



Transforming Mystery to Mastery...



WHO WE ARE

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PinakInMicro offers Microbiology consulting and coaching services to FMCG, pharmaceutical and food industries, independent laboratories and educational institutes.

In PinakInMicro, we provide Microbiological Excellence across end-to-end Product Lifecycle and testing operations.

WHAT WE OFFER

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Our goal is to enhance and protect business of our clients by amplifying solutions through expertise in –

- **Audits and Inspections** – Preparing laboratories and facilities for Regulatory and Quality Compliance audits/inspections
- **Speed to Markets** – Microbiological controls in manufacturing and releasing quality products rapidly (Rapid Microbiological methods, PAT, Parametric releases) to the markets.
- **Design robustness assessments** – Scientific risk model-based assessment of manufacturing facilities, formulations, Raw materials and packaging materials
- **Failure Investigations and resolutions** – Marketed Product failure investigations, CAPA and risk assessment for Objectionable organisms.
- **Training and coaching** – Prepare teams and organization for Lab of the future/future generation of Microbiologists
- **Claims substantiation** – Creating and supporting new Microbiological claims on the products (including claims for prebiotics, probiotics, preservative free)
- **Sterilization process controls** – Microbiological Qualification of sterilization processes for Steam, Gamma, Ethylene oxide etc
- **Laboratory processes and QMS** – Establishing laboratory and Microbiological Quality Management Systems (QMS) for greenfield projects
- **Implement Data Integrity risk assessment (DIRA) and contamination control strategies (CCS)**

Why PinakinMicro Consultancy ?

Our Founder and Principal Consultant **Pinakin Shah** is a Global Microbiology leader with three decades of experience in leading Global FMCG, Medical, OTC, and Personal care product industry having proven track record of value creation through Microbiological solutions in Quality,R&D and Regulatory Compliance

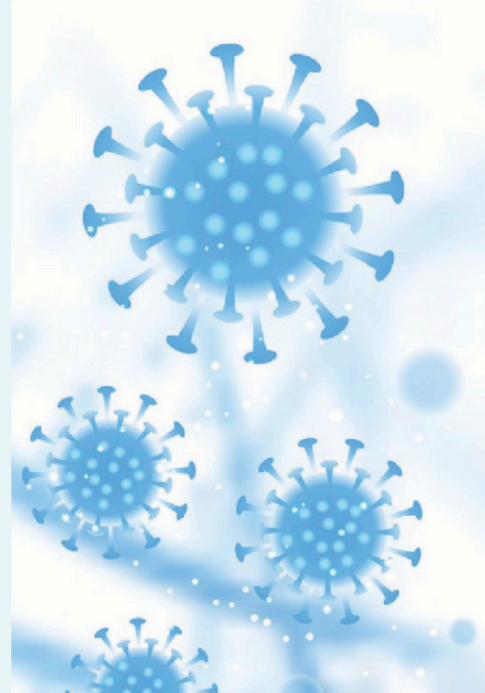
He has a Masters degree in Microbiology from Mumbai and has undergone Business management program from international business school. Driven by his passion for microbiology and desire to prevent microbiology related disruptions/flow blockers in product supply chain and laboratory operations, he has started "PinakinMicro" consultancy.



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Some of the notable achievements of his journey are –

- Deployed **Rapid Microbiology methods** for product release (Led Six sigma green belt project of Rapid product release to market using Celsis) and **led multiple Global projects on Innovation and Simplification** (Sterilization elimination, optimization of stability, product preservation etc).
- Instrumental in developing comprehensive **risk level-based assessment Programs/models for Formulations and Raw materials**.
- Led successful certification/accreditation of Microbiology laboratory for **US FDA (with Zero 483 Observation)**. Conducted Microbiological GMP audits for manufacturing plants, laboratories and suppliers at multiple countries in APAC region.
- Investigated and **identified correct root causes for complex failures/contamination issues** in manufacturing plants Globally.
- **Developed and supported multiple claims and demos** for consumer cosmetic brands.
- Collaborated and **Partnered with Regulatory bodies** e.g USP, ISO, BIS, Chinese pharmacopeia etc. to design Microbiological standards.
- **Trainer/Instructor for Global Microbiology laboratory workshops/trainings**.



To learn more or ask for assistance, write to us at consult@pinakinmicro.com or call us at **+91 83693 47927** or visit www.pinakinmicro.com