**HECTOR I. SANTIAGO**

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**SUMMARY**

Experienced professional in the Manufacturing Industry, covering the areas of Engineering Specifications, Electronics, Medical Devices, Pharmaceutical, and Textiles. Extensive experience in documentation practices, computer skills and exposure to FDA regulations and management, training and development of subordinates. Management skills extend to personnel supervision, resolution of conflicts, Packaging order reviews, personnel operational and functional reviews. Thoroughly involved with programs such as Project Management, knowledge of Six Sigma Methodology (Method I), and cGMP in the Pharmaceutical and Medical Devices Industry. These fields extend to Product Transfer, Technology Transfer (Laser Welding , Hot and Cold Transfer Silicone and LSR Molding, Use of Adhesives, ), Manufacturing and Maintenance Support, Engineering Specifications (technical documentation, generation of **IQ, OQ, PQ, and CAPA** **investigations**), Manufacturing (Manufacturing Instructions, Sop’s , Engineering Change Orders, Material MRB decisions, Packaging documentation, Packaging MRB ), Maintenance and Packaging Supervision . Consistently supports Quality Assurance and Quality Control operations through compliance and assistance with CAPA investigations, Problem Analysis for daily production problems dealing with Quality Control issues, Standard Operating Procedures and cGMP operational compliance and audits. Knowledge of Six Sigma Methodology (Root Cause Analysis / Kepner Tregoe), and cGMP in the Pharmaceutical and Medical Devices Industry.

**CAREER ACCOMPLISHMENTS**

* Preparation, Training, and Supervision of Kepner Tregoe adapted program to engineering operational personnel as part of a Corporate Quality Initiative (Personnel consisted of over 30 operators and technicians).
* Transfer of old Textile Cutting Operations and implementation of new Cutting Technology to a new Facility for Playtex / Sara Lee Intimates.(Included recruitment of supervisory personnel, training coordination , product development, Quality regulations for Cutting applications )
* Transfer of Laser Welding and Molding Activities from an old to a new facility without disturbance of manufacturing requirements. (Included IQ / OQ executions and reports, design molding matrix to support mold and equipment transfer, supervise removal, transfer and installation on site).
* Participation of the design, build, programming of a new Compact / Mobile YAG Laser system for the CRM / Low Voltage Manufacturing line (Design parameters adjusted to operators needs, program laser welding routines into a three axis turntable PLC controlled, participate in the troubleshooting, IQ, OQ and PQ of the System and use the system as an anchor fixture for the Mfg Line Transfer from one facility to the other).

**EDUCATION**  
University of Puerto Rico, Mayaguez Campus, Bachelor in Science, Mechanical Engineering, 1983

Major: Mechanical Engineer Minor: Mathematics

**SKILLS & PERSONAL TRAITS**  
Knowledge of MICROSOFT OFFICE (WORD, EXCEL, and POWERPOINT), VISIO, Statistical Process Control (SPC), Rational Process and Decision Making (Kepner Tregoe), Purchasing negotiation skills, MOST (Maynard Occupational Sequence Technique), “Train The Trainer” certification.

**EXPERIENCE**

**BAUSCH & LOMB SURGICAL / KELLY SERVICES Clearwater, Fl**

**Manufacture of Intra Ocular Lenses 06/14 till present**

**Validation Specialist (Contract).** Initiate and execute validation studies throughout the facility. Interact with all levels of management and staff to manage and facilitate the validation process from inception to completion by enlisting cooperation, support and approval for identified validation projects Plan, schedule and organize validation projects for new and existing areas, including manufacturing processes, plant systems, cleaning and equipment. Develop and implement all necessary Standard Operating Procedures for validation of plant processes, equipment installation and operational qualification (IQ/OQ), performance qualification (PQ) and requalification of critical systems, utilities and production processes. Design IQ/OQ/PQ and validation campaigns as well as develop, prepare and write the protocols for process validation, cleaning validation, IQ/OQ and performance qualification.

**STRYKER SUTAINABILITY SOLUTIONS / ONCORE USA Lakeland, Fl**

**Reprocessing of Single Use Medical Devices 08/13 till 05/14**

**Manufacturing Engineer (Contract).** Assist Advanced Operations Engineers in the development, transfer, and validation of new manufacturing processes to support new products. Responsible for pilot production work orders specific to the new processes / products. Assist Advance Operations engineers in the development of test protocols, procedures, and reports related to equipment qualification and process verification & validation. Participate in training associates on: new standard operating procedures, new test procedures, equipment, and new product in-service training.

