

**Name:** Ankith Kumar

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### **Career Objective:**

Highly motivated and seeking to utilize my Pharmaceutical development experience in regulatory affairs to apply learned concepts and experiences to contribute in organisation's growth with continuous improvement.

### **Education**

<b>Duration</b>	<b>School/ University</b>	<b>Degree</b>	<b>Grade</b>
06/2017 - 05/2019	SRM Institute of Science and Technology, Kattankulathur, Chennai.	M.Pharm (Pharmaceutics)	First Class (9/10)
07/ 2013 - 04/ 2017	SRM Institute of Science and Technology, Kattankulathur, Chennai.	Bachelor of Pharmacy	First Class (81%)
04/ 2012 - 04/ 2013	Bethel Matriculation Higher Secondary School, Chennai.	12 <sup>th</sup> Higher Secondary Examination Certificate (HSC)	First Class (86%)

**Languages:** Fluent in English, Hindi and Tamil.

**Present Work Experience:** 2.5 Year (April 2019- Till date) in **PAR Formulations, PVT LTD-(An ENDO International) Pharmaceutical company manufacturing site-Chennai.**

**Job Profile:** Technical Service and Validation – Research Associate  
**Primary Resonsibilities (CMC – Oral solid dosage unit)**

- ✓ To analyze the shared eCTD modules for site transfer products and to evaluate the information with respect to product criticality and solve the predicted complexity issues.

- ✓ To review the technical documents received from manufacturing site such as product development report, Batch manufacturing record, specifications, method validation and to evaluate the gap analysis and present the data with respect to required type of filing (CBE 30), Prior approval supplement
- ✓ To support the required document for any CRL query with respect to manufacturing process
- ✓ To request documents from site function as required
- ✓ To assess and raise the required change control with CFT impact assessment
- ✓ To Scale-Up the site transfer product in large scale aspect by understanding the product background and criticality
- ✓ Responsible for meeting the timelines for Product launches/ PPIC requirement
- ✓ To understand the trend of impurities and hazards with respect to stability issues in finished product
- ✓ To prepare investigational report for the deviation and incident observed in the process and to provide scientific justification with appropriate CAPA (Corrective and Preventive Action)
- ✓ Preparation and evaluation of, Protocol / Report for trial batches, Batch manufacturing record, Hold time, Cleaning verification, Split study.
- ✓ Preparation of documents required for CBE 30 regulatory filing of product and to respond the regulatory queries from FDA for approval of product
- ✓ On requirement, Lab trial execution for process understanding or product behavioural studies
- ✓ Execution of Submission Batch/ Process optimization, Trial batch, Scale up and Validation Batches

### **Secondary Responsibilities**

- ✓ Preparation & Evaluation of data using MS word, Excel, PowerPoint
- ✓ Planning and presentation of reports/ Gate meeting with cross functional teams for future process and development
- ✓ Understanding and evaluating the process parameters during development
- ✓ To Validate the process and equipment
- ✓ Co-ordination with cross functional team for planning and execution of batches
- ✓ Involvement and supporting intended proposals required for the company

### **Experience gained in Previous Organization**

- ✓ Familiar with documents required for submission batch filing
- ✓ Established Capability of Individual Project Handling
- ✓ Developed skill for supporting the process development to the operation groups for manufacturing
- ✓ Collaboration with process development, Operational process, Quality control, Quality assurance in project meetings
- ✓ Recognition of common source of failure and improve documentation to reduce deviation and error

**Past Work Experience:** Part Time in Retail pharmacy (Chennai)

**Job Profile:** Pharmacy Assistant (May 2016- May 2018)

- ✓ Experienced in detailing the benefits and features of the medicinal product
- ✓ Management of sales and Purchase of SKU as per the requirement
- ✓ Experienced in dealing with healthcare professional and customer
- ✓ Billing and Filing of data
- ✓ Alternative approaches to satisfy the customer
- ✓ Developed strategy to increase the sale
- ✓ Hands on experienced in dealing with medicines

**Skills:**

- ✓ Intermediate Knowledge of MS word, Excel, PowerPoint
- ✓ Ability to grasp new concepts quickly and efficiently
- ✓ Better efficient skills in data management and statistics
- ✓ Decision Making
- ✓ Ability to come up with effective plans
- ✓ Self-Motivation
- ✓ Problem Solving
- ✓ Coordinating events

**Project:**

- 1) **M.Pharm Thesis(2019):** Design Space Development for Sublimating Agent in Sublimation Tablet: A DOE APPROACH
- 2) **B.Pharm Thesis (2017):** Treatment Pattern of Type 2 Diabetes Mellitus differs in rural and urban region of south India with patient's social economic position.

**Achievements:**

- Nominated and Won Best performer **“Reward and Recognition”** award for significant role and responsibility in the Technology transfer department
- Publication of review article in **International Journal of Applied Pharmaceutics** entitled **"Artificial Neural Networks: Functioning and Applications in Pharmaceutical Industry**
- Won second prize for Oral Presentation on my project entitled **“Design Space Development for Sublimating Agent in Sublimation Tablet: A DOE APPROACH”**2019 held at SRM Institute of Science and Technology

- Participated in the workshop on "QbD Case Studies: An Integrated Multivariate Approach in Drug Product and Process Development" in 2018
- Won second prize in Dumb Charades in World Pharmacist Day Silver Jubilee Program 2018 held at SRM Institute of Science and Technology

#### **Hobbies and interests:**

- ✓ Solving puzzles, Traveling, cycling, organising things, volunteering, Theatre.

#### **Extracurricular activities:**

- ✓ Actively Participated as a delegate in National and International seminar in the field of Pharmaceutics, Pharmacology, Pharmacognosy, Regulatory Affairs.
- ✓ Actively volunteered in activities held at SRM University, Kattankulathur, Chennai.

#### **Declaration:**

I acknowledge that above given information is correct to the best of my knowledge and belief.

Date: Nov - 2021

Place: Chennai

A handwritten signature in black ink, consisting of several loops and a horizontal line.

Signature: