

CONSULTANT

Professional Summary

Highly organized Microbiologist successful at managing people and time, with expertise in Molecular Genetic Research, Quality Control System Operations, Cross Functional Leadership, Consulting, Training and Development and Validation of new products and facilities.

Skills

- RNA isolation knowledge
- Proficient in PCR
- In-vivo transcription
- Published researcher
- Skilled in genotyping
- Protein isolation
- Southern blotting
- Transcription profiling
- Equipment maintenance
- Statistical analysis
- ELISA assay
- Expert in design control
- ISO 9001 environment
- Extraction
- Separation and purification techniques
- Trained in lab safety
- MS Office proficiency
- Training proposals
- Expert in developing inventory systems
- Creative instruction styles and techniques
- Certified Training Specialist in Consulting
- Project management
- Presentations expert
- Charismatic public speaker
- Skilled in working with special needs adults
- Proficient in creating and maintaining schedules
- Taught Aseptic technique lessons to over 400 participants
- Instructional technologies knowledge
- Intuitive people management skills
- Assisted in OOS Investigations
- Change Control for Quality Systems RDP, NCBI, TIGR, KEGG, OMIM, Entrez, Minitab, PSI-Blast, Tree View, Gen Bank, Pub Med, Gene Pix Pro 5.0 analysis of COGS and CDD
- MS Office, MS Outlook, Citrix Sever, FTP clients, LIMS, SAP, Isotrain, and IKAT, VIBES, COGNOS, Word, Power Point, Access, Outlook.

Work History

Consultant 04/2016 to Current

Company Name – City , State

- As a Consultant, I provide consulting and technical training on proper aseptic techniques and FDA regulatory compliant behavior required while working in an aseptic and/or clean environment.
- Clean-room (Aseptic)Gowning Technique Training (ISO 5 - ISO 8)* Clean-room Technique Training (ISO 5 - ISO8) Clean-room (Aseptic)Manufacturing Technique Training (ISO 5 - ISO 8) Environmental Monitoring Technique Training Aseptic Cleaning Technique Training Sterile Gloves Techniques Training Basic Aseptic Technique Training.

Consultant Microbiologist 12/2016 to 05/2017

Company Name – City , State

- Conduct Bio Burden testing, Media Testing, water and clean steam testing for Aseptic GMP Facility Qualification.
- Facility Qualification and equipment/process or methods validation MODA (environmental monitoring system) development and uses.
- Commissioning Qualification Validation (CQV) activities Lead teams of validation professionals, and provided subject matter expertise in the validation of a variety of utility, facility and process equipment.
- Developed project scope statements, estimates and proposals.
- Developed policies, programs, and standard operating procedures.
- Developed and executed validation of documents/protocols for equipment compliance.
- IQ and OQ documentation development and execution of MODA System.
- Provide regulatory, quality and compliance solutions for the pharmaceutical, biotech, medical device and other regulated industries.
- Develop microbiological monitoring, control and continuous improvement strategies for API and fill-finish manufacturing, fermentation, recovery and purification, and aseptic processing and non-sterile manufacturing.
- Design and administer microbiological programs including environmental monitoring, investigations of laboratory and manufacturing microbial

excursions and out-of-specification findings, laboratory audits, optimization and management, laboratory and facility design and qualification, cGMP compliance, Pharmacopoeia compliance, barrier isolator design and microbiological validation, microbiology method and protocol development, validation and technology transfer, contact lens care formulation development, manufacturing, stability testing and product release, disinfection, sterilization and the use of biological indicators, cleaning validation, process development, regulatory audit response (e.g., FDA 483 and warning letters), regulatory dossier development support, and Process Analytical Technology (PAT).

- Support microbiology and rapid microbiological method suppliers and industry end-users in developing next generation technology platforms, validation and testing plans, financial and return on investment (ROI) strategies, commercialization approaches, and global regulatory and pharmacopoeia compliance.
- Act as subject matter expert for microbiology technology companies during due diligence, partnership, collaboration, merger and acquisition activities.
- Expert witness for matters related to pharmaceutical microbiology, ophthalmic formulations, contamination control, antimicrobial and preservative effectiveness, sterilization, pharmacopoeia interpretation and compliance, USP microbiology test methods, laboratory and manufacturing GMPs, formulation development and stability, sterile and nonsterile manufacturing, research and development, and product quality.

Corporate Trainer/Lead Aseptic Technique/Behavior Specialist 12/2011 to 12/2015

Company Name " City , State

- Spearheaded expansion and development initiatives in Aseptic Area.
- Used role-playing, simulations, team exercises, group discussions, videos and lectures to instruct participants in a variety of ways.
- Assessed training needs through surveys, interviews with employees, focus groups and consultation with managers.
- Created an online training program to be used during video training conferences.
- Organized training for 25 new employees per week.
- Increased performance scores by 80% by developing new employee processes.
- Extensively trained new and existing employees.
- Planned and delivered account management training to an average of 10 account managers per week.
- Reviewed daily metrics of account executives and employees to evaluate their strengths and weaknesses.
- Monitored participant workflow and behaviors throughout the training process.
- Conducted one-on-one tutoring sessions for new employees.
- Administered performance reviews to evaluate each participant's progress.
- Clearly communicated objectives for all lessons, units, and projects to all participants.
- Used a variety of assessment tools and strategies to improve instruction methods.
- Addressed all questions from training program participants.
- Created online training courses in Aseptic and Terminally Sterile Area.
- Assumed ownership of all training program initiatives.
- Align with functional managers on the management of training records to ensure that individual training plans and training records are accurate and up to date in accordance with 21 CFE Part 11 Identified core competencies of assigned functional areas to develop, within the Quality System, short and long-term planning strategies and initiatives in accordance with 21 CFR 820 Assess external service providers and/or site staff training needs and to support the development of eventual training programs for Terminal Sterilization Filling Line.
- Participated in research of regulatory issues and dissemination regulatory information to Production, QA, QC, and R&D departments and senior management as required.
- Actively, participated in the evaluation of regulatory compliance of documents/ products/ process/ test method changes.
- Reviews labeling and labels for compliance with regulatory requirements.
- Conducted internal audits.
- Lead department initiatives to improve current processes and procedures.

