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Farmazia, bioteknologia eta gailu medikoen sektoreko hautaketa prozesua

Farmazia-sektorean espezializatutako **"Life Science Consultants"** enplegu-agentziak eta **"Lanbide EURES"**zerbitzuak hautaketa-prozesu bat antolatu dute, Irlandara joateko interesa duten profesionalak bilatzeko.

Batez ere, **ingeniariak** eta industriako beste espezialista batzuk behar dituzte, **Farmazian**, **Bioteknologian eta Gailu medikoen** sektorean esperientzia dutenak. Begiratu lanpostu bakoitzerako eskaturiko konpetentziak, ez bakarrik titulazioa. **GARRANTZITSUA:** NAHITAEZKOA DA INGELES-MAILA ALTUA ETA UNIBERTSITATE-TITULUA IZATEA.

Kontsulta ezazu eskaintzaren deskripzioa, jakiteko ea zure profila ondo egokitzen den eskatzen diren eskakizunetara. Dokumentu honi itsatsita, enpresak une honetan dituen eskaintza batzuk ikusi ahal izango dituzu, baina guztiak –130 plaza libre– ikusteko, begira ezazu web-orrian: www.lsc.ie

Irlandan ez dago ondo ikusita, kulturalki, enplegu-eskaintzetan soldata ere adieraztea, negoziatu egiten baita. Nolanahi ere, Irlandako soldatak nahikoa altuak dira, eta bat etortzen dira langilearen kualifikazioarekin. Zalantzarik izanez gero, jar zaitez harremanetan Espainiako erreklutatzailearekin –Amparo Montaner–, posta elektronikoz (aruiz@lsc.ie), edo telefonoz (00353 214 777 329)

Prozedura:

Eskaintza bat, edo gehiago, interesatzen bazaizkizu, hona eskariak egiteko jarraibideak:

- Bidali zure CVa, ingelesez, aruiz@lsc.ie helbidera, eures.euskadi@lanbide.euserako kopiarekin.
- Mezuaren gaian, idatzi interesatzen zai(zki)zun **lanpostuaren edo lanpostuen izena(k).**
- Enpresak zure profila egokia dela iritziz gero, elkarrizketa-ekitaldira gonbidatuko zaitu, lan-elkarrizketa egiteko.

EURESen TTE-FSE laguntzei esker, lan-elkarrizketetarako bidaietako gastuak ordainduk ahal izango dituzu. Betekizunak betetzen ote dituzun jakiteko, sakatu **hemen**.

VACANCIES ADVERTISED

VACANCY REFERENCE: VAC-15003
POSITION TITLE: QA Specialist
LOCATION: Little Island, Cork.
CONTRACT LENGTH: 12 months

POSITION SUMMARY: This position is responsible for carrying out tasks and projects related to management of Quality Assurance activities at JSCI as required by Good Manufacturing Practice (GMP). These activities include Material release, Change control, Event management, supplier qualification, Annual product review and validation compliance activities.

PRIMARY RESPONSIBILITIES:

- Batch Record Review & material release to ensure compliance with GMP requirements.
- Carries out tasks related to the administration of event management systems including Review & Approval of Event, Deviations, and Customer complaints.
- Carries out tasks related to the management of batch records design and approval. Ensures that Batch Operating Instructions are compliant with filed descriptions.
- Carries out administration on SAP MRP.
- Carries out tasks relating to the management of site change control systems.
- Supports & GMP conducts GMP/ICH Q7a training as required.
- Compiles Annual Product Reviews.
- Approves and compiles where appropriate validation protocols and reports (analytical, cleaning, computer, process, equipment, etc.).
- Supports system qualification and process validation activities.
- Reviews and approves SOPs/work instructions/forms from other departments on behalf of Quality Assurance
- Participates in the introduction of new process or modified process steps, as part of a New Product Introduction Team (NPI)
- Perform GMP audits on-site and vendor facilities as required.

EDUCATION AND EXPERIENCE:

- Third level Scientific degree
- At least 5 years QA/Validation experience within the biological and/or pharmaceutical industry.
- Demonstrated knowledge and application of industry regulations as they apply to qualification and validation, including those of FDA, IMB, EMEA and other authorities.
- Ability to apply GMP regulations and other FDA and international guidelines to all aspects of the position.
- Desirable: Experience in statistical sampling plan development

VACANCY REFERENCE: VAC-15001
POSITION TITLE: Validation Technical Specialist
LOCATION: Galway
CONTRACT LENGTH: Permanent

PRIMARY RESPONSIBILITIES:

- Responsible for reviewing and maintenance of Validation lifecycle documentation to ensure there is sufficient documented evidence to support product manufacturing in accordance with appropriate regulatory agency validation requirements, customer expectations, internal company standards, and current industry practices.
- Provide technical writing & support to quality systems records including; Deviations, CAPAs, and Change Controls which are associated with validated systems.
- Provide sound scientific and compliance expertise during the development of cGMP validation documentation; i.e. protocols, reports, SOPs, etc.
- Responsible for evaluating and maintenance of validation and process data to support recommendations for changes and/or improvements to the process.
- Co-ordinate workshop sessions and develop knowledge sharing platforms supporting the Validation/Technical Departments and knowledge transfer across the site.

