G. GNANASEKARAN, PhD
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PROFESSIONAL SUMMARY

- PhD professional with 20+ years of industrial experience in Pharma, Biopharma and Biotech.
- Demonstrate excellent leadership skills and the ability to promote a cohesive team work environment and motivate members to perform their best in completing tasks.
- Proven track record in effectively handling multiple projects simultaneously, taking full responsibility and initiative to deliver quality results on time.
- Equipped with well-honed interpersonal and communication abilities; capable of giving credit to others and dealing effectively with individuals from different backgrounds.
- Reputed for exceeding expectations in conducting research and managing projects, utilizing critical problem solving skills and keen attention to details to produce effective outputs.

OBJECTIVE

I am seeking a position that will enable me to expand my career in the science and education field while working in a productive and healthy work atmosphere.

SKILLS

• Strong background in Biotechnology	Administrator in lab	Team management
• Solid training in research laboratory	Independent Researcher	Analytical thinker
• Critical thinking and problem solver	Decision making	Troubleshooting
• Communication and coordination	Complaint Handler	Resource allocator

CAREER SUMMARY (Work Experience)

QC Manager - Nutraceutical and Pharmaceutical: 2002 - 2005 | *Raptakos, Brett & Co Ltd*, Chennai.

Technical Officer - Bioethanol, Biopolymer and Enzymes production: 2005 - 2009 | *Central Salt & Marine Chemical Research Institute* (*CSIR-CSMCRI*), Gujarat.

Principal Scientist - Biologics (mAbs) production: 2016 - 2019 | *AbGenics Life Sciences Pvt Ltd*, Pune.

Senior Manager - Vaccine production: 2020 - 2021 | *Bharat Biotech Intl Ltd*, Hyderabad.

Scientific Manager - Biosimilar production: 2022 - 2023 | *Krishgen Biosystems Pvt Ltd*, Mumbai.

GM - Antibiotics and Peptides production: Present | *Gujarat Themis Biosyn Ltd*, Vapi, Gujarat..

Academic Experience

Post-doctoral Scientist in Biotechnology: 2014 - 2016 | *Seoul National University*, South Korea.

PhD in Molecular Biology & Biochemistry: 2009 - 2013 | *Vaccine R&D Center*, South Korea.

MSc & BSc in Microbiology: 1999 - 2001 | *University of Madras*, Chennai, India.

Roles and responsibilities (QC)

- Supervising the QC functions to support the cGMP Manufacturing services offered by the Company
- Supervising the cleaning and sanitization of the area and equipment's and ensuring that environmental
- Monitoring of the area is being done regularly as per approved SOPs
- Supervising several GMP stability programs for various novel and biosimilar molecules
- Implementing the Quality Plan and Quality Control Plans in the facility as per GMP guidelines

- Managing the microbiology function and all aspects of microbiological services in support of sterile
- Injectable product manufacturing plant operations
- Guiding the QC team to prepare SOPs, protocols, reports and stability sections for Regulatory audit
- Ensuring every batch of product meets the defined standards for identity, safety, purity and quality
- Monitoring Quality staffs work performance, delegate responsibilities and stimulate career development
- Reviewing of OOS/OOT results in the laboratory and Review of Change Control/Deviations/ Incidents
- Review and monitoring regulatory compliance of site QC laboratories
- Documentation as per cGMP guidelines; Complaint management; Implementation of CAPA;
- Ensuring QC standards as per USFDA; Manage regular US FDA audits in a GMP compliant manner
- Ensuring proper and timely training of all QC personnel as per the training planner / schedule
- Troubleshooting and discussion of experimental assays with QC staffs
- Coordinating with cross-functional team (EHS, RA and Production) for better functioning
- Collaborate with operations managers to develop corrective action plans
- Resolve production and manufacturing problems to minimize cost and delay
- Conducting training programs for employees (Lab Safety, Policy, Regulations, Sanitation, GMP, GLP)

Microbiology Testing (SOP): Water, Environment monitoring, Finished products and Raw material analysis, Microbial limit test (MLT), Bacterial endotoxin test (BET), Sterility test, Pyrogen test, Growth promotion test, Swab analysis, Shelf life study, Method validation, Cleaning validation, and Internal calibration

Chemical Testing (titration, volumetric, gravimetric): pH variation, LOD, Consistency, Dissolution, DT, stability, bioavailability and physicochemical properties (analysis by HPLC, UV Spec, LC-MS/MS)

Handled analytical experiments: HPLC, GC, GC, GCMS &/ or TGA, DSC, XRPD, Particle sizer, UV, FTIR, Dissolution, Melting Point apparatus, KF apparatus, Autoclave, Hot air Oven, and other QC instruments

Audits Handled:

- Handling of major International and National regulatory audits and compliance
- **Reviewing Audit documents**: Quality Manual, Lab policy and procedures, Lab safety, SOPs, STPs, IOPs for Instruments, SOPs for Calibration, Internal Audit and Validation;
- **Record Maintenance:** Master list of Policies, Procedures, Files, Agenda, Employee details, Analytical results, equipment calibration records, Staffs training, Master list for chemicals and instruments

QC Manager in Raptakos, Brett & Co (Pharmaceutical Company)

