1.QC Analyst

Job Responsibilities:

1. Responsible for the routine QC work including sampling, in-process control, finished product release.
2. Responsible for the establishment, execution of method validation project.
3. Support the R&D and stability sample testing
4. Responsibility for daily maintenance of lab equipment and environment
5. Handle routine quality system investigation procedure in operation process such as OOS, Deviation, and CAPA.
6. Establish and review the Lab documents such as SOP, Protocol, validation reports.
7. Strictly follow the SOPs and EHS rule of company
8. Other task as assigned by superior

Job Requirements:

1. Bachelor degree or above. Majored in medicine analysis or chemical or related
2. Basic knowledge of pH, UV, IEF, SDS-PAGE, etc.
3. The experience of GMP environment or pharmaceutical company
4. Good communication, cooperation and organization skills
5. Computer Literate MS Office to include Excel and Word
6. Working as part of a team or alone/remotely

2.Medical Information Specialist

Job Responsibilities:

40% Medical inquiry management

1. Provide prompt and accurate responses about all Henlius' products from external customers within 24 hours
2. Forward the inquiries to relative counterparts, including Quality Assurance, Marketing or Medical Affairs
3. Develop a tracking document to track and archive external inquiries and outcomes

40% Medical review management

1. Develop standard reviewing procedure of materials planned to release to public or HCPs per local regulations.
2. Develop a tracking document to track and archive medical review and outcomes

20% Pharmacovigilance reporting

Timely report adverse event/adverse drug reaction obtained from the inquiries per Pharmacovigilance SOP

Job Requirements:

1. Master degree above (in pharmaceutical, medical or other relevant biological science)
2. Experience in presenting complex scientific data
3. Experience in scientific related field in hematology/ oncology is plus

4. Ability to understand and effectively communicate information in package inserts of all Henlius' product
5. Excellent interpersonal and communication (oral and written) skills including communication with patients, health care providers and commercial counterparts
6. Ability to work and manage multiple projects in a rapid-paced, high pressure environment with minimal supervision

3.Medical Science Liaison

Job Responsibilities:

40% Scientific Communication,

1. Support the medical community with up-to-date medical information, robust disease expertise and product information as a peer disease expert
2. Regularly peer-to-peer discuss with key opinions leaders (KOLs) to collect medical insights
3. Respond to unsolicited scientific information requests, manage questions and ensure proper response has been provided and that data is fair and balanced.
4. Maintain highest scientific standards in all external communications (ensure credibility, accuracy, and completeness of scientific and clinical information)

30% KOL engagement,

1. Develop and maintain peer-to-peer collaborations and relationships with KOLs in a relevant therapeutic area
2. Responsible of medical affairs initiatives including advocacy programs, advisory boards, medical education opportunities

30% Data Generation

1. Manage Investigator Sponsored Research (ISR), including scientific rationale of study design and timeline
2. Identify the unmet needs of clinical information and requirements on collecting real-world data that align with medical strategy

Job Requirements:

1. Master degree above (in pharmaceutical, medical or other relevant biological science)
2. Experience in presenting complex scientific data
3. Experience in scientific related field in hematology/ oncology is plus
4. Ability to understand and effectively communicate scientific, medical and regulatory information
5. Excellent interpersonal and communication (oral and written) skills including communication with health care professionals and commercial counterparts
6. Ability to work and manage multiple projects in a rapid-paced, high pressure environment with minimal supervision
7. Approximately 50% business travel, including international

4.E&L Research - Associate Researcher / Researcher

Job Responsibilities:

1. Research and experimental design of extractables and extracts of disposable materials
2. Analytical methods Development of E&L (NVR, TOC, IR, HPLC, GCMS, LCMS, ICPMS, etc.)
3. Development and establishment of methodologies for qualitative and semi-quantitative analysis of unknowns in materials and pharmaceuticals
4. Technical reports and documents preparing for drug declaration
5. Writing relevant SOPs for analytical method, tracking and training of laws and regulations
6. Equipment maintenance and management

Job Requirements:

1. Master or Ph.D specifically in analytical chemistry, pharmacy, bioengineering or related major
2. At least one long-term analytical experience in GCMSMS\LCMSMS\ICPMS, ICPMS is preferred
3. Have a certain understanding of the structural analysis of unknowns
4. Familiar with quantitative analysis methods of small organic molecules, inorganic elements and biological macromolecules
5. Understand the domestic and foreign regulatory requirements for formulations and drug packaging materials, like CDE, CFDA, ICH, etcs.;
6. Understand the biopharmaceutical process
7. Proficiency in searching and reading of English literatures and materials

5.Pharmaceutical Packaging Compatibility Researcher

Job Responsibilities:

1. Compatibility studies and platform establishment of internal packaging materials and pharmaceuticals (plans, reports and corresponding SOPs, etc.);
2. Write technical reports and prepare documents for drug declaration;
3. Development of small molecule analysis methods, establishment of method validation;
4. Selection of pharmaceutical packaging materials for different dosage forms, and establishment of quality standards;
5. Communicate and coordinate with colleagues within and between departments to ensure projects schedule.

