CURRICULUM VITAE

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OBJECTIVE: To lead Pharmaceutical Organization and excel by making mark in industry, profession by utilizing innovative ideas, technical skills and abilities to achieve organizational and individual goals.

PROFILE: A profile with more than **24 years** of blended strong **e**xperience in **pharmaceutical manufacturing / packing,** and **Quality Assurance Activities withexposure to regulatory audits.**

Capabilities to lead Plant Operations and teams

Experienced in complete OSD formulations, Liquid orals, Creams & ointments, Ophthalmic ointment, Soft gelatin caps, ENGG and QC / QA activities

Knowledge of scale up , validation / execution of site transfer, Exhibit batches Troubleshooting , handling ofVariations , deviation in line with regulatory requirements.

Core Competence: Manufacturing of Solid orals tablets/capsules, pellets & Liquids, Injections , Handling of projects / Quality management system, Audits & Compliance

POTENTIAL STRENGTH:

- **Experience as a Block head / Plant In charge and ability to work in a team as well as individual.**
- **Good knowledge of inter departmental activities of QA , QC , ENGG, PDL, SCM, PPIC & HR s**
- Professional , honest & ethical in building long term relationships with all levels of management.
- Innovative perseverant, motivating supportive & accommodative
- Experienced In MFG, Packing, Tech transfer, projects , trainings and Compliance

M S PROJECT: F & D & Evaluation of Anxiolytic Drug Buspirone HCl Tablets (Dividose tablet)
Approved Chemist in liquids and solid orals department

EDUCATIONAL QUALIFICATION DETAILS:

Sl No	Degree	University	Grade
1	Master of Science (Pharma Operations & Management)	BITS Pilani	CGP 7.50 / 10
2	B Pharmacy	Gulburga university	First Class
3	D Pharmacy	Board of Examining Authority	Second Class
4	SSLC	Secondary School Board Karnataka	First Class

Brief Experience Summary

Name of company	Designation	Period	Formulations handled
Eris Therapeutics Limited Ahmedabad	Production Head **(MFG / PKG)**	AUG 2022 to till date	Tablets, Hard gelatin capsules , liquids and Liquid Injections.
Evertogen Life science Jadcherla Telangana	AGM Production **MFG/PKG**	July 2021 to April 2022	Tablets, Hard gelatin capsules , powder and Sachets filling.
Aric Health care Pvt Ltd Vishakapatnam	Pharma consultant	April 2020 to June 2021 (1yr 2 Months)	Pharma Greenfield project and systems setup for OSD
VKT Pharma Pvt Ltd Vishakapatnam	AGM Production **MFG /PKG**	23.03.2017 to March 2020 (**3yrs)**	Tablets, Hard gelatin capsules and pellets
Aurobindo Pharma Ltd Hyderabad	Manager Production **MFG**	07.10.2013 to 31.01.2017 **(3 yrs 4 months)**	Tablets, Hard gelatin capsules and liquids
Aristo Pharma Pvt Limited Bhopal	DY.Manager Production **MFG / PKG**	11.05.201 to 21.09.2013 (**2yrs 5 months)**	Tablets, Dry syrups & Hard gelatin capsules
Strides Arcolab Ltd Bangalore	Team Leader **MFG**	28.11.2007 to 06.05.2011 **(3 yrs & 6 months)**	Tablets & capsules
M/s. Medreich Ltd Unit I Bangalore	Senior Executive **MFG**	25/09/200 to 26/11/2007 **(1yr 2 months)**	Tablets, dry syrups & caps
M/s Kemwell Pvt Ltd Bangalore	Production Chemist MFG/PKG	28.04.2003 to 17.09.2006 (**3 yrs 5 months)**	Liquids, sterile ophthalmic ointment, Cream & ointment, Powder Dept
M/s.Anglo French Drugs & Industries Ltd., Bangalore	Jr.Executive MFG / PKG	19.02.2001 to 26.04.2003 **(2 yrs 2months)**	Tablets, Liquid orals and Powder Department
M/s.Amazon drugs Pvt Ltd Bangalore	Production chemist	19.09.1999 to 17.02.2001 **(1 yr 5 months)**	Tablets, liquid orals, capsules, and Dry syrups **(MFG/PKG)**
M/s.Crystal Pharma Ltd. Hubli	Trainee chemist	FEB 1999 to JUL 1999 **(6 months)**	Tablets, Liquid Orals and Capsules **(MFG/PKG)**

KEY SKILLS:

1. Production
   - Knowledge of planning, production, scheduling and management of workforce.
   - Performing of qualification like DQ,IQ,OQ & PQ on various equipments
   - Technique of air handling/ water system (AHU/ R.O and loop system)
   - Familiar with cGMP technique & Regulatory requirements.

