biotecnika
Your Bio Resource

INDUSTRY-READY QA/QC JOB TRAINING PROGRAM

Real-World Compliance Practice & Placement Support

45 Days Training+ 1 Month Project

With 100% Placement Assistance

Become Industry-Ready in QA/QC

Mail: info@biotecnika.org

stores.biotecnika.org

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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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PROGRAM OVERVIEW

- Industry-oriented QA & QC certification designed for Graduates (Life sciences, Biotechnology, Pharmaceuticals)
- Freshers in the fields of medical devices, diagnostics, food & cosmetics who want to take their first step in the industry or make their impact felt in any organization.
- Hands-on, real-life experiences and case study-driven, audit-ready training
- Covers core quality systems, regulations, audits, CAPA, data analytics & AI in quality, Career prospects
- Designed to make learners job-ready, audit-ready, and compliance-ready

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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

- **Mode: 100% Online**
- **Duration: 45 Days Training + LIVE 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**

What Makes This Program Different?

- End-to-end QA/QC lifecycle coverage
- Real industry case studies across 7+ sectors
- Reliable resources and guidance on use of SOPs, CAPA, Audit checklists, Risk assessment and Method Validation Reports
- Exposure to global regulations & standards
- Practical use of QA/QC software, data analytics & AI tools
- Strong focus on documentation, data integrity, compliance & inspections

WHAT YOU WILL BE ABLE TO DO AFTER THIS PROGRAM?

- Create and review SOPs, batch records, and quality documents
- Implement Advanced Documentation & Data Integrity
- Perform internal audits and gap analyses
- Handle deviations, non-conformances & CAPAs
- Execute High-Precision Analytical Validation
- Support regulatory inspections and certifications
- Apply statistical tools and analytics in QA/QC
- Solve Complex Industrial Problem
- Understand emerging trends and impact of AI, digital QMS & Pharma 4.0 in the field of QA and QC

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.

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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.

Industry-Aligned Mini Projects (Interview-Ready Portfolio)

- 1 month Mini Projects.
- You get to choose and work on 1 out of 12 options.

S.No.	Domain	Topic
1	Quality Systems	SOP Development, QA Documentation Flow & Change Control
2	Analytical Method Validation	HPLC-UV Method Development & Compliance
3	Deviation to Compliance	Root Cause Analysis & CAPA Design
4	Data Integrity & Digital Quality Systems	21 CFR Part 11, LIMS & ELN Audit Project
5	Pharmaceutical / Biotech Manufacturing Operations	Microbiological Environmental Monitoring Program Design for GMP Facilities
6	Internal Quality Auditing in Biotech Manufacturing	Compliance & Risk Assessment
7	Control Chart Analysis	Advanced SPC & Process Capability Analysis for Continuous Quality Improvement
8	Regulatory Pathways for Emerging Biotech Products	QA/QC Challenges & Compliance Strategy
9	Supplier Qualification & Audit Excellence	GMP-Based Vendor Assessment Project
10	Quality Risk Management (ICH Q9)	FMEA-Driven Risk Assessment & Control Planning
11	Analytical Quality Assurance & Method Transfer	Analytical Method Transfer & Inter-Laboratory Validation under ICH Q2 (R2) and USP <1224>
12	Control Charts & Trend Analysis	Statistical Process Control for Quality Excellence

Industry-Aligned Mini Projects (Interview-Ready Portfolio)

HOW IT WORKS:

- 1-month guided project
- Choose 1 project from 12 industry domains
- Mentored review & feedback
- Project certificate issued

WHAT STUDENTS GAIN:

- Real QA/QC documentation experience
- Practical problem-solving exposure
- Strong resume & interview talking points

TOOLS, TEMPLATES & PRACTICALS - YOU WILL LEARN

Industry-Standard Software & Tools

- **Statistical Analysis**: Minitab, JMP, JASP, JAMOVI.
- **Data Analytics & Viz:** Power BI, Tableau, Excel (Advanced Statistical Plug-ins).
- **Programming for QA**: Python & R (focused on SciPy, Statsmodels, Pandas, and SPC libraries).
- **Lab Management**: Demo access/walkthroughs of LIMS (Lab Information Management) and ELN (Electronic Lab Notebooks).
- **Quality Management (QMS)**: Exposure to workflows used in MasterControl, TrackWise, or Qualio.
- **Chromatography Data Systems**: Training on the logic of Empower and Chromeleon.

