biotecnika
Your Bio Resource

Industry Ready QA/QC Online Training Program

With Project Work & Placement Assistance

45 Days Training+ 1 Month Project

With 100% Placement Assistance

Become Industry-Ready in QA/QC

Mail: info@biotecnika.org **stores.biotecnika.org**

biotecnika
Your Bio Resource

Approximately **65%** of QA/QC jobs in the pharmaceutical and biotech industries require expertise in GMP/GLP practices and Regulatory requirements

Freshers with Knowledge of GMP, GLP & SOPs more employable in QA/QC roles

Not Just Training We Train You Like You're Already on the Job!

Toll Free - 1800-1200-1818

www.Biotecnika.org

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Why Choose This Program?

- **Industry-Aligned Skills – Training mapped to GMP, GLP, ISO & ICH guidelines.**
- **Project-Centric Learning – Real-world inspired projects and simulations**
- **Career Boost – Mock interviews, resume workshops, and placement assistance**
- **Expert Trainers – Learn from seasoned QA/QC professionals across industries.**
- **Work Experience Advantage – Project work certificate for your portfolio.**

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Program Details

- **Start Date: 12th September 2025**
- **Time: 7:00 – 8:00 PM IST**
- **Mode: 100% Online**
- **Duration: 45 Days Training + 1 Month Project**
- **Bonus: Mock Interviews & Career Mentorship**

Who Can Apply?

- **Students & Fresh Graduates – B.Sc./M.Sc./B.Tech./M.Tech. in Biotechnology, Microbiology, Biochemistry, Life Sciences, Pharmacy, Food Technology, Chemistry.**

- **Working Professionals – QA/QC, R&D, Production, Regulatory professionals looking to upskill**

- **Basic lab knowledge recommended; no prior QA/QC work experience required**

Complete Course Curriculum

Module 1: Core Fundamentals of QA & QC

- **Day 1 –** Introduction to QA & QC – Definitions, scope, QA vs. QC distinctions, lifecycle approach to quality
- **Day 2 –** Quality Systems & Concepts – SOPs, change control, deviations, CAPA.
- **Day 3 & 4 –** Documentation Practices – GDP, ALCOA+, 21 CFR Part 11, LIMS, ELN.
- **Day 5 –** Sampling & Specification Setting – Sampling techniques, Control charts, Statistical sampling.
- **Day 6 –** Batch Record Review – Master batch records, line clearance, in-process checks.

Course Curriculum

Module 2: Analytical Methods in QA/QC Labs

- **Day 7 & 8 –** Basic Instrumentation in QC Labs – HPLC, GC, FTIR, ELISA, PCR, balances, pH meter , Micropipettes
- **Day 9 –** Analytical Method Validation – Accuracy, precision, specificity, LOD, LOQ.
- **Day 10** – Calibration & Maintenance – IQ, OQ, PQ, calibration logs.
- **Day 11** : Microbiological QC – Sterility, bioburden, endotoxin, environmental monitoring.

Course Curriculum

Module 3: Regulatory Guidelines & Quality Standards

- **Day 12 –** GMP (WHO, FDA, EU GMPs)
- **Day 13 –** GLP (OECD principles, raw data, archives).
- **Day 14 –** ISO Standards (9001, 13485, 17025, 22000, 15189).
- **Day 15 –** ICH Guidelines (Q8–Q10, Quality by Design).
- **Day 16 –** Emerging Regulatory Trends – AI/ML in QC, cloud LIMS, sustainability, ICH Q12/Q14

Course Curriculum

Module 4: Industry-Specific QA/QC Applications

- **Day 17 & 18 –** GMP, QC of drugs, Case: Batch rejection due to OOS results
- **Day 19 & 20 –** Biotechnology – Biologics QC, biosimilars, contamination control. Case: Failure investigation in monoclonal antibody production
- **Day 21 & 22 –** HACCP, shelf-life, microbial QC, allergen recalls. Case: Product recall due to allergen mislabelling
- **Day 23 & 24 –** Stability, preservative efficacy, Case: Non-compliance in SPF claim validation
- **Day 25 & 26 –** Medical Devices – ISO 13485, EU MDR, FDA expectations.
- **Day 27 & 28 –** Clinical Research & CROs – GCP, protocol QA, trial master file audits. Case: QA audit findings in Phase II trial documentation

Day 29 – QMS in Technology Transfer – Validation, reproducibility, regulatory compliance

Course Curriculum

Module 5: Data Analytics & Statistical Software in QA/QC

Day 30 & 31 – Control Charts – X-bar, R-chart, Cp, Cpk, Minitab, JMP, Python.

Day 30 & 31 – Control Charts – X-bar, R-chart, Cp, Cpk, Minitab, JMP, Python.

Day 34 & 35 – Trend Analysis – Outlier detection, PCA, dashboards with Power BI/Tableau.