**ROMANO GROUP LLC Miami, Fl**

**Manufacture of Cosmetics 01/13 till 06/13**

**Compounder (Contract).** Using production schedules, prepare batches according to mixing instructions and recipes. Measure components, support raw material inventory, and move equipment and materials with forklifts, drum lifters and other equipment. Update recipe and mixing instructions in accordance with Lean Manufacturing guidelines. Modify and change Recipe and Standard Operating Procedures in preparation for ISO certification. Prepare, modify and update manufacturing instructions for compounding facility. Reports to the Plant Manager.

**ACUDERM, INC Ft Lauderdale, Fl**

**Manufacture of Dermatology products 02/12 till 04/12**

**Operations Manager (Contract)**. Supervise and lead the manufacturing, purchasing, quality and facility operations within the Acuderm, Inc Facility. Purchase, Plan and Overview manufacturing raw materials and finished goods for production inventory. Plan and expedite Manufacturing Work Orders for completion. Overview facilities and utilities operations and services. Report to the CEO.

**TARMAC PRODUCTS INC Hialeah, Fl**

**Manufacture of OTC and Nutritional Products 05/11 till 02/12**

**Facilities Manager**. Supervise and lead the Facilities, Utilities & Manufacturing departments. Create all foundation / GMP Sop’s for support and manufacturing areas. Lead and Supervise the Utilities and Manufacturing Support team to provide compliance to cGMP and manufacturing products. Create Implement and Approve Validation activities (IQ/OQ/PQ) related to Pharmaceutical Equipment and processes.

**SOL INC Palm City, FL**

**Manufacture of Outdoor Solar Lighting 02/11 till 04/11**

**Manufacturing Engineer (Contract)**. Provide Support to the Manufacturing Area in defining and designing Manufacturing Environment & Documentation for present and new products.

**BOSTON SCIENTIFIC MIAMI / AEROTEK Miami, FL**

**Manufacture of ENT Surgical instruments 06/10 to 11/10**

**Manufacturing Engineer (Contract)**. Provide Engineering Support to the EM2 Jagwire Manufacturing Area during the transfer procedures to Costa Rica. These include Supply manufacturing changes to documentation, support validation and qualification activities for Yield and Production improvements. Generate and Collect process test data, specifications, order materials and components for Quality Control Specifications and Manufacturing processes. Reports to the Manufacturing Engineering Manager.

**MEDTRONIC SURGICAL TECHNOLOGIES Jacksonville, FL**

#### Manufacture of ENT surgical instrumentation 09/08 to 04/10

**Sr Manufacturing Engineer.** Support the Mfg Engineering Group, Develop, refine and maintain new and existing Manufacturing Processes including the creation of Manufacturing Processes Documentation, Equipment operation, product routers. Design, Construct and maintain assembly fixtures. Generate and Collect process test data, specifications for Quality Control Specifications and Manufacturing processes. Qualify or validate manufacturing processes and train production personnel. Participate in new product project teams; provide design for manufacturing input during the product design phase.

**SIEMENS HEALTHCARE DIAGNOSTICS INC, (CONTRACT) Flanders, NJ**

**Manufacture of immunochemistry and integrated chemistry systems. 03/08 to 08/08**

**Product Engineer (Contract).** Support the Instrument Manufacturing Group as an interface to R&D, Commercial Manufacturing Plant and suppliers. Primary duties were to work with cross-functional teams reviewing designs, module assemblies & systems for manufacturability, develop capable commercial assembly and test processes and work with vendors on fabrication processes. Ensure compliance of Vendors with Quality Control First Article Information and assure compliance with purchasing and engineering specifications.

**GUIDANT / BOSTON SCIENTIFIC DORADO, Dorado, PR**

**Manufacture of Medical Devices for Cardiac Rhythm Surgery 0207 - 08/07**

**Manufacturing Engineer (Contract)**. Transfer, coordination and implementation of various manufacturing processes and products covering the Medical Devices' industry, specifically the Cardiovascular Surgery Area. Provide and execute technical coordination, write validation protocols (IQ/OQ), and G.M.P. guidelines to the manufacturing area. Provide engineering technical assistance, technology transfer, and coordination with Quality Assurance to provide Incoming, In Process and Final Inspection verifications in the manufacturing documentation. Provided engineering assistance to quality assurance daily manufacturing problem resolution through clarification of Quality Specifications, engineering evaluations and CAPA assistance.

**PFIZER PGM CAGUAS, Caguas, PR**

**Manufacture and Packaging of Controlled Medication** **06/00 - 03/06**

**Process Flow Assurer (2nd shift Packaging Supervisor).** Provide supervision, support and guidance to the 2nd and 3rd shift packaging area within the Pharmacia / Pfizer Caguas environment. Assure packaging production schedules are worked according to cGMP guidelines and market requirements. Execute IQ, OQ, PQ within the packaging environment area and in accordance to the **Master Validation Plan**. Verifies and assures complete and correct documentation pertaining to the packaging process operations including packaging specifications and records. Assure that all packaging equipment has validation documentation and history record up to date. Initiate CAPA and Root Cause Analysis investigations pertaining to events belonging to the Packaging lines.  
  