EDUCATION AND EXPERIENCE:

- Minimum of a Bachelor's degree (or equivalent) in a Technical Discipline with a minimum of 4 years' post graduate experience in Technical Services / Manufacturing Support /Validation within a cGMP manufacturing environment in a biologics/ pharmaceutical setting.
- Direct experience within liquid & lyo fill finish technology is a strong plus.
- Must have knowledge of current industry best practice & validation requirements for pharmaceutical manufacturing processes.
- Proficiency in speaking, comprehending, reading and writing English is required.

VACANCY REFERENCE: VAC-14996
POSITION TITLE: Senior Project Engineer
LOCATION: Carraigtowhill, Co. Cork
CONTRACT LENGTH: Permanent

POSITION SUMMARY:

The Senior Project Engineer reports to the Senior Engineering Manager. This position has been identified as a key development position in order to identify future Engineering Managers for the site. The successful candidate will be working on and have responsibility for delivering key strategic projects on site due to current site expansion. **TRAVEL:** 10%

PRIMARY RESPONSIBILITIES:

- Generate and implement detailed plans for continuous, on-going New Product Introductions/installations and product enhancements through creative thinking, incorporating market research, competitive analysis, customer input/feedback, advances in technology and business judgment
- Ensures execution of all project activities and supervision of all engineering disciplines in adherence to the existing site procedures and the Project Management System
- Detailed budget management & adherence
- Develop the design of the process with the design consultants to meet the site needs. The role will involve the supervision of design consultants and contractors as well as liaising with suppliers and site management.
- Co-ordinates the development of project design through design consultants to meet the site needs
- Makes day-to-day decisions related to successful accomplishment of project objectives.
- Responsible for the design, commissioning and handover process packages to the end-user departments
- Maintain accurate and complete product and project documentation in accordance with cGMP, EHSE Regulatory requirements and electrical, mechanical & automation standards

EDUCATION AND EXPERIENCE:

- B.Sc. degree in Process; Chemical; Mechanical; Electrical Engineering or other related discipline. (Masters Desirable)
- Project Management Qualification desirable
- Ideal candidate will have experience and taken lead role in all or some of the following areas Projects, Facilities, Maintenance, or Manufacturing areas
- 5 + years' experience with the design and installation of process equipment & facilities in the pharmaceutical industry (Desirable) or medical device industry
- Strong project experience and proven ability to influence others are essential.
- Lean Six Sigma Experience / Certified Green Belt or equivalent preferred.
- Management of People (Desirable) or Project Team Leadership (Essential)
- Experience of current cGMP requirement of an FDA/HPRA approved facility
- Experience working on validated systems
- Experience of Statistical Process Control in pharmaceutical process systems.

VACANCY REFERENCE: VAC-14828

POSITION TITLE: QC Analyst
LOCATION: Co. Cork
CONTRACT LENGTH: Permanent

JOB PURPOSE:
This QC Analyst will be part of the QC department supporting analysis of raw materials, in-process material, and finished product.

RESPONSIBILITIES:

- Execute analysis of raw materials, in-process material, and finished product in compliance with schedule.
- Complete analysis in accordance with SOP and standard methods.
- Calculate results and report data, including trend analysis as required.
- Execute analysis of water, cleaning samples etc as required.
- Carry out routine maintenance activities for QC systems:
- Execute calibrations and PM of equipment as required to ensure equipment is appropriate for use for analysis.
- Co-ordinate maintenance schedules with external suppliers to ensure compliance with schedule and in house procedures.
- Prepare all solutions, reagents etc. associated with analysis.
- Execute stock control on laboratory consumables including reagents, solvents to ensure there is adequate supply to execute tasks. Complete purchase orders as required and manage materials on receipt.
- Participate in the preparation of QC documents including SOPs, specifications, methods
- Participate in training and development activities to ensure that new technologies are applied and that skill level is developed.
- Execute validation studies and transfer studies to ensure equipment, methods and personnel are appropriately qualified.
- Participation in investigations into failures, out of trends and out of specifications as required.

