

Marisol Jimenez-Santiago

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PROFESSIONAL PROFILE

Highly Ethical and Detail-Oriented **Office Administration Professional** with more than fifteen years of experience in world class organizations. Expertise in areas such as office administration, data and document management, proofreading, word processing and handling confidential information. Broad knowledge of validation/qualification and regulatory process. Excellent leadership, time management, change management, organization, teamwork, and interpersonal relations skills. Able to perform very well with minimum or no supervision in high pressure work environments. Advanced knowledge in Microsoft Office (Word, Excel, Power Point), Plateau Learning Management System, Share Point, Trackwise, Midas, and SAP. Fully Bilingual (English and Spanish).

KEY ACCOMPLISHMENTS

- Led department records management process for off-site retention of documents pertinent to the decommissioned API site.
- Supported the implementation of Plateau Learning Management System. Curriculums; master curriculums and job positions were created which included safety; regulatory; compliance and job training requirements for a department staff of 40 professionals.
- Created a share point site for all qualifications and validation documents for electronic retrieval by plant personnel.
- Created databases and spreadsheets that improved inventory management and facilitated retrieval of information and documents.
- Facilitated change control process by centralizing documents both electronically and hard copy for easier retrieval of regulatory information.
- Served as liaison for corporate regulatory and external audits providing on a timely basis information requested during audit process.
- Supported the implementation of CIMS System accomplishing the close out of 15 open projects before Go-Live.

PROFESSIONAL EXPERIENCE

MERCK, BARCELONETA, PUERTO RICO

Nov/1992 - Dec/2014

Documentation Specialist (Technical Operations Department) DEC/2003 – DEC/2014:
Responsible for managing cleaning and process validation, equipment qualification, change control, Process Safety Library, technical documentation and scanning/uploading document. Administered indexes with updated document description/document control number assigned and approval dates. Follow up was given to assure proper handling of procedures governing these documents. Acted as change analyst within the SAP system by creating DIRs in SAP to continue with the flow of ECRs and provide

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support to personnel regarding the approval process flow via SAP. Generated changes to Bill of Materials and Packaging Component Specifications. Assisted in the revision and cancellation of Standard Operating Procedures, revised forms and guidelines related to business and plant processes via electronic document management system. Provided the annual review information to quality department for process changes including validation information/implementation dates and batches impacted. On a weekly basis reviewed training curriculums and assured that all department personnel completed 100% of assigned trainings. Provided site personnel with information regarding the cleaning and process validation and equipment qualification as well as copies of official documents. Assigned control numbers to documents in order to maintain a proper tracking system. Supported various agencies audits such as the FDA, EMEA, ANVISA, Safety and Corporate.

Associate II (Packaging Technology Department) APR/1996 – DEC/2003:

Responsible for the administrative work for the Packaging Technology Department. Provided administrative support to 5 engineers and 1 Manager. Served as liaison between finance and packaging technology department in the implementation of the Capital Management System. Assured all projects were closed and met budget requirements prior to CIM System implementation. Generated/revised packaging component specification, bill of materials assuring these were provided to plant personnel and uploaded into an electronic repository.

Administrative Assistant/Purchasing Expeditor (Purchasing Department) NOV/1992 – APR/1996:

Responsible for the administrative work for Purchasing Department supporting 5 Buyers and 1 Manager. Provided support as Purchasing Expeditor for 6 plants within the site. Accurately created, updated and maintained material exception report to ensure that all chemicals/intermediates and packaging components would arrive on schedule for all 6 plants. Effectively communicated and reported on a weekly basis material status to corresponding plant and procurement personnel. Worked cross-functionally (suppliers and plant personnel) to ensure that any discrepancies with supplies be resolved in order to avoid any interruption with production.

EDUCATION

IN PROGRESS BACHELORS DEGREE INFORMATION SYSTEM
UNIVERSIDAD DEL ESTE (SISTEMA UNIVERSITARIO ANA G. MÉNDEZ)

Secretarial Certification:
Career Center - Yonkers, New York

TRAINING AND CERTIFICATIONS

- Yellow Belt Training
- Plateau Learning Management System