References, Resources and Handouts

- **Core QMS:** SOP (Standard Operating Procedure) and Work Instruction templates.
- **Validation**: Analytical Method Validation (AMV) Report and Protocol templates.
- **Risk Management**: ISO 14971 Risk Assessment Matrix and FMEA (Failure Mode and Effects Analysis) worksheets.
- **Corrective Action**: CAPA Form, Non-Conformance Report (NCR), and Out-of-Specification (OOS) Investigation forms.
- **Auditing:** 20-Point Internal Audit Checklist for ISO 17025/13485.
- **Regulatory**: Clinical Trial Protocol (CTP) templates and ALCOA+ Data Integrity checklists.
- **RCA Tools**: Automated Fishbone (Ishikawa) and 5-Why Analysis templates.
- **Reference Guidelines**: FDA GMLP, 21 CFR Part 11, ICH Q12/Q14, WHO, FSSAI, BIS, EU, ISO 13485, ISO 14971, FDA, CDSCO, EMA

Real world and Industry case based problems and practical projects

- Real world and Industry case based problems and practical projects
- Digitizing the Lab: Designing a digital SOP for a Biologicals manufacturing facility.
- Method Validation Simulation: Calculating Accuracy, Precision, and Linearity using raw lab data in Python/Excel.
- The Audit Simulation: Conducting a "Gap Analysis" on a simulated medical device facility.
- Root Cause Deep-Dive: Investigating a failure in Biologicals production using RCA tools.
- Advanced Data Monitoring: Plotting real-time Control Charts (X-bar, R-chart).
- Calculating Cp/Cpk to determine if a manufacturing line is "capable."
- Predictive Quality Project: Using Machine Learning to predict batch success based on historical deviation data.
- Experimental Design: Setting up a 2-factor Design of Experiments (DoE) to optimize a chemical assay.

OUTCOMES & VALUE

- Strong QA/QC documentation portfolio
- Industry-recognized skillset
- Audit & compliance readiness
- Career clarity across multiple industries
- Future-ready exposure to digital & AI-driven quality systems

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.

Dr. Prangya Rath

Cancer biology & Biotech Expert

Dr. Prangya Rath (PhD) is a CSIR-SRF NET (Life Sciences) qualified researcher & academician interested in the fields of life sciences, biotechnology, molecular biology, and cancer biology. She has more than 5 years of experience in the field. She completed her graduation in Zoology (H) from Delhi University, post-graduation in Biotechnology from the South Asian University Delhi, and completed her PhD with Biotechnology sp. from Amity University with funding from the Council of Scientific & Industrial Research (CSIR).

She has qualified CSIR UGC NET (Lectureship) Life Sciences in 2013 & 2016, CSIR JRF & NET Life Sciences 2017, and CSIR SRF & NET Life Sciences 2021. Her interest deals with molecular biology, metabolic disorders, cancer biology, biotechnology, genetic engineering, environmental biotechnology, etc. She has published over 30 scientific articles and has a good track record of scientific writing, publications, teaching, and biotechnology experiments.

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.

Kavitha Murugesan

Clinical Research Trainer

Kavitha is a dedicated Clinical Research Professional with two years of hands-on experience in clinical research and clinical operations. With a strong foundation in Good Clinical Practice (GCP) guidelines and regulatory requirements, Kavitha has supported the planning, coordination, and execution of clinical trials across various phases.

As a Clinical Research Trainer, she is passionate about sharing knowledge and supporting the professional development of research teams. She specializes in creating and delivering training sessions that cover essential clinical research concepts, site operations, protocol compliance, and ethical practices. Her approach is practical, engaging, and focused on building confidence and competence in new professionals entering the clinical research field.

With a keen eye for detail and a commitment to quality and compliance, Kavitha aims to foster a learning environment that supports operational excellence and high standards in clinical trial conduct.

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.

Job Role Mapping

What Jobs You Can Get After This Program?

