At Kotra Pharma, we believe that everyone deserves a healthier tomorrow. It’s every individual’s right to live a healthy life to the fullest, and thus, we are committed to bring top-notch health products to the world. By humanising healthcare, we see beyond instruments and medicines for the general well-being of everyone. If you want to make a difference in this industry, begin with us.

<table>
<thead>
<tr>
<th>1. Senior Chemist (Method Development)</th>
<th>Key Responsibilities:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level II</td>
<td>* To report to R &amp; D Manager on all matters related to analytical method development or improvement for existing starting materials and finished products.</td>
</tr>
<tr>
<td></td>
<td>* Establishing, managing, planning, scheduling and executing analytical method development or improvement programs for existing starting materials and finished products following regulatory requirements.</td>
</tr>
<tr>
<td></td>
<td>* Responsible to review and establish finished product and starting material test procedures, specification and COA in accordance with latest official monographs/pharmacopoeia.</td>
</tr>
<tr>
<td></td>
<td>* Responsible to train and qualify R &amp; D chemists and lab technician on development or improved analytical methods for existing starting and finished products.</td>
</tr>
<tr>
<td></td>
<td>* Direct assistance to the Validation Team in process validation, cleaning and other qualification or validation, in which laboratory testing support is required.</td>
</tr>
<tr>
<td></td>
<td>* To participates in troubleshooting laboratory equipment failure and provide proposals for improvements.</td>
</tr>
<tr>
<td></td>
<td>* To work towards achieving the R &amp; D department KPI.</td>
</tr>
<tr>
<td></td>
<td>* Comply and work towards meeting the company’s quality, health safety and environment objectives and policies.</td>
</tr>
<tr>
<td></td>
<td>* Responsible for executing method transfer from R&amp;D to QC.</td>
</tr>
</tbody>
</table>

**Job Specifications:**

* At least Master in Analytical/Organic Chemistry, Pharmacy or equivalent. Below 35 years old.
* At least 3 to 5 years working experience in analytical pharmaceutical healthcare or analytical testing house. The experience should be in Formulation Analytical Department and in a Research and Development Department.
**Research & Development**

## Key Responsibilities:

- Able to handle analytical procedures pertaining to all dosage forms (solids, liquids, semi solids etc).
- Strong working knowledge in products development and familiarity with quality assurance procedures.
- Knowledge in new products developed compliance to cGMP, National regulatory Guidelines and other law regulating the manufacturing and commercialization of medical products.
- Responsible to review and establish finished product and starting material test procedures, specification and COA in accordance with latest official monographs/pharmacopoeia.
- With good command of spoken and written English.
- Core competency should be method development and method troubleshooting.
- Must be able to review and interpret analytical results.
- Self starter and needs to lead the Method Development group.
- Hands on analytical equipment such as GC, HPLC, dissolution, Auto titration is a must.

## Job Specifications:

- At least Master in Analytical/Organic Chemistry, Pharmacy or equivalent. Below 35 years old.
- At least 3 to 5 years working experience in analytical pharmaceutical healthcare or analytical testing house. The experience should be in Formulation Analytical Department and in a Research and Development Department.
- Able to handle analytical procedures and validation pertaining to all dosage forms (solids, liquids, semi solids etc).

### 2. Senior Chemist (Method Validation) Level II

**Key Responsibilities:**

- To report to R & D Manager on all matters related to analytical method validation.
- Establishing, managing, planning, scheduling and executing analytical method validation as per latest regulatory guidelines.
- Responsible to train others R & D chemists and lab technicians on activities pertaining to method validation.
- Should be a strong reviewer and must be able to review the protocol and reports.
- Direct assistance to the Validation Team in process validation, cleaning and other qualification or validation, in which laboratory testing support is required.
- To participates in troubleshooting laboratory equipment failure and provide proposals for improvements.
- To work towards achieving the R & D department KPI.
- Comply and work towards meeting the company’s quality, health safety and environment objectives and policies.
- Responsible for executing method transfer from R&D to QC.

