Design Control Consultant Design Control Consultant Design Control Consultant - Clinical Innovations LLC Salt Lake City, UT To develop safe and effective devices for the customer utilizing sound engineering, business strategy, and hands-on experience. To implement Life Science & Technology based solutions that meet current QSR/ISO EU MDR 2020 requirements. To contribute to the company's bottom line by performing value added work, paying attention to detail, being energetic and professional. To help improve patient wellness in the Medical Industry by advancing research and innovation while sharing my talents with colleagues. Over 25 years of experience with medical device, Pharma, and BioTech Products. Worked for Fortune 100 major medical device companies: Johnson & Johnson, Baxter, Zimmer-Biomet, Abbott, Sulzer, Arthrex, Pfizer. Authorized to work in the US for any employer Work Experience Design Control Consultant Clinical Innovations LLC - Salt Lake City, UT March 2019 to Present Clinical Innovations, LLC engages in the research, development, and manufacture of medical devices that improve the lives of mothers and their babies. It focuses on labour and delivery. The company offers traxi panniculus retractor, a retraction device used for predictable, reliable retraction of the panniculus during surgical procedures and postpartum haemorrhage dual-balloon catheter. It also provides an air-charged, single-patient-use tocodynamometer for the placement and improved readings on difficult to monitor patients primarily high BMI patients or preterm patients. Function will require successful R&D Engineering experience with multiple product launches and Quality principles to implement and meet the EU MDR requirements. This function will be rewriting the current design control process in harmony with EU MDR requirements with a focus on Reliability, Design, Quality, and validation remediation efforts in support of the DHF and future product launches. Execute new product design reviews to the EU MDR design control process for Class I and II single use/disposable devices for QA compliance to EU Risk management. Implement Design Verification & Validation and document results with a high-level understanding of the entire R&D process. Process Engineering Consultant ACUMED LLC - Portland, OR February 2018 to December 2018 Process Engineer consultant for medical devices, automatic machinery, CNC Equipment, process development, and validation (IQ, OQ and PQ) protocols/execution/reports. GD&T critical dimension process validations on CNC Mills, Lathes,

Cleaning/Sonics, & blasters process mapped to design V&V. (TMV) total measurement variation studies (R&R) and process changes (ECO) for continuous improvement. Calculating process capability/centering and remediation, establishing project timelines. Strong knowledge of materials in machining~Titanium, Stainless, Ultem, Delrin, and Aluminum components for medical device assembly. CAPA remediation of existing legacy products and processes including VOF verification studies on effectiveness. Product development and Validation of components in support of Fibula, Forearm, Shoulder, Elbow, Hand/Wrist, Hip/Pelvis, Foot/Ankle, and Biologics. Validation Engineering/ IT Consultant ARTHREX Medical Inc - Naples, FL February 2017 to December 2017 Supported major CNC software/equipment move (1850+ machines) from Naples to Ave Maria Facility including special processes. Assist in Design and development of new Methods for Tooling, Fixtures, Laser inspection to eCad File comparisons for R&R studies and Process Ppk. Ensure compliance to cGMP Standards using best practices, Work Instructions, and regulatory requirements to be in a ready state for auditing. Create validation protocols in stand-alone templates to allow for re-validations due to engineering changes and best practice advancements. Assess and update risk assessments using Process/Design Failure Mode and Effects Analysis (PFMEA/DFMEA). Support CAPA, Change Control, Deviation, Root Cause Analysis, and Impact Assessments on deviations and to Quality Systems. Partner Natus Medical Inc - Seattle, WA December 2016 to February 2017 with Suppliers on a Program Remediation effort to qualify and improve Electro -Mechanical Medical Devices for increased safety/performance using risk-based analysis. Establish design & contract manufacturer agreements and supplier certifications to ISO 13495/9001. Perform Supplier Audits, initiate SCAR's, Process Improvements, Validations, and verification of effectiveness to reduce non-conformance. Execute Calibration of tools, perform Gage R&R, verify tolerance stack ups, improve process capabilities and document (IQ/OQ/PQ) Validations. Participate on Material Review Board Metric meetings to investigate and correct any supplier non-conformance. Consultant/Contractor Natus Medical Inc - Seattle, WA October 2016 to February 2017 UDI Label Designer/Drafter Natus Medical Inc October 2016 to December 2016 Design Device Labels using CODESOFT and Label View Software for Baby Care products

