**VARUN KUMAR PRABHAKAR**

V.P.O SANTOKHGARH, DISTT UNA (H.P), INDIA

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**QUALITY ENGINEER**

**Quality Engineer** with proven experience in ISO 13485 environment, Quality Management System (QMS), Process and product Validation for ISO class 8 clean room, Risk Assessment and Vendor control for medical device manufacturing company. Deliver continuous improvement for quality enhancement. **Engineering in Life Science background and pursuing online Post graduate diploma in Quality Assurance and Quality Control.**

**KEY VALUE OFFERED**

 ISO 9001 & 13485 QMS Establishment & Maintenance

 Documentation Control Validation (Process & Product)

 CAPA Supplier Control

 Internal & External Audit Customer complaint & Feedback Activities

**CAREER TIMELINE**

**Quality Engineer – Hitex Healthcare,** una, H.P, INDIA. From- **09/08/2011 to Present**

**PROFESSIONAL HIGHLIGHTS**

Dina International group was established in 1987 whose global headquarter is at Moscow. Dina International group is parent company of Dina-Hitex Czech Republic and Hitex Healthcare India which are manufacturer of surgical medical disposables (class I & II a). Dina International group turnover in excess of 100 Million USD. Dina has manufacturing facilities in three continents Europe, Asia and Africa.

**JOB DESCRIPTION**

 **Quality Management System:**

* Maintenance and control of Quality System
* Scheduling and chairing of Quality Management Review meetings.
* Execution of Internal Quality Audits, issuance of audit reports
* Raising of Corrective and Preventative Actions and coordinating and monitoring to ensure completion of the agreed activities by the relevant departments.

 **Documentation Control:**

* Revision of procedures, SOP & Forms.
* Issuance and receipt of controlled document revisions, maintenance of controlled docs logs, etc.
* Supervisory maintenance of all logs (e.g. raw material reports, in process reports, finished product reports, NC reports, CAPA reports, etc.)
* Control and day to day upkeep of Master Documents record, issuance of Report Numbers, etc.
* Maintenance and control of all other relevant records: Training Files, Calibration Records, etc.

 **Validation:**

* Process and Product Validation and verification.
* Costing, scheduling and supervision of all validation activities for ISO 8 Clean room and HVAC.
* Requalification of outsourced sterilization chamber.
* Acquisition of validation quotations.

 **Auditing:**

* Managed internal and external ISO audit program.

 **Vendor Control:**

* Assessment and approval of vendors, including issuance receipt and inspection of Quality Questionnaires, receiving inspection of goods.
* Execute supplier complaint report for any non conformance.
* Establish and maintain comprehensive system of Product Traceability.

 **Customer Feedback Activities:**

* Control of customer feedback/ vigilance
* Nonconforming/defective product activities and controls
* Control of customer complaint and feedback forms
* Control of and responses to customer complaints.

**EDUCATION & PUBLICATION**

**Education: Bachelor of Technology, Biotechnology Engineering (2007-2011) –** Lovely Professional University, Punjab, INDIA.

**Pursuing online Post Graduate Diploma in Quality Control & Quality Assurance (2014-2015)** - Quality Council of India.

**Publication: Varun Kumar Prabhakar,** Aakanksha jaidka & Ravinder Singh. In vitro study on *α-amylase* inhibitory activity and phytochemical screening of few Indian medicinal plant having anti-diabetic properties. International Journal of Scientific and Research Publications, Volume 3, Issue 8, August 2013 1 ISSN 2250-3153. <http://www.ijsrp.org/research-paper-0813/ijsrp-p2042.pdf>.