europass

# Rashmi Godeshwer

**Nationality:** Indian **Date of birth:** 21 Dec 1988

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## WORK EXPERIENCE

### Deputy Manager- Regulatory Affair & Clinical Research

***Chetan Meditech Pvt. Ltd.*** [ 25 Nov 2021 – Current ]

**City:** Ahmedabad | **Country:** India | **Website:** www.biotekortho.com | **Email address:** contact@biotekortho.com | **Name of unit or department:** Regulatory Affair - **Business or sector:** Manufacturing

**Device Class:** Class Ir, Im, IIa, IIb, III (Non-active implantable/non-implantable device)
**Therapeutic Area:** Orthopaedic & musculoskeletal system
**Work Responsibility:**

Medical Device Technical File Documentation:
Develop technical file documentation as per MDR (EU) 2017/745, mainly to: Create, review, maintain, and update documents such as:

- Clinical evaluation plans and reports (CEPs/CERs) including benefit-risk analysis of residual risks
- Summary of Safety and Clinical Performance (SSCP)
- Post-market surveillance plans
- Periodic Safety Update Reports (PSUR)
- Post-market Clinical Follow-Up plans and reports
- Risk management plans and reports
- Information material
- Device Description

All these documentation are in compliance with applicable regulations and guidelines including: REGULATION (EU) 2017/745; MDSAP AU P0002.008; ISO 13485:2016; Brazil (ANVISA): RDC ANVISA 67/2009; ANVISA Guide No. 31 version: 2; MEDDEV 2.7/1 rev.4, 2.12/2 rev.2, 2.12/1 rev.8; IMDRF MDCE WG/N56:2019, WG/N55 FINAL:2019, WG/N65FINAL:2021; GHTF/SG2/N54R8:2006; MDCG 2019-9 Rev.1, 2020-5, 2020-6, 2020-8, 2020-7, 2022-21, 2023-3; ISO/TR 20416:2020; EN ISO 14971:2019; ISO/TIR 24971:2020; ISO 20417:2021; ISO 15223-1:2021

Post-Market Studies in India (Class III and Class IIb Devices):

- Identify clinical gaps from existing clinical data, risk management, and other post-market data.
- Study design and ethical considerations.
- Medical writing (protocol development, informed consent, case record forms, clinical study reports, manuscript writing, statistical plan reviews).
- Site feasibility reviews, selection, and negotiation.
- Process for final agreement including budget and responsibilities.
- Regulatory approval and site initiation.
- Development and management of clinical trial master files
- Subject track record and monitoring/closeout visit identification and activities
- Ensure compliance with regulations and guidelines such as ISO 14155:2020 and New Drugs and Clinical Trials Rules, 2019.

Clinical Evidence Evaluation and Analysis:

- Analyze clinical evidence from investigations, published literature, post-market surveillance, risk assessments, and post-market clinical data

Risk Management Documents Review:

- Review risk control measures, residual risk analysis and monitoring, vigilance trend reporting, and benefit-risk analysis
- Ensure compliance with MDR (EU) 2017/745, ISO 14971, and ISO/TR 24971 requirements

Stakeholder Interaction:

- Lead interactions with marketing, regulatory, and clinical stakeholders to collect information, clarify requirements, and ensure compliance with clinical evaluations and CER updates

Quality Management System Auditing:

- Qualified as an internal auditor for quality management systems for medical devices as per ISO 13485 and MDSAP

International Country Registrations:

- Handle international country registrations as required

### Assistant Manager- Regulatory Affair

***Omni Lens Pvt. Ltd.*** [ 5 May 2014 – 14 Oct 2021 ]

**City:** Ahmedabad | **Country:** India | **Website:** http://www.omnilens.in/ | **Email address:** info@omnilens.in | **Name of unit or department:** Regulatory Affair - **Business or sector:** Manufacturing

**Device Class:** Class Im, IIa, IIb (Non-active implantable devices)
**Therapeutic Area:** Ophthalmology
**Work Responsibilities:**

Medical Device Technical File Documentation:

- Developed comprehensive technical file documentation, focusing on: Creating, reviewing, maintaining, and updating documents such as clinical evaluation reports (CERs), post-market surveillance procedures and reports, risk management documents, etc.

All these documentation were in compliance with applicable regulations and guidelines including: Council Directive 93/42/EEC amended by Directive 2007/47/EC1; MEDDEV 2.7/1 rev.4; MEDDEV 2.12/2 rev.2; MEDDEV 2.12/1 rev.8; IMDRF MDCE WG/N56:2019; IMDRF MDCE WG/N55 FINAL:2019; GHTF/SG2/N54R8:2006; ISO/TR 20416:2020; EN ISO 14971:2019

International Country Registrations:

- Managed product registrations across approximately 35 countries, including Russia, Brazil, South Korea, Egypt, UAE, Kyrgyzstan, Kazakhstan, Ukraine, Australia, etc.