according to the Class ll & lll FDA UDI Label requirements for readability. Generate Engineering label specifications in SolidWorks, Agile Change Orders, BOMs, and DHR/technical files. Apply manufacturing and Process Validation experience to Zebra Printers/Verifiers for UDI equipment using (IQ/OQ/PQ) testing. Create Visio Process Workflow, Assembly, and Inspection procedures of 2D Barcodes. Utilize Agile Systems experience to update production label use in manufacturing and Quality procedures. Champion and coordinate ECO's through meetings to process updates needed for various levels of packaging, device, and shipping labels. Update DHF/DHR with validation reports; label Designs, BOMs, and Agile Tracking. Sr. Manufacturing Engineer Johnson & Johnson - Palm Beach Gardens, FL June 2016 to October 2016 Improve the manufacturing engineering process in support of the surgeon power tools line of devices. Generates specifications requirements and purchase new Capital Equipment (EDM, Lathes, Mills) to automate and validate equipment to J&J safety standards. Perform Factory Acceptance Testing (FAT) at the Vendors for Equipment Capability prior to conducting process validations. Act as the Team Leader utilizing cross functional teams to drive new Capital Equipment Requests, Tooling & Fixtures, Inspection & Gauging, including CAPA to optimize quality. Plan and execute all aspects of process design, continuous SPC improvement, risk assessment, and Critical Process Attributes. Lead the Design for Manufacturability Process, pFMEA, Improve productivity and cost performance, and Root cause Analysis. Plans with Facilities for new Equipment Installations, qualifications, initial build planning, and generates Project Schedule to track deliverables for completion on time. Sr. Mfg. Eng. Science & Technology Novartis - Houston, TX March 2016 to May 2016 Lead multiple teams of SME's to Map Design Output/Verification Critical Design Specifications through Manufacturing/Inspection processes to identify Critical Quality Attributes (CQA) and Process Control Plans. Perform risk-based assessments (pFMEA) and Quality Control Mitigation tools for all products in Houston (Infiniti, Constellation, Centurion, Laureate, LenSx, & Custom Pak). Support a parallel effort to implement an electronic data collection and analysis system for production equipment in an effort to implement better process controls and measurement monitoring, Identify CQA's and CPP's (Critical Process Parameters) for all products with Flow Diagrams, Perform Design Reviews, establish a Risk

based Process Matrix'. Write controlled procedures and mapping to document the process. Sr. Validation Engineer/ IT Analyst Baxter HealthCare - Cleveland, MS July 2015 to December 2015 Automate manufacturing assembly of Drug Delivery Devices and validate process controls using software test cases including new UDI FDA Label requirements for Bar Code Vision Systems. Knowledge of applications such as Touch Screen Vision Systems, Wonderware, Allen-Bradley PLC, Access, Windows 10 and Microsoft Project. Produce design requirements and manufacturing documents for DQ-IQ-OQ-PQ Validations. Write Protocol test cases, and debug Software throughout the device life cycle. Support team dynamics with Manufacturing Engineering to implement new automation systems. Computerize the identification and trace of lot serialization in the labelling process. Ensure computer systems and applications are in compliance with EU/US Regulatory quality standards through validations activities. Ability to communicate effectively in written and verbal form on environmental health and safety regulations. Quality Analyst II / IT Validation Engineer Pfizer - Austin, TX April 2015 to July 2015 Responsible for the theory and content of automated process control systems (APCS) and software validation for manufacturing including programmable logic controllers (PLC's), Robotics, Bar-Code Readers, Vision Systems, & IT Network Applications. Perform Validations to written Protocols (DQ-IQ-OQ-PQ) and document CAPA's in timely manner using Track wise to make improvements traceable under change control system. Provide guidance to project teams and support staff on Design Assurance and Risk Management. Demonstrate the ability to manage multiple and competing priorities in a complex environment. Strong knowledge of global regulatory requirements for Drug Delivery, Medical Devices, and computer systems. Support product clean room technology and sterilization-microbiology at the aseptic transfer and terminal kill packaging level for Hospira IV Bags. Sr. CAPA /Quality Engineer III Zimmer Biomet Inc - Chicago, IL October 2014 to February 2015 Responsible for supporting and leading CAPA Teams with cross-functional resources to close CAPA's within FDA time-lines in accordance with Quality System Regulations. Knowledge of blueprint reading and GD&T to gather factual information and statistical data to identify and determine root causes and implemented effectiveness challenges (Verification of Effectiveness). In

