**(925)360-9955** 10013 Foxboro Cir., San Ramon, CA 94583 *borlipn@gmail.com*

**Boris Lipnitsky**

**Quality Assurance Engineer**

* Senior Quality Engineering Professional with 11+ years of experience in quality assurance and 8+ years of experience working in a medical device companies. Knowledge and experience in quality management of hardware and software engineering processes in compliance with 21 CFR 820 and QSIT regulations, ISO 13485 & 14971, and IEC 62366 & 62304. Strong knowledge and experience with GMP, 21 CFR 820.30
* Review and perform Product, Functional, and Software Requirements documents for: functionality and capability, inputs and outputs, interface, security, data definition, installation, acceptance and regulatory requirements etc.
* Extensive experience in evaluating risk control measures and assigning to risk management file. Defined risk control measure for each potential cause and documented based. Effectively assist with product risk assessment (PRA). Review and contribute to all types of test documents: test plan, test protocol, test report, traceability matrix and deviation/ defect reports. Maintain and update the validation records, protocols, completion reports.
* Experience leading both local and offshore / outsourced QA teams. Support multiple projects at varying life cycle stages. Participate in Product Life Cycle Phase Reviews. Enforce product release and configuration management procedures and support all on site audits
* Collaborates with the functional stakeholders on establishing and/or improving product/process quality based problem solving efforts. Strong leadership and ability to work independently with minimum supervision.
* Provide Quality Engineering support for purchased products or components and provide input to the decision of whether to accept the product and future purchases from the vendor. Reviewed and approved V&V protocols, report, traceability matrix file, integration between HW -SW items, units, created set of tests (IQ,OQ, PQ). Responsible for development , directing, and controlling activities for project planning, cost management, resource management and scheduling, quality, and risk management.

**Education/ Certification/ Training:**

|  |
| --- |
|  |

* **BS in Electrical Engineering**, State University of Telecommunications, Minsk, Belarus
* **Quality Assurance Certificate**, QA Portnov School, Mountain View, California
* **Java** programming language classes, DVC College, Pleasant Hill, California
* **Selenium Test Automation classes with using Ruby** language

**Technical/Computer Skills**

Software tools: SilkTest Database: MS SQL, Oracle, Crystal Reports

Programming: VB, C, JavaScript, Java Bug Tracking Systems: Bugzilla, Clear Quest, Partera, TestTrackPro

**EXPERIENCE**

**Stryker Inc., Phoenix, AZ 05/2013-07/2013**

**Advance Quality Engineer**

* Participated in **remediation of existing Design History File documentation** including medical device design and risk documents. Product and process FMEA, Design Inputs/Review and design verification, included are designs for manufacturability.
* Perform complex analyses using appropriate tools. Develop and implement test methods and equipment.
* Plan and implement actions to ensure that all quality deliverables are completed according to the project timeline. Leads design reviews to communicate the adequacy of design, and risk activities and demonstrate competency of the remediation effort and any identified gaps.
* Perform reviews of validation protocols to ensure that regulatory and technical/functional requirements are fully satisfied (longer term). Apply appropriate statistical and analytical techniques to problems, and provide assistance to other engineers in the use of these techniques

**Thoratec Inc., Pleasanton, CA 04/2012-12/2012**

**Sr. Quality System Engineer**

Company products are help to survive the heard failure patients with ventricular assist devices (VADs). VAD(s) is electro-mechanical device that circulates blood throughout the body when the heart is too weak to pump blood on its own.

Primary responsibilities include product risk management (Class III device) and technical problem-solving as it relates to making company products 60601-1 3rd edition compliant in accordance with corporate and regulatory requirements.

1. Work with cross-functional teams to assure their product development, design change, risk management, verification and validation activities and the resulting work products are in compliance with IEC60601-1 3rd Edition in finalizing a gap analysis between current product documentation generated to meet 2nd and the 3rd edition requirements, else, assist in the executing of activities to address the identified gaps from UL/CSA reports.
2. Lead and ensure completion of Risk Management activities: RMF include the generation and remediation efforts for RMP, RMI, (x) FM EA, HFUE. Effectively assist with risk assessment (PRA) and complaint management, CAPA root cause analysis and resolution of accurate documentation consistent with applicable quality standards..
3. Knowledge and experience in quality management of hardware and software engineering processes in compliance with 21 CFR 820 and QSIT regulations, ISO 13485 &14971, and IEC 62366 and 62304

**St. Jude ANS, Plano, TX** **05/2011-11/2011**

**Sr. Quality System Engineer**

Primary focus: Provide support to assigned projects is advanced Neuromodulation System delivers electrical stimulation therapy

for a pain management. This includes Multi Program Trial Stimulator (MTS) Systems and Rechargeable Implantable Pulse

Generator (R-IPG)s, Clinical and Patient Programmers, and Renew® RF receivers .

