GAUTAM SINGH

Village Bagwar, District Azamgarh, Zip Code- 276122-Uttar Pradesh India

PROFILE SUMMARY

Experienced Regulatory Specialist with a demonstrated history of working in the Medical Devices, Pharma, Nutraceutical & Food industry. Skilled in Quality Management System, Risk Management and Control, Clinical Evaluation. Currently in Global Medical Device Harmonization as per WHO Global Atlas. Strong research professional with a B.Sc. (Hons.) Biotechnology from Amity University Noida focused in Biotechnology and Health Industry.

Experience

Assistant Manager-Regulatory Affairs Medical Devices

QVC Certifications Pvt. Ltd./ Jul 2022-Till Date

Roles and Responsibilities;

- Review of Technical Documentation as per EU MDR, IVDR and Management System Standards e.g ISO 9001, 13485, 22000 etc.
- Review of Technical File as per CDSCO (Central Drug Standard Control Organization)
- Performing Audit as per CDSCO (Central Drug Standard Control Organization)
- Review of Clinical Study data

General Manager & Operations Head -Dec 2020-Jul 2022

Venkatramna Industries *(Manufacturer of Essential oils and Active Pharmaceutical Ingredients used in the pharma, Cosmetic, Ayurveda and food industry to formulate finished products and medicines. The Company is certified with ISO 9001:2015, HALAL and Organic recognized by Government of Uttar Pradesh, India)*

Process Knowledge Acquired*: Batch manufacturing record, Steam Distillation, CO_2 Extraction Method of Oils, Quality Management System, Complaints Handling and resolution, Preservation of Essential Oils.*

Similarity to Medical Device Industry

The API and Pharmaceutical manufacturing includes multi-step chemical synthesis and fermentation, purification, crystallization, drying, milling, packing, labeling, and testing of the Drug Substance, The Medical Devices which are being coated with drug follow the similar manufacturing process like catheters coated with antibiotic, bone cement coated with antibiotic, drug eluting stents(for slow release of drug), Condoms coated with spermicides, Prefilled Syringes (Insulin, metered dose inhaler, etc.), Drug delivery System

Roles and Responsibilities;

- Document approval and implementation of Quality and Quality control measures as per ISO 9001:2015 and ISO 14001:2015
- All kind of Testing of Raw Material and Packaging Material as per Standard Operating Procedures vide Drugs and Cosmetics Act 1940 and New Drug Rules 2016.
- Documentation as Per applicable regulatory requirements and Regulatory Body.
- Systemic Study on the Essential Oils and their efficacy as per Drugs and Cosmetics Act 1940.

Quality Control Executive June -2020 – Nov 2020

Super Surgmed Pvt. Ltd*. (The Company is Certified with ISO 13485:2016, and recognized by Central Drug Standard & Control Organization licensed by Food and drug Administration of India. The company is Manufacturer of Surgical Sutures Absorbable and Non Absorbable, & Surgical Mesh which placed in sterile condition in market)*

Process Knowledge Acquired*: Batch manufacturing record, sterilization (ETO, Dry Heat, Steam Sterilization), Needle Crimping and tensile strength testing, Quality Control Testing, Stability Study Plan as per ICH*

Roles and Responsibilities;

- Perform In-process Quality Control Check during the Production (i.e Crimping of Needle and Cutting of Thread, processing, ETO sterilization, Packaging, Loading and Unloading etc.
- Submission of Test licenses and making of Device Master File as per ISO 13485:2016 and Medical Device Rules India 2017 under the Drugs and Cosmetics act 1940.
- All kind of Testing of Raw Material and Packaging Material as per Standard Operating Procedures vide ISO 13485:2016 and Medical Device Rules 2017 (India)
- ETO Sterilization validation including Bioburden test and Incubating the Biological Indicators as per ISO 11135:2018.
- Packing material (Medical Grade paper) validation as per ISO 11607, its GSM, Porosity and its ability under extreme ETO Sterilization condition.
- Review of the Study Plan and Study reports of Biocompatibility of Sutures and Mesh as per ISO 10993:2018 and regulatory requirements.
- Perform Stability Study of Sutures as per ICH Q1R2 guidelines for validation of the devices.
- Quality Control and validation of Clean Room at set duration and in accordance of ISO 14644-3:2019.

