# K. Nagendra Babu

Andhra Pradesh

Senior Vice President-Quality Operations(QA, QC, DQA, CQA) and Head of Global Audit&Compliance(API&FDF) at Granules India Limited

---

## Summary

# Head of Quality Operations and Global Audit and Compliance at GIL for the API and Formulation Sites.
# Oversee and direct the quality systems to ensure business, customer and regulatory requirements.
# Responsible to provide leadership, direction and coordinate all Quality Assurance activities in accordance with the cGMP.
# Ensures cGMP Compliance through functional and global auditing systems.
# Experience in auditing more than 500 facilities till date both in India and abroad. Facilities include API / Finished Dosage / Excipients / Testing (GLP) / CRO / C&FA / Primary & Secondary Packaging components manufacturers in accordance with appropriate regulatory guidance and/or any corporate reference standard.
# Experience in QMS remediation projects and actively participated in due diligence audits with specific focus on Data Integrity.
# Experience in manufacturing sites of Bulk API (Manufacturing, Quality Control and Quality Assurance) and Finished Dosage Formulations (IPQA, Quality Assurance, CQA , DQA and GQA).
# Prepare all associated documentation including audit plans and audit reports under strict confidentiality and review Corrective and Preventive Actions for appropriateness and submit for closure in TrackWise.
# Managed the team of 5, 15 and 180 peoples in Aurobindo Pharma , Mylan and in Granules respectively.
# Managed 35 contact manufacturing locations in Dr. Reddy’s & GSK.
# Successfully managed various regulatory and customer audits like: USFDA, EDQM, PMDA, KFDA, WHO, COFEPRIS, HC, TGA and various domestic & international customer audits.
# Design various training programs and provided training to employees on Good Manufacturing Practices, QMS and regulatory requirements.
# Managed all Quality Notifications such as Deviations, Change control Management, OOS, Product complaints, Failures and other system related issues.
# Carry out routine analysis of incoming RM, PM and FP.

---

## Experience

Senior Vice President-Quality Operations(QA,QC,DQA, CQA)and Head of Global Audit&Compliance(API&FDF) at Granules India Limited

October 2018 - Present (4 months)

Present job responsibility includes Quality Functions (Quality Assurance, Quality Control, Development Quality Assurance, Corporate Quality), Global Audit & Compliance and Vendor management for the API and Formulation sites across Granules India Limited (GIL).

Oversee and direct the quality systems that ensure business, customer and regulatory requirements across GIL.

Responsible to provide leadership, direction and coordinate all quality function activities in accordance with the cGMP.

Ensure cGMP Compliance through functional and global auditing systems across GIL.

Responsible for auditing of various manufacturing locations for cGMP compliance. This includes new facility audits of out sourced manufacturing locations including CRO.

Senior Vice President- Quality (FDF),Head of Global Audit&Compliance and Vendor Management(API&FDF) at Granules India Limited

April 2018 - October 2018 (7 months)

Present job responsibility includes Quality (QA & QC), Global Audit & Compliance and Vendor management for the API and Formulation sites across Granules India Limited (GIL).

Oversee and direct the quality systems that ensure business, customer and regulatory requirements across GIL.

Responsible to provide leadership, direction and coordinate all quality function activities in accordance with the cGMP.

Ensure cGMP Compliance through functional and global auditing systems across GIL.

Responsible for auditing of various manufacturing locations for cGMP compliance. This includes new facility audits of out sourced manufacturing locations including CRO.

Head - Global Audit and Compliance (API&FDF),Quality Assurance (FDF) and Vendor Management (API&FDF) at Granules India Limited

October 2017 - April 2018 (7 months)

Head of Global Audit and Compliance & Quality Assurance at GIL. Responsible for Global Audit and Compliance and vendor management for the API and Formulation sites.

Responsible for auditing of various manufacturing locations for cGMP compliance. This includes new facility audits of out sourced manufacturing locations including CRO and periodic audits.

Oversee and direct the quality assurance systems to ensure business, customer and regulatory requirements.

Responsible to provide leadership, direction and coordinate all Quality Assurance activities in accordance with the cGMP.

Ensures cGMP Compliance through functional and global auditing systems.

Associate Vice President Of Quality (API& FDF) at Granules India Limited
September 2016 - October 2017 (1 year 2 months)

Responsible for quality compliance across GIL for the API and Formulations and vendor management .

Senior Global Quality Auditor (DGM) at Mylan Pharmaceuticals
December 2009 - September 2016 (6 years 10 months)

Audit and Compliance of facilities include API / Finished Dosage / Excipients / Testing (GLP) / C&FA / Primary & Secondary Packaging components manufacturers in accordance with appropriate regulatory guidance and/or any corporate reference standard.

Quality Assurance Manager at Mylan Laboratories Limited
September 2008 - December 2009 (1 year 4 months)

Responsible for day to day operations of Quality and Implementation of Quality Management System across the site.

Assistant Manager, Corporate Quality at GSK
May 2007 - September 2008 (1 year 5 months)

Monitoring and evaluation of cGMP compliance of Loan License locations which involved release of product to market, risk mitigation and host of other allied activities. Managed more than 10 contract manufacturing locations.