1. Responsible for the identification of best practices FDA QSR and International regulations, specifically related to

Class III medical device in design control areas. Overview and upgrade the verification and validation protocols by

remediation process optimization (RPO) on products that contain implantable electrical stimulation

1. Review and contribute to all types of test documents: test plan, test protocol, test report, traceability matrix and

deviation/ defect reports. Maintain and update the validation records, protocols, completion reports.

1. Support the implementation, simplification and remediation a local Quality System and Standard Operating Procedures defining all the processes for managing Design Controls and Risk Management activities.
2. Participate in regulatory audits and inspections with DHF of SJ products. Provide guidance to the teams to assure the usage of the test method validation methodology, standards: IEC 60601-1,2,4; EN 45502-1; IEEEC95.1

**Biocare Medical LLC, Concord, CA 2009-2010**

**Verification & Validation Manager**

The full automated one hand robot system that the covers IHC and ISH by use of antibodies, chromogens and detection systems

from any source and is designed to maximize flexibility for both anatomic pathology and research laboratories.

Primary focus: Monitored and evaluated product quality issues through risk evaluations, product quality holds, field actions/corrections and technical communications to ensure that distributed product conforms to quality standards;

1. Responsible for the overall leadership and operation of the QA/QC Instrumentation department.   
   Defined the strategic direction through the identification of best practices and interpretation base on GMP, IEC62304, ISO13485, IEC 61010-1 regulations and industry standards. As required (through members of the QA team), reviewed, approved and monitored: product inspection and test data, SOP’s, batch records, product labeling, raw material and product specifications, test methods, deviations, failure analysis, CAPA’s
2. Implemented project V&V strategies by defining, managing and delivering verification and validation project deliverables. Else, produced and reviewed V&V plans, create block and grey box testing by (IQ’s, OQ’s, PQ’s, FAT’s, SAT’s) protocols, executed

the its and resolved deviations. In addition, participated in development of the Operation and Maintenance manuals for standard

and custom purification equipment.

1. Led investigations and tracked software and hardware defects and change requests in support of configuration management. Reviewed and approved Engineer Change Requests (ECRs) and track status. Participated in product development activities, including Design Reviews and Hazard Analysis. Executed Device History Record reviews in conjunction with manufacturing.
2. Monitored DHF, RMF and design change readiness for regulatory inspections and audits Utilizes Quality tools to drive continuous improvements by identifying trends during the product development and design change activities

**Chattanooga Group,** Chattanooga, TN **01/2009-08/2009**

**Quality System Analyst**

Primary focus: Assistance in the implementation SQR for Complaint System, Nonconforming Material Report, CAPA systems. Secondary focus is support the QMS for flexible ultrasound muscle therapy systems with dual frequency operation.

1. Performed professional Quality Engineering assignments of a high degree of complexity with wide latitude for independent action and decision.
2. Integrated, collaborated, actualized design control, document control, validation activities with systems referring to products, such as: SMARTEAM system– regulatory compliance framework referring to industrial regulation, optimization business processes and formal validation control, base on GMP and 21 CFR Part 11, 820.100; NCMR; CAPA;

Customizing Complaint system.

1. Planned and conducted the analysis, inspection, design, test, and/or integration to assure the quality of assigned product.  Initiated document changes and updated SOP/QA procedures; generated protocols, system documents and test reports. Performed quality engineering reviews of design documentation for compliance with stated requirements, including vendor quality manuals and company quality records.

**Bausch & Lomb Cor.,** St. Louis, MO | **Sr.QA Engineer** | **04/2008-11/2008**

.

Primary focus: Support the QMS for Microsurgical system is line of phacoemulsification equipment for eye treatment. Secondary focus is audited and corrected SWQA documentation based on Design Control Requirements

1. Supported the Quality System by following the policies, SOP, WI and performed the responsibilities under the authority. Designed or specified inspection and testing mechanisms and equipment required to conduct quality assurance tests, such us: DHF, Design Change, Design Input, Design Output, Design Verification, Design Validation, Software Design Description.
2. Performed internal audits base on GMP, IEC62304, ISO13485, 14971 regulations, including audit planning and execution.
3. In collaboration with the Quality Systems policies, implemented and maintained engineering performance metrics to identify actionable trends using control techniques and supply related reporting to QS group for inclusion in semi-annual management reviews.
4. Assisted to the development of next generation microsurgical device, provides day-to-day guidance for software process development practices used to mitigate causes of defective software. Performed modularization traceability using RequisitePro (Rational Suite) Tools.