EDUCATION AND EXPERIENCE:

- A BSc in Analytical Science or Equivalent
- 2-3 years' experience in GMP lab environment (preferably solid dose pharma)
- Direct experience of HPLC analysis and strong raw materials testing experience.
- Experience of protein handling and ELISA analysis will be an advantage
- The ability to travel ~5% of the time

VACANCY REFERENCE: VAC-14808
POSITION TITLE CQV Engineer
LOCATION: Dublin
CONTRACT LENGTH: 24 months

PRIMARY RESPONSIBILITIES:

- Participate in a CQV Team with key emphasis on: membership of Combined CQV Team (Vendor, Craft Contractor, Operations and CQV Personnel); planning of Own Activities and ownership and Closure of open issues (Punch Items, Non-Conformances etc).
- Execution of CQV protocols on Liquid chromatography and / or membrane filtration (UF/DF) operation and principles, downstream processing and CIP/SIP.
- To review & approve automation FDS for DeltaV (CM's, EM's, Graphics & Phases)
- To have a detailed knowledge of specific Bio-Process and Clean Utility unit operations
- Draft and review CQV test documentation.
- Accountable for ensuring activities are scheduled, tracked and reported appropriately, and achieving project deadlines
- Input into the core aspects of Operations SOP's.
- Planning and execution of all commissioning activities in adherence to site safety procedures.
- Understanding and applying industry specific compliance standards/regulations to all CQV activities
- First-hand experience of a Risk Based Verification CQV (ASTM E2500) project execution
- Leading Risk assessments, root cause analysis and investigations.
- Generation and review of protocols, reports, project change controls and deviations
- Participates in internal and external audits and inspections where required.

EDUCATION AND EXPERIENCE:

- Commissioning, qualification and validation experience in Bulk Drug Substance Manufacturing Facility (min 2 – 5 years)
- Experience in Liquid chromatography and / or membrane filtration (UF/DF) operation and principles, downstream processing and CIP/SIP.
- Experience in using DeltaV automation platform and review/approval of associated documentation.
- Experience in IMB/FDA environment advantageous.
- Proven track record in RFT generation of validation/verification documentation

VACANCY REFERENCE: VAC-14840
POSITION TITLE Automation Engineer
LOCATION: Dublin
CONTRACT LENGTH: 12 months

RESPONSIBILITIES:

- Ownership and administration of equipment control systems in a GMP regulated manufacturing setting
- Support Drug Product manufacturing within the Formulation, Vial/Syringe Filling, Lyophilisation, Component Preparation and Packaging areas
- Lead and support system improvements, development of detailed specification, engineering documents, and standard operating procedures
- Lead technical root cause analysis, incident investigations and troubleshooting issues related to electrical, instrumentation and equipment control systems
- Support new product introductions or new technology introductions by performing engineering assessments, implementing automation system configuration changes and supporting engineering runs
- Solving complex problems, project management, lifecycle management and operational excellence
- Develop and manage change control requests per established SOPs and processes
- Support a safe working environment by complying with all pertinent environmental health/safety practice, rules and regulation

EDUCATION & EXPERIENCE:

- Bachelors in Electrical Engineering or Computer Science, Chemical Engineering, Biotech Engineering or related life science engineering with 4+ years' experience in operations/manufacturing environment
- Manufacturing automation experience in biopharmaceutical Formulation/Fill/Finish or Active Pharmaceutical Ingredient (API) facilities
- Excellent control systems automation background focused specifically in design, installation, programming, validation and lifecycle maintenance of automated equipment specifically in the areas of Formulation, Vial/Syringe Filling, Lyophilisation and Packaging
- Experience with Rockwell Automation PLC/SCADA/Batch, Siemens PLC/HMI, iFix, Wonderware, Elau/Kinetix Motion Control, ControlNet, DeviceNet, Profibus and OSIsoft PI Data Historian
- Knowledge of GAMP software development lifecycle, ANSI/ISA-S88 and S95 industry standards and 21 CFR Part 11
- Strong network architecture or engineering proficiencies including TCP/IP, Routing, Switching, Network IDS/IPS, Active Directory, Domain Integration and Firewalls
- Solid leadership, technical writing, and communication/presentation skills
- Experience in change control, non-conformance, corrective and preventative actions, and validation practices

VACANCY REFERENCE: VAC-14816

POSITION TITLE: Validation Associate

LOCATION: Ringaskiddy, Co. Cork

CONTRACT LENGTH: 12 months

POSITION SUMMARY:

This position is responsible for the execution, review and approval of validation activities in a GMP regulated environment, focused on implementation of new manufacturing processes, equipment, cleaning & steaming, computer systems, laboratory systems and changes to existing equipment/processes.