Day 36 – Predictive Quality Management – AI/ML, digital twins, Pharma 4.0 QC

Course Curriculum

Module 6: Audits, CAPA & Root Cause Analysis

- **Day 37 –** Types of Audits – Internal, external, regulatory.
- **Day 38 –** Non-Conformance Management – Deviation investigations.
- **Day 39 –** CAPA – Writing effective CAPAs, monitoring.
- **Day 40 –** Root Cause Analysis Tools – Fishbone, 5 Whys, FMEA, fault tree.

Course Curriculum

Module 7: Seven QC Tools & Case Studies

- **Day 41 & 42 –** 7Basic QC Tools – Cause & effect, Pareto, control charts, flowcharts, Check sheet, histogram, scatter diagrams
- **Day 43 –** Case Applications – Real-life QA/QC problem solving.

Module 8: Scope & Career Prospects

- **Day 44 –** QA/QC Roles – Entry, mid, senior positions, salary insights, job market.
- **Day 45 –** Career Growth – Certifications (ASQ, ISO 9001 Auditor), career roadmap.

Project Work (1-Month)

Students will complete 1 major + 1 mini project, such as

- SOP System Design for a Biotech Lab
- Analytical Method Validation (HPLC/UV simulation)
- Control Chart Development & Interpretation
- Root Cause & CAPA Case Study
- Data Integrity Audit (21 CFR Part 11)
- Environmental Monitoring Plan (Cleanroom)
- Quality Audit Simulation Report

- SPC Chart Analysis & Process Improvement Proposal
- Regulatory Compliance Assessment (Novel Product)
- Supplier Qualification Audit Checklist
- Quality Risk Management (ICH Q9 plan)
- Analytical Method Transfer & Validation (R&D ↔ QC Labs)

Importance of Project Work Experience

- Bridges classroom learning with real-world practice.
- Projects act as a portfolio for interviews & recruiters.
- Provides simulation of actual QA/QC tasks (audits, SOP drafting, CAPA).
- Boosts confidence and clarity on job roles before placement.

About the Instructor

Ms. Snigdha Tiwari

Clinical Research & Bioinformatics Trainer | Expert in Computational Biology, Telemedicine & Data-Driven Healthcare

Ms. Snigdha Tiwari, a highly accomplished Senior Research Fellow from IIT Roorkee, with over five years of experience in Computational Biology, Bioinformatics, and Telemedicine System Design.

Ms. Snigdha has made significant contributions at the intersection of basic and applied research, particularly in protein-protein and protein-ligand interactions, molecular docking and simulation studies, and healthcare/clinical data management. One of the highlights of her work includes leading the development of the UTSARJAN App, a digital health platform designed for pediatric nephrotic syndrome data collection & clinical research in collaboration with AIIMS Delhi.

Currently pursuing a PhD in Computational Biology at the Translational Bioinformatics Lab, [Ms. Sngdha] brings a rich academic foundation with a background in Chemistry and Bioinformatics, alongside a passion for interdisciplinary research and advancing biotechnology/healthcare through innovation and collaboration. She currently serves as an Academic Support Specialist in the BIO-IT and Clinical Research department in Biotecnika.

About the Instructor

Dr. Ganeshan

Scientific expert, QA QC and Regulatory affairs

Dr. Ganeshan holds a Ph.D. in Microbiology and possesses extensive experience across diverse domains, including biosimilars, quality assurance, medical diagnostic laboratories, and medical devices. She has served as Clinical Director at Medical Electronic Systems India Pvt. Ltd., Research and Development, where she led the development of an advanced diagnostic testing kit for semen analysis.

Her expertise spans clinical trials, data analysis, and regulatory affairs, areas in which she has demonstrated both proficiency and passion. Dedicated to bridging science with real-world applications, she enjoys teaching and continuously learning new concepts, as well as conveying complex scientific ideas in a relatable and engaging manner.

Mrs. Divya S.

Precision medicine expert Biotecnika

With a strong academic foundation in plant biotechnology and molecular biology, Ms.Divya S. holds over two years of research and mentoring experience from the University of Kerala, where she guided both postgraduate and undergraduate students through their dissertation work.

Her expertise lies in plant tissue culture, molecular techniques, and gene expression analysis. She secured an All India Rank of 20 in the CSIR NET Life Sciences examination in 2018. For the past six years, she has been contributing as an AcademicSupport Specialist at Biotecnika, helping students and researchers excel in competitiveexams and research domains within the life sciences.

About the Instructor

Mrs. Tithi Saha

Genetics Scientist

Tithi Saha is a seasoned educator and life sciences expert with a strong academic and research background in Biotechnology. She holds a Master's degree in Biotechnology from the prestigious Nirma University, Ahmedabad, and successfully qualified the CSIR-NET examination in 2009, a testament to her academic excellence and deep subject understanding. She has also been a Gold Medallist of her batch.

She began her academic career as an Assistant Professor at Guru Ghasidas Vishwavidyalaya, Bilaspur, where she played a pivotal role in teaching and mentoring

students in core areas of life sciences. For the past 10 years, she has been an integral part of Biotecnika, one of the most trusted platforms for life sciences education and research training in India and currently working as Category Head of Competitive Exams.