three months, the group reduced the total open CAPA's from 87 to 35 by 60%. Changed specifications and procedures, work instructions/forms, inspection sheets, protocols, reports, test methods, validations, executed audits, trended quality data such as complaints, supplier data, and NCR's. Implemented corrective and preventative actions including controls and maintenance to update the Device History Files. Provided strong communication skills to work well within a dynamic team environment and built relationships (suppliers, regulatory agencies, auditors etc.) to facilitate engineering project deliverables. knowledge of QSR/ISO/GMP Regulations. Director of Operations M & L Industries - Austin, TX 2009 to 2014 Developed business plans and manufacturing operations to meet projected goals. Responsible for writing operating procedures & policies, Monthly P&L, and a 3-year Vision/Tactics/Strategy Plan. Contracted and permitted construction to architectural drawings for business layout of equipment, plumbing, electric, & HVAC. Managed all phases of start-up in design, permit review, zoning, and code inspections to receive city permits. Successfully grew operations 500% in four years and reduced expenses in outsourcing areas. Managed four departments of 25 personnel to achieve company goals and process development. Supplier Project Engineer Abbott Spine, TX 2006 to 2008 Supplier QA Engineering for the Spine/Trauma implant division for medical device manufacturing of orthopaedics/instruments. Managed supply chain quality engineering to determine the critical. vendor processes required for validation master plans and audits for certification. Wrote the Validation Protocols for every supplier to perform in three months (prior to FDA audits). Utilized Windows 8 UI testing to verify effectiveness. Project Engineer/Consultant SQA Services, TX 2003 to 2005 Performed MIL-Std Process Inspections & Q.A. Engineering Third Party first article inspections on aircraft components in machining/coatings division. Reviewed drawings for GD&T call-outs and provided technical performance reports including methods to improve lean manufacturing on time. R&D Project Engineer-Visual Systems 3M Austin Research - Center, TX 2000 to 2002 Responsible for lab development of 15 new media products including performance qualifications focus groups, and formal reports using Ink Jet Technology. Served as the project engineer in Austin and travelled to St. Paul, MN to present development results to the 3M Office Supply Division. Wrote specifications

