

**JOB DESCRIPTION**

<b>TITLE</b>	<b>CLINICAL DEVELOPMENT LEADER (CDL)</b>	<b>GRADE:</b>	
<b>REPORTING TO</b>	<b>HEAD OF CLINICAL DEVELOPMENT</b>		
<b>DEPARTMENT</b>	<b>CLINICAL DEVELOPMENT DEPARTMENT</b>		
<b>FUNCTION/AREA</b>	<b>CLINICAL DEVELOPMENT UNIT (CDU) /DEPEND ON EACH CDL</b>		
<b>NO OF REPORTS</b>	<b>DIRECT: 0 OR 1</b>	<b>TOTAL STAFF: 0 OR 1</b>	

**PURPOSE OF THE ROLE**

**PREPARE HIGH QUALITY CLINICAL RELEVANT DOSSIERS/DOCUMENTS SUCH AS CLINICAL DEVELOPMENT PLAN, PROTOCOL, CLINICAL STUDY REPORT AND CTD WITH STRONG LEADERSHIP TO PROJECT/CLINICAL TEAM.**

**MAIN INTERFACES (Please describe in detail, list multiple items as necessary including team membership)**

**INTERNALLY:**

1. LOCAL PROJECT TEAM (LEADER)
2. LOCAL CLINICAL TEAM (MEMBER)
3. PORTFOLIO ASSESSMENT TEAM (AD-HOC MEMBER)

**EXTERNALLY:**

1. GLOBAL MEDICAL LEADER FOR THE CORRESPONDING PROJECT
2. GLOBAL PRODUCT TEAM LEADER
3. GLOBAL PRODUCT TEAM (MEMBER OR ASSOCIATE MEMBER)
4. GLOBAL CLINICAL TEAM (AD-HOC MEMBER)
5. LOCAL KOL(S) FOR CLINICAL DEVELOPMENT

**KEY TASKS & RESPONSIBILITIES (Please describe in detail, list multiple items as necessary)**

1. Propose/report project plan, status, issues and measures periodically to MSJ stakeholders at Project Review Meeting, Project Dev. Committee and so on.
2. Establish sound relationship with KOLs in his/her responsible therapeutics area and keep it.
3. Prepare clinical development strategy/design in cooperation with GPT to reach agreement with KOLs and PMDA
4. Organize and coordinate MSJ Project Team Meeting to clarify issues and measure
5. Coordinate and facilitate communication between MSJ and GPT to solve any issues
6. Make action lists (by when & by whom), update & monitor them to keep timeline proactively
7. Finalize Japanese IB and prepare Japanese protocol as primary responsibility
8. Communicate with Data Management for the preparation of CRF
9. Communicate with Clinical Operations for the preparation of CTN and Informed Consent Form
10. Prepare draft position paper for PMDA consultation (clinical part) and reach agreement with GPT
11. Ensure KOL feedback for smooth PMDA consultation and clinical operations
12. Support clinical team to conduct clinical study in compliance with J-GCP
13. Review (or prepare) CSR in cooperation with MSJ & Global Clinical Teams
14. Review Japanese CTD (clinical part) prepared by Medical Writer with MSJ Clinical Team
15. Facilitate deliberation process by replying authorities inquiries in cooperation with MSJ & Global Project Team
16. Take roles as Global Project Team Leader, if he or she is assigned.
17. Other related task as necessary or as required by the manager

**CANDIDATE'S PROFILE (Please describe in detail, list multiple items as necessary)**

**EDUCATION/LANGUAGES**

- Bachelor (or master) degree on medical or science area
- Japanese and English fluent

**PROFESSIONAL SKILLS & EXPERIENCE**

- To have a minimum of 10 years drug research and development experience with a pharmaceutical company, a medical institution or a clinical research organization.
- To have a minimum of 5 years clinical development experience as well as people management responsibility
- To have a minimum of 5 years management position or cross-functional leader
- To have enough medical knowledge to judge and/or interpret the outcomes from clinical studies

**PERSONAL SKILLS & COMPETENCIES**

- Strong communication skill to clarify issues and discussion point in both Japanese and English with good presentation skills
- Protocol writing skill
- Project Management skill
- Thinking logically

Form completed by: (Function head) PRINT NAME & SIGNATURE	Dr. Kenji Kon	Date :	March 23 <sup>rd</sup> , 2009
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\* Obtain employee's signature after joined the company:

Understood and agreed by: (Employee) NAME & SIGNATURE		Date :	
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**FOR HR USE**

DATE RECEIVED:	Request for hiring form attached: <input type="checkbox"/> YES <input type="checkbox"/> NO
RESPONSIBLE RECRUITER:	
REMARKS	