



BHANU MELVIN

M.Pharm - RA /PV/ Clinical SAS

About Myself

Skills & expertise

- SFDA, JFDA, MoIAT, Montaji, SASO, ECOSMA, Saber, ESMA.
- CDSCO - Sugam portal.
- ISO 9001 : 2015
- Regulatory submissions.
- ICSR, Medra, Argus, CTD & eCTD.
- Narrative writing.
- ICH - GCP guidelines.
- Clinical SAS Base & Advanced.
- SQL.
- SAS ODS.
- CDISC SDTM IG, Adams,
- EU MDR
- Lean Six Sigma Black Belt

Certifications

- Pharmacovigilance & RA certified.
- Lean Six Sigma Black Belt Certified.
- Clinical SAS (Ongoing).

Journals Published

Simultaneous Determination And Validation Of Nebivolol And S-Amlodipine By Zero Order Derivative And First Order Derivative Method In Bulk Drug And Pharmaceutical Formulation

I am a detail oriented, optimistic, agile thinker and a perennial learner with 7+ years of International experience, who would intend to build a career with a leading corporate of hi-tech environment having committed and dedicated people, helping me to explore and take-up challenging new tasks and be a key player in contributing to the firm and myself.

Contact

- ☎ +91 8714040888
- ✉ bhanumpharm548@gmail.com
- 📍 Trivandrum, Kerala, India.

Experience

CLINICAL SAS TRAINING 2023-2024 BCRI, BANGALORE.

- Training for Base & Advanced SAS programmer. Fundamentals of SAS. writing programmes and application of SAS graphs, SAS Stat, Macros, reporting.
- Thorough knowledge and training on CDISC, SDTM IG, ADAMS.

REGULATORY AFFAIRS & QA SPECIALIST 2021-2023 TRUCARE FZC, UAE.

- Submission of regulatory documents.
- updating new regulatory changes as per GCC regions.
- Liaising and coordinating with various regulatory bodies like SFDA, JFDA, MoIAT, ESMA, DUBAI MUNICIPALITY, MOHAP, DHA, SASO.
- Leading meetings with International clients wrt regulatory requirements for GCC the region.
- Updating domain knowledge by attending seminars and webinars by various CB's like SGS, Intertek, QIMA.
- Registering cosmetics and food supplements, medical devices under respective regulatory bodies.
- Tracking the renewal of various certifications.
- Taking part in factory audits of various manufacturing units.
- Ensuring proper labelling and storage of various products like cosmetics, medical devices, dietary supplements.
- Obtaining certifications for TOYS, LVE, FCM, COSMETICS, DIETARY SUPPLEMENTS, TEXTILES.

MOTHERHOOD BREAK 2019-2020

Languages

- English
- Telugu
- Hindi
- Malayalam
- Kannada
- Tamil

Reference

- Ms. Pooja Suryavanshi
Group HR Manager
Trucare FZC
United Arab Emirates
+971 589745984
poojasurya84@gmail.com

HEALTH INSURANCE APPROVALS OFFICER 2015-2019

- To prepare the price list as per the CPT and CDT codes.
- To contact various insurance companies and to negotiate for the empanelment.
- To prepare protocols as per the individual companies.
- To handle the Insurance- Interpretation and processing claims on day- to-day basis dealing with Insurance companies and TPA'S.
- Familiar with E-claim link submission, resubmission, conciliation,
- and reconciliation of the claims.
- Taking approvals as per the policies with respect to diagnosis and conditions.
- To effectively manage ensuring maximum profitability of the business unit.

ASSOCIATE PROFESSOR 2012-2014 ACHARYA B.M REDDY COLLEGE OF PHARMACY , BANGALORE.

- To prepare Lesson plans and educate students with university allocated syllabus as well as up-to-date developments in the field of Chemistry.
- Conducting lab practical.
- Develop hands on expertise in doing various lab practical.
- Evaluate students and plan for individual development.
- Prepare and provide notes for easy learning.
- Giving assignments to check on individual skills.
- Conduct and give PPT's and take seminars for updating with new skills and recent developments in the field of Pharmacy.

Education

2010-2012 **Master Of Pharmacy**
Rajiv Gandhi University of Health Sciences

2006-2010 **Bachelor's of Pharmacy**
Rajiv Gandhi University of Health Sciences

Declaration

I hereby declare that the information furnished above
is true to the best of my knowledge.

 BhanuMelvin.