PRIMARY RESPONSIBILITIES:

- Developing validation plans for specific system implementation projects.
- Execute (protocol generation, execution, and final package preparation and reports) validation activities related to the implementation of process, cleaning, procedures and practices to establish approval criteria, and identify and implement solutions.
- Establish Site Validation Policies, through development, generation and implementation of validation master plans, guideline documents and SOP's.
- Lead and represent Validation in multi-departmental meetings & project teams.
- Identifies and implements improvements to the QA Validation systems.
- Participation in the change control program for modifications to qualified systems.
- Coordinate validation activities involving cross-functional, multi-departmental teams including: Manufacturing, Process Sciences, Process Development, Quality Control, Quality Assurance, Regulatory Affairs, and others.

EDUCATION AND EXPERIENCE:

- Bachelor of Sciences degree, or higher, in a technical discipline (physical, engineering, chemical or biological sciences) is required.
- 1+ years' experience in a cGMP regulated manufacturing environment, with exhibited knowledge and a high level of proficiency in process and cleaning validation.
- Ability to comprehend technical information related to equipment, processes, and regulatory expectations.
- Experience with participation in regulatory inspections presenting or defending departmental functions in audits or regulatory inspections.
- Understanding and familiarity with FDA & European regulatory requirements, guidelines, and recommendations for process and cleaning validation expectations.

VACANCY REFERENCE: VAC- 14888

POSITION TITLE: QC Chemist

LOCATION: Carrigtwohill, Co Cork

CONTRACT LENGTH: Permanent

QC Chemist required for a market leading, top Ten Biopharmaceutical Company based in Cork. The Cork campus specialises in Tabletting, Solid Dose, Packaging & Distribution of a range of products. The site is a strategically important site within their global operations and has grown consistently since its founding almost 15 years ago. Today the site is responsible for Tablet manufacturing, quality control, packaging, and the release and distribution of the company's products in the EU and other international locations. The Cork campus is a team focused organisation, who work to ensure their medicines are delivered on time and to the highest possible quality.

PRIMARY RESPONSIBILITIES:

- Performs final product /raw material testing.
- Reviews testing, and Release commercial batches from QC so that commercial manufacturing/packaging activities are not impacted.
- Update Department metrics and present to QC management
- Assists in laboratory method and/or instrumentation validation activities and act as an instrument SME
- Conducts procedure updates in QC lab and GMP reviews of logbooks
- Coordinates LEAN and 5S efforts.
- Coordinates compliance activities within the department and trending of results.
- Perform/Co-ordinate QC and cross functional projects as assigned.
- Act as a technical resource within the department as well as cross functionally

EDUCATION AND EXPERIENCE:

- BS degree in Chemistry or equivalent.
- 4+ years of relevant experience in a pharmaceutical operations environment.
- Working knowledge of GMPs, pharmacopoeial, and regulatory requirements for testing and validation.
- Advanced knowledge of current Good Manufacturing Practices (GMPs).
- HPLC experience essential.
- Instrumentation skills.
- Detail orientation and problem solving skills.
- Organizational skills and common sense.
- Strong verbal, written, and interpersonal communication skills are required.
- Proficiency in Microsoft Office.

VACANCY REFERENCE: VAC-14463
POSITION TITLE: Validation Lead
LOCATION: Carrigtohill, Co. Cork
CONTRACT LENGTH: Permanent

PRIMARY RESPONSIBILITIES:

- Responsible for performing the validation of equipment, utility systems, facilities, processes and/or automation systems for projects. This includes developing validation master plans with minimum supervision, preparing protocols independently, analyzing test results, and preparing technical reports.
- Contributes directly to the completion of validation projects through the development of validation schedules, master plans, validation protocols and reports for systems that may be complex in nature, to support clinical and commercial manufacturing.
- Coordinates validation activities with, and seeks team supports from, Validation, Development, Manufacturing, Engineering, Quality, third Parties, and other groups on validation projects to ensure validation projects are carried out on time and on budget.
- Coordinates the activities of assigned validation and contract personnel and ensures the quality of completed work.
- Reviews protocols, reports and data tables generated by peers and contract personnel.
- Represents the department on cross-functional project teams.
- As required, assists in preparation of regulatory submissions and presents validations in respective SME areas to regulatory authorities during routine internal and pre-approval inspections.

EDUCATION AND EXPERIENCE:

- In-depth understanding and application of validation principles, concepts, practices, and standards.
- Proficient in current Good Manufacturing Practices (GMPs).
- Extensive working knowledge of equipment and systems.
- Extensive knowledge of industry practices.
- Excellent verbal, written, and interpersonal communication skills are required.
- Demonstrated investigation and report writing skills.
- Proficient in Microsoft Office applications.
- Some years of relevant experience and bachelor's degree in science or related field.

VACANCY REFERENCE: VAC-14922
POSITION TITLE Systems Engineer
LOCATION: Mulhuddart, Dublin
CONTRACT LENGTH: Permanent

POSITION SUMMARY:

Maintain and develop the site's control systems (Emerson DeltaV, RS3 and PLCs) and process information systems in support of current plant production and in accordance with regulatory requirements (GMP). Provide on-going engineering and troubleshooting support to production operations.

