

## JOB DESCRIPTION

|               |   |                     |  |
|---------------|---|---------------------|--|
| TITLE         | ASSOCIATE MEDICAL LEADER (MED.L)                      | GRADE:              |  |
| REPORTING TO  | HEAD OF CLINICAL DEVELOPMENT                          |                     |  |
| DEPARTMENT    | CLINICAL DEVELOPMENT DEPARTMENT                       |                     |  |
| FUNCTION/AREA | CLINICAL DEVELOPMENT UNIT (CDU) /DEPEND ON EACH MED.L |                     |  |
| NO OF REPORTS | DIRECT: 0 OR 2  | TOTAL STAFF: 0 OR 2 |  |

### PURPOSE OF THE ROLE

PREPARE HIGH QUALITY CLINICAL RELEVANT DOSSIERS/DOCUMENTS SUCH AS CLINICAL DEVELOPMENT PLAN, PROTOCOL, CLINICAL STUDY REPORT AND CTD IN COOPERATION WITH PROJECT TEAM

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

#### INTERNALLY:

1. MSJ LOCAL PROJECT TEAM (AS MEMBER)
2. CLINICAL DEVELOPMENT TEAM (AS MEMBER)
3. PROTOCOL REVIEW COMMITTEE (AS MEMBER)
4. DRUG SAFETY EVALUATION COMMITTEE (AS MEMBER)
5. PORTFOLIO ASSESSMENT TEAM (AD-HOC MEMBER)

#### EXTERNALLY:

1. GLOBAL PRODUCT TEAM (ASSOCIATE MEMBER)
2. GLOBAL CLINICAL TEAM (ASSOCIATE MEMBER)
3. MEDICAL LEADER IN GLOBAL CLINICAL DEVELOPMENT UNIT (COMMUNICATION LINE)

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

1. Input medical issues/information/matters to local and global project team in order to facilitate project on truck in any case. (primary objectives)
2. Involve Japan Portfolio to provide medical issues/information
3. Involve the preparation of PDC and FDC presentation especially for medical part to receive the approval from MSJ and Headquarters executives, respectively
4. Prepare clinical development strategy/design in cooperation with CDL and GPT in order to reach agreement with KOLs and PMDA
5. Prepare draft concept sheet in cooperation with CDL and GPT
6. Prepare draft position paper for PMDA consultation (especially for medical part) in cooperation with CDL in order to reach agreement with GPT
7. Ensure KOL feedback for smooth PMDA consultation and clinical operations
8. Prepare draft clinical protocol in cooperation with CDL and GPT
9. Support finalization of Japanese IB and Japanese protocol by reviewing medical point of view
10. Input medical information at MSJ Project Team Meeting to clarify issues and measure
11. Coordinate and facilitate communication between MSJ and GPT to solve medical issues
12. Input medical interpretation/information to Data Management for the preparation of CRF
13. Input medical interpretation/information to clinical team in order to conduct clinical study logically and scientifically
14. Support solving medical issues during clinical study
15. Review (or prepare) CSR in cooperation with MSJ & Global Clinical Teams
16. Review Japanese CTD (medical part) prepared by Medical Writer with MJ Clinical Team
17. Input medical interpretation/information to facilitate deliberation process by replying authorities inquiries in cooperation with MSJ & Global Project Team
18. Support handling of drug adverse events/reactions to report regulatory authorities from medical point of view
19. 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**

- Medical or doctor degree on medical or science area
- Japanese and English fluent

**PROFESSIONAL SKILLS & EXPERIENCE**

- To have a minimum of 5 years medical 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 (preferable)
- To have enough medical knowledge to judge and/or interpret the outcomes from clinical studies
- To have enough capability to prepare clinical protocol and clinical study report.

**PERSONAL SKILLS & COMPETENCIES**

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

**Abbreviation:**

PDC: Project Development Committee (Local Decision Body)

FDC: Full Development Committee (Global Decision Body)

MSJ: Merck Serono Japan

PMDA: Regulatory agency in Japan

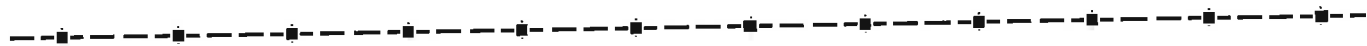
CDL: Clinical Development Leader, who belongs to the same function of (associate) Medical Leader.

GPT: Global Project Team (project team in Headquarters)

Concept Sheet: Medically oriented development plan to be approved by corresponding committee.

|   |               |        |                                 |
|---|---------------|--------|---------------------------------|
| Form completed by:<br>(Function head)<br>PRINT NAME & SIGNATURE | Dr. Kenji Kon | Date : | October, 6 <sup>th</sup> , 2008 |
|---|---------------|--------|---------------------------------|

|   |  |        |  |
|---|--|--------|--|
| Understood and agreed<br>by: (Employee)<br>NAME & SIGNATURE |  | Date : |  |
|---|--|--------|--|



**FOR HR USE**

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