

From,

Permanent Address:

Anil Umarethiya

At:Bhalgam (Mota)

Tq:Visavdar

Dist:Junagdh

Post:Bagasara-365440

Gujarat.

Email : Umaretiaanil@gmail.com

: Anilumaretiya@yahoo.com

Mobile : **7670955649**

To,

Subject:- Application for a suitable position in **Quality Assurance-Qualification,CSV/CSA, IT-QA, CQA, QMS and IPOA** department in your esteemed organization.

Respected Sir/Madam,

With reference to the above cited subject, myself, ANIL UMARETHIYA here by enclosing my Curriculum Vitae for your kind perusal. Hoping that you will be kind enough to consider my candidature, I promise to give my very best effort to uphold the name and dignity of realistic organization in your leading function. Kindly consider my candidature for the same.

Thanking You.

Place: Ahmadabad, India

Yours Faithfully,

ANIL UMARETHIYA

Curriculum Vitae

➤ Personal Detail:



ANIL UMARETHIYA

**Father : Mr. RAMESHBHAI
UMARETHIYA**

➤ Present Address:

Flat no: C-403

Gajanan & Sanidhya park,

Opp.Uma School,

Nikol-382350

Ahmedabad,Gujarat

Mobile no: 7670955649

Office no: 8511154618

➤ E-mail:

: Umaretiaanil@gmail.com

: Anilumaretiya@yahoo.com

➤ Personal Data:

DOB : 26th June '1988
Gender : Male
Nationality : Indian
Marital Status : Married
Caste : Patel, Hindu

♣ Career Objective:

To obtain challenging career in a professionally managed organization which will take full benefit of my technical skills and give me ample opportunity to exhibit my abilities.

♣ Education Profile:

Professional Qualification:-

➤ M. Pharmacy in Quality Assurance:-

- M.M.U college of pharmacy (Ramanagara)
- Affiliated To Rajiv Gandhi University Of Health Sciences (RGUHS),
karnataka

Qualification	University	Percentage
D.PHARMACY 1&2	KARNATAKA EDUCATION BOARD (Karnataka)	70.90% & 66.60 %
S.Y.B.PHARMAC Y	RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCE, BANGALORE (Karnataka)	74.00 %
T.Y.B.PHARMAC Y		76.50%
FINAL B.PHARMACY		77.50%
M.PHARMACY		80.50%

➤ M. Pharmacy Project:-

- Simultaneous estimation of albendazole and ivermectin using
reverse Phase-HPLC.

➤ H.S.C.:

Shree Sardar Patel education trust, mandavad sankul.

Gujarat secondary and Higher secondary Education Board
(G.S.H.E.B.), Gujarat.

**Percentage 57.80%,
YEAR-2005.**

➤ S.S.C.:

Middle School of Bhalgam- Junagdh

Gujarat secondary Education Board (G.S.E.B.), Gujarat.

**Percentage 61.57%,
YEAR-2003.**

♣ Area Of Interest:

Quality Assurance-Qualification & CSV/CSA,QMS and IPQA

Languages Known:

English, Hindi, Gujarati, Kannad.

Hobbies:

Reading Books, Magazine, News paper, and interacting with the people.

Strengths:

- Excellent skills in communication and collaboration
- Positive Thinker
- Leadership, dedicated to work
- Qualitative Decision Making
- Highly Inquisitive
- Creative and Resourceful
- Passionate for learning and personal growth
- Create excellence in work
- Encourage team to work and Manage team work
- Build up ownership of work
- Encourage to build up cross functional bridge

♣ Experience:

10.8 Year in QA (Qualification of Injectable and CSV/CSA for OSD, Non-OSD, ANT including QC Laboratory, Utility and Warehouse, Server and Infrastructure, Engineering Quality etc.)

♣ Current company and Designation: January-2016 to till date.

Zydus Lifescien, USFDA approved Facility, Moraiya, Ahmedabad-
Deputy Manager-Quality Assurance (CSV & Qualification.)

♣ Carrier exposure of activity from 21/06/20 to till date :

