

CURRICULUM VITAE

NAGENDRA KUMAR SHUKLA

H-201, Aditya Heights B/H Devin international school Akruti Residency Narol.

DIST-Ahmedabad (Gujarat)

PIN CODE- 382405

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Total Exp.: 11yrs (approx.)

Salary: 9.0 Lacs/annum

Notice Period: 2 months

CAREER OBJECTIVE

To obtain a challenging position in the field of Production within an innovative, progressive company which will effectively utilize my skills, potential, knowledge and enhance them and also provide an opportunity for advancement and challenge to grow.

REPORTINGS:

- Currently work as HOD & report to Sr.GM / AVP.
- 120 No's persons are reporting to me.

JOB EXPERIENCE

Company Name	Designation	Department	From	To
Intas Pharmaceutical Ltd, Ahmedabad, SEZ	Sr. Executive Production	Tablet/capsule – Production (Oncology Solid Oral)	Mar-2016	Till date
Aurobindo Pharmaceutical Ltd, Hyderabad, Telangana (India)	Production Executive	Tablet Manufacturing	Dec -2014	Mar-2016
Sun pharmaceutical industries , Halol, Gujarat (India)	Jr. Officer	Tablet Manufacturing	Dec -2012	Nov-2014
Ipca laboratories Ltd- Silvassa, Dadara & Nagar Haveli (India)	Jr. Officer	Tablet Manufacturing	Jun-2011	Dec -2012

Achievement: -

- Victorious project completion of eBMR & EMS system within time line,
- New Plant setup as per USDFA / MHRA regulatory requirement.

Audit Exposers: -

Company Name	Year	Audit
Ipca laboratories Ltd- Silvassa, Dadara & Nagar Haveli (India)	2011- 2012	MHRA , WHO
Sun pharmaceutical industries , Halol, Gujarat (India)	2012-2014	USFDA , TGA , ANVISA, MHRA, WHO, FDA consultant , Internal audit (CQA, cGMP,)
Aurobindo Pharmaceutical Ltd, Hyderabad, Telangana (India)	2014-2016	USFDA, MHRA, NHL,WHO, Internal audit (CQA, cGMP,)
Intas Pharmaceutical Ltd, Ahmedabad, SEZ	2016- Till date	USFDA , MHRA , NHL, Internal audit (CQA, cGMP), Vendor Audit .i.e. KRKA, Novartis, Sandoz, SATADA,

Training:

Company Name	Year	Training
Ipca laboratories ltd- Silvassa, Dadara & Nagar Haveli (India)	2011- 2012	SCM management , Quality management
Sun pharmaceutical industries , Halol, Gujarat (India)	2012-2014	cGMP, GDP , Team leadership, QMS management, BMR/BPCR review
Aurobindo Pharmaceutical ltd, Hyderabad, Telangana (India)	2014-2016	CAPA effectiveness, Team management, Nichlon (L&T), BMR/BPR review
Intas Pharmaceutical Ltd, Ahmedabad, SEZ	2016- Till date	Leadership, SAP, eBMR, NIRMAN, WDMS, Training management, Planning & execution, m/c operation, PiSCADA, CAPA & Compliance, Quality management, EHS, OHC, Fire fighter, Project management etc.

OVERALL EXPOSURE:

- Good time management skills with a good eye – able to manage own and our team's workload, even in a fast-paced and changeable environment to meet targets.
- Green field project & new plant setup.
- Good level of technical expertise / aptitude.
- Experience of managing and motivating a team, including identifying training requirements.
- Experience as Team Leader role within a highly regulated, GMP or clean room manufacturing environment.
- Take initiative, ownership of tasks and has the tenacity, drive and ambition to get the job done.
- Exposure to face audit individually.
- A logical forward-thinker, always switching between the detail and bigger picture in order to make links between projects, and use experience to anticipate problems.
- Excellent communication skills – happy relating to people of all levels of authority and navigating cultural differences to get the best from people.
- Finasteride / Methotrexate (Onco product) project launch in Europe as a Project leader.
- Knowledge of Data integrity & 21 CFR compliance
- Worked with SAP, ERP, SCM, e-MPCR, Qedge software (change control, deviation, investigation, CAPA, RA), Qedge software (Training) and EMS (Environment monitoring system).
- Overall responsible to achieve monthly production target through successful execution of the plan.
- Ability to manage own workload to meet deadlines and maintain a keen eye for detail, even in a fast-paced and changeable environment, but with an awareness of when to escalate issues
- Accountability of manpower utilization, departmental discipline, inventory of machine spares, maximum utilization of the available resources, online job training based on SOP's and evaluation through feedback, Environmental monitoring, MIS and Document Review.
- Communication with the interrelated departments, Suppliers, providing information to reporting head, providing data related to purchase, requirements, production etc.
- Hand on experience on tablet/capsule manufacturing Equipments like FBE/RMG, Compression, Coating & Inspection machines.

JOB RESPONSIBILITIES:

- Section Head of Oncology Solid Oral.
- Job allocation and effective management through system.
- Planning according to Production requirement.
- Team leader in process validation.
- Review of all document and maintain the Record as per cGMP.
- Increase Productivity by proper planning & manpower handling.
- Co-ordination with various Dept. (Store, HRD, QC, QA & F&D Maintenance etc.) for smooth-functioning of dept. activity.

- Utilization of machines, materials, man power effectively & efficiently.
- Practically and Documentary knowledge about Capex/PR, URS, FAT, SAT, DQ, IQ, OQ, PQ & Validation.
- Coordination with other CFT to solved the problem ASAP with compliance mode.
- Preparing and review of all documents like BMRs, Protocol, SOPs, Validation Report, Change Controls, Deviation and Incidents etc.
- Follow up with PPMC for material availability to avoid delay in production activity.
- Down time calculation for production delay.
- Follow up with QC for batch release.

EDUCATIONAL QUALIFICATION

Sr. No.	Degree	Board/Uni.	Percentage
1	B.PHARM	Aligarh College of pharmacy (U.P.T.U)	67.0% Approx.

Skills:-

- Manufacturing management.
- Team leadership.
- Manpower handling
- Quality inspection.
- Production line management & Qualification of Equipment's.
- Target Oriented.
- Excellent communication skills.
- Training & Audit Compliance.

COMPUTER SKILLS

- Computer Knowledge: SAP, ProceeXe, quality Edge. PiSCADA. StackTrack, Good written, highly numerate with good computer skills IT abilities etc.

M/C operated:-

- **Granulation:** - Sifter (Vibro, Russell), RMG, FBE, FBD, Blender, Colloidal mill.
- **Compression:** - Korsch, Fette, Killian, Cadmach, Sejong, Gea, Legacy, Kambert with isolator.
- **Coating:** - Sejong, ACG, Gansong,
- **Inspection :-** Visitab, Thickness sorting.
- **Soft gel :-** ACG GKF 72, Gelatin preparation, gel preparation, Tumble dryer, Printing m/c.
- **Others:-** CIP system, WIP system, Washing & drying, Sampler, IPQC instrument like Hardness tester, DT apparatus, Friability tester, leak tester, sieve shaker, tap density tester etc.

PERSONAL INFORMATION

Name : Nagendra Kumar Shukla
Father's Name : Mr. Shriram Shukla
Mother's Name : Mrs. Sakuntala Devi
Date of Birth : 16thOct, 1989
Marital Status : Married
Religion : Hindu
Nationality : Indian

DECLARATION:-

I sincerely declare that all the information furnished above are true and correct to the knowledge and belief.

Nagendra Kumar Shukla