PRIMARY RESPONSIBILITIES:

- Ensure the safe and efficient operation of the site's control and production information systems - DCS
- Support and maintain the above systems' hardware, networks, servers and peripherals.
- Maintain the validated status of the above systems, in accordance with EU GMP, GAMP requirements.
- Support manufacturing production targets by ensuring consistent system performance.
- Conduct maintenance on the system as required.
- Provide timely response to systems / manufacturing issues.
- Keep safety and operability of the system under constant review.
- Identify, develop and deploy control and manufacturing systems projects to enhance site operations and processes.
- Generating relevant reports as requested.
- Source and purchase equipment, software and services as required.
- Other systems duties/projects as they arise

EDUCATION AND EXPERIENCE:

- Degree / Diploma in an Engineering / IT / Science discipline
- Candidate should be able to demonstrate some experience in programming (e.g. PLC, DCS , VB, JAVA. Python, Web development etc.). Specific system training will be provided.
- Experience with control systems, instrumentation, IT administration or other technical discipline is highly desirable.
- Also beneficial would be experience with: Emerson DeltaV DCS, Rosemount RS3 (DCS), OSI PI, GMP regulations
- Good interpersonal skills
- Ability to work on own initiative
- Self Starter/Motivated.

VACANCY REFERENCE: VAC-14699
POSITION TITLE Senior Product Development Scientist
LOCATION: Mulhuddart, Dublin
CONTRACT LENGTH: Permanent

PRIMARY RESPONSIBILITIES:

- Perform tasks with a focus on oral formulation of conventional and controlled release solid dosage forms using the following processes (as applicable to on-going and future projects): High Shear and Fluid Bed Granulation, Roller compaction, Tableting, Coating, Encapsulation, Oral Liquid Formulation
- Identify and implement formulation and process development/optimisation programmes with clear objectives, participate and lead project team meetings and act as a role model for high standards of performance.
- Develop Design of Experiment (DOE), interpret results and issue relevant documents.
- Supporting new product introduction, scale up and commercialization of manufacturing processes.
- Continue to develop knowledge in relevant areas and expand breath of knowledge, including areas outside of direct function, with a view to transferring to others.
- Support the preparation of formulation/process development documentation (e.g. CMC sections of IND, NDA, CTD) to support global regulatory filings.

EDUCATION AND EXPERIENCE:

- Minimum of a BSc (Hons) Degree in any of the following:
- At least 5 years' of relevant work experience in pharmaceutical product development
- Experience in physical chemistry techniques and applications.
- Ability to critically analyse and interpret bioanalytical and physiochemical data.
- Excellent project management and time management skills with ability to work to strict deadlines.
- Strong technical writing skills in oral formulations, new product introduction, design of experiments and statistical analysis of results
- Experience of liquid/ointment formulations
- Experience of supporting regulatory filling of new products US/EU (IND/NDA)

VACANCY REFERENCE: VAC-14620

POSITION TITLE: Project Engineer

LOCATION: Ringaskiddy, Co. Cork

CONTRACT LENGTH: Permanent

PRIMARY RESPONSIBILITIES:

- Project Management of Site projects including:
    - Project scoping
    - Cost estimation
    - Scheduling
    - Procurement
    - Design
    - Tendering
    - Construction/Installation Supervision
    - Commissioning/Validation
- Managing facilities service contracts
- Ensuring the site facilities are maintained in good order
- Provide technical support to production and other departments.
- Supervise and liase with external facility contractors.
- Work in a proactive manner to improve safety awareness and metrics.
- Prepare budgets within the area and control expenditure

EDUCATION AND EXPERIENCE:

- A science or engineering primary degree
- A minimum of 5-10 years projects experience in a cGMP environment with demonstrated ability to support customers and manage projects
- Excellent interpersonal and communication skills.
- Experience working in an IMB/FDA regulated environment is essential.
- Good knowledge of GMP requirements with respect to automation activities.
- A proven track record in the management of Projects and facilities.

