**SARAVANAN.P**

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**HEALTHCARE**

**PROFESSIONAL SNAPSHOTS**

* A seasoned professional with over 11years of experience in the field of Ophthalmic Medical devices.
* Currently associated with Biotech Healthcare, Ahmedabad as a Sr.Manager Quality Control.
* Expertise in medical devices manufacturing, Production, quality, application and servicing along with

in-depth understanding medical devices regulatory requirement.

* Highly committed and result orientation.

**AREAS OF EXPERTISE**

|  |  |  |  |
| --- | --- | --- | --- |
|  | * Medical device Manufacturing * Quality control and Quality Assurance |  | * Project Management * Demo Ophthalmic Surgeries |
|  | * ISO 13485, ISO 14971, CE Certifications |  | * People Management |
|  | * New Product development |  | * Training & Development |

**Growth Path:**

* 20/10/2009 to 31/12/2011 : Engineer Quality Control and Production
* 01/01/2012 to 28/02/2019 : Manager Quality Control surgical & Diagnostics devices
* 01/03/2019 to Till date : Senior Manager Quality Control Surgical devices

**EMPLOYMENT RECITAL**

**Biotech Healthcare.**

**Ahmedabad- Gujarat**

Sr. Manager Quality Control Surgical Medical devices

March 2019-Present.

**Key Roles:**

* Incoming Inspection, In-process and Final Quality Inspections.
* Recording Quality activates in SAP Quality Module-Core user.
* Preparation and revising of regulatory documentation such as Technical Master File (TMF), Device File, Risk management, PMS and Clinical evaluation.
* Root cause identification and proposing counter measures for customer complaint through CAPA.
* Collecting and recording surgeon feedback inputs for PMS surveillance.
* Preparation and revising of ISO/13485 QMS documents such as SOP’s, Quality Specs, User manual, Installation manual, Service manual & IFU’s
* Maintaining the tractability of record and Quality reports.
* Attending Phaco and Vitrectomy surgeries in various ophthalmic Hospitals.
* Assisting Phaco surgeons to perform smooth phacoemulsification in the OR.
* Sourcing of Quality Vendors for surgical accessories Procurement.
* Handling service team for Phaco & SciCan Autoclave Sterilizers/trading equipment by Biotech.
* Training Application and Service engineers for equipments Installation Demo and Servicing.
* New Product development document of understanding and thesis preparation.

**Biotech Vision Care PVT Ltd, Ahmedabad.**

Manager Quality Control Surgical and Diagnostic Medical devices.

Jan 2012 to Feb 28th 2019.

**Key Roles:**

* Inspection of raw materials, In-process production line and finished product.
* Calibration maintenance of Measuring devices such as Digital Manometer, Cathode Ray Oscilloscope, Frequency Generator, Multimeter & Flow rate Cups
* Maintains manufacturing and Quality control documents like inspection reports and records.
* Manufacturing Standard Operating Procedures follow-up.
* In-house Trouble shooting of production failure machines.
* Validation and Verification of products.
* Attending ophthalmic anterior IOL Surgeries and Posterior Vitrectomy surgeries in various Hospitals.
* Servicing of Phaco Surgery machines on the customer field area.
* Maintains Machine History/Batch record files.
* Training of Service and application engineer for the new model machine.

**Appasamy Associates, Chennai.**

Engineer Quality Control & Production

Oct -2009 to Dec-2011.

**Key Roles:**

* Inspection of Incoming raw materials used for manufacturing.
* Assembling & wiring of ophthalmic surgery machines like Phaco Machines, Vitrectomy Machines, Green laser, Corneal cross linking & Air injectors.
* Maintains 5S Principles in the workshop area.
* Manufacturing Standard Operating Procedures follow-up.
* Maintains Machine History/Batch record files.

**Significant Highlights:**

* Obtained CE- Certificate for the Product- Phaco Machine class-llb medical device
* Developed New product called Corneal cross linking for keratoconus surgery.
* Certified six sigma green belt and ISO 13485:2016 Internal auditor.

**ACADEMIC CREDENTIALS**

Master of Science-Applied Electronics From Hindusthan College of Arts & Science, Coimbatore-TamilNadu in 2009.

**Date of Birth:** 20th October 1986

**Languages Known:** English, Hindi and Tamil