Name: MOHAMMED FAIZAL M

Stream: M PHARM (PHARMACEUTICS), PGD Regulatory Affairs

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CAREER OBJECTIVE

To be associated with a progressive organization that provides an opportunity for a challenging and rewarding career by applying my knowledge, skills and in this profession. I would like to make positive contribution towards your organization with promoting team spirit and own professional growth.

PROFILE SUMMARY

I believe that logical thinking and organization qualities are my greatest procession. Ability to deal with people to grasp things fast and willingness to work always has been my strength. I can apply my knowledge, skills and attitude to maximum and with dedicating to achieve organizational skills.

ACADEMIA

Course of Study	Year of Passing	Institution	Percentage
PG Diploma in Regulatory Affairs	May, 2020	JSS Academy of Higher Education and Research, Mysuru, Karnataka	78
M. Pharmacy	May, 2018	JSS Academy of Higher Education and Research, Mysuru, Karnataka	8.81 (C.G.P.A)
B. Pharmacy	Aug, 2015	P.S.G. College of Pharmacy, Coimbatore, Tamilnadu.	69.2
Higher Secondary	May, 2011	St. Michael's Hr. Sec. School, Coimbatore, Tamilnadu.	62.5
10 th	May, 2009	St. Michael's Hr. Sec. School, Coimbatore, Tamilnadu.	75.8

WORKING EXPERIENCE

Experience of 2 Years 7 months in Regulatory Information Management System (RIMS) in Aris Global Software Pvt. Ltd.

Company Name	Duration	Tenure of Job
Aris Global Software Pvt Ltd.	2 Years 8 months	23.07.2018 to till date

JOB DESCRIPTION AND EXPERIENCE

• Worked as Associate Consultant in roles in business services with focus on Computerized System Validation (CSV) engagements for life sciences clients.

- Good Knowledge in RIMS tools like LS-RIMS and Register application functionality, especially in the system configuration, security model defining, xEVMPD submission and Local Affiliate Model Defining.
- Experienced in cGMP/GAMP, 21 CFR Part 11 Regulation specific to computer system validation
- Hands on experience in creation of Validation Documents like Validation Plan, Protocol, OQ's, PQ's, and Summary Report.
- Hands on experience in preparation of **SOP** (**DISP**), Work Instructions and Business Process documents.
- Experienced in Detailed business knowledge on the "xEVMPD" guidelines and submission for drugs, cosmetics and devices
- Ability to planning execute Validation Activity like the CSV document authoring and execution.
- Good Knowledge in the HP QC ALM tool to authoring and executing validation activity.

PROJECT RELATED EXPERIENCE

- **Register** and **LSRIMS** are the world's leading Regulatory Software system for IDMP and xEVMPD submission to EMA, mostly Used by Pharmaceutical and Device Companies, with more than 200 companies maintaining their critical drug.
- Worked with more than 10 customers on the Go-Live Activity from the Development to Production Environment setup.
- Helped closely Quality Compliance Team for reviewing Validation Documents.

Tools Knowledge: JIRA (for defect tracking), HPQC ALM (testing tool), Register, LSRIMS

STRENGTH

- Organizing, Leadership Quality, Punctuality, Dedication and Hard Working.
- Ability manage and execute the work by efficient way.
- Adaptable character and ability to work for long hours with presence of mind.

LINGUISTIC SKILLS

English and Tamil

ACADEMIC ACTIVITIES

• Project Handled

Worked on and submitted a project "Development of Robust Process for Antipsychotic Drug Immediate Release Dosage Form by QbD Technique" during master.

Worked on and submitted a research project entitled "Synthesis of Azetidine-2-One Derivatives" during graduate.

• Industrial Training / Experience

Undergone internship in Formulation Development Department at 'Strides Shasun Pvt. Ltd., bangalore, Karnataka' during 19th July, 2017 to 31st January, 2018.

Undergone internship in Quality Control Department at 'Hospira Healthcare India Pvt. Ltd., Chennai, Tamilnadu' during 12th May, 2015 to 22nd May, 2015

CO-CURRICULAR ACTIVITIES

- Dancing, Athletic Events.
- Participated as team leader in own college sports and cultural meet.
- Participated as one of member in National Service Scheme.

CO-CURRICULAR ACHIEVMENTS

- Successfully participated and effectively organized cultural event in college and achieved 'Best Outgoing Student of 2011 Batch for Cultural Events'.
- Successfully achieved 2nd place in group dance held at district level cultural event.

	I solemnly declare that statements made by me are correct to the best of my knowledge
and belief.	

	Mr. Mohammed Faizal M
	Signature
Place:	
Date:	