**MEDTRONIC PR INC Villalba, PR**

**Manufacture of Brady and Tachycardia Leads for use in Heart Pacing**  **10/96–06/00 Manufacturing Engineer**. Transfer, coordination and implementation of various manufacturing processes and products (from R&D to Manufacturing site) covering the Medical Devices industry, specifically the Low Voltage leads. Provide and execute technical coordination, write validation protocols (IQ/OQ/PQ), and G.M.P. guidelines to the manufacturing area. Provide engineering technical assistance, lean Manufacturing activities to reduce lead-time (Poka Yoke, Kaizen), validation and technology transfer to the Laser Welding, Silicone Molding and Preventive Maintenance areas for manufacturing support. Verify, modify and evaluate fixtures and manufacturing equipment to assure complete adherence to standards and manufacturing protocol, including the revision of the manufacturing process. Function as part of the manufacturing process revision group in charge of reviewing processes and updating manufacturing documentation (MRB for packaging and manufacturing activities).

**REEDCO INC. / DENTCO INC. Humacao, PR**

**Manufacture and Packaging of OTC products such as toothpaste and balms 03/96 – 10/96**

**Maintenance Manager**. Supervise and guide the maintenance and support personnel in the Manufacturing Area. This leadership can be construed as G.M.P. guidelines overview, Departmental Budget preparation and approval, Review maintenance mechanics performance in accordance to Company guidelines and goals. Provide counsel, training and support in the Total Quality Control Programs. Counsel the Quality Control area in Material Review Board decisions (M.R.B.), approves Spare parts purchases and overview Engineering Accounts to comply with budgetary goals. (Moved to a job which provided better job benefits and security).

**SARA LEE INTIMATES, PLAYTEX DIVISION Vega Baja, PR**

**Manufacture cut and lace parts for sewing operations 10/94 – 03/96**

**Process Engineer** Develop manufacturing process standards for the new cutting process, including recruit, training and equipment installation. Participated in the initial recruitment of supervisory personnel. Developed Operational and Preventive maintenance systems for cutting area and supervise activities for the Maintenance supervisor and his four mechanics. Responsible for procurement of operational supplies, determine material usage for new processes including Spreading. Cutting and Packaging. Coordinated Logistic Support for Automated Cutting area from a remote warehouse. Recruited, trained and placed in site Color Tone Coordination Group for matching textile color rolls. (Corporate Personnel Reduction)

**MOVA PHARMACEUTICAL CORP. Caguas, PR**

**Contract Manufacturing Services (In-Site) for Pharmaceutical Companies 03/91 – 10/94**

**Maintenance Supervisor**. 1st and 2nd shift supervision for Contract manufacturing and packaging (MSD/CIBA GEIGY) and MOVA proprietary, also Utilities 2nd shift supervision and coordination’s: 1st shift supervision for Contract manufacturing (MSD), MOVA Solid Dosage, and Parentherals area. Provide lessons, process guidance on the Rational Analysis and Decision Making System for the Engineering Personnel. Participated in **Risk Analysis** for manufacturing processes in the MSD contract. Evaluate alternate sources for spare parts and cost savings. Prepared engineering budget for maintenance accounts.

**The next four positions all share the same job description**

**BARD CARDIOPULMONARY INC,** (Corporate Personnel Reduction) **Las Piedras, PR**

**Manufacture of Medical Devices such as Pulmonary and Arterial Blood Filters 11/89– 11/90**

**BECTON DICKINSON, MICROPETTE INC.** **Juncos, PR**

**Manufacture of Medical Devices such as Arterial and Spinal Needles 04/87- 11/89  
UNITED STATES SURGICAL CORP.** **Ponce, PR**

**Manufacture of Medical Devices such as Urological and Stomach Staplers 08/86 -04/87**  
**MOTOROLA TELCARRO** **Vega Baja, PR**

**Manufacture of Radio components for Police and Civil Service uses 10/85 -08/86**

**Manufacturing Engineer**. Provide and execute technical coordination, validation protocols, and G.M.P. guidelines to the manufacturing area. These include external and internal coordination of contract work, Manufacturing Resources and Others (M.R.O.) purchases along with Spare Parts maintenance and procurement. Support manufacturing environment in technical and mechanical troubleshooting of product problems.  
  
**DEPARTMENT OF THE NAVY, NAVAL AIR ENGINEERING CENTER Lakehurst, NJ**

**Support Division for Naval Air Systems Command Aircraft Carriers 06/83 -06/85**  
**Mechanical Engineer** (1st. Puerto Rican Engineer to be recruited from UPR, Mayaguez Campus)   
Specifications and Standards preparations and First Article overview with Approved Vendors for Government Contract Procurement.