VACANCY REFERENCE: VAC-14999
POSITION TITLE: Manufacturing Engineer
LOCATION: Ringaskiddy, Co.Cork
CONTRACT LENGTH: 12 months

PRIMARY RESPONSIBILITIES:

- Support the day to day manufacturing operation environment to allow operations to meet its targets.
- Support business key metrics with ongoing process improvements and introduction of new technology.
- Deliver key projects to the Value Stream which will positively impact on the key metrics.
- Drive process improvements/capacity increases through New technology/equipment introductions.
- Competent in validation requirements on new equipment introductions/processes/process changes.
- Design & develop tools, fixtures, gages and special equipment for manufacturing operations and new product / process introductions in conjunction with Toolroom Technicians and Manufacturing Engineers.
- Identify capital spend and budget requirements for process improvements.
- Preparation and maintenance of all relevant manufacturing specifications.
- Preparation and project management of all line extensions/NPI including supporting documentation as reqd.
- Focus on reduction of unit cost of production, through accountability for specific cells i.e. Consumable Cost, Scrap Cost and Cell Efficiency.
- Support ongoing Safety Incident corrective actions and ERGO team initiatives/actions
- Identify and lead cost and technical improvements under the departments continuous improvement program.
- Actively interfacing with cross-functional team members, always practicing good team work in support of day to day operating requirements.
- Demonstrate strong leadership and a clear identifiable work ethos within the Projects Engineering team.
- Preparation and maintenance of manufacturing specifications for specific projects.
- Ensure effective closure on Quality System documents (Audit Actions, NCR's, CAPA's, etc).
- Ensure all process developments, NPI etc are managed in accordance with the Quality management system.

EDUCATION AND EXPERIENCE:

- Degree qualified in a relevant Engineering / Science discipline, with 2+ years relevant experience.
- Experience in 5axis CNC machining including Siemens Unigraphics NX CAM programming.
- Experience in regulated industry, FDA, ISO, etc.
- Demonstrated ability to lead significant projects to completion, on time and within budget

VACANCY REFERENCE: VAC-14933
POSITION TITLE: Quality Engineer
LOCATION: Ringaskiddy, Co. Cork
CONTRACT LENGTH: 18 months

PRIMARY RESPONSIBILITIES:

- Support quality improvement initiatives such as process and product characterizations that lead to continuous / cost improvements.
- Review/analyse the effectiveness of PDCA, Six Sigma, Kaizen, Lean Techniques and/or other improvement tools and programs.
- Supports the development of quality engineering and quality compliance with the right skill sets for new product introductions, and product life cycle management.
- Review/analyse whether current product and processes (including actions or decisions conducted) are in compliance to standards such as the QSRs, ISO 13485, etc.
- Champions compliance to applicable Global Regulations and standards (e.g. QSRs, ISO, EN and Medical Device Directive (MDD) requirements) including providing support during internal and external audits.
- Conduct periodic line audits to assess for production controls such as lot segregation. Review results of area audits to ensure that corrective and preventive actions are adequate.
- Partners with R&D and other cross functional partners to ensure the proper application of design controls, risk management and the investigation/correction of design failures/challenges.
- Prepare documentation to support any regulatory submissions as a result of implementation of new technologies / inspection methods.
- Conduct investigation, bounding, documentation, review and approval of non-conformances, CAPAs and customer complaints. Escalation of quality issues as appropriate.
- Analyse/review effectiveness of preventive and corrective actions. Review root cause investigation according to an established process.
- Accountability and ownership of Quality metrics including maintenance and reviewing of leading and lagging indicators of quality.
- Generate IQ, OQ, PQ, TMV Protocols and Reports.

EDUCATION AND EXPERIENCE:

- A minimum of a Bachelor's Degree, preferably in Engineering or related technical field. Generally requires 2-4 years related experience.
- This position will require relevant experience working in manufacturing/operations.
- In-depth knowledge of product/process Risk Management (FDA and ISO standards)
- Experience with a proven track record of implementing appropriate risk mitigation.
- Technical training and experience using Statistics, Lean and Six Sigma Methodologies is preferred including Measurement System Analysis, SPC, DOEs, Reliability, etc.
- Understanding of the NPI (New Product Introduction) process and Process Validation expertise is preferred.
- This position may require up to 10% travel and will be based in an MD&D manufacturing facility.

VACANCY REFERENCE: VAC-14897
POSITION TITLE: Senior Metrology Engineer
LOCATION: Ringaskiddy, Co. Cork
CONTRACT LENGTH: 6 Months

PRIMARY RESPONSIBILITIES:

- Interprets drawings featuring Geometric Dimensioning & Tolerancing (GD&T) per ASME Y14.5 to identify product inspection requirements.
- Writes and edits programs utilized in manufacturing PC-DMIS, COSMO & CALYPSO, etc
- Serves as technical expert for metrology inspection.
- Facilitates, encourage and coordinate continuous improvement with respect to inspection activities.
- Set-up data collection parameters for inspection measurements where required.
- Installation of inspection assets as to follow local validation lifecycle.
- Develops inspection strategies to meet business needs.
- Development of new inspection techniques as required.
- Development of standard platforms where applicable (vision systems, contact/non contact inspection systems.
- Develop method of "gauge" evaluation to consider, calibration frequencies, gauge life, fit for purpose, etc.
- Generates the inspection report per the customer requirements.
- Performs 1st Article inspection of newly developed product.
- Site lead on development of inspection fixturing to ensure minimum measurement error during inspection.
- Inspect complex machined fixtures, and parts using advanced measuring and layout instruments and equipment.
- Participates in design reviews on cross-functional teams to ensure that conformance to specifications, inspect ability, reliability, and quality system objectives are met.
- Prepare detailed inspection documentation such as written descriptions of inspection results including deviations from engineering specifications.
- Work from written or verbal instructions, detailed engineering drawings, and 3D models.
- Writing of work instructions for inspection techniques relating to standard platforms for associates.

