

# KARTHIK B

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Senior Executive – Biotechnology & Quality Control  
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## PROFESSIONAL SUMMARY

Results-oriented Biotechnology professional with 9+ years of experience in molecular diagnostics, pharmaceutical quality control, and laboratory operations. Proven expert in bridging clinical and industrial testing environments, with specialized knowledge in Pharma (GMP) and Agricultural Biotechnology regulations. Adept at managing high-throughput testing, ensuring clean room and AHU validations, and leading polymerase lyophilization projects. Demonstrated track record of effective staff management, CFT collaboration, and driving workflow optimization.

## FUNCTIONAL EXPERTISE & TRANSFERABLE COMPETENCIES

*This section highlights your specialized technical and operational skills.*

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- **Regulatory Cross-Compliance (QA):** Expertise in navigating both Pharmaceutical GMP/GLP and Agricultural Biotechnology regulations, ensuring strict adherence to safety and quality norms.
- **Facility & Vendor Management:** Proven ability to validate clean room environments (AHU monitoring) and manage vendor relationships for instrument maintenance and calibration.
- **Advanced Molecular biology:** Technical mastery of ELISA, qPCR, and polymerase lyophilization techniques for robust pathogen detection and seed analysis.
- **Operational Leadership:** Strong background in staff management, workflow optimization, and Cross-Functional Team (CFT) collaboration to reduce turnaround times.

## PROFESSIONAL EXPERIENCE

### PLASMAGEN BIOSCIENCE PVT LTD | Bangalore

*Senior Executive - Plasma & Product Testing Lab | Feb 2024 – Present*

- Execute plasma and drug substance testing using automated platforms (Evolis Biorad, Cobas 5800 NAT), ensuring strict adherence to **GMP guidelines and regulations** specific to plasma fractionation.

- Manage **facility validation** protocols, including **AHU (Air Handling Unit)** performance monitoring, **clean room** certification, and environmental monitoring.
- Oversee **vendor management** for preventative maintenance and calibration of lab instruments, ensuring zero downtime.
- Spearheaded **digital transformation** of lab operations to eliminate backlogs and improve traceability.
- Direct **staff management** and **workflow optimization**, fostering strong **Cross-Functional Team (CFT) collaboration** to resolve quality issues.
- Lead IQ, OQ, and PQ validations and maintain comprehensive GMP documentation for regulatory audits.
- Achieved zero under-test samples and reduced invalid stock through rigorous inventory control.

### **SYNGENTA INDIA LTD | Hyderabad**

*Supervisor - Seed Analyst | Sep 2022 – Feb 2024*

- Conducted high-throughput ELISA and qPCR, utilizing specialized **polymerase lyophilization** techniques in bioassays for enhanced stability and precision.
- Ensured rigorous Quality Assurance (QA) compliance with **Agricultural Biotechnology regulations** and global seed health standards.
- Validated SNP data and managed reporting via **SAP and LIMS**, ensuring data integrity across workflows.
- Collaborated with cross-functional teams to validate new testing protocols and ensure biosafety compliance.

### **DR LAL PATH LABS | Bangalore**

*Molecular Technician | Aug 2021 – Sep 2022*

- Specialized in *\*Mycobacterium Tuberculosis\** testing via culture methods and qPCR.
- Supported high-throughput diagnostic workflows while maintaining accurate records.
- Ensured strict compliance with biosafety protocols for handling infectious samples.

### **GKNM HOSPITAL | Coimbatore**

*Molecular Technologist | Oct 2020 – Aug 2021*

- Supervised molecular diagnostics lab operations and coordinated **NABL audits**.
- Developed SOPs and validated COVID-19 testing methods during critical demand periods.
- Maintained quality logs and ensured regulatory compliance.

## MICROBIOLOGICAL LABORATORY | Coimbatore

*Laboratory Technician | May 2016 – Sep 2020*

- Conducted microbiology and clinical pathology tests ensuring high standards of lab hygiene.
- Managed inventory, data entry, and front-desk operations.

## EDUCATION

- M.Sc. Biotechnology (73%) | Hindusthan College of Arts and Science, Coimbatore | 2018 – 2020  
Project: Molecular diagnostics of CHIKV and DENV using RT-PCR & ELISA.
- B.Sc. Biotechnology (64%) | Hindusthan College of Arts and Science, Coimbatore | 2015 – 2018  
Project: IFGBT Genetics variation studies.

## CERTIFICATIONS & AWARDS

- GEMS Award-2022, Syngenta India Ltd
- Best Team of the Year - 2021, GKNM Hospital

## TECHNICAL SKILLS

- **Molecular Techniques:** Polymerase Lyophilization, DNA/RNA Extraction, qPCR, ELISA, Bioassays, NAT Systems.
- **Quality Assurance:** GMP/GLP, Pharma & Agri-Biotech Regulations, NABL, ISO, Clean Room Validation.
- **Lab Operations:** AHU Monitoring, Vendor Management, Inventory Control, Staff Management, Workflow Optimization.
- **Software:** SAP, LIMS, Microsoft Office Suite.

## LANGUAGES

- Tamil, English, Telugu