**Name: Navin Kumar Agrawal  
Age: 49 Years**

Marital Status: Married.  
Native Place: Indore, M.P. India  
Educational Qualification: M.Sc. Inorganic Chemistry,  
From Barkatullah University Bhopal, M.P.

Experience: Total Experience = 26+ Years

* Manufacturing/Production APIs = 3 Years

(1992 to 1995)

* Site Quality (QC& QA) = 16 Years

(1995 to 2011)

* Corporate Quality (QA & QC): ~6 Years

(2011 to 2017)

* Corporate Quality Compliance (API and Formulations) = April 2017 onwards

Regulatory Inspection faced successfully:

* USFDA Inspections = 21 Nos
* Others: 3 TGA, 4 MHRA, 4 Cofepris, 2 Anvisa, 2 PMDA.

**Current Job description:**

**Associate Vice President Corporate Quality & Compliance:**

**Sun pharmaceutical ltd**

* Responsible for oversight of compliance at various API and Formulations sites.

Review of effective implementation of QMS, Global Quality Policies, Standards and procedures at manufacturing sites.

* Perform gap analysis pertaining to GXP/ Quality Systems and work closely with sites for remediation.
* Review site quality index, trends of deviations, market complaints and OOS.
* Review of investigations for adequacy of RCA, CAPAs and effectiveness of CAPAs.

Review of open QMS documents beyond time lines and support sites to address the same in timely manner.

* Review internal and external inspection trends and prepare sites proactively to meet agencies/ customer expectations. Review of inspection observations and extrapolate findings to other systems and sites to assess the need for Global CAPAs.
* Provide support to sites for Inspection Readiness. Assess previous inspection responses and committed CAPAs and effectiveness.

Participate in key regulatory inspections and provide necessary support/ guidance.

Support sites to prepare regulatory responses and work with sites for remediation and successful closures of inspections.(483s and others)

* Review Site Quality Matrix, assess and provide technical inputs to address product quality issues i.e. Confirmed and Invalidated OOS, Market Complaints, deviations, RCA, CAPAs
* Educate and train personnel at corporate and at sites on QMS and compliance.

Provide technical education and training on burning topics like Human Error, Invalidated OOS, Investigations, RCA and on Product Robustness.

* Sharing best industry /regulatory practices or best practices followed by one site to other sites.
* Drive Quality Compliance and Operation Excellence projects (OE) through simplifications with science. (LESS IS MORE)
* Simplification projects for reducing complexity at shop floor to make the life of operators and analysts SIMPLE.

**Briefs of Achievements at Sun:**

**(Period Feb -15 to Jun -19)**

Regulatory Inspections:

* Participated in 10 very successful USFDA, 4 EUGMP, 2 PMDA, 1 MHRA, 1 TGA, 1 Cofepris, 1 Health Canada, 1 Anvisa inspections as key team member at various API and formulation sites. Supported site teams to prepare & face regulatory inspections successfully.

Operation Excellence Projects:

Strengthening Compliance through Simplification

Reducing waste w.r.t. Reprocessing, Reworking by focusing on PACA than CAPA.

* Implemented Reduce Testing for chemical &microbiology testing of Purified Water & WFI.
* Removed undesired chemical tests from PW/WFI specifications based on scientific rationale.
* Reduce testing in Stability Studies. Stability specifications revised for 120 products.
* Reduce testing for In Process analysis to expedite QC and hence overall productivity of unit.

Reduce (Scientific/logical) Testing during Process & Cleaning Validations.

* Lot size optimization for Raw Materials to reduce QC analysis load.
* Specification Revisions with scientific rational, EDQM and US DMF Amendment / CBE-30 (FP/DS) received Eg. Pantoprazole Na, Tetrabenazine, Imatinib etc.
* Interacted with USP for monograph revision of Gabapentin, revised monograph published by USP 41- 2S effective from Dec 1st 2018.

* Product quality issues and 100 + Invalidated OOS addressed through technical inputs for monograph and test procedure/specification revisions
* Implementation of Retest Dating for Raw Materials. Successfully moved about 1200 API- Raw Materials from Expiry to Retest category.
* Simplifying SOPs to ensure the compliance as well as Analyst/Operators friendly approach considering practical aspects of shop floor.
* Testing procedures improvisation at various sites to reduce lab errors resulting in lab events and unconfirmed OOS. (> 100 ATP revisions facilitated)
* PW& WFI System sanitization frequency rationalized, resulted saving of ~100 Lakhs INR.
* Reference & Impurity standards, Quality Excellence realizing a saving of about 1725 Lakhs INR(~ 2.5M USD) in fy 18-19.
* Product Robustness Program:

A scientifically sound program with ICH Q8, Q9 and Q10 knowledge to deal with quality issues of legacy & new products and remediation through continual improvements.

* Remediating Product Quality issues through Product Robustness Program which includes

Product Assessment Report (PAR),

Product Understanding Report (PUR).