Responsible for auditing of various manufacturing locations for cGMP compliance. This includes new facility audits of out sourced manufacturing locations and periodic audits.

Sr.Executive at Dr. Reddy's Laboratories
September 2004 - May 2007 (2 years 9 months)

Monitoring and evaluation of cGMP compliance of Loan License locations which involved release of product to market, risk mitigation and host of other allied activities. Managed more than 10 contract manufacturing locations.

Responsible for  auditing of various manufacturing locations for cGMP compliance. This includes new facility audits of out sourced manufacturing locations and periodic audits.

Executive - QA at Aurobindo Pharma
January 2004  -  September 2004 (9 months)

Responsible for the implementation of Quality Management Systems.

## Education

Madurai Kamaraj University
M.Sc, Chemistry, 2003 - 2005
Activities and Societies:  M.Sc (Chemistry)

Sri Venkateswara University
Bachelor's Degree, mathematics , Physics and Chemistry, 1994 - 1997
Activities and Societies:  B.Sc (M.P.C)

# K. Nagendra Babu

Andhra Pradesh

Senior Vice President-Quality Operations(QA, QC, DQA, CQA) and Head of Global Audit&Compliance(API&FDF) at Granules India Limited

---

LinkedIn Recruiter

## 10 people have recommended K. Nagendra

"I know Mr. Nagendra Babu for more than 12 years. He has been working with me in Dr. Reddys Laboratories,Hyderabad in Quality Assurance . Nagendra Babu has good exposure in QA . He has good overall knowledge about quality function , validations & Vendor Audit."

—DATTA JOGDAND, Assistant General Manager, Mylan Laboratories Limited, worked directly with K. Nagendra at Mylan Pharmaceuticals

"I have known Nagendra Babu during the preparation of the first FDA inspection of our Indian Joint-Venture company Granules OmniChem. Nagendra Babu's experience with GMP in general and US-FDA inspections on Indian territory in particular has proven to be very helpful and contributed to the successful outcome of our inspection. "

—Dieter Vanderlinden, Head of QC & External Compliance, Ajinomoto Bio-Pharma Services, worked with K. Nagendra at Granules India Limited

"Narendra Babu has very good in deployment and implementation of QA systems in a very large API setup. I found him to be a very keen learner. Further he has an excellent grasp on technical knowledge pertaining to API manufacturing. Also find him to be very good in understanding US/EU standards. Striking characteristics - honest, hardworking and integrity."

—Vasan Thatai, Associate Vice President, Shantha Biotechnics Lyd, managed K. Nagendra at Aurobindo Pharma

"I know the Nagendra babu sir in Mylan since 2006. He is excellent leader and supportive and motivative to his team."

—Ramesh Bankuru, Executive, Mylan Laboratories Limited, worked directly with K. Nagendra at Mylan Laboratories Limited

"He is a nice gentleman and very responsible. He also very enlightened about the work he does."

—Ronald Inyangala, Director of planning , Policy , R&D and Regional coordinatio, Pharmacy and Poisons Board, was a consultant or contractor to K. Nagendra at Granules India Limited

"following:I know K. Nagendra Babu since 2004. I really got an excellent feed back on him about his technical knowledge and auditing skills. I remember one statement from Nagendra in 2004 ( i.e. he need to reach heights in the pharma industry along with good name) and tell me he is on the right path to reach the destination. Apart from all the technical knowledge, he is an excellent human and extend his arm to help people who are in need."

—Gopalakrishna G.V, AGM- OSD Quality, Mylan, worked directly with K. Nagendra at Dr. Reddy's Laboratories

"Nagendra is a thorough and professional Senior Auditor and proficient in GMP standards across many geographies such as US, EU, TGA, Japan, etc., as well as experienced in a multi-national company setting. "

—Charles "Chuck" Koon, Head of Global Operations Auditing and Training, Mylan, worked directly with K. Nagendra at Mylan Pharmaceuticals

"Nagendra is a very knowledgeable Sr. Auditor for our Global Operations Auditing Team at Mylan. He has a great understanding of GMPs from a global perspective and how to apply them."

—Frank Poling, Sr. Director, Global Quality Systems, Mylan, managed K. Nagendra at Mylan Pharmaceuticals

"Mr.Nagendra Babu is extraordinary talented and full fledged quality professional in pharmaceutical industry. He always have complete focus on his assignments. His skills in quality auditing especially in data integrity is absolutely marvellous. He is having good hold in establishing and implementing quality systems. His commitment to quality is commendable. It is very great to work with Mr.Nagendra."

—S.Syed Noor Mohamed (ASQ CQA), Quality Assurance Manager, Riyadh Pharma, managed K. Nagendra at Mylan Pharmaceuticals

"Mr. Nagendrababu is a highly focussed and committed professional. We are colleagues working in Global Operations Auditing group. He never says no to challenging tasks and a consistant star performer. He is open for discussions and a team player. He reaches out to colleagues in case of professional discussions/guidance. I wish him all the very best for his endeavours and recommend him for senior management role as he is an asset to the organisation."

—Dr.M.A. Ashok, Global Quality Auditor, Mylan Pharmaceuticals Pvt Ltd, worked directly with K. Nagendra at Mylan Pharmaceuticals

---

## Profile Notes and Activity (1)