Quality Control - Assistant Scientist 10/2010 to 10/2011

Company Name " City , State

- Executed experimental tasks Obtained and interpret experimental data Conducted TMC, LAL, Micro-ID, TOC, and Purification Test Reviewed and edited protocols and standard operating procedures (SOPs) Maintain regular laboratory and system functions for the group Ensure compliance with cGMP, FDA, and SOPs guidelines and regulations.
- Performed tests on water, and the environment to detect harmful microorganisms and to obtain information about sources of pollution and contamination.
- Cleaned and maintained laboratory equipment.
- Stocked and rotated all prepared growth media.
- Performed routine monitoring of cleanroom manufacturing environments Performed micro-ID and organism analysis.
- Perform compliance adherence checks to all FDA, GMP regulations Collected and analyzed biological data about relationships between organisms and their environment.
- Interpreted research findings and summarized data into reports.
- Complied with Good Laboratory Practices and Title 21 CFR Part 11.
- Collected and processed specimens for clinical protocols.

Laboratory Manager - Laboratory Technological Assistant/ Research Assistant/Trainer 08/2007 to 06/2009

Company Name " City , State

- Ordered laboratory equipment and supplies

- Ordered laboratory equipment and supplies.
- Operated a genetic analyzer to sequence DNA.
- Kept accurate databases of specimens collected and stored in a repository.
- Collected and processed specimens for clinical protocols.
- Successfully completed transcription profiling experiments.
- Complied with Good Laboratory Practices and Title 21 Code of Federal Regulations Part 11.
- Scheduled and trained student staff members.
- Managed overall laboratory functions.
- Investigated the impact of intrinsic target properties on siRNAs pharmaceutical properties.
- Extracted DNA and genotype samples using SNP technology.
- Interpreted research findings and summarized data into reports.
- Collected and analyzed biological data about relationships between organisms and their environment.
- Programmed computers to store, process and analyze data.
- Maintained laboratory instruments and developed new laboratory equipment.
- Interpreted test results and developed nonstandard tests.
- Ordered chemicals for analysis and prepared reagents for analysis.
- Maintained compliance with DEC and EPA.
- Set up standards for sampling analysis and data interpretation using effluent analysis.
- Operated wet methods and instrumentation analysis.
- Accurately inventoried lab chemicals and supplies.
- Monitored and maintained specialized lab equipment (e.g. Minispec, shared microscope, etc.), laboratory supplies, and materials.
- Trained and developed undergraduate research assistants on proper protocol and procedures in the HIV lab.
- Conducted one-on-one tutoring sessions for new students.

Microbiology- Laboratory Technician 06/2007 to 09/2008

Company Name " City , State

- Maintained laboratory instruments and developed new laboratory equipment.
- Organized lab test solutions, compounds, and reagents.
- Routinely calibrated scales to minimize leakage due to calibration errors.
- Determined equipment operating efficiency.
- Interpreted test results and developed nonstandard tests.
- Maintained records for Michigan Department of Health audits.
- Ordered chemicals for analysis and prepared reagents for analysis.
- Recorded test results using a variety of chemistry-specific software programs.
- Operated wet methods and instrumentation analysis.
- Accurately inventoried lab chemicals and supplies.
- Collaborated with business units for cost model analysis.
- Created a rapid screening and testing factory to find acceptable materials.
- Steered process development experiments in the lab and support scale-up processes.
- Computed taxes owed by applying prescribed rates, laws and regulations.
- Complied with Good Laboratory Practices and Title 21 CFR Part 11.

Education

B.S : Microbiology May 2009 Michigan State University - City , State Microbiology

Skills

21 CFR Part 11, account management, API, aseptic techniques, Aseptic Technique, Basic, calibration, chemistry, Citrix, cleaning validation, COGNOS, conferences, Consultant, consultation, Consulting, continuous improvement, clients, databases, DEC, Department of Health, DNA, documentation, due diligence, ELISA, staff training, Equipment maintenance, senior management, experiments, Filling, financial, focus, FTP, functional, GMP, Good Laboratory Practices, in design, instruction, internal audits, interpretation, inventory, IQ, ISO 5, ISO 8, ISO8, ISO 9001, laboratory equipment, lab test, regulatory compliance, letters, LIMS, people management, materials, Access, MS Office, MS Outlook, Outlook, Power Point, Word, Minitab, next, optimization, OQ, PCR, performance reviews, policies, Presentations, process development, processes, process equipment, progress, Project management, proposals, protocols, public speaker, Quality, QA, research, researcher, safety, SAP, Southern blotting, specification, Statistical analysis, surveys, taxes, technical training, TOC, training programs, Transcription, tutoring, Validation, video, View, workflow