Regulatory Affairs Executive -Feb 2020 – April 2020

Qaaf Health International *(A Regulatory Consultancy service provider as per Drugs and Cosmetics Act*

1940 India, CDSCO, New drug Approval, New Device Registration, Medical Device Licensing)

Roles and Responsibilities;

- Filing Bioequivalence and Bioavailability No Objection Certificate Application to Indian Drug Regulatory Authorities, CDSCO (Central Drug Standard Control Organization) and State Drug Authorities.
- Biocompatibility Study Plan and Application reporting to Medical Device Testing laboratory as per Central and State Licensing Requirements.
- Handles Documents of Serious Adverse Events, Pharmacovigilance, Periodic Safety Update Reports and Bioequivalence No Objection Certificate reporting to Drug Controller General of India and CDSCO (Central Drug Standard Control Organization) offices.
- Checking the dossiers as per new Clinical Trial rules and authenticating Batch Manufacturing Records.

Regulatory Coordinator- May 2019 – Feb 2020

Biovencer Healthcare Pvt. Ltd. *(The company is certified with ISO 9001:2015 & FSMS 22000:2018 recognized by Food Safety & Standard Authority of India licensed by Ministry of Ayush. The Company is Manufacturer of Nutraceutical, and Ayurveda Products in Powder, Solid and Liquid Dosage Forms)*

Process Knowledge Acquired*: Batch manufacturing record, Granulation, coating on tablets, tablet Compression & Testing, Stability Study, Testing Requirements on Tablets and capsules*

Similarity to Medical Device Industry

The Company involved in manufacturing of Tablets, capsule and Powder, however the manufacturing process involved are quite similar based on the

- GMP REQUIREMENTS (GMP REQUIREMENTS ARE QUITE SIMILAR IN PHARMA AND MEDICAL DEVICE)
- CLEAN ROOM REQUIREMENTS (FOR BOTH INDUSTRIES CLEAN ROOM REQUIREMENST ARE ALMOST SAME) AS PER ISO 14644
- DEVELOPMENT OF EXTENDED RELEASE, SUSTAINED RELEASE DRUGS (ENTERIC COATED TABLETS AND CAPSULES) WITH THE HELP OF POLYMERS (A QUITE SIMILAR MECHANISM IS USED IN MEDICAL DEVICE TO DRUG DELIVERY SYSTEM)

Roles and Responsibilities;

- Monitor and audit in-process quality check and analysis of the goods to ensure the quality compliances (Good Manufacturing and Good lab Practices) in accordance with ISO 9001:2015 and Food Safety Management System ISO 22000:2018.
- Maintaining the documents and records of products Batch Manufacturing Records and Certificate of Analysis irrespective to product requirement in accordance with the Food Safety Act 2006 (India).
- New product development: involved in the new product design and development based on customer requirements. In lined with the requirements of Ayurveda and Food Act.

- Maintain the Records and monitor the Production activities as per Food Safety Act and ISO 22000:2018, i.e Granulation, coating on tablets, Powder Mixing, Powder drying and Syrup base mixing.
- Responsible for maintain and implementing of Food Safety Management System in accordance with ISO 22000:2018.
- Review and plan Stability study for the products in accordance with ICH guidelines.

Subject Matter Expert Life Sciences –Mar 2019 – Apr 2019 (As a Trainee)

Acadecraft Pvt. Ltd. *(A MNC Life Science Content Management Company)*

- Preparation of Training course & Study material for potential clients.