and selected new suppliers that meet 3M product performance requirements. Conducted statistical data analysis (Minitab) reports and presented recommendations to management to launch new products. Managed project tasks/time-lines including laboratory workers and established a network of support channels between divisions. Manager/ Asst. Director Sulzer Carbomedics, Inc 1996 to 1999 Sulzer Carbomedics, Inc 1990 to 1999 Manager OEM Engineering Sulzer Carbomedics, Inc 1993 to 1996 Supervisor QA Eng. /Sr. Engineer Sulzer Carbomedics, Inc 1990 to 1993 Acting Director when QA Director Travelled. Managed development of new heart valves (polymer & biologic) and OEM Sustaining ceramic valves. Lead 2 departments of QAE's to perform Design Reviews, Validate high risk processes, equipment, and software systems. Presented formal training programs to staff, controlled department budgets, maintained supplier quality metrics, and motivated staff performance to exceed objectives. Performed all design transfers/pilot production reviews. Closed open CAPA's~Complaints~QIR's~NCRs for compliance. Wrote and reviewed all Validation Master Plans and Protocols for risk analysis, safety, and effectiveness. Promoted twice from Sr. QAE to Manager OEM Engineering and then to New Product Development QA Engineering. Held Metric Review meetings on incoming/process quality including all Suppliers/NCR's. Launched first Proprietary (CPHV) Valve by performing Design Control Reviews, Software Validations, Equipment Qualifications on Coatings, Supplier Audits, and Process Validations Master Plans (IQ,OQ,PQ) including software testing and code reviews. Reviewed all regulatory submissions and ordered material analysis of heart valve returns on MDR's to make process/product improvements. Developed & wrote policies on the Quality Manual, Design Control Program, Pilot-Production procedure, Process/Software Validation Policy, Failure Investigation Procedures (CAPA), Audit Procedure/schedule, & Metrology Practices. Member on the Management Steering Committee reporting to the president. Key member of the Metrics Board and a key contributor to Management Reviews of the total Quality System performing GMP Audits. Forecasted annual resources and budget expense accounts for two departments including headcount, capital, cost reductions, outside lab services, and professional development. Sr. Quality Assurance Engineer Becton Dickinson Company 1988 to 1990 Expert SME on Cannula (Needle) Technology and Molding syringes and

installing automated manual inspection using vision detection systems to improve manufacturing processes. Represented the company under legal discovery by testifying in two company needle stick litigation's to prove product safety using needle shields. Developed a Blow Molded Sharps Collector to dispose of used needles and qualified the processes. Successfully managed a product recall from an OEM Molding supplier. Presented formal project status reports to upper management including statistical analysis. Developed documentation packages and qualified new contractors to mold our Sharps Collector Line to reduce cost. Installed and validated needle lubricant systems, geometry point testing methods, and an automated vision software detection system for dimensions and cleanliness for quality improvement. Supervised the mechanical inspection laboratory and Metrology lab technicians. Project Engineer assigned to resolve a resilient rubber and mold to correct a chronic sleeve leakage problem. Resolved complaint accounts by flying to hospitals to instruct nurses on proper technique of the product via demonstrations. Quality Control Supervisor Ohaus Scale Corporation 1987 to 1988 Managed 3 departments (16 technicians) in CNC, Machine shop, Metrology, Electro-Powder Painting, Receiving-Final Inspection, Semiconductor/Transformer Test, and PC Board Assembly. Set department goals, managed budget accounts, trained and motivated employees. Designed and implemented a new department layout that improved work flow and space utilization. Started a Metrology Gauge & Tooling calibration program. Wrote the QC manual for internal quality systems. Installed a metallographic micro hardness tester to measure material hardness and composition. Quality Assurance Engineer Ohaus Scale Corporation 1985 to 1987 Was requested by the President Jim Ohaus to write a technical report comparing Ohaus Scales to the Competition and highlight new Scale Technology and Competitive features. Bench marked technology and Suppliers to implement state of the art design features to gain market share. Implemented design improvements using statistical analysis of our warranty database (component failures) and review of product complaints. Wrote new test standards in design, quality, and reliability. Wrote inspection methods for Die & Investment Castings, CNC Machining, CMM & Automated Video Inspection programs, PCB Assemblies, and in-process/final balance tests. Set-up testing at incoming on EPROM's, Op Amps, Integrated