Job Requirements:

1. Master or Ph.D. in analytical chemistry, pharmacy, bioengineering or other related fields. And direct relevant work experience or Ph. D. preferred;
2. Have at least one long-term analytical experience in GCMSMS\LCMSMS\ICPMS, ICPMS is preferred;
3. Familiar with GMP and GLP requirements and other regulations;
4. Team oriented, self-motivated, communication skills and open minded.

5. Proficiency in searching and reading of English literature and materials.

6.Protein Characterization Scientist

Job Responsibilities:

1. CEX peak collection and characterization.
2. Forced degradation study.
3. Develop and implement analysis for protein characterization, including intact mass, peptide map, post-translational modification, glycan analysis, glycan structural analysis, disulfide bound analysis.
4. Author method development and characterization reports, technical memos, and SOPs.

Job Requirements:

1. Master's degree in Biological Sciences or Analytical chemistry; PhD in Chemistry, Biochemistry, or related Biological Sciences; Research experience in protein Mass Spectrometry is preferred.
2. Understanding of protein analytical chemistry methodologies such as mass spectrometry, chromatography, and carbohydrate analysis.
3. Excellent laboratory technique and experimental design.
4. Proficient in data keeping, data review, and data reporting.
5. Work independently in lab but with strong collaboration and communication skills.
6. Time management and organization skills.

7.Associate Scientist/Scientist for Process Development Downstream

Job Responsibilities:

1. Optimize and Scale-up purification process of antibody products in early stage
2. Responsible for non-GMP 200 L production
3. Responsible for Tech-transfer from non-GMP to GMP
4. Manufacture support for Phase I-Phase III
5. Responsible for process characterization study in late stage
6. Report writing support for IND filing and NDA filing

Job Requirements:

1. Master degree or above, major in biology related, experiences with the production of
2. antibody / protein products is preferred
   Experienced with downstream process of antibody / protein purification development
3. and scale-up is preferred;
4. Familiar with Process characterization、Process Validation、Quality by Design、CQA, or experienced with GMP production management is preferred
5. Familiar with protein purification instrument like AKTA is preferred
6. Good expression and communication skills

7. Good oral and writing skills in English

8.Associate researcher/researcher for Formulation Development

Job Responsibilities:

1. Responsible for the formulation development and fill & finish production of biological drugs, including liquid injection, freeze-dried powder injection and pre-filling of syringe.
2. Responsible for process characterization and process validation.
3. Responsible for technical transfer of Fill and Finish process and support non-GMP production.
4. Responsible for the study report, IND, NDA and other filing documents, support on-site verification.
5. Participate in the management of laboratory platform, including but not limited to the writing of relevant SOP, management and maintenance of instrument and equipment, technical training for employees.
6. Capable of completing other related tasks assigned by superior and submit work reports as required.

Job Requirements:

1. Master degree or above, majored in biochemistry, biophysics, analytical chemistry, pharmacy.
2. Working experience of developing or analyzing method of pharmaceutical protein drugs is preferred.
3. Familiar with protein drug analysis and analysis techniques, including but not limited to SEC, CE_SDS, DLS, etc.
4. Strong learning ability, good experimental skills, solid summary and analysis ability, capable of solving the complex problems encountered in process development.
5. Open-minded personality, good communication skills and teamwork spirit; dedicated to work, strong sense of responsibility, able to work under pressure.
6. Fluency with English listening, speaking, reading and writing.

9.Bioanalytical Assistant Scientist /Scientist

Job Responsibilities:

1. Develop and validate pre-clinical and clinical biological sample analysis methods, and design experiments based on product characteristics.
2. Analyze and solve problems encountered in the experiments independently. Authoring PK/ADA/Biomarker assay validation and sample analysis reports to support R&D and clinical project progress.
3. Prepare SOPs and protocols according to current guidelines and regulations.
4. Conduct technology transfer subsequent to method development and guide implementation of methods.

Job Requirements:

1. Immunology- or pharmacology- related majors, with some knowledge on antibody development. A candidate

must have Master's degree or above

2. Familiarity with ELISA and MSD operations is preferred.
3. Have good communication skills and teamwork spirit. Have good trouble-shooting and active