Regulatory Affairs- May 2018 – June 2018 (As a Trainee)

Biovencer Healthcare Pvt. Ltd. *(The company is certified with ISO 9001:2015 & FSMS 22000:2018 recognized by Food Safety & Standard Authority of India licensed by Ministry of Ayush. The Company is Manufacturer of Nutraceutical, and Ayurveda Products in Powder, Solid and Liquid Dosage Forms)*

- Involved in the Operational Process to develop the process flow in the Manufacturing unit as per Compliances.

EDUCATION & ENDORSEMENTS

1. Educational Details

S. No	Education	Institution/Subjects	Year	Grade
1	B. Sc. (Hons) Biotechnology	Amity Institute of Biotechnology, Amity University Noida, India *With Subjects* • Clinical Biochemistry • Omics and Genomics • Bioinformatics (Data and analysis pertaining to the technology and software used in Medical Science) • Bio-instrumentation • Industrial Microbiology • Biomaterials and Nanotechnology with Biomedical Sciences	2019	8.38 CGPA
2	Senior Secondary, Class XII	Gautam Buddha Balak Inter College, Greater Noida, India With Subjects Biology, Physics, Chemistry and Physical Education	2016	82.7%

3	High School , Class X	Gautam Buddha Balak Inter College, Greater Noida, India With Subjects Biology, Physics, Chemistry, Math, Social Science and Physical Education	2014	9.4 CGPA

2. Published Literature in International Journal of Pharmaceutical Sciences Review & Research

Title-Mechanism and Antimicrobial Application of Histatin 5, Defensin and Cathelicidin Peptides Derivatives

3. Freelancing Done

I. Info Edge India Limited

Collection of Statistical Pharma Health Data generated from FDA and National Library of Medicine for disease rate data collection.

II. Asian Paints Limited

Involved with the Expert members of Asian paints for Sharing technical and academic knowledge in development of Nano Silver Paints having antimicrobial activities due to Nano material of Silver (Ag).

4. Trainings and Seminars Attended

S. No.	Title	Year	Certificate Type
1.	Mechanism and Antimicrobial Application of Histatin 5, Defensin and Cathelicidin Peptides Derivatives-Publshed Literature in International Journal of Pharmaceutical Sciences Review & Research	Feb 2018	See Here
2.	Training on ISO 9001:2015 at Biovencer Healthcare Pvt. Ltd.	June 2019	In-house Training
3.	Training on ISO 2200:2018 at Biovencer Healthcare Pvt. Ltd.	Nov 2019	In-House Training
4.	Food Safety Act and FSSAI (Food Safety & Standard Authority of India) Regulation at FSSAI Head Office Ghaziabad	April 2019	Seminar Organized by FSSAI
5.	5 Days Lead Auditor Training Course for ISO	Jan	BMQR

	13485:2016	2020	
6.	Cleanrooms: Classification, Design & Testing at Venkatramna Industries	Aug 2020	In-house training
7.	Challenges in Medical Device Industry: Regulatory Compliance, Quality Management System, Clinical & Surveillance Requirements in accordance with Medical Device Rules India and Europe at Conference FDA (Food & Drug Administration) Bhawan, Delhi	Nov 2022	Conference

KEY SKILLS

- ISO 13485
- ISO 14971
- MDR (2017/745)
- IVDR (2017/746)
- ISO 9001
- GMP and ISO Audit
- MS-Office

Pharma Exposure

- INDIAN REGULATORY AFFAIRS (CDSCO)
- BIOAVAILABILITY/BIOEQUIVALENCE/BIOCOMPATIBILITY NOC FILLING GOVT.
- CLINICAL TRIAL APPLICATION FOR GENERIC DEVELOPMENT
- NUTRACEUTICAL MANUFACTURING
- FSSAI (FOOD SAFETY & STANDARDS AUTHORITY OF INDIA)
- SCM-MANAGEMENT
- NEW PRODUCT DEVELOPMENT

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