



Dipak Bhoi

Mechanical Engineer

4/A, Vrundavan Society, Kacchai Road,
Mahemdavad, Gujarat, 387130, India.

11/04/1994 dmdipakbhoi5@gmail.com 9033883048 Dipak Bhoi

Experienced Quality Assurance Engineer & Regulatory Affairs with a demonstrated history of working in the medical device industry. Skilled in Research, Management, Strategic Planning, Leadership, MD Quality Assurance and MD Regulatory Affairs. Strong engineering professional with a Bachelor of Engineering - BE focused in Mechanical Engineering from Ahmedabad Institute Of Technology.

EDUCATION

Ahmedabad Institute of Technology, Ahmedabad, Gujarat, India. Bachelor Engineer - Mechanical Engineering	6.43 (CGPA)
Government Polytechnic, Valsad, Gujarat, India. Diploma Engineer, Mechanical Engineering	6.56 (CGPA)
Sheth J. H Sonawala High School, Mahemdavad, Gujarat, India. SSC	74.62%

WORK EXPERIENCE

Management Representative & Sr. Regulatory Affairs Executive	
Miraclus Orthotech Pvt. Ltd. Vavdi, Kheda, Gujarat, 387550, India www.miraclus.com	16/01/2024 - Present
Head Quality Assurance, Management Representative & Head Regulatory Affairs	
Uteshiya Medicare Pvt. Ltd. Unit-2, Rohisa, Kheda, Gujarat, 387110, India.	01/09/2019 - 12/01/2024
Uteshiya Medicare Pvt. Ltd. Unit-1, CTM, Ahmedabad, Gujarat, 380026, India www.uteshiyamedicare.com	02/07/2018 - 30/08/2019

PROJECTS

Manufacturing License (MD Implants Category) MD-9 Manufacturing License from Central Drugs Standard Control Organisation (CDSCO) At Uteshiya Medicare Pvt. Ltd, CTM, Ahmedabad, Gujarat, India.	Year - 2019
Free Sale Certificate (MD Implants Category) (Offline) Free Sale Certificate from Central Drugs Standard Control Organisation (CDSCO) At Uteshiya Medicare Pvt. Ltd, Rohisa, Kheda, Gujarat, India.	Year - 2019
New Plant – Rohisa Unit New Plant as per USFDA Guidelines for Medical Devices Location: Uteshiya Medicare Pvt Ltd, Rohisa, Kheda, Gujarat. Position: Project Co-Ordinator Role: Prepare Documents and Plant Design/Construction as per USFDA guidelines/requirements for Medical Devices	Year – 2019 - 2021
Manufacturing License (MD Implants Category) MD-9 Manufacturing License from Central Drugs Standard Control Organisation (CDSCO) At Uteshiya Medicare Pvt. Ltd, Rohisa, Kheda, Gujarat, India.	Year - 2020

