**JOB DESCRIPTION**

<table>
<thead>
<tr>
<th>Job title</th>
<th>Biomarker/Translational Medicine Director</th>
<th>Reports to</th>
<th>Head of Early Development</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of direct reports</td>
<td>0</td>
<td>Effective date</td>
<td>01-July-2019</td>
</tr>
<tr>
<td>Department/Division</td>
<td>Early Development</td>
<td>Location</td>
<td>Shanghai</td>
</tr>
</tbody>
</table>

**DUTIES & RESPONSIBILITIES** (Summarizes the job’s purpose or role and why it exists in the organization)

- Involvement and input from project entry through FIH study design, Interact with biologic and discovery research teams to address key development questions, design experiments, analyze results and provide strategic direction to help identify those constructs that have the greatest chance of success for further development or to stop the development programs.
- Development of target or mechanism-based methods to guide rational human translation and data interpretation; Work with CRO or external consultants using a variety of tools and approaches. Integrates, interprets and reports data to project teams and other customers; Support for the efficient application and integration of biomarkers in toxicology and pharmacology studies in support of clinical and candidate selection
- Define translational requirements in clinical project development; plan appropriate strategies in accordance with the Health Authorities requirement; contribute to the design for clinical projects; identify potential project hurdles and suggest solutions
- Contribute expert input into regulatory documents including clinical study protocols, clinical study reports, modeling reports, investigator brochures, IND and NDA's within agreed timelines; Prepare, compile, and review appropriate sections of CTA dossiers/ NDA documents; represent Early Development in interactions with health authorities and external partners
- Proactively manage links with other functions to ensure that pre-clinical and clinical results are used optimally; facilitate constructive collaboration within drug development teams and with other internal partners.
- Monitor timelines and objectives, ensure accuracy of project and activity progress, assure rapid and effective communication of high-quality data and results to project teams.
- With the assistance of PK/PD experts to apply PK/PD modeling concepts, and assess basic research on target engagement, receptor occupancy and antidrug antibody for biologic drug candidates.
- Accountable for determining the starting dose for FIH, write and/or review technical reports, interact with global regulatory agencies and be involved in helping preclinical and related sections in an IND or CTA.
- Monitor timelines and objectives, ensure accuracy of project and activity progress, assure rapid and effective communication of high-quality data and results to project teams.

**JOB REQUIREMENTS** (the minimum skills, knowledge and experience required for the role)

- Ability to design and implement biomarker studies required to support first in human up to PoC clinical trials
- Ability in independently searching and collaborating with external consultants for translational solution
- Demonstrated ability to work in a matrix environment and experience working in a global environment is a plus, with experience on biotherapeutic projects.
- Knowledge of related disciplines (e.g., pharmacology, PK/D, toxicology, regulatory) in the drug development process.
- Strong oral and written communication skills.
- Strong organizational and project skills.
- Critical thinking and problem solving skills.
- Knowledge of I/O and immunology advantageous
- Strong written, presentation and verbal communication skills are essential.

### SCOPE OF ROLE

Based in Shanghai