

CURRICULUM

Name : Manish Sharma
Quality Assurance (IPQA & QMS)

E-mail I.D.: Sharmamanish207@gmail.com
Contact No.: 08460134579
08153909334

Carrier Objective

To seek a challenging position in progressive organization that gives me the opportunity to utilize my skills, knowledge and experience. To enhance the comprehensive and strategic understanding of pharmaceuticals dosage forms.

Professional Experience:-

Total 6.2 years working experience in Quality Assurance in Pharmaceutical formulation and expertise in the IPQA and QMS of Solid oral formulation.

Work Experience

- ❖ Currently working at Alembic Pharmaceuticals Pvt Ltd, Panelav , Baroda as a QA Executive from 23 Aug 2018 till Now.
- ❖ Worked at Zydus Cadila Healthcare Limited, Moraiya, Ahmedabad as a QA Executive, from April 2013 to 18 Aug 2018.

Educational Qualification

- ❖ Bachelor of Pharmacy from Shree Swaminarayan College of Pharmacy (GTU), Kalol (Gujarat) in year 2012 with first division.
- ❖ Diploma Pharmacy from S.M.K.T.M Diploma Pharmacy College (Atkot) Rajkot in year 2009 with first division.
- ❖ Higher secondary school (12th) from G.S.H.E.B (Gujarat Board) in year 2007 with 54.80%
- ❖ High secondary school (10th) from G.S.H.E.B (Gujarat Board) in year 2005 with 75.43%

Area of interest:-

IPQA, QMS, CQA, DQA.

Current Job Profile

- ❖ Responsibilities in IPQA on shopfloor:-
 - ✓ Responsible for stage wise review of executed batch manufacturing record (commercial and exhibit) and batch packing records.
 - ✓ Monitoring of cGMP compliance on shopfloor.
 - ✓ Responsible for Line clearance at different processing and packaging stages.
 - ✓ To draw in-process sample, finished sample, control sample, QP sample, Stability samples, Purified Water Sampling, Swab samples as per SOP or any other requirement.
 - ✓ To monitor Process validation batches & collection of samples as per approved process validation protocol.
 - ✓ Handling of shopfloor issue on day to day basis.

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- ✓ Verification and Calibration of IPQA instruments.

❖ Responsibilities in QMS activity:-

- ✓ Responsible for preparation and review of Annual Product Quality Review.
- ✓ Performed the statistical evaluation and assessment of product through Minitab software.
- ✓ Preparation and revision of SOP in Documentum software.
- ✓ Responsible for approval of master batch manufacturing and master batch packing records.

❖ Other functional responsibilities:-

- ✓ Gap assessment in view of actual/practice v/s SOP or any other established documents.
- ✓ Responsible for performing of QA related activities in SAP and LIMS.
- ✓ Perform the ZYTIMS activities for training updation.
- ✓ Responsible for training to new joiners and / or any system updation and SOP revision.
- ✓ Preparation of the responses related to compliance of all internal / regulatory audits.
- ✓ Interacting / Coordinate with Manufacturing, Quality control, Formulation and Development, ADL, IRA and Engineer for shopfloor and QMS activity.

Software Skill

MS-office, SAP, LIMS, Documentum and Minitab, Trackwise, Zytims.

Audit Exposure:-

- ❖ US-FDA
- ❖ MHRA-UK
- ❖ MCC-South Africa
- ❖ ANVISA-Brazil
- ❖ WHO- Geneva
- ❖ AFFSAPS/ANSM-France/Spain
- ❖ UNICEF- United Nations International Children's Emergency Fund
- ❖ NDA – Uganda
- ❖ MOH - Ukraine
- ❖ Taiwan
- ❖ Consultant Audit i. e. Lackman, Blue Point & 5-W

Personnel Profile

Father's Name : Late Shree Balkumar Sharma

Mother's Name : Smt. Kiranben Sharma

Marital Status : Married

Date of Birth : 30/11/1988

Nationality : Indian

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Caste : Brahmin

Language : English, Hindi & Gujarati

Hobbies : Songs listening, playing Cricket, Chess and Reading Novels.

Personal Attributes : Mobility for any new location

: Work well under pressure to meet given deadlines.

: Team building and leadership quality

: Enjoy working as a part of team

: Personal qualities of honesty, reliability and amiability

Rewards, Certification and Extra Curriculum Activities:

- ✓ First prize in inter College project fair for Microchip Based Drug delivery system at Degree pharmacy Level.
- ✓ Actively participate in many other inter school and inter collage competition.
- ✓ Participated in Novel Drug Delivery System at Jetpur pharmacy college.
- ✓ Rewarded as the Man of Match during Cricket Championship at diploma Pharmacy Level.

Permanent Address:

Manish Sharma

Plot No.139, Vinod Park Society B/H Shalvi Flat, Jashodanagar,

Ahmedabad, Gujarat,

Pin code — 382445

Declaration:

I have declared that above mentioned information are true and best of my knowledge and if any information is found false than terminate me without any intimation.

Thanking you

Sincerely

Manish Sharma