EDUCATION AND EXPERIENCE:

- Certificate / diploma in Quality / Manufacturing / Engineering
- Minimum 3 years in CMM programming PC-DMIS/COSMOS/CALYPSO programming experience desirable.
- Experience of laser scanning techniques and other inspection technologies.
- Knowledge of 21 CFR 820, 21 CFR 11 and European regulations associated with the medical device industry
- High understanding of GMP
- Working knowledge of Quality Systems (FDA/ISO) within a regulated environment.
- Familiarity with statistical analysis software.

VACANCY REFERENCE: VAC-14886

POSITION TITLE: Manufacturing Engineer

LOCATION: Limerick

CONTRACT LENGTH: 12 months

PRIMARY RESPONSIBILITIES:

- Technical support for manufacturing
- Utilise Lean Manufacturing tools
- Develop and improve planned maintenance regimes
- Train maintenance engineers on planned maintenance regimes
- Improve fault diagnosis skills within engineering
- Deal with equipment suppliers and service providers
- Develop support relationships with external sources:
    - Equipment suppliers
    - Service suppliers
    - Spare Suppliers
    - Professional bodies
    - Consultancies
- Support improvement projects on manufacturing equipment
- Upgrade existing equipment to improve:
    - Quality
    - Throughput
    - Workflow
    - Yield
- Support change control
- Support new product and process introduction
- Be aware of quality elements of new products and assess their impact on current manufacturing process equipment

EDUCATION AND QUALIFICATIONS:

- Degree qualified in a relevant Engineering or Science discipline (Manufacturing, Mechanical, Electronic, Production etc.).
- A minimum of 3 years relevant experience
- Previous experience in engineering support roles in a high volume manufacturing environment

Desirable:

- Experience in process transfer or large project roles in medical device environment
- Demonstration of sound methodology in fault-finding techniques
- Experience of Validation processes in a GMP environment
- Design review experience
- DOE Experience
- MTBF, MTTR. OEE experience
- Lean Manufacturing experience

VACANCY REFERENCE: VAC-14576

POSITION TITLE: Automation Engineer

LOCATION: Limerick

CONTRACT LENGTH: 12 months

PRIMARY RESPONSIBILITIES:

- Provide ongoing operational support and maintenance of the sites Distributed control systems, Data Historians and reporting systems.
- Directly support operations with troubleshooting and issue resolution with respect to automation systems and applications,
- Own and Perform technical and validation tasks on distributed Automation systems
- Participate and act as automation expert (SME) in cross functional teams in support of large capital projects.
- Investigation of manufacturing deviations and anomalies related to automation and software and manage projects related to corrective action or equipment performance improvement including Site Change Control.
- Program PLC and HMI applications for automated process equipment, capable of troubleshooting and demonstrates knowledge of instrumentation and controls.

EDUCATION AND EXPERIENCE:

- Bachelor's degree in Engineering, Computer Science or related technological field and 5+ years of relevant work experience.
- Experience with implementing or supporting the operation of one or more the following platforms: FactoryTalk View, Proficy Data Historian, Allen Bradley PLCs, iFIX.
- Experience working in a regulated industry (i.e. FDA / cGMP).
- Experience authoring and reviewing standard operating procedures, system test plans, on-the-job-trainings manuals and other controlled documents.
- Effective written and verbal communication skills

VACANCY REFERENCE: VAC-14611
POSITION TITLE: Manufacturing Automation
LOCATION: Cork
CONTRACT LENGTH: Permanent

PRIMARY RESPONSIBILITIES:

- Support cleanroom automated assembly lines as the manufacturing engineer providing line support for technical issues.
- To understand, learn and develop in-depth knowledge for a range of equipment and to become the Subject Matter Expert (SME) for specific assigned processes and equipment.
- Responsible for managing the overall equipment performance through the appropriate use of Lean Manufacturing tools and techniques.
- Implement/improve equipment maintenance procedures for critical equipment and responsibility for sustaining line maintenance routines
- To develop and improve current standard operating procedures (SOP).
- Prepare detailed technical reports on process and quality issues.
- Work effectively within a team and cross functionally to expedite completion of critical tasks.
- Ensure that all Health, Safety, Environmental and Regulatory requirements are fulfilled

EDUCATION AND EXPERIENCE:

- A technical Engineering qualification at or equivalent to Level 8 degree in the National Framework of Qualifications in an approved Engineering discipline
- 2/5 years' experience in a similar automated production and support role in Hi-Volume manufacturing.
- Experience with vision systems, PLCs servo motors and general automation.
- Strong aptitude for troubleshooting electromechanical equipment problems
- Excellent communication skills, both written and verbal, coupled with a high level of commitment to the delivery of projects against agreed deadlines and targets.
- A very practical, constructive and analytical approach to problem solving.