Market Standing Certificate Market Standing Certificate from Central Drugs Standard Control Organisation (CDSCO) At Uteshiya Medicare Pvt. Ltd, CTM, Ahmedabad, Gujarat, India.	Year - 2021
Non-Conviction Certificate Non-Conviction Certificate from Central Drugs Standard Control Organisation (CDSCO) At Uteshiya Medicare Pvt. Ltd, CTM, Ahmedabad, Gujarat, India.	Year - 2021
Manufacturing License (Endorsement- MD Implants Category) MD-9 Manufacturing License from Central Drugs Standard Control Organisation (CDSCO) At Uteshiya Medicare Pvt. Ltd, Rohisa, Kheda, Gujarat, India.	Year - 2022
Free Sale Certificate (MD Implants Category) Free Sale Certificate from Central Drugs Standard Control Organisation (CDSCO) At Uteshiya Medicare Pvt. Ltd, Rohisa, Kheda, Gujarat, India.	Year - 2022
Manufacturing License (Surgical Instrument Category, Class A & B) (with Free Sale Certificate) MD-5 Manufacturing License from Central Drugs Standard Control Organisation (CDSCO) At Uteshiya Medicare Pvt. Ltd, Rohisa, Kheda, Gujarat, India.	Year - 2022
Manufacturing License (Endorsement - Surgical Instrument Category, Class A & B) (with free Sale Certificate) (For 98 + MD Product Categories) MD-5 Manufacturing License from Central Drugs Standard Control Organisation (CDSCO) At Uteshiya Medicare Pvt. Ltd, Rohisa, Kheda, Gujarat, India.	Year - 2023
ISO 13485 Certification ISO 13485 Certification from Intertek India Pvt. Ltd. (Certified Notified Body by CDSCO) At Uteshiya Medicare Pvt. Ltd, Rohisa, Kheda, Gujarat, India.	Year - 2022-2023
CE Certification (EUMDR) (As OEM for Healthium Medtech Limited) (CE - EUMDR 2017/745, Product Registration with preparation of Technical File for entire Arthroscopy Implants and Instruments) At Uteshiya Medicare Pvt. Ltd, Rohisa, Kheda, Gujarat, India.	(Year – 2022-2023)
USFDA Registration/Certification (As OEM for Healthium Medtech Limited) (USFDA Site Registration with 03 Arthroscopy Implants Registration including preparation of Technical File) At Uteshiya Medicare Pvt. Ltd, Rohisa, Kheda, Gujarat India.	(Year – 2023)
Manufacturing License (Surgical Instrument Category, Class A & B) (with free Sale Certificate) MD-5 Manufacturing License from Central Drugs Standard Control Organisation (CDSCO) At Miraclus Orthotech Pvt. Ltd, Vavdi, Kheda, Gujarat, India.	(Year – 2024)
Manufacturing Loan License (Surgical Instrument Category, Class A & B) (with free Sale Certificate) MD-4 Manufacturing License from Central Drugs Standard Control Organisation (CDSCO) At Miraclus Orthotech Pvt. Ltd, Vatva, Ahmedabad, Gujarat, India.	(Year – 2024)
ISO 13485 Certification (Surgical Instrument Category) ISO 13485 Certification from Zenith Quality Assessors Pvt. Ltd. (Certified Notified Body by CDSCO) At Miraclus Orthotech Pvt. Ltd, Vavdi, Kheda, Gujarat, India.	(Year – 2024)
CE MDD-MDR Transition Successfully Completed CE MDD-MDR Transition Audit with getting NB Confirmation Letter as per Article 120, EUMDR 2017/745.	(Year – 2024)
Country Registration (Columbia, South Africa and UAE) In-process (Miraclus Orthotech Pvt. Ltd.)	(May-2024 - Present)
CE Certification (EUMDR) In-process (Miraclus Orthotech Pvt. Ltd.)	(June-2024 - Present)

PROFESSIONAL SUMMARY

- Extensive understanding of problem resolution techniques and processes.
- Impressive organizational and planning skills.
- Ability to maintain confidentiality as necessary.
- Strong ability to prepare quality assurance reports.
- Ability to meet strict deadlines while retaining quality standards.

SKILLS

QMS Documents	Computer Hardware and Networking
Microsoft Office	Strategic Planning
Leadership	Team Work
Country Registration	Technical Dossier Preparation for Various Countries

STRENGTH

Dedicated to Task
Learning Attitude
Individual Hardworking
Positive Approach
Performance Oriented Work Attitude

LANGUAGES

Gujarati ●●●●●
Hindi ●●●●●
English ●●●●○

AWARDS

Employee of The Month 01/08/2019
Uteshiya Medicare Pvt. Ltd.

CERTIFICATIONS

ISO 13485 Internal Auditor Intertek India Pvt. Ltd 05-01-2021
<https://www.intertek.com/india/>

Field Technician - Computing And Peripherals Year- 2017
National Skill Development Corporation - India

Course On Computer Concepts (CCC) 21-02-2021
GCE

Excel Crash Course (MS - Excel Master) 16-07-2024
E- Learning Course- Learn More Pro

Declaration:

I hereby declare that is all information given above is best to my knowledge.


Dipak Bhoi