- Concepts of sterilization techniques like Dry heat, moist heat, Gaseous sterilization Irradiation and sterilization by filtration.
- Basic Concepts involved in tablets, liquids, capsules, Dry syrups, injectables & semisolid dosage formulation.

2. Tech transfer & Process standardization

- Knowledge of scale up techniques , validation / execution of site transfer batches
- Troubleshooting , handling of Variations , deviation & change control during execution of EXHIBIT, SITE TRANSFER & VALIDATION batches

3. Equipments handled during the Experience

- **Manufacturing equipments:**
- **Oral solid dosage form:** Handled Rapid mixer granulator, Fluid bed drier / processor, sifter , multi mill, roll compactor , integrated granulation, tray drier , VTD , Blender (OGB, Conta blenders), RCVD, hot melt extruder, compression machine, coating machine, thickness sorter , capsule filling machine, Check weigher, inspection machine etc.
- **Liquid filling :**Mfg tanks, colloid mill, Bottle washing machine, liquid filling machine, cap sealing machine, labeling machine etc
- Injectable : Mfg tanks, Autoclave, Ampoule washing , Ampoule filling etc
- **Semisolids**. Mfg tanks, Tube filling machine, cartonators.
- **Sterile Ointments:** MFG tank, Autoclave, ointment filling machine, filling machine for DPI etc
- **Packing Equipments:** Knowledge of Blister pack machine, strip packing machine, bulk packing machine, Dry Syrup filling machine, auto cartonators et

EXPERIENCE

1. **Working as Head Production in M/s. Eris therapeutics Limited since AUG 2022 to Till date Handling Mfg of Solid oral dosage forms, liquids and Injectable.**

A) To achieve production (MFG & PKG) targets, ensure cGMP compliance, training and development of production staffs and workmen.
B) Key team member in Projects in procurement , approval of DQ , IQ, OQ and PQ.
C) Interact with SCM, warehouse, QC / QA to review monthly inventory, production plan timely release , to achieve Plan V/S actual and monthly plan.
D) Effective manpower, area and capacity utilization and monitoring of critical process and products.
E) Manufacturing of New , site transfer products , Validation batches
F) Interact with **Engg team** for requirements related to process equipments , AHU , Water system and projects requirements,

G) Interact Cross functional Team member for qualification, validation and projects team

H) Handling of QMS approve protocols, PVP, PVR, initiate & review change controls , perform internal audits.

I) To approve SOPs / BMRs / BPRs/Art works & Qualification protocol and reports.

J) Assess and minimize risk involved in manufacturing of products (QRM)

K) Key role in procurement of equipments, compression machine tools, change parts etc.

2. Worked as Assistant General Manager (Head Production) in M/s. Evertogen life science since July2021 to April 2022 (Handling MFG / PKG of Solid oral dosage forms).

JOB RESPONSIBILITIES:

A) To achieve production (MFG & PKG) targets, ensure cGMP compliance.

B) Interact with SCM, warehouse , QC / QA to review monthly inventory, production plan timely release , to achieve Plan V/S actual and monthly plan.

C) Interact with local Govt authorities like Factories inspector, Drug dept personal , Excise etc

D) Effective manpower, area and capacity utilization and monitoring of critical process and products.

E) Manufacturing of New , site transfer products , Validation batches

F) Prepare annual operating budgets **(CAPEX)** for production departments.

G) Interact with **Engg team** for requirements related to process equipments , AHU , Water system and projects requirements,

H) Interact Cross functional Team member for qualification, validation and projects team

I) Handling of QMS approve protocols, PVP, PVR, initiate & review change controls , perform internal audits.