Circuits, and wave solder boards. Performed Environmental testing on products to calculate reliability (MTBF life & load cycles). Performed Design Reviews, Packaging qualifications on Magnetic Force/Strain Gauge load cells. Technical Lead on all MRB dispositions (developed the system) for non-conforming materials. Sourced and tested an OEM SPC Data-Printer as an accessory to our product line of balances. Set-up the Metrology department and procedures to fill/calibrate weights for class certification. Industrial Engineer/Materials Manager Simmons USA 1984 to 1985 Rated union operators using the Ready Work Factor (MTM) method and completed Time Studies to set operation piecework standards for Machinist and Upholster Unions. Installed hydraulic riveting and pneumatic packaging lines for mechanical frames. Set up inspection gauging and measurement systems. Reported to the GM/Plant Manager and made formal recommendations in all these areas. Responsible for the Production & Inventory Control and Capacity Planning for a one-million Sq. Ft. plant operation. Set-up computerized inventory controls based upon production demands and adjusted material procurement accordingly. Hospital Administrator & Security John F. Kennedy Medical Center 1980 to 1983 Worked for the Hospital Management Engineering as an Administrator to evaluate and establish department goals for feasibility of operations and cost. Studied outpatient service quality, manpower staffing, and lab equipment output. Conducted time and work flow studies to assess department efficiency for expansion. The results of this study reduced the overall cost of nursing labor. Implemented rescheduling outpatient nursing shifts to address peak health care service times. This shift staggering minimized nursing idle time by creating Flex Scheduling to improve overall quality to patient. Responsibilities of a Security Officer provides a safe and secure environment for patients, visitors, physicians, volunteers, vendors and employees. Completes duties of the position in a positive and professional manner maintaining focus on the System Service Excellence Standards and the Department Management Plan. Tool & Die Machinist &Inspector RICCI TOOL COMPANY 1972 to 1982 Worked as an apprentice toolmaker in the manufacture of precision tolerance metal fixtures & tooling for automated machines and electronic PCB assembly jigs. Performed contour milling and tapping/threading holes, reaming, boring, and counter boring to tight blueprint specifications. Performed Methods set up to for part

cost quotes. Developed a full understanding of cutter feed rates and speeds of different tools to correctly perform material removal with minimal wear and optimal precision. Operated Milling machines, tool makers' lathes, Bridgeport milling machines, Hardinge drill press, surface grinders, band saws, screw tapping machines, and punch presses. Verified product quality using Vernier calipers and height indicators including digital micrometers. Performed 100% inspection and improved processing methods to reduce piecework cost. Calibrated inspection devices using metrology blocks to verify accuracy. Delivered fixtures/piece work to customers and inspected their facilities to apply knowledge back into the design/process. Education MBA Shaftesbury University 1997 to 1999 BS Industrial Engineering-NJ Institute of Technology 1980 to 1984 Engineering Austin Community College 1982 to 1983 Engineering Rutgers College New Brunswick 1980 to 1981 Computer Science West Chester University 1979 to 1980 Skills Marketing, Powerpoint, Training, CRM, Microsoft Office, Customer Service, Business Development, Sales Links http://Linkedin.com/in Additional Information Core Competencies: New Product Development: Design Controls, FMEA, Process Validation, Process Control Plans, Risk Mitigation Quality Engineering: (CQE) IT Analyst, Software Code Testing, Supplier Audits/Certifications, Equipment Safety Validations: DQ/IQ/OQ/PQ, SPC Process Monitoring, Packaging & Sterilization, Clean Rooms, Risk Assessment Decisions Remediation's: CAPA~NCR~QIR~MDR~SCAR~FAI, Recall/Complaints, Audits, Gap Analysis Management Leadership: Recruiting, Training, Development Planning, Training, Mentoring, & Coaching Technology Transfers: Mfg. Pilots, Decommissioning, Site VMP, Risk-Safety-Hazard Analysis OSHA. QSR cGMP 21CFR Part 11 Compliance, ISO 9001, IT Big Data/ Security, PCS~HMI-PLC Robotic Automation & Code Inspection Technology, Total Measure' Variation CMM~CNC~QC~Calibration /Metrology & Traceability Gauges/R&R Capability, Process Controls Measurement: Statistics, Sampling Plans, Kaisen, 6-Sigma/ Lean Bar Code Traceability, Labelling, UDI Software Design Testing: Vision/Packaging Systems , Clean Rooms Microbiology, Aseptic Transfer, Supplier Certification testing, Regulatory Affairs: Clinical Trials PMA~IDE & 510k Submission, Design Reviews, Technical Writing, Field Support, Clinical Reports.

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