

Curriculum Vitae

Ameena Bi

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Career Objective:

To be associated with a progressive organization & work with an urge to learn and willingness to perform with a team that would help me nurture my professional skills and contribute to its growth.

Academic Profile:

Qualification	Institute	Aggregate	Year of passing
S.S.L.C	Good Shepherd convent, Mysore	80.48%	2007
P.U.C (PCMB)	St. Philomena's college, Mysore	55.00%	2009
BSc (CBZ)	Maharanis science college, Mysore	81.07%	2013
MSc (Chemistry)	Manasagangotri, Mysore	73.49%	2015

Research:

Dissertation done on 'Powder XRD studies of Antidepressants' In partial fulfillment of MSc Chemistry course, submitted to University of Mysore.

Training and Certification:

Medical Transcription.

Work Experience: 3.11 Years

SENIOR DRUG SAFETY ASSOCIATE

Bioclinica India Pvt Ltd - Mysore

<https://www.bioclinica.com>

Feb 2016 to Dec 2019

Roles and Responsibilities:

- Subject matter expert for multiple projects.
- Review and validate if medical information provided by the representative is correct as per the FAQ, SRL and product labeling.
- Perform checks for consistency, accuracy and completeness of information documented.
- Providing feedbacks regarding the errors and other quality improvement measures.
- Responsible for handling escalation calls for US process, related to adverse events, medical information, and product complaints and for book-in of cases received by all source types (phone call/email/fax/mail) into ARIS-g.

- Serve as a backup for handling calls for US process, related to adverse events, medical information, and product complaints.
- Thorough understanding of use of FAQs and product labeling for handling medical queries.
- Involved in case distribution and work allocation to the team in accordance with resource availability.
- Handling of mailbox, ensuring the collection of follow up information and queries are resolved.
- Perform follow via Telephone contact, Email, and fax with consumers/HCP's
- Responsible for initiating replacement or refund by following up with the pharmacy.
- Responding to clients in a timely manner (attending weekly meetings and preparing MOM).
- Working knowledge of major safety database system (Arisg 5.0 and 7.2.1).
- Duplicate check and creating AE/ PQC/ MI cases/ queries in Respective database (ARISg/ Track-wise/ IRMS).
- Triaging of the literature, spontaneous, and solicited cases as a triager and determining the validity of the case and seriousness and acknowledging the same to the client.
- Case processing of individual case safety reports (ICSR) of serious and non-serious cases.
- Good knowledge of medical terminology.
- Responsible for following good documentation practices while completing AEM form.
- Product and event coding.
- Narrative writing.
- Assist with AE, PQC and MI reconciliation.
- Engaged in conducting periodic training sessions and huddles.

Work Experience: 7 months

QUALITY CONTROL

LifePharma FZE - Jabel Ali, Dubai

<http://www.lifepharmafze.com>

March 2020 - Present working

Roles and Responsibilities:

- Preparation and revision of specification and standard test procedures of raw materials and packaging materials and stability.
- Preparation and revision of specification and STP of intermediate, semi-finished, finished products, and stability.
- Preparation of certificate analysis.
- Preparation and revisions of general test procedures and general test procedures.
- Preparations of miscellaneous documents like summary reports, trends, etc. for implementation of new policies and practices and in response to regulatory/client queries
- Testing and implementation of new SAP procedures which include preparation of system requirement specification, risk assessments, and operational and performance qualification.
- Preparation and attachment of inspection plans in SAP doe result recording of batches, generation of COA, and subsequent batch release.

- Uploading of all documents (STPs and SOPs) in SAP for approval and reference.
- Initiation of change controls, deviation, and CAPA (For QC) monitoring and closure.
- Execution of miscellaneous QC related SAP procedures
- Preparation and validation of excel sheets for analytical calculations.
- To follow good laboratory practices (GLP) in the laboratory.

Seminars attended:

- National conference on 'Pure and Applied Chemistry'
- One day national seminar on 'Chemistry and Chemical biology'

Key and Technical skills:

- Strong interpersonal skills, adaptive, willingness to explore
- Excellent written and verbal communication skills
- Quick learner and positive thinking
- Leadership skills
- Time management skills
- MS Office Suite: MS Word, MS Excel, and Power point
- Typing skills: 52 wpm

Awards :

🏆 Pillar of Strength Award 2018

🏆 All-rounder Q4 Award 2019

🏆 Listed as key employee in business continuity plan and took role as and when required.

🏆 Received appreciation from client for maintaining quality

Personal Information:

Date of Birth : 18th July 1991

Nationality : Indian

Passport number: Z4153960

Visa Type : Residence

Residency No : 201/2020/3114960

Marital Status : Married

Languages : English, Hindi and Urdu

Hobbies : Shopping, Playing shuttle, watching movies, travelling and listening to music

Declaration:

I hereby declare that the above furnished details are true to the best of my knowledge and consideration.

Place: Dubai

Date: 05-09-2020

Signature,
(Ameena Bi)