**Job Specifications:**

- At least Master in Analytical/Organic Chemistry, Pharmacy or equivalent. Below 35 years old.
- At least 3 to 5 years working experience in analytical pharmaceutical healthcare or analytical testing house. The experience should be in Formulation Analytical Department and in a Research and Development Department.
- Able to handle analytical procedures and validation pertaining to all
### Research & Development

- Strong working knowledge in products development and familiarity with quality assurance procedures.
- Knowledge in new products developed compliance to cGMP, National regulatory Guidelines and other law regulating the manufacturing and commercialization of medical products.
- With good command of spoken and written English.
- Core competency should be method validation (inclusive of protocol writing to executive and report general.
- Must be able to review and interpret analytical results.
- Self starter and needs to lead the Validation group.
- Hands on analytical equipment such as GC, HPLC, dissolution, Auto titration is a must.

### 3. Senior Chemist (Raw Mat Testing)  
**Level II**

**Key Responsibilities:**

- To report to R & D Manager on all matters related to analytical raw material testing/material qualification method for existing starting materials and finished products.
- Establishing, managing, planning, scheduling and executing analytical raw material testing/material qualification method or improvement programs for existing starting materials and finished products following regulatory requirements.
- Responsible to review the DMF and other analytical procedures. Establish finished product and starting material test procedures, specification and COA in accordance with latest official monographs/pharmacopoeia.
- Responsible to train and qualify R & D chemists and lab technician on development or improved analytical methods.
- To participates in troubleshooting laboratory equipment failure and provide proposals for improvements.
- To work towards achieving the R & D department KPI.
- Comply and work towards meeting the company’s quality, health safety and environment objectives and policies.

**Job Specifications:**

- At least Master in Analytical/Organic Chemistry, Pharmacy or equivalent. Below 35 years old.
- At least 3 to 5 years working experience in analytical pharmaceutical healthcare or analytical testing house. The experience should be in Formulation Analytical Department and in a Research and Development Department.
- Able to handle analytical procedures pertaining to all dosage forms.
- Strong working knowledge in products development and familiarity with quality assurance procedures.
- Knowledge in new products developed compliance to cGMP, National
regulatory Guidelines and other law regulating the manufacturing and commercialization of medical products.
* With good command of spoken and written English.
* Core competency should be raw material testing including API, Excipient and packaging material.
* Must be able to review and interpret analytical results.
* Self starter and needs to lead the raw material group.
* Hands on analytical equipment such as GC, HPLC, dissolution, Auto titration is a must.

<table>
<thead>
<tr>
<th>4. Senior Chemist (Method Development/Validation)</th>
<th>Key Responsibilities:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level II</td>
<td></td>
</tr>
<tr>
<td></td>
<td>* To report to R &amp; D Manager on all matters related to analytical method validation and analytical method development or improvement for existing starting materials and finished products.</td>
</tr>
<tr>
<td></td>
<td>* Establishing, managing, planning, scheduling and executing analytical method validation and analytical method development or improvement programs for existing starting materials and finished products following regulatory requirements.</td>
</tr>
<tr>
<td></td>
<td>* Responsible to review and establish finished product and starting material test procedures, specification and COA in accordance with latest official monographs/pharmacopoeia.</td>
</tr>
<tr>
<td></td>
<td>* Responsible to train and qualify R &amp; D chemists and lab technician on development or improved analytical methods for existing starting and finished products.</td>
</tr>
<tr>
<td></td>
<td>* Direct assistance to the Validation Team in process validation, cleaning and other qualification or validation, in which laboratory testing support is required.</td>
</tr>
<tr>
<td></td>
<td>* To participates in troubleshooting laboratory equipment failure and provide proposals for improvements.</td>
</tr>
<tr>
<td></td>
<td>* To work towards achieving the R &amp; D department KPI.</td>
</tr>
<tr>
<td></td>
<td>* Comply and work towards meeting the company’s quality, health safety and environment objectives and policies.</td>
</tr>
</tbody>
</table>

