

## Job Description: Bio-clinical Analyst

<b>JOB TITLE</b>	<b>DEPARTMENT / GBU</b>	<b>LOCATION (COUNTRY)</b>
Bio-clinical Analyst	QA/RA, Covidien China	Shanghai, China
<b>DIRECT REPORT (JOB TITLE)</b>	<b>FUNCTIONAL REPORT(JOB TITLE)</b>	<b>APPROVAL DATE (DD/MM/AA)</b>
RA/QA, Sr. Director (Greater China)		

**1. Position Summary:** What is the main purpose of this job? Why does it exist? (e.g., to create marketing strategies; to develop, support and grow Compliance awareness etc.) Please summarize in two to three sentences.

- Studying, analyzing product's features, bio-compatibility between host & device;
- Communicating with GBU, or/and web searching product related clinical evidences from existing resource;
- Providing appropriate data for product registration, clinical trial preparation, etc

**2. Principal Accountabilities:** What are the key responsibilities of this job? List the what, how and why of each responsibility and provide examples, as necessary. Use specific verbs of action, such as "manages", "operates", "analyzes", "designs", etc. Indicate three to five accountabilities in descending order of importance and approximate % of time spent on each.

1. Clinical evidence is very important for product registration. Evidence based medicine is current requested by MoH & SFDA;
2. According to registration requirement, deeply study & understand new product's tech features, familiar with product's clinical application, indications, and insights of users;
3. Well communicate with GBU R&D researcher, engineer, RA colleagues, clinical affairs, as well as marketing colleague for collecting clinical evidences, including product related articles, comment from clinician, certificate from authorization, e.g. FDA, USA Dept. of Health, etc, medical center, etc.
4. Prepare document, either clinical evidence, or prepare clinical trial plan for product registration in SFDA.

**3. Experience:** What unique knowledge are needed to successfully perform the job and what would you consider most skills are most desirable (e.g., sales experience, ability to operate within a marketplace that is complex, management skills etc), years of experience.

- Healthcare unit working experience, including Intern, Class II, and above hospital working experience;
- Working experience pharmaceutical or medical industries, especially in the field of clinical affairs, medical affairs, etc.
- Working experience in health care R&D fields, etc / or authorization agencies, e.g. SFDA (provincial level), or MoH / BoH (卫生局).

**4. Education** (specific educational requirement or technical training, multi-language, Global, computer knowledge, etc)

- Master/PHD majored healthcare or Bio is required.

**5. Job Competencies:** What competencies are needed to successfully perform the job (business Acumen, Negotiation Skills, etc)

- Well understanding on health care system of China, and MoH, SFDA regulations on medical device, esp. for device clinical trial;
- Good knowledge background on biology, bio-engineering, device-materials, and bio-statistics, etc;
- Fluent English reading, writing, communicating skills, esp. on medicine;
- Work with a spirit of persistent and dauntless;
- Solution driving personality.

**6. Scope of Responsibilities:** What is the job's responsibility for setting and achieving goals, objectives and strategies (work group, function, department, major function, division, etc)? Does the job have responsibility for strategic planning, or tactical or operation goals? What are typical timeframes for goals and strategies? (e.g. – less than one year, one year, one to three years, three to five years)

- Closely work with RA specialist, product manager, GBU RA specialist, clinical affairs to have as more, as detail as possible clinical evidence data;
- Organize Clinical Evidence Data for figure out SFDA's requirement for renew product registration;
- Apply re-organized clinical evidences discuss SFDA officer for waive clinical trials for new product registration;
- If do need a trial, apply re-organized clinical evidences appropriately to reduce the trial cases.

#### Organization Structure

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**Reporting Layer (Direct  
report to Country Mgr)**

**Revenues of organization  
unit (FY )**

**Operating income**

**Total direct reports**

**Sales/Billings (FY )**

**Other (specify)**