J) To approve SOPs / BMRs / BPRs/APRs & Qualification protocol and reports.

K) Key role in procurement of equipments, compression machine tools, change parts etc.

L) Guide for investigation for OOT , OOS and failures if any and provide **CAPA** for the same. Evaluation of effectiveness of CAPA

M) Part of Internal Audit team. Conduct internal Audit / Play role of Auditee during audits.

N) Ensure shop floor compliance in accordance with ATR (Any time preparedness for audits) Provide response to observations if any.

3. Engaged as consultant for Aric health care Pvt ltd in Vishakapatnam since April 2020 to June 2021

A. Design , Review and approval of plant layout , Preparation of SMF, set up of Production, QC/ QA and Engg departments.

B. Procurement of equipments related to above departments. Approve URS, and review Qualification of equipments and instruments (DQ, IQ, OQ and PQ).

C. Set up HVAC, Water and Quality management system.

D. Training personnel on systems and procedures.

4. Worked as Assistant General Manager (Head Production Manager) in M/s. VKT Pharma Pvt Ltd Vishakapatnam since 23/03/2017 to March 2020 (Handling Mfg / Pkg of Solid oral dosage forms)

JOB RESPONSIBILITIES:

A) To achieve production targets, ensure cGMP compliance, training and development of production staffs and workmen.

B) Effective manpower, area and capacity utilization and monitoring of critical process and products.

- Manufacturing of New , site transfer products (Exhibit / Scale – up batches) formulations relating to production with other **Tech transfer and R&D**
- Prepare annual operating budgets **(CAPEX)** for production departments.
- Interact with **Engg team** for requirements related to process equipments , AHU , Water system and projects requirements,
- **Interact Cross functional Team member for qualification, validation and projects team**
- Handling of QMS approve protocols, PVP, PVR, initiate & review change controls , perform internal audits.
- To approve SOPs / BMRs / BPRs/APRs & Qualification protocol and reports.
- Assess and minimize risk involved in manufacturing of products (QRM)
- Key role in procurement of equipments, compression machine tools, change parts etc.
- Part of Internal Audit team. Conduct internal Audit / Play role of Auditee during audits.
- Ensure shop floor compliance in accordance with ATR (Any time preparedness for audits) Provide response to observations if any.

Key Achievement at VKT pahrma:

- **MFG / PKG of Exhibit batches for molecules Like Ranitidine 75, 150 and 300 mg, Leveteracetam tablets 250, 500, 750, and 1000 mg, Tadalafil 2.5, 5 , 10, 20 mg, Ranolazine 500 mg and 1000 mg, Hydroxy chloroquinine tablets, Chlordiazepoxide capsules, famotidine tablets 20 & 40 mg**
- **Received ANDA of 5 molecules 15 products &Approval for Products Ranitidine and Levetiracetam tablets**
- **Successfully shipped First three consignments (62 batches of levetiracetam tablets to USA)**
- **Key Member in 1st USFDA & 2 nd consecutive USFDA Audit site with Zero observation**
- **Faced Europe and QP audit zero observation in Production**
- **Key Role in finalizing L1, L2, L3, L4 and L5 solutions for track and trace and implementation.**

5. Worked as Production Manager in M/s. Aurobindo Pharma Ltd Unit-III and Unit-XII Hyderabad since 07/10/2013 to 31.01.2017 (Handling Mfg of Solid oral dosage forms)

JOB RESPONSIBILITIES:

1. To achieve production targets, ensure cGMP compliance, training of production personnel.
2. Interact with SCM , PPIC , QA and QC to review for monthly inventory, production plan, to achieve Plan V/S actual , OTIF (On time in full) and improve operational excellence.
3. Review formulations relating to production jointly with other **Departmental heads PDL and R&D** depending on effect on other functional areas.
4. **Interact Cross functional Team member for qualification, validation and projects team**
5. To approve SOPs / BMRs / BPRs/APRs & Qualification protocol and reports.
6. Assess and minimize risk involved in manufacturing of products (QRM)
7. Perform investigation for OOT , OOS and failures if any and provide **CAPA** for the same.
8. Investigation of Market Complaints to find the root cause and implement CAPA
9. Preparation of URS for equipments. .
10. Part of Internal Audit team. Conduct internal Audit / Play role of Auditee during audits.