**Job Specifications:**
* Master/PHD in Analytical/Organic Chemistry, Pharmacy or equivalent. Below 35 years old.
* At least 6 to 10 years working experience in analytical pharmaceutical, healthcare. 2-3 years of supervisory experience is mandatory. The experience should be in Formulation Analytical Department and in a Research and Development Department.
* Besides being hands on HPLC, GC, UV, Dissolution, IL should have worked on GC-MS, HPLC-MS/MS.
* Able to handle analytical procedures pertaining to all dosage forms.
* Strong working knowledge in products development and familiarity with quality assurance procedures.
Research & Development

- Knowledge of new products development compliance to cGMP, National regulatory Guidelines and other law regulating the manufacturing and commercialization of medical products.
- Excellent communication skill, good command of spoken and written English.
- Core competency should be method development and method validation.
- Must be able to review and interpret analytical results.
- Should be able to work independently and lead team members.
- Knowledge of extractable/leachable studies is highly recommended.

1.R&D Formulation (parenteral)

**Key Responsibilities:**

- Development of new Formulation for Parenterals products (Powder, liquid and suspension Injectables).
- Literature search and background analysis of the allocated products.
- Sourcing and Material qualification of new raw material and packaging materials for new parenterals product.
- Initiate Trial batch, Pilot batch for Stability study of formulated Parenterals products.
- Ensure proper management of data and documents generated during product development and stability studies in accordance to the Good Documentation Practices.
- Assist in the investigation and resolution of designated product complaints related to formulation and stability issues as captured by CAPA issued by QA.
- Monitoring and updates on the project's progress/status.
- To ensure that the final product for product launch complies with the input requirements and Market Authorization requirements.
- Prepare Registration Dossiers for the new Parenterals products for NPBC submission and follow up on the correspondence & queries.
- Assist and liaise with other departments in coordinating the Scale up batch/Process Validation of new Parenterals products upon NPCB approval prior to Commercial Batch.
- To participate as an auditor in internal and external quality audits, including vendor audit, when requested.
- Responsible for parental product development from R&D till commercialization stage which requires excellent communication skill.
Research & Development

Job Specifications:
* At least Master in Pharmacy or equivalent. Below 35 years old.
* At least 5 to 7 years working experience in handling of sterile formulation (liquid injectables form, powder for analytical etc) in a R&D department in pharmaceutical.
* Familiar with sterile environment manufacturing process and clean room technology.
* Knowledge of GMP, PICs, ICH guidelines and other law regulating the manufacturing and commercialization of the medicinal product.
* Knowledge of process validation, scale up and analytical testing will be an added advantage.
* Should have a very good knowledge on sterilization techniques.
* Should possess good knowledge of QBD, PAT and Risk Assessment.

2. R&D Formulation Scientist

Key Responsibilities:
* Reports to the R & D Manager on matters pertaining to New Product Development (NPD).
* Responsible for the development of new formulations and dosage forms as requisitioned.
* To ensure products are developed and launched in accordance to Marketing requirements and that project completion are within agreed timelines.
* To ensure that, in carrying out product research and development, adherence to Good Laboratory Practice and Good Manufacturing Practice is observed at all times as necessary.
* To ensure that the final product for product launch complies with the input requirements and Market Authorization requirements.
* To coordinate Material Qualification for new starting materials and primary packaging materials.
* Assist in the improvement of product quality for current products under the Product Quality Improvement (PQI) program.
* Ensure proper management of data and documents generated during product development and stability studies in accordance to the Good Documentation Practices.
* Assist in the investigation and resolution of designated product complaints related to formulation and stability issues as captured by CAPA issued by QA.
* Ensure that the department properties such as machines and instruments as designated, are properly used at all times.
Research & Development

