

#### JOB DESCRIPTION

<b>Position Title</b>	Line Transfer Engineer
Primary Location	America Free Zone, Heredia, Costa Rica
Available for remote work	No
Condition of Job	Full Time –Permanent – Monday to Friday

#### **ABOUT HCL TECHNOLOGIES**

**HCL Technologies** is a next-generation **global technology company** that helps enterprises reimagine their businesses for the digital age. Our technology products, services, and engineering are built on **four decades of innovation**, with a world-renowned management philosophy, a strong culture of invention and risk-taking, and a relentless focus on customer relationships.

HCL also takes pride in its many diversities, social responsibility, sustainability, and education initiatives. Through its worldwide network of R&D facilities, co-innovation labs and global delivery centers, and over **209,000+ 'Ideapreneurs' across 52+ countries**, HCL delivers holistic services across industry verticals to leading enterprises, including 250 of the Fortune 500 and 650 of the Global 2000.

We offer an integrated portfolio of products, solutions, services, and IP through our Mode 1-2-3 strategy, built around Digital, IoT, Cloud, Automation, Cybersecurity, Analytics, Infrastructure Management, and Engineering Services, amongst others.

#### **ABOUT THE ROLE**

The position of Line Transfer Engineer is at America Free Zone, Heredia, Costa Rica supporting to top leading industry customers around the world. This role will participate in production line transfer, including gap assessment, project planning, process knowledge acquisition, protocols drafting, execution and approvals, personnel training and corrective action management as part of a dynamic Agile team. This individual will contribute as part of team to promote a culture of quality to resolve product issues before manufacturing readiness. The ideal candidate will value culture as much as technical skill.

This job description will be reviewed periodically and is subject to change by management.

#### **PURPOSE OF THE JOB**

We are looking for Engineers at all levels of seniority, from Associates to Principals to join our team in HCL Costa Rica. You will be part of a team that will:

- Understands the customer's requirements and quality expectations and define a plan to successfully transfer manufacturing process from customer to receiving site.
- Work in project governance and enterprise customer management.
- Help with detailed project planning; process transfer and validation, including risk management, validation protocols and reports drafting, execution and documentation;



- assessment of requirements, planning of verification, execution of validation plans, and operations transferring of knowledge.
- Manage complex machine, process and product knowledge transfer for a large-scale highly regulated medical device's company.
- Evaluate and mitigate risk on transferred process of existing product and process line transfer incursions for medical devices, among other responsibilities.

## RESPONSIBILITIES / A DAY AS A LINE TRANSFER ENGINEER:

- Proactively gain proficiency as an **expert of team's software and process systems to understand customer' experience and quality expectations.**
- Translate process requirements into project plan.
- Develop new **strategies for complex process validation systems** to optimize product and process knowledge transfer.
- Promote new technologies and project management practices within the team.
- **Provide process validation review feedback** to foster knowledge transfer best practices within the team.
- Receives general direction, exercises considerable discretion as to **personal work details** as well as the work details of other technical personnel.
- Performs complex assignments requiring a high degree of technical competence.
- Interacts with functional groups as necessary to conduct Test Method Validations, Equipment and Process Qualification, Process Failure Mode Effect Analysis (PFMEA), process characterization and Training of receiving site.
- Reviews, **generates**, and approves related PDP deliverables in cPDM such as (but not limited to): **drawings and specifications**, **PFMEA**, **test and validation reports**, **among others**.
- Create, update, review, approve and release drawings using SolidWorks or any other CAD software, related to material specifications for spare parts, machines, fixtures or products.
- **Evaluates vendor capabilities** to provide required processes or services such as (but not limited to): calibration, maintenance, fixture production, machine repairs and part replacement.
- Integrates multiple approaches to **solve problems or optimize solutions** in complex or cross functional manufacturing processes or product validations.
- Creates efficient **protocols for validation** of complex system functions and defines validation process.
- Generate, Support, Review and Approve Validation Plans, User Requirement Specifications, Installation Qualification/Operational Qualification/Process Qualification Protocols and Reports, DOE for process characterization and Test Methods related to Validation/Qualification of Facility, Utility, Equipment, Production Fixtures and Non-Product Software.
- **Perform qualifications assigned,** including to update test protocols as well as execution of protocols, creation of work orders for protocol execution, update drawings and specifications, update PFMEA and create and train in process instructions.
- Perform quality system inspections in order to determine **compliance to FDA, ISO,** and internal quality systems requirements.
- Adhere to regulatory standards associated with design and manufacturing of medical systems
- Participate in **continuous improvement initiatives** to assure continuation of quality measurement, planning, and improvement.