11. Ensure shop floor compliance in accordance with ATR (Any time preparedness for audits) Provide response to observations if any.
12. **Exposure to WHO , UK-MHRA , TGA , MCC , GCC , ANVISA , US-FDA &** other countries customer audit

6. Worked as DY. Production Manager (Block Head) in M/s. Aristo Pharmaceuticals Pvt Limited Mandideep Bhopal since 11/05/2011 to 21.09.14 (Handling Mfg and PKG of Tablets , Hard gelatin Caps and dry syrup

JOB RESPONSIBILITIES:

1. **InCharge** of BETALACTUM BLOCK looking after MFG / Packaging of the block
2. Preparing of Daily , Weekly and monthly Mfg & PKG plan, Co-ordinating with Planning / materials for Inventory management and FP despatches
3. Monitoring of daily Production outputs and QC Sample release. Check BMR, Reviewing of Executed BMR/BPR
4. Preparation of URS , drawing approvals , preparation SOP,s etc.
5. Training Staff , Workmen regarding GMP , Process and Equipment operation
6. Monitoring of calibrations, validation and preventive maitainence activities
7. Indenting of Stereos for Coding of packaging materials
8. Exposure to WHO , African countries & other countries customer audit

Other unique skills / Achievements

1. **Started the New Betalactum Block (Greenfield project)**
2. Max Area , Equipment and Manpower utililization. (Increase Batch Size and reduce process / analysis cost)
3. Improvement in Quality / increase yield.
4. Automation , Improving of skills of workmen and reduction in manpower.
5. Applying of Scientific tools in problem solving, Trouble shooting & Decision making
6. Started low RH area / Handling of Low Humidity Betalactum Product .
7. 10 % reduction in manpower every year by Automation (Change part modification and by performing online operation. Increase in output of Megapen kid tablets by 40 %)
9. Played Key role in framing systems and preparation of Documents

7. Worked as Team Leader M/s. Strides Arcolab Limited (Oral dosage form division) Bangalore since 28/11/2007 to 06 /05/2011 in Production Process Standardization & Documentation dept

JOB RESPONSIBILITIES:

1. Validation, Execution & monitoring of EXHIBIT , SITE TRANSFER BATCHES
2. Validation of products for source change, change in equipment, change in batch size & change in area.
3. Participate in CFT , Checking of draft BMR, Reviewing of Executed BMR, compiling of Process &validation data & process standardization

Other unique skills

1. Knowledge of basic technicalities of tablet manufacturing

A)Pelletization B) Hot melt Extrusion C) Mfg of Dividose tabs D) Filling of liquid in Hard Gel caps

2. Identifying of critical control points & process standardization
3. Knowledege of procurement of equipments, idea of URS, FAT , Performing of DQ, IQ, OQ & PQ
4. Knowledge of cleaning validation, determining of worst case , matrix & bracketing
5. Knowledge of working on integrated granulation system and high end compression machine
6. **Exposure to WHO , UK-MHRA , TGA , MCC , GCC , ANVISA , US-FDA &** other countries customer audit

8. Worked as senior production Executive in M/s. Medreich Limited Unit I (Betalactum Unit I) Bangalore since 25/09/06 to 26/11/07 in dry syrup & tablets dept

JOB RESPONSIBILITIES:

- Production planning, shift management & scheduling Implementing GMP at all stages.
- Monitoring of manufacturing & filling activities of branded products for MNC like GSK, Johnwyeth etc apart from numerous own products.
- To co-ordinate with QA for the equipment & process validation.
- Worked in EOU Betalactum unit were around 30 products are mfd. In dry syrup and tablets dept. and are exported to around 80% south African countries, UK, France, Netherlands & Asian countries.
- Awareness of Building Automation System & System Validation techniques.
- Worked in plant were audits & Visits are almost part of daily activity, with exposure to UK-MHRA,TGA, MCC, GCC and other countries customer audit.