<table>
<thead>
<tr>
<th>Research Assistant</th>
<th>Key Responsibilities:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>* To report to the R&amp;D Manager or designate on all matters related to the scope of responsibility.</td>
</tr>
<tr>
<td></td>
<td>* Responsible to plan and ensure the smooth running of all activities in Medical device laboratory.</td>
</tr>
<tr>
<td></td>
<td>* Responsible to perform Quality control testing on every existing and new product before product release.</td>
</tr>
<tr>
<td></td>
<td>* Responsible to present and compile results of research that has been conducted and to report all the results and findings to the R&amp;D Manager.</td>
</tr>
<tr>
<td></td>
<td>* Responsible to plan and conduct stability study for the manufactured or new products.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Job Specifications:</th>
</tr>
</thead>
<tbody>
<tr>
<td>* At least Master in Pharmacy or equivalent from a reputable university. Below 35 years old.</td>
</tr>
<tr>
<td>* At least 5 to 7 years working experience in handling of formulation and development of various dosage forms.</td>
</tr>
<tr>
<td>* Should have worked in research and development of reputed pharmaceutical.</td>
</tr>
<tr>
<td>* Knowledge of GMP, PICs, ICH guidelines and other law regulating the manufacturing and commercialization of the medicinal product.</td>
</tr>
<tr>
<td>* Knowledge of process validation and analytical testing will be an added advantage.</td>
</tr>
<tr>
<td>* Should have a very good knowledge of process scale up and process validation.</td>
</tr>
<tr>
<td>* Should possess good knowledge of QBD, PAT and Risk Assessment.</td>
</tr>
</tbody>
</table>
### Research & Development

- Work in liaison and in cooperation with various departments in Kotra Pharma.
- Ensure compliance to cGMP, GLP and GSP.
- Formulation of New Product Development projects for Sterile Potentials (powder, liquid and suspension).
- Initiate Trail batch and Stability study of formulated Parenteral products.
- Prepare Registration Dossiers for the new Parenterals products.
- Sourcing and Material qualification of new raw material and packaging materials for new parentals product.
- Initiate Process Validation of new Parentals products upon NPCB approval prior to Commercial Bath.

**Job Specifications:**
- Minimum 2 years working experience in Pharmaceutical manufacturing environment
- Good leadership and communication skill with the ability to interact well with all parties concerned
- Able to work under pressure to meet tight deadline with minimum supervision

---

### Analytical Chemist

**Key Responsibilities:**
- To develop and validate analytical test methods for pharmaceutical products Quality controls.
- To plan and execute all analytical testing for starting materials and finished pharmaceutical products for Quality Improvement and routine testing
- To prepare the protocols for inter-department transfer of approved analytical test methods and qualification report for new Product Quality Improvement (PQI) projects.
- To check, monitor record and maintain designated analytical instruments in accordance with the Instruments, Machine and Equipment Maintenance Procedure.
- Ensure strict compliance to the company’s policies on Quality, Safety, Health and Environment.
- To guide and supervise Laboratory Technicians in the analytical department in either R&D or QC departments.

**Job Specifications:**
- 28 years old and above.
- Bachelor’s Degree or Master’s in Chemistry/ Food Science/ Pharmacy or equivalent.
- At least 5 years working experience in pharmaceutical, healthcare or cosmetic manufacturing industry.
Research & Development

* Strong working knowledge in HPLC and other spectrophotometric equipment and familiarity with quality assurance procedures.
* Hands-on experience in validation of analytical test methods.
* Familiar with compliance to GLP, cGMP and other National Regulatory Guidelines regulating the manufacturing and commercialisation of medical products.
* Good communication skill and good command of written & spoken English.

Interested candidates are encouraged to apply. Kindly send your resume to:

Recruitment, Human Resource Department
Kotra Pharma (M) Sdn Bhd (90082-V)
No. 1, 2 & 3 Jalan TTC 12, Cheng Industrial Estate
75250 Melaka, Malaysia

Or

E-mail to: hr@kotrapharma.com