- Participate in internal and regulatory agencies audits.
- Support investigation of reported field issues to identify root cause
- Support and coordination of documentation release in cPDM, including but not limited to: work instructions, drawings, protocols, reports, PFMEAs, validation plans, specifications, among others.
- Create new processes as required, train associates, and release Test Reports in cPDM.
- Assist with line transfer activities between suppliers as well as inter-company transfers.
- Perform any other assigned responsibility.

## BASIC QUALIFICATIONS / QUALITIES WE LOOK FOR:

- Demonstrated ability as a **self-learner**.
- BS degree in technical discipline such as (but not limited to): Mechanical Engineering, Electro-Mechanical Engineering, Mechatronic Engineering, Industrial, Engineering, Process Engineering, Industrial Production Engineering, Industrial Engineering, Chemical Engineering, Biomedical Engineering, Production/Manufacturing Engineering and Electro-Mechanical Engineering; and at least 4 years of relevant technical experience.
- Proficient with **CAD software** for Concept Design: Part, Assembly and Drawing modelling such as: **SolidWorks, Autocad and/or Unigraphix**.
- Demonstrated experience in **readability of Engineering Drawings and Schematics** and capability to handle legacy drawings data, system requirement understanding and geometric dimensioning and tolerances guidelines and analysis, based on **ASME Y14.5.**
- At least 3 years in Medical Devices Manufacturing, Operations or Research & Development.
- Familiarity with medical domain knowledge and awareness of **ISO 13485**, **ISO 14971** and **FDA Quality System Regulations** and the ability to apply that knowledge with an understanding of business operations to achieve regulatory compliance, process transfer and process control.
- Demonstrated proficiency in IQ/OQ/PQ/TMV or process characterization and software validation protocols drafting, review, execution and approval.
- At least an English Level B2 (70%-79%).

## PREFERRED OUALIFICATIONS / BONUS POINT IF YOU HAVE:

- Master's Degree in any Engineering related field such as (but not limited to):
  Mechanical Engineering, Electro-Mechanical Engineering, Industrial Engineering,
  Electronic Engineering, Mechatronic Engineering, Electrical Engineering, Chemical
  Engineering, Medical Devices, Modern Manufacturing Systems and Software
  Engineering.
- 2+ years as Project lead with demonstrated evidence of ability to manage multiple projects, strategic prioritization of activities and managing cross-functional team's stakeholders and/or requirements within Operation and Manufacturing.
- Experience on Agile and Waterfall methodologies for **Project Management**.
- Familiarity with industry standard processes for **Engineering/Design Change Orders**.



- Experience on **documentation management using cPDM**, including creation, submission, review and approval of any PDP deliverable such as: drawings and specifications, PFMEA, test and validation reports, among others.
- Experience in **Non-Product Software Validation** (Equipment Software Validation).
- Capable working directly with customer.
- Experience at an international / Multinational manufacturing company.
- Experience using statistical software tools such as Minitab or SPSS.

## **COMPETENCIES:**

- Critical thinking / Problem-solving.
- Communication, written and verbal.
- Continuous learning.
- **Teamwork / Collaboration** with cross-functional teams.
- Adaptability / Work with minimal direction.
- Innovative and resourceful.

#### **SPECIAL POINT OF INTEREST:**

- Competitive salary according to experience and knowledge.
- Life and medical insurance.
- Tuition reimbursement.
- Opportunity to belong to a multinational with more than 187 thousand employees around the world focused on innovation.
- Be a key player on One of the most trusted organization worldwide.
- And many more benefits...

# **READY TO APPLY?**

- If this job sounds like a fit for you, then send your resume in English format to ALL of the following mails below. Good luck!
  - o <u>hectorfernando.ramir@hcl.com</u>
  - o gerald.delgadochaves@hcl.com
  - o <u>mauricioarturo.cambr@hcl.com</u>