

## Disc Dynamics Career Openings – updated August 25, 2008

### Aseptic Quality Assurance Engineer

Disc Dynamics Inc., is seeking an analytical and technical QA Engineer familiar with aseptic manufacturing operations. This individual will work closely with Manufacturing to improve processes and procedures in order to ensure high quality product in compliance with applicable specifications, standards, and regulatory requirements.

#### Essential Qualifications:

- Five (5) years Quality Assurance experience in the medical device or pharmaceutical industry.
- Three (3) years minimum Quality Assurance experience in aseptic manufacturing.
- BS in Microbiology, Science, or Chemistry.
- ASQ CQE/CQA preferred.
- Working knowledge of ISO 13485 and 21 CFR Part 820,.
- Knowledgeable in cleanroom requirements and guidelines including FDA 5882fml, ISO 13408, ISO 14644, ISO 14971, GLP, and USP.
- Knowledgeable in aseptic processing and validation requirements.
- Experience with CAPA process requirements.
- Experience interfacing with testing laboratories.
- Proficient in Microsoft Word and Excel.

#### Desired Qualifications:

- Working knowledge of SPC, statistical analysis & DOE applications.
- Project Management experience.
- FMEA and Risk Analysis experience.
- Six Sigma belt desirable.

#### Abilities:

- Proven good organizational and leadership skills.
- Effective communication and interpersonal skills.
- Attention to detail and excellent documentation skills.
- Real-time problem solving abilities in a manufacturing environment.
- Ability to travel in the US and OUS.

Please send your resume to:

Human Resources, Disc Dynamics, Inc., 9600 West 76th Street, Suite T, Eden Prairie, MN 55344. EOE.

Or email to Patty Berg, [pattyb@discdyn.com](mailto:pattyb@discdyn.com)

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