**Abbott Diabetic Care Laboratory, Alameda*,* CA** **03/2007-10/2007**

**Sr.QA Engineer**

Primary focus: Corrective action issue of Claim Center and secondary focus of next generation of ADC product.

* Reviewed non-product SWQA documentation for accuracy, clarity, consistency, completeness and compliance, including System Specifications/Requirements documents, Validation protocols, Trace Matrices base of IBM DOORS and Validation Summary Reports. Verified design activities ADC internal application for collecting and tracking Customer Claim Center, based on FDA regulation, system architecture, quality audit.
* Reported unexpected events, issues or software bugs which occurred during validation, to project team and management. Maintained schedule and drove to meet SWQA schedule as aligned with project goals. Supported software audits for internal or external audits, provided feedback and reported results of audit to SWQA lead on audit.
* Responsible for performing work required to design, specify, procure, commission and qualify equipment, methods, purification processes, and other relevant manufacturing support for Blood Glucose Monitoring System. Conducted conceptual, basic and detailed engineering, developed scopes, create and monitoring black and grey box testing activity, such us - IQ, OQ, PQ for Test Scripting Tools (TST) software. Worked with Cyclic redundancy check (CRC) functions for simple detection of common errors, and implemented correction in the input data.

**Blue Jungle, Inc., San Mateo, CA 05/2006-11/2006**

**SQA Engineer**

• Thoroughly testing BlueJungle preventive system to ensure proper operation and freedom from defects. Create, Review and Execute manual test scripts and test cases, against different type of controls, applications, systems, and data developing by BlueJungle.

• Contribute to unit testing, functional testing, regression testing and scripting for automating tests using open source and commercial tools. Coding and execute test script for automation testing Front/End Web application (base of JavaScript) using QTP and Client/Server applications (base of Java) using Silk.

* Drive the automation efforts for the Quality Assurance Team.  Mentor the Quality Assurance team on automation.  Assist other Quality Analysts with approach and technical issues while creating and executing automated test cases.
* Participate in defining functional regression test cases for the Master Regression Test Plan. Coordinates information with the development, professional services, merchandising and operations to resolve the application setup and configuration issues. Track and report software defects and verify resolved issues using bug tracking system Bugzilla

**Primavera Inc*.* Bala Cynwyd, PA 09/05-03/2006**

**SWQA Engineer**

* Involved in perfection and improvement of the PrimeContract system design by Primavera. It is a management tool used to manage project steps at the construction area.
* My responsibility was to write the test plan and test cases for testing ‘mouse over’ actions on Web applications (base of JavaScript). Verification parameters URL correspond to New Project or Template Project against user requirements
* Responsible for analysis on project data, error messages with using mouse over action, creating a script (base of using Silk) for verification of the copy procedure between template project and new project, and imaging verification using mouse over action.
* Also managed QA documentation and bug reporting using Quality Center and bug tracking system – (Bugzilla)

**Boston Scientific Corp., Fremont, CA 2002 – 2005**

**Software Validation Engineer**

* Established test plans and test protocols/reports for software testing, verification, and validation to ensure that software design and performance were consistent and to the required standards, this documentation applied to ultrasound system medical devices produced by Boston Scientific Corporation. Functional testing of the entire device system, including software and hardware including (GUI, Measurement Accuracy system, and X-ray system, Motor Drive Unit).
* System validation –verification by objective evidence that software requirements have been implemented correctly and completely and are traceable according to the SRS and UI Specification. Designed and executed automation scripts using SilkTest and Rational Robots
* Performed manual and automation unit, system, and performance tests as well as comprehensive regression testing

Maintained and supported Rational ClearQuest bug trucking system to record bugs and follows up on all found anomalies. Communicated the problems to development team

* Worked closely with customers to better understand and identify expectations and develop new concepts and ideas for future projects. Developed “Data Base Complaint” system for the medical field with FDA regulation requirements
* Responsible for the maintenance of the Rational Suite Enterprise SW such as: Robot. Knowledge and experience with DOORS

**BizBot. Com, San Francisco, CA 2000 - 2002**

**SQA Engineer**

Primary focus: Corrective action Stock Trading Web application with secondary focus on established quality criteria and process auditing.

1. Performed detailed testing of Internet application software for the product-engineering group.
2. Created test plans, test scenarios, and test cases using automation tools (SilkTest), etc., for testing application functionality, performance, and usability.
3. Established quality criteria and released management methods that conformed to specifications and requirements. Worked closely with analysts and designers, application developers, and product management.
4. Wrote script for test cases in C, VB languages. Performed PC HW/SW installation and configuration.
5. Reported software defects utilizing various bug-tracking databases. Followed up with bug reports to complete resolution. Configured online Bug tracking system (Partera).