Quality Management System:

- Played a key role in preparing and managing quality system documents, including the Quality Manual and applicable procedures and formats, specifically addressing clauses: 4.2.3, 4.2.4, 4.2.5, 5.4, 5.5, 5.6, 7.2, 7.5.6, 7.5.7, 8.2, 8.4, 8.5 of EN ISO 13485:2016.
- Conducted thorough analysis of product complaints, providing recommendations for corrective and preventive actions, and ensuring comprehensive follow-up.
- Actively participated in both internal and external audits, delivering necessary post-inspection follow-up information as per requirements.
- Reviewed and approved product promotional materials, labelling, Instructions for Use (IFUs), specification sheets, etc., ensuring alignment with applicable regulations and company policies.

## EDUCATION AND TRAINING

### ISO13485- Internal Auditor Training

***DQS India*** [ 4 Jul 2022 – 5 Jul 2022 ]

**Address:** 5th Floor Anjaneya Techno Park #147, HAL Airport Road, Kodihalli, 560 017 Bengaluru (India) | **Website:** www.dqsglobal.com

### GOOD CLINICAL PRACTICE- Online training

***NIDA Clinical Trials Network*** [ 9 Jun 2022 ]

**Address:** Not Applicable , | **Website:** https://gcp.nidatraining.org/

### Training - ISO 14155:2020

***Landmark Research & Academy*** [ 22 Feb 2022 ]

**Address:** D1003, The First commercial complex Behind ITC Narmada Hotel Behind Keshav Baugh Party Plot, Vastrapur, 380015 Ahmedabad (India) | **Website:** https://landmarkcro.com/

### Training on - ISO 10993-1:2018

***GLR Laboratories Pvt Ltd*** [ 18 Feb 2019 ]

**Address:** ibis Navi Mumbai D 266, Ttc Industrial Estate, Turbhe, 400705 Mumbai (India)

### Master in Clinical Pharmacy

***Shri Sarvajanik Pharmacy College*** [ Sep 2011 – Aug 2013 ]

**Address:** Mehsana Shri Sarvajanik Pharmacy College, , 384001 Mehsana (India) | **Website:** http://sspc.edu.in/

### Bachelor of Pharmacy

***B. M. College of Pharmacy*** [ Sep 2008 – Jun 2011 ]

**Address:** BMEF Campus Bharthana Road, Vesu, 395017 Surat (India) | **Website:** http://bmbba.bmefcolleges.edu.in/

## LANGUAGE SKILLS

**Mother tongue(s):** Gujarati

**Other language(s):**

### Hindi

**LISTENING** C2 **READING** C2 **WRITING** C2

**SPOKEN PRODUCTION** C2 **SPOKEN INTERACTION** C2

### English

**LISTENING** B2 **READING** C2 **WRITING** B2

**SPOKEN PRODUCTION** C1 **SPOKEN INTERACTION** B2

*Levels: A1 and A2: Basic user; B1 and B2: Independent user; C1 and C2: Proficient user*

## DIGITAL SKILLS

Microsoft Office / Google Drive / Social Media / Outlook / Microsoft Video Editor / Video meetings and conferences / onedrive / ·Adobe Photoshop ·PhotoScape

## DRIVING LICENCE

**Driving Licence:** AM

## CONFERENCES AND SEMINARS

[ 15 Sep 2022 – 17 Sep 2022 ] Coimbatore

**Annual Conference of Indian Arthroscopy Society**

Link: https://indianarthroscopy.co.in/

[ 5 Feb 2016 ] Ahmedabad

**Workshop on International Business - EEPC India**

Link: http://www.eepcindia.org/

[ 11 Dec 2009 – 22 Dec 2009 ] Ahmedabad

**Indian Pharmaceutical Congress**

Link: https://www.scientificipca.org/

## PROJECTS

[ Jul 2012 – Aug 2013 ]

**Comparative Evaluation Of Antimicrobial Activity Of Oral Clavulanate Containing B-Lactam Antibiotics Against ESBL Producing Microorganisms** It was a Master Degree thesis project on In vitro Comparative Evaluation Of Antimicrobial Activity Of Oral Clavulanate Containing B-Lactam Antibiotics Against ESBL Producing Microorganisms At Civil Hospital, Ahmadabad.

## MANAGEMENT AND LEADERSHIP SKILLS

**Relationship building, Innovation and creativity, Employee motivation, Decision-making, Conflict management.**

## ORGANISATIONAL SKILLS

**Strategic planning, Analytical thinking, Setting goals, Time management, Decision-making**

## HOBBIES AND INTERESTS

**Art & Craft, Reading, Listening music**

## COMMUNICATION AND INTERPERSONAL SKILLS

**Awareness, Caring about other people, Collaborating and working well together with others, Clear communication skills, Conflict management and resolution skills, Constructive feedback**

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*I hereby inform herewith that the above information is to the best of my knowledge. I assure that I'll be fully dedicated and co-operative in every aspect.*

Ahmedabad, Gujarat, India., 25 Jun 2024

Rashmi Godeshwer