With over a decade of teaching and mentoring experience, her areas of expertise include Genetics, Molecular Biology, Molecular Tools, and Evolution. She is known for her clarity of concepts, structured teaching approach, and her ability to make complex topics both engaging and accessible to students. Passionate about nurturing the next generation of scientists, she continues to inspire thousands of GATE, CSIR-NET, and life sciences aspirants across the country.

About the Instructor

Dr. Elamathi

ALML & Bioinformatics Scientist

Dr. Elamathi Natarajan is a dedicated bioinformatician with a robust background in computational biology, data analysis, and genomics. Holding a Doctorate in Bioinformatics from Dr. A.P.J Abdul Kalam Technical University and an MBA in Information Systems Management, she has made significant contributions to the field through both research and teaching.

she has served as an Assistant Professor and Head of Department (HOD) In-Charge at Kalinga University, Raipur, where she excelled in lecturing, research, and departmental management. At Biotecnika Info Labs Pvt Ltd, Bangalore, she played a key role in academic support, enhancing student success through coaching and program development.

Elamathi's expertise includes developing bioinformatics pipelines, conducting quality assessments, and applying machine learning algorithms to genomics data.

Recognized for her work, including a Senior Research Fellowship from the Indian Council of Medical Research (ICMR), she continues to drive innovation in bioinformatics and is seeking a new challenge to further advance scientific discoveries.

About the Instructor

Ms. Geethanjali

Pharmacovigilance & Drug Safety Trainer

Ms. Geethanjali holds a Master's degree in Pharmacy and brings 3.5 years of diverse experience across multiple domains. She previously worked as a Pharmacovigilance Associate, gaining valuable expertise in drug safety and Case Processing. Currently, she is working with Biotecnika as an Academic Support Specialist in pharmacovigilance.

Dr. Nilofer K Shaikh

Bioinformatics global Scientist, Biotecnika

With a strong background in big data analysis using computational approaches in cancer omics data, Ms. Nilofer K Shaikh brings a wealth of experience from MIT ADT University. Her expertise spans cancer research, drug design, molecular dynamics simulation, data mining, and various omics technologies. Proficient in Python, R, and computational methodologies, she has a deep understanding of genomics, metabolomics, proteomics, transcriptomics, pharmacogenomics, and AI for cancer treatment. Her skillset also includes machine learning, MySQL database management, and natural language processing (NLP).

About the Instructor

Dr. Neeraj Kumar, Ph.D.

Computational Biologist
& Bioinformatics Scientist

Dr. Neeraj Kumar is a computational biologist and bioinformatician with expertise in AI- driven drug discovery, cheminformatics, and structural bioinformatics. He holds a Ph.D. in Bioinformatics from CSIR-IHBT and AcSIR, India, specializing in machine learning (ML)and deep learning (DL) for virtual screening, drug repositioning, and lead optimization. His postdoctoral research at Pennsylvania State University focused on developing computational algorithms for immunoglobulin analysis.

He obtained extensive experience in ML/DL frameworks (TensorFlow, PyTorch), cheminformatics (RDKit, OpenBabel), and molecular modelling (AlphaFold, Rosetta, GROMACS) and has contributed primaily to AI-guided virtual screening pipeline development and HIV drug discovery and structrual bioinformatics projects. His research work has been published in esteemed journals including Journal of Cheminformatics, Medicinal Research Reviews, Computer in Biology and Medicine, with more in progress. He has also qualified prestigious national-levelexams including UGC-NET, GPAT, NIPER-JEE, and GATE.

Career Scope in QA/QC

Pharma & Biotech – GMP/GLP roles in manufacturing & biologics QC.

Food & Beverages – HACCP QA, microbiological testing.

Medical Devices – Risk management, ISO 13485 compliance.

Cosmetics & Personal Care – Stability & safety claim validation

Clinical Research / CROs – QA in trials, audit preparation.

Companies Recruiting in India & Abroad

Pharma

Biocon

Cipla

Dr.Reddy's

LUPIN

SUN PHARMA

CROs

Syngene

IQVIA

JUBILANT MOTORWORKS

parexel

Food

Nestlé

Amul

BRITANNIA

ITC Limited

Devices

Medtronic

SIEMENS Healthineers

Meril

Companies Recruiting in India & Abroad

Pharma/Biotech

Pfizer, NOVARTIS, Roche, GSK, AMGEN

CROs

charles river, labcorp, ICON

Food/Nutrition

DANONE, Mondelēz International, PEPSICO

Devices

PHILIPS, Abbott, Johnson & Johnson

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Your Bio Resource

Placement Assistance

Resume & LinkedIn Profile Building

Mock Interviews with QA/QC Experts

Recruiter Connects & Job Alerts

Project Experience Certificate + Work Experience Letter

Career Outcomes

1. QA/QC Officer / Executive
2. QC Analyst / Documentation Specialist
3. Validation Specialist
4. GMP/GLP Compliance Officer
5. QA/QC Auditor
6. Regulatory Affairs Associate

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