DESIRABLE:

- Knowledge of Medical Device Manufacturing or other highly regulated industry.
- Understands the requirements of process monitoring and control of validated processes.
- 6-sigma green belt and/or experience of lean practice implementation

VACANCY REFERENCE: VAC-14968
POSITION TITLE: Validation Engineer
LOCATION: Carrigtohill, Co. Cork
CONTRACT LENGTH: 12 month

PRIMARY RESPONSIBILITIES:

- Have knowledge of and ability to provide Interpretation and Guidance on Regulations, Corporate, Divisional and Site Local procedures as they relate to validation activities.
- Participate on both Corporate and Divisional Validation Teams to discuss/feedback and approve revisions to Validation Procedures.
- Represent validation at both internal and external audits.
- Ensure that QE's and Validation Practitioners receive training/coaching to allow them to effectively support and/or perform validations for current and anticipated projects.
- Ensure that Appropriate Systems are in place to evaluate changes to Validated/Qualified Systems to ensure their continued validated/qualified state.
- Ensure that appropriate Site Validation Listing is established and controlled as per Current Regulatory and Company Requirements.
- Review/Approval of Validation/Qualification Documentation.
- Ensure that Validation Logging System is maintained, tracking Validations, Validation Files and ensuring accessibility when required.
- Assist in the evaluation of the validation status of contract manufacturers and provide guidance where needed. Review validation documentation from contract vendors ensuring that company requirements are met.

EDUCATION AND EXPERIENCE:

- Bachelor's Degree in Science /Engineering is required.
- Minimum of 3+ years direct experience in a Validation Role in either Medical device or Pharmaceutical Industry.
- High level of PC skills required. The successful candidate must be proficient with Microsoft Word, Microsoft Excel and PowerPoint packages.
- Knowledge of Computer System Validation including GAMP 5 and 21 CFR part 11 requirements desirable.
- Working Knowledge/experience of Risk Based Techniques i.e. FMEAs, FTAs etc.
- Have a good understanding of statistical techniques, in particular statistical sampling plans, Process Capability, Gauge R&Rs.
- Lean Six Sigma training a distinct advantage.
- Must be willing to work as part of a multi-site team, be able to travel as part of the job
- Ability to effectively work cross-functionally with Product Dev., Quality, etc.

VACANCY REFERENCE: VAC-14664
POSITION TITLE: Process Engineer
LOCATION: Ringaskiddy, Co.Cork
CONTRACT LENGTH: 12 months

PRIMARY RESPONSIBILITIES:

- We are a high-performing, team based organization, whom are flexible, multi-skilled and empowered to make decisions. A high level of initiative, energy and motivation are key role requirements, as well as organizational skills. Reporting to the appropriate Manufacturing Manager - the primary role of the Process Engineer is to support the manufacturing team in successful site start up, process validation and product launch activities.
- Participate in cross-functional teams, as applicable, to troubleshoot and resolve technical issues using root cause analysis tools
- Develop, define scope and support the implementation of technical solutions under the guidance of site change control systems
- Support and partner closely with peer team leads, Biotechnicians, and other colleagues to ensure master batch records, SOPs, training records and other documents are current and compliant under cGMP conditions – ensure Manufacturing systems and practices are consistent throughout the organization
- Own, investigate, write and approve associated deviations as well as support & coaching Biotechnicians in these functions – ensure adoption of 'zero late' mentality in meeting timelines.
- Ensure areas meet compliance standards and audit areas against standards - highlight any issues and work proactively with the area team and others to ensure resolution.
- Develop and demonstrate an active approach to safety, industrial hygiene, environmental and regulatory compliance.
- Coach, mentor and train team members on area processes, procedures, use of operational excellence tools, and high performance team behaviours.

EDUCATION AND EXPERIENCE:

- Minimum of 4+ years of experience in a similar role
- Bachelor Degree in a Science or Engineering related field or equivalent experience is preferred.
- Demonstrable experience Root Cause Analysis tools and Change Control systems
- In depth understanding of Process Engineering and technologies pertinent to Cell Culture, including bioreactor operations, cleaning/steaming out of place and harvest operations such as depth/ultra filtration.
- Knowledge of the DeltaV process control platform is desirable
- Knowledge of FDA and EU regulations is desirable