DMAIC= Define, Measure, Analyze, Improve & Control and Improving process capability

* Reduction in number of invalidated and confirmed OOS and market complaints..

**Learning & Development:**

A certified professional by NSF-IDMA in APPQM, i.e.

“Advance Program on Pharmaceutical Quality Management System”

Has done successful completion of world class international certification course consist of 5 modules.(Total 20 days in a period of one year, 2017-2018)

* Categorized as one of the CHANGE AGENTs for Indian Pharma Industry by NSF & IDMA.

**Career History:**

**AurobiondoPharma Ltd from Nov. 2008 to Feb 2015.**

**Senior General Manager Corporate Quality Control (CQC)**

Key Responsibilities:

* Responsible for overall Quality Control functions at corporate level.
* Ensure cGMP compliance and smooth services of Quality Control 7 API mfg sites with respect to GMP requirements.
* Responsible for facilitating necessary infra-structure with respect to Men, Machine & Material atvarious Quality Control Labs.
* Management of a sound equipment calibration and qualification program.
* Management of Preventive & Breakdown Maintenance Program.
* Responsible for updating and harmonizing quality procedures at different sites.
* Gap assessment w.r.t. 21CFR-11 requirements and address the weakness in QMS and practices with respect to current GMP requirements.
* Notify senior management on critical quality issues and support sites for timely remediation.
* Coordinate with different functions like QA, Mfg., R&D and regulatory affairs on day to day issues.
* Review of product quality, OOS, deviations, market complaints and providing technical inputs to derive scientifically sound RCA and CAPAs.
* Participate in Quality review meetings at various mfg sites with Quality, Mfg, Engineering

**Achievements:**

* Successfully faced 9 USFDA during tenure with Aurobindo Pharma Ltd
* Worked with PWC for Men Power / Operation Excellence Projects
* Worked for various projects for multinationals like Pfizer, GSK, Takeda successfully.
* Headed a large team size i.e. about 700 quality personnel, successfully.
* Based on various successful audits, was elevated at Corporate level as Senior General Manager and headed Corporate Quality Control functions for entire Aurobindo API operations.

Career Progress with Aurobindo:

* Year 2008: Joined as Asst. General Manager QC
* Year 2011: Promoted as Dy. General Manager QC
* Nov.- 2011: Elevated as General Manager Corporate CQC ( 7 API Mfg.)
* March-2014- Promoted as Senior General Manager Corporate Quality.

Career Progress with Orchid Chemical &Pharmaceuticals: (2003 to 2008)

* Year 2003: Joined as Asst. Manager Quality Assurance
* Year 2005: Promoted as Deputy Manager Quality Control
* Year 2006:Promoted as Head Stability Management (Manager Quality Control)
* Year 2007: Promoted as Sr. Manager, Head Quality Control

Career Progress with Ranbaxy Labs Ltd: (1992 to 2002)

* Year 1992-1994: Joined as Production Chemist at Dewas API Mfg.

Worked in API Manufacturing Process and Solvent Recovery at Dewas&Toansa API sites

* Year 1995 to 1997: QC Analyst:

-Analysis of RM, Ints, APIs by HPLC/ UV/IR/KFT/Auto Titration/PSD etc

-Qualification of Working Standard (WRS), Management of Reference Std.

-Management of Lab Calibration Program.

* Year 1998 to 2002: Executive Quality Assurance:

-Review of analytical data

-Management of change controls and deviations

-Review of Batch Production and Master Records, Batch Release.

-Annual Product Review

**Miscellaneous:**

* Certified by NSF International UK on APPQM in 2017-2018

i.e. Advanced Program on Pharmaceutical Quality Management by NSF at Banglore.

* Attended workshops on 21st Century Product Robustness
* Conducted workshop on inspection readiness&Global Quality &Compliance.
* Conducted workshops on invalidated OOSand Human Errors at various plants and in GQLT-2019
* Other Prominent Seminars/ training/workshops:

-Prominence HPLC seminar in Singapore in 08/2005 (M/s Shimadzu Ltd.

-Waters HPLC/UPLC Training Program at Dubai in Feb.2011.

-Qbd workshop in June 2013 by Dr. Line Lundsberg at Hyderabad

-Invited at Asia Executive Meet at Milford USA by Waters Inc (Aug. 2013)

-Participated in India Pharma Alliance meeting with USFDA,MHRA& DCGI at Mumbai

.

-Attended Leadership Development Program by Dr. Anand David, Manford at Lonavala in 2015.

* Experienced in working with PWC, McKinsey, for Men Power and Operational Excellence projects

Salary Drawing: 73 + Lakhs /Annum.

Bonus: Avg. 3 lakhs/ annum,Otherbenefits Company Car, family health insurance&term life insurance.

Notice Period: 3 Months

Navin Kumar Agrawal

navinchery1@yahoo.co.in

Vadodara, India. Ph. 917573010631Bottom of Form

Top of Form

Bottom of Form