

PINAKIN SHAH

+91 9821937240

1008vipa@gmail.com

<https://www.linkedin.com/in/pinakin-shah-63002235/>

Career Focus: Lead End to End Microbiology teams to enable business growth

PROFILE

- Accomplished achiever in Microbiology and Quality and Compliance within the FMCG, Medical/OTC/Nutritional industry with 29+ years of experience
- Led Global microbiology teams and Projects
- Laboratory management and Global compliance (US FDA, EU, TGA etc)
- Demonstrated ability in implementing end to end microbiological quality systems at In-house and External Manufacturing sites.
- Building High Impact teams

KEY SKILLS

- QA & R&D Micro Expertise
- Contamination Controls
- Quality Assessments
- Laboratory Management
- Project Management
- Leadership

DOMAIN EXPERTISE

- ✓ End to End Microbiology Leadership
- ✓ NPD/RM Centre/Quality/Supply Chain Interface
- ✓ Leading teams for US FDA and Global Regulatory compliance audits
- ✓ Micro Risk Assessment – Product, Raw materials and manufacturing facility
- ✓ Sterilization technologies
- ✓ Training & building teams

PROFESSIONAL EXPERIENCE

Johnson & Johnson & Kenvue – R&D Role (2005 to 2024)

- Led successful certification/accreditation of Microbiology laboratory for US FDA. Zero 483 Observation in three audits by US FDA in last 12 years.
- Led Global project on Rapid microbiology methods for product release by Celsis
- Collaborated with Global cross functional partners to lead Global Project (Project ChuckNova) of Simplification in Microbiology stability of consumer products.
- Led Global Microbiology team for Product preservation, Product claims and demos, Raw material simplification and Laboratory compliance.
- Represented Microbiology function in the cross-functional due-diligence team for multiple Licensing & Acquisitions.
- Acquired the status of Global Subject Matter Expert for Microbiology robustness of formulations, raw materials and Microbiology Laboratory compliance.

- Led hosting of Global Microbiology meet in India for Consumer sector and for JNJ Enterprise (MATCP -cross sector).
- Global Training lead for Microbiological stability of consumer Products.
- Hired, nurtured & exported local talents to different functions and countries, establishing India as a talent bank.

Johnson & Johnson– Quality Assurance/Quality and Compliance Role (1995 to 2005)

- Hands on experience of Qualification of Steam sterilizers, Sterilization by Gamma radiation and Ethylene oxide for consumer and medical device products. Acquired training in Sterilization science and Technology (SST), USA. Certification on radiation process from Isomed (Govt of India facility for radiation)
- Acquired the status of Regional Subject Matter Expert (Microbiology) with specialization in Purified Water System design, manufacturing equipment design and auditing Microbiology laboratories.
- Led Microbiology QA laboratory from 2001 for J&J consumer, India. Was responsible for Microbiology labs of J&J In-house and External manufacturers
- Led deployment of Rapid microbiology method (Celsis -formerly known as Lumac) in AP countries
- Acquired training and working knowledge of statistical & quality tools like FMEA, DOE & SPC
- Led Six sigma green belt project of Rapid product release to market using advance rapid technology.
- Led project of elimination of decontamination for consumer products (B.aids and Tampons). Received Regional Vice President award for the same.
- Led Investigations and corrective /preventive action implementation for Microbial contamination of products at Manufacturing sites of AP region.
- Partnered with Regulatory bodies (Represented India in ISO meeting at New Zealand) to design microbiological standards for consumer cosmetic products

EDUCATION

Masters of Science - Microbiology	Mumbai University	1994
Bachelor of Science - Microbiology	Mumbai University	1992
Management Development Program (MDP)	Asian Institute of Management (AIM)	2007

TRAININGS & CERTIFICATIONS

FDA certification for Microbiologist by Maharashtra FDA	1999
Statistical tools for Quality	1999
Conducting Quality Assessments	2000
Validation Principles	2002
Process Excellence Six Sigma Green Belt	2003
Plant and Manufacturing Equipment Hygiene Training	2009
Formulation Chemistry for Microbiology	2010
Rapid Microbiological Methods by United States Pharmacopeia	2014

AWARDS & ACHIEVEMENTS

Best Performer QA	2000
VP Award of APAC region for EO elimination of B.aids	2001
Best Performer R&D	2002
VP Award of APAC region for stability transfer	2006
Best Innovation award	2015
Best Simplification project	2018