Quality Assurance (QA) Roles

Possible Job Titles	What They Will Do
1.QA Executive / Officer	• Prepare and review SOPs, batch records & quality documents
2.QA Associate	• Handle deviations, support change controls & CAPA
3.Quality Documentation Specialist	• Support internal and external audits
4.Compliance Executive	• Ensure GMP, ISO & regulatory compliance

Quality Control (QC) Roles

Possible Job Titles	What They Will Do
1.QC Analyst	• Perform analytical and microbiological testing
2.Quality Control Officer	• Handle instruments like HPLC, UV, FTIR, ELISA, PCR
3.Laboratory Analyst	• Manage calibration, validation & data review • Apply SPC, control charts & trend analysis

Regulatory & Compliance Roles

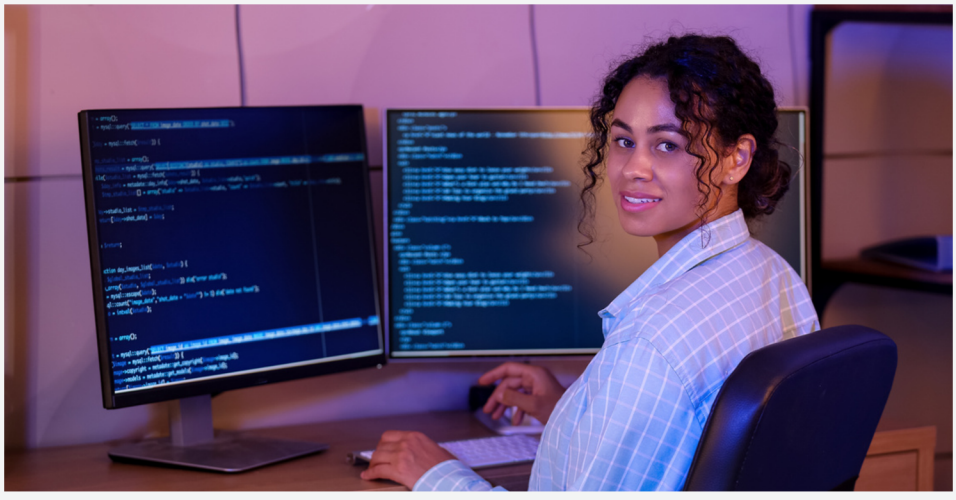
Possible Job Titles	What They Will Do
1.Regulatory Affairs Executive	• Support GMP, GLP, GCP & ISO compliance
2.Compliance Associate	• Assist in regulatory submissions & inspections
3.Quality Systems Executive	• Maintain documentation for audits & approvals • Track regulatory updates and guideline changes

Audit & Quality Systems Roles

Possible Job Titles	What They Will Do
1.Internal Auditor	• Conduct internal audits & gap analysis
2.QMS Executive	• Prepare audit reports & follow-up actions
3.Quality Systems Analyst	• Maintain QMS, EDMS & training records • Support certification and inspection readiness

Take-Home QA/QC Toolkit

- SOP and Work Instruction templates
- Analytical Method Validation report template
- CPT template
- Template and format of ISO 17025 and ISO 13485
- Fishbone & 5-Why templates, ALCOA+ checklist,
- Guidelines
  - FDA GMLP
  - 21 CFR Part 11,
  - ICH Q12/Q14,
  - WHO
  - FSSAI
  - BIS
  - EU
  - ISO 13485
  - ISO 14971
  - FDA
  - CDSCO
  - EMA
- Risk Management Plan and Risk Assessment Template, Quality Manual Template
- Templates for Non Conformity Reporting, CAPA form template, Compliant form
- Template : Fish bone excel, Pareto chart excel and control chart excel
- Python / Jupyter, Pandas, NumPy, Matplotlib, Seaborn, Plotly, SciPy, Statsmodels, Scikit-learn, Yellowbrick, spc, Openpyxl, Excel / LibreOffice Calc



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

& MANY MORE

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PLACEMENT ASSISTANCE

Resume & LinkedIn Profile Building

Mock Interviews with QA/QC Experts

Recruiter Connects & Job Alerts

Project Experience Certificate + Work Experience Letter

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DURATION
45 DAYS TRAINING
+ 1 MONTH PROJECT

STARTS: 26TH FEB 2025

TIME: 7–8 PM IST

MODE: 100% ONLINE

Enroll Today!

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