certificates of insurance (general and professional liability, workers compensation, employee theft, automobile and umbrella policies), which led to marked improvement in meeting regulations and renewal deadlines.

- Created an accurate and up-to-date listing of approved vendors by researching vendor database to identify discrepancies and eliminate duplicate records.
- Collaborated with managers in developing an assessment, screening and hiring process, which aligned with Toyota's newly implemented program that established employment standards.
- Provided administrative support to company's participation in diversified business enterprise program by tracking vendors with Minority Business Enterprise/Women's Business Enterprise certifications and preparing monthly/quarterly dollar spent report for client/senior management review.
- Composed content for Jorgensen's Business Management Handbook, which defined management and compliance standards for personnel assigned to Toyota contract.

MEDIMMUNE, INC., Gaithersburg, MD

1994 to 2005

The worldwide biologics business for AstraZeneca PLC has approximately 3,300 employees worldwide and is headquartered in Gaithersburg, Maryland.

Operations Associate, Clinical Operations Department

Performed administrative and compliance monitoring activities for department responsible for managing clinical trials, developing protocols, contracting third-party providers and managing trial data. Began tenure as administrative assistant to department medical director; advanced to clinical operations associate charged with identifying, developing, and managing processes and initiatives aimed at achieving Good Clinical Practice (GCP) clinical standards established by the Food and Drug Administration (FDA.)

- Researched and applied GCP guidelines to assist in developing and implementing standard operating procedures for establishing a document library and maintaining key regulatory records.
- Reviewed and identified document management process deficiencies and determined corrective action to maintain audit-ready compliance.
- Managed quality control, long-term maintenance, and archiving of essential documents ensuring records were in audit-ready form. Assisted regulatory staff by retrieving critical documents for FDA submissions and audits.
- Searched, retrieved and provided documents in support of customer, audit, or agency requests.
- Maintained financial disclosure forms and other required documents to ensure clinical trial investigators adhered to the letter of the law resulting in significant reduction in out-of-compliance violations.
- Assisted in developing user-friendly standards for posting information on clinical trial websites (*ClinicalTrials.gov* and *CenterWatch*) and maintained content to ensure patients and researches access to timely and accurate information.
- Conducted clinical staff training on essential document SOP management maximizing adherence to GCP guidelines. Prepared PowerPoint presentation and handouts for core management team and associates.
- Performed and enforced work in accordance with all internal and external regulations.
- Completed numerous industry training programs including basic training in clinical monitoring and GCP certification; strategies for effectively managing financial disclosure; auditing techniques for clinical research professionals; GCP audits and FDA investigations; and orientation to FDA and regulatory processes.