- Bacterial Endotoxin test (LAL test), Sterility test; Pyrogen test in rabbits, Toxicity test in mice;
- **Microbiological analysis**: Water, Raw material and finished good (As per IP, IS, BP, USP)
    - Microbial limits test (MLT); Aerobic microbial count (AMC);
    - Enumeration of coliforms (MPN); Enumeration of Yeast and mould;
    - Water analysis by membrane filtration and Water validation
    - Growth promotion test (GPT); Bioburden testing; Disinfectant efficacy test
- **Pathogens isolation and identification**: *E.coli, Pseudomonas aerugenosa, Salmonella, Staph aureus, Streptococcus, Bacillus, Klebsiella, Shigella, Vibrio,* etc.
- Performing the hygienic test (swab test) for worker and supervisor in production area
- Calibration and validation of Instruments: Autoclave, Incubator, Hot air oven, Biosafety and LAF
- **Environmental monitoring and Qualification of Air class**: (Passive and active air sampling, Surface sampling-RODAC and compressed air sampling by Pinocchio super air sampler)
- Particulate matter analysis by LBPC method, membrane filtration and visible inspection
- SOPs preparation and review, Preparation of Batch Manufacturing Record (BMR) and Batch Production Record (BPR), Review of completed BMR and Product release;
- Reviewing the equipment IQ, OQ & PQ documents

Technical Officer in CSIR-CSMCRI | Biotechnology and Microbiology

- Biopolymer (Polyhydroxyalkanoate) and Enzymes production from marine bacteria (US Patent)
- Bioethanol production from red algae, *kappaphycus alvarezii* (US Patent)

Principal Scientist - Biologics (mAbs) development & production

- mAbs production against breast, oral, skin, esophageal cancer (Phage display)
- sdAbs production against AMR pathogens (*Staph*, *E.coli*, *Pseudo*, *Klebsiella*, *Candida*)
- Antibody Drug Conjugate (ADC) development (Ab + antimicrobial peptides)
- Antibodies validation: ELISA, Western Blotting, Flow cytometry
- Antibodies target identification: Peptide sequencing by LC-MS/MS (Agilent)

Senior Manager - Hepatitis B vaccine production (In-charge), Bharat Biotech

- Hepatitis vaccine: Hepatitis B surface antigen (HBsAg) production from *Pichia* yeast
- Covid vaccine: Vero cell lines production for indigenous vaccine development (R&D team)

Scientific Manager - Biosimilar production (operation)

- Recombinant enzymes production (polymerase, trypsin, carboxypeptidase)
- Recombinant HIV-1 gp120, HIV-2 gp36 production (HIV diagnosis)
- Host cell proteins (HCPs) production from BL21 *E coli* (ELISA kit)
- Upstream: BL21 *E coli* biomass production (2 L bioreactor, New Brunswick)
- Downstream: DEAE sepharose (Ion-exchange) and Sephacryl S-200 resin (Size-exclusion)

Scientific Manager - Biosimilar production (operation)

- Recombinant enzymes (polymerase) and viral proteins (HIV antigens) production
- Host cell proteins (HCPs) production from BL21 *E coli* (ELISA kit)

GM - Antibiotics production and Peptides development:

- Antibiotic: API rifampicin (TB) and its derivatives (Rifa O & Rifa S) from *Actinomycetes*
- Peptides development: shikimic acid (antiviral drug, Tamilflu), Semaglutide (diabetes)

Post-doctoral Scientist: Microbiology Laboratory, Biotechnology Department

Project 1: The role of quorum sensing (cell-cell communication) in plant pathogen

- Molecular Biology techniques: Gene cloning, sub-cloning and protein expression
- Proteomics: Protein purification by chromatography; Protein characterization by LC-MS/MS
- Blotting techniques: Southern, Northern and Western blot hybridization
- Mutants construction by Site-directed mutagenesis / Marker-exchange mutagenesis; Gene knockout;

Project 2: PacBio Genome sequencing (Genomics)

- Isolation of food-borne pathogens for sequencing: *Yersinia enterocolytica* & *Bacillus cereus*

PhD: Molecular Biology and Biochemistry Laboratory, Molecular Medicine Department
Thesis: Part I: Discovering cancer Biomarkers from Brain tumour (Proteomics)

- Autoantibodies and cancer biomarkers were isolated from cancer patient
- Cancer biomarkers were identified by LC-MS/MS (MassLynx)
- Biomarkers were cloned, protein expressed and purified (*E.coli* BL21)
- Biomarkers were used for the diagnosis of cancer patients (ELISA)

Part II: Cloning, over-expression and characterization of hypothetical proteins (Ligand-binding study)

- ATP-binding, GTP-binding, ppGpp-binding proteins were separated from *E.coli* K-12

- Hypothetical proteins were identified by LC-MS/MS (MassLynx)
- Hypothetical proteins were cloned, protein expressed, purified (*E.coli* BL21)
- Ligand binding study: Binding study performed between ppGpp ligand and YjgA protein
- YjgA gene knockout in *E.coli*; Established YjgA role; YjgA protein crystallization

PERSONAL DATA

Name	Dr. G. Gnanasekaran
Date of Birth	30th January 1979
Gender	Male
Nationality	Indian
Languages	English (proficient), Hindi and Telugu (medium), Tamil (proficient)

PUBLICATIONS: 2 US Patents; 10 Research Articles; 2 Posters; 5 talks; 4 Genomes submission

DECLARATION: I certify that the above facts are true to the best of my knowledge.