9. Worked as production chemist in M/s KEMWELL PVT LTD.Unit:BIOKEM Bangalore since 28.04.2003 to 17.09.2006 date in sterile /non sterile ointments, liquids, creams & powder dept.

Approved chemist in liquids department by FDA department of Karnataka

JOB RESPONSIBILITIES:

- Dispensing of raw/ packaging material
- Monitoring of manufacturing filling & packaging activities of branded products for MNCs like Glaxo Smithkline, wellcome Burroghs, John weyth , Johnson & Johnson, astrazeneca, Novartis, Pfizer etc.,
- Managing resources (Utilities/ Manpower) Increasing. yield/ out put, reducing cost & manpower handling.
- Training of personal regarding safety and in execution of activities as per BMR BPR, & SOP's
- Monitoring of inprocess checks and technical assistance and support in machine setting, and training of personnel in operating machine
- Participated & co-ordinate as member of team in validation activity

Other Activities

- Identification of key results area (KRA)
- Calculation of efficiency of man/machine, generation of data & its analysis
- Break down analysis of equipments & machines
- Working on different types of formulation oral drops, ear drops, nasal drops creams gels lotions shampoo, sterile & non sterile ointments & non sterile powder.

10. Worked as Quality Assurance (Production parallel QA) Jr. Executive in M/s.Anglo French Drugs & Industries Ltd., Bangalore from 19.02.2001 to 26.04.2003 in Tablets & Liquid orals

Job Responsibilities

- Sampling at all stages starting from raw materials, packaging materials, semi finished and finished products.
- Preparation of BMRs, SOPs, participate, co-ordinate and monitoring of validation and calibration activities , Perform In process checks at all stages, Monitoring of process variables.
- Timely review of master copies of MFR, BMR, BPR & SOP's all other QA documents
- Review of executed commercial batches BMR BPR & release of products for dispatch.
- Maintain control samples, stability samples and its documents
- Knowledge of operation of various machine of oral drops & tablets dept
- Incidence reporting & handling for deviation.Auditing of contract manufacturing location & documents

Other Activities

- Scaling up of pilot batch to commercial batch
- Vendor validation Handling and disposal of market complaints
- Undergone 2 days training on 6th & 7th July 2001 on latest trends in cGMP by faculty Mr. S.R. Parthasarthy, Director Ascent consultants, Hyderabad.

- Undergone 2 days training on 14th & 15th November 2002 cGMP with latest requirement under schedule M by faculty K.P. Petkar, Ujwal Prabha consultants, Nasik.

11. Worked as production chemist in M/s.AMAZON DRUGS PVT. LTD. Bangalore, 19.09.1999 to 17.02.2001 in liquid orals, capsules, Tablets and Dry syrups.

JOB RESPONSIBILITIES

Planning monitoring of manufacture and packing activities of liquid orals tablets & capsules department

- Knowledge of operation of equipments of liquid orals tablets & capsules department.

Other Activities

- Formulation development of Norfloxacin tablets
- Formulation of Amoxycillin kid tablets
- Formulation related comprehensive problem solving (eg. DT, dissolution hardness capping PH solubility etc…)

12. Worked as Asst. Chemist (production) in Tablets, Liquid Orals and Capsules in M/s. Crystal Pharma Ltd., Hubli for a period of Six months.

Undergone implant training for 400 hrs in M/s. Madhur Pharma and Research Labs, Bangalore

PERSONNEL DETAILS :

Father's Name	:	Rangacharya
Date of Birth	:	31st March 1973
Sex	:	Male
Marital Status	:	Married

Languages Known

Language	speak	read	Write
Kannada	yes	yes	yes
English	yes	yes	yes
Hindi	yes	yes	yes
Telugu	yes	yes	no
Tamil	yes	no	no

1. Mr KANNAIYA. M
   AVP OrBion Pharmaceuticals pvt Ltd CHENNAI Cell 08220196509

2. Mr. JAGADESHWARA RAO (M Pharm) Manipal college of Pharmacy
   Entrepreneur: Remington Pharma
   Retired. GM Plant Head VKT Pharma VIZAG Cell 9849768081

Place:
Date: **Yatgal Srinivas**