- Legacy Equipment GAP Assessment and GAP Mitigation as per GAMP 5 and 21 CFR PART 11 as well EU annexure 11.
- SCADA Based Equipment CSV deliverables preparation, review as approval and PLC/HMI validation as per GAMP5 guidance also ensure consistency through periodic review.
- Software like chromeleon 7.2, Trackwise, Lab Solution etc.
- Software Supplier Assessment and ER-ES applied on GxP system.
- Data Audit Trail and System Audit Trail implementation on SCADA based equipment as well all manufacturing GxP system.
- Different project handling like CLEEN 4.0 for cleaning.
- Eminence Business Media's Virtual Conference on **"2nd Annual Computer Software Assurance 2022"**- Applying CSV and Transiting to CSA Compliantly attended.
- **Injectable- Qualification and Validation:-**
 - **Preparation, Execution and Review of Validation Protocol and Summarized Report including system release:-**
 - **Equipment Qualification (Manufacturing and Packaging)**
 - ✓ Steam air sterilizer (Autoclave-Component & Terminal)
 - ✓ Washing machine and Depyrogenation tunnel,
 - ✓ Filling machine and Capping machine,
 - ✓ Lyophilizer,
 - ✓ Manufacturing tank,
 - ✓ X-ray machine for dry powder cake particle evaluation,
 - ✓ Bonfiglioli for leakage, Brevettie Inspection machine etc.
 - Smoke pattern evaluation: - Protocol preparation, planning, co-ordination, execution & review and protocol summarized for Smoke Study at static and dynamic condition with aseptic practice
 - **HVAC Systems Qualification:-** Protocol preparation, planning, co-ordination, execution & review & protocol summarized as a **Subject Matter Expert in Hospira a Pfizer company for HVAC validation** :- AHU Qualification, Area Qualification, LAF, UDF, Dynamic Pass Box, Mobile Trolley etc.
 - Air handling unit-DQ, FMEA, IQ, OQ, PQ and PRQ.
 - **Subject matter expert in Zydus moraiya facility for Aseptic Process simulation**: - Media fill protocol preparation, BMR preparation and Executed BMR review and compliance, Protocol compilation and summarized aseptic process simulation and facility release as per cGMP requirement CQ implementation in all injectable manufacturing facility.
 - **"Filter validation and sterile filtration of complex injectable"** Aseptic forum attended as a SME.

Key Skills:

- Familiar with computer software like Fundamentals of Computer, MS-Office, Excel, Windows XP, Internet networking, Thermal validation software, ISO-train, Zytims, Trackwise etc.
- Ability to work as a team player as well as an individual with excellent communication skill with Leader/Superior/Corporate Leader as well cross functional team.

- Utilities Qualification of Compressed air, PW, WFI & PSG distribution system, Nitrogen gas, Online Non-viable and Viable monitoring system and area recovery study.
- Preparation and review and updation of Validation Master Plan.
- Change Control initiation in Trackwise, impact assessment and approval of change control, Deviations and CAPA, Action item, Extension handling in trackwise as per management commitment
- Regulatory audit faced with USFDA (Directly exposure with FDA Auditors like Mr.Thomas Arista, Mr. Pitter Bekar as a SME), MHRA, ANVISA, TCI, ANVIMA, MCC, Mexico, NDA Uganda, NSF and CDSCO.
- Conduct internal audit in manufacturing facility and utility floor and vendor audits for third party manufacturing and GAP analysis in system v/s CQ policy, SAT, FAT, Quality MOM Handling.
- VMP, Facility and documents of validation update as per CGMP requirement and current industrial guideline.
- Preparation and review of SOPs and SOP GAP Implementation.
- Risk assessment, Rational preparation for validation approach.
- Cleaning and Process Validation.
- Handling of Engineering QA,IT & CSV for OSD and NON-OSD.

♣ **Thermal and Analytical Instrumental knowledge:-**

- ▣ **Kaye validator, HTR, CTR, LTR, IRTD, Kaye Val probe for emulsion product sterilization.**
- ▣ **HPLC, LPC, UV, Malvern Master Sizer.**
- ▣ **Auto titer, Polarimeter, pH meter, conductivity meter**
- ▣ **Total Organic Counter (TOC)**
- ▣ **Aerosol photometer, Contact smoke study**

♣ **Software Undergone:-**

- ▣ **Kaye validator ,TrackWise, Documentum (D2), IMS**
- ▣ **ISO-train & Zytims as a Training coordinator in Moraiya.**

♣ **Past Company Exposure :**

- **Hospira(A Pfizer company) PVT. Ltd,** USFDA approved Facility, Visakhapatnam, Andhra Pradesh, Junior Executive.
From: -January-2014 to December-2015-QA Validation
Worked in **New Green Field Project HVAC and Utilities Qualification** as a subject matter expert.
- **Claris Lifesciences Limited,(Injectable plant)**
(Recently known as Baxter) Ahmedabad-Officer
From: -January-2012 to December-2013-QA Validation
All Equipment Qualification including Thermal Validation and Mixing, SIP, CV and PV, Sample Analysis and calibration etc.
- **Mackur laboratories Limited (Injectable),** Ahmadabad,
From: -August-2011 to December-2011 **Quality Assurance**.
The above information stated by me is true as per my knowledge.

Thanking you.

**Yours faithfully,
ANIL UMARETHIYA**