

GRACE L. GARDNER
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QUALIFICATIONS

- ◆ Over six (6) years of Sales and Marketing experience within the pharmaceutical, medical device and biotechnology industries.
- ◆ Assist coordinators in the two-week Aseptic Processing Program at the Parenteral Drug Association's Training and Research Institute in Baltimore, Maryland.
- ◆ Extensive experience in implementing and validating cGMP software.
- ◆ Knowledgeable in environmental monitoring/ sampling.
- ◆ Excellent communication, organizational and leadership skills.

EXPERIENCE

2001 - Current *Aseptic Solutions, Inc., El Granada, CA*
Headquartered in Northern California, ASI is a consulting firm offering specialized solutions to pharmaceutical manufacturers relative to sterility assurance, aseptic processing and environmental control. In-depth experience with HVAC and water systems, all aspects of environmental control and training.

Marketing Manager/Consultant

Reporting directly to the President, responsible for all sales and marketing efforts for the company. Provide consulting services to pharmaceutical companies with emphasis in data integrity, airflow studies, environmental monitoring and document preparation.

1997 - 2000 *KMI/PAREXEL, LLC, Aliso Viejo, CA*
Headquartered near Boston, Massachusetts, KMI is the largest compliance consulting and validation services company for FDA-regulated pharmaceutical, biotechnology, and medical device companies.

Integration & Technical Support Specialist (*March 2000 to October 2000*)

Reporting directly to the President of KMI Systems, Inc., a subsidiary of KMI/PAREXEL, this position is the key link between KMI Systems and its customers. This position works with clients to implement KMI Systems' software products (GMPware™), integrate the support tools into their existing processes, and conducts training for software users. In addition to executive-level office support, key responsibilities include quality assurance of deliverables, planning and conducting software installation & training, providing technical support, participate in the development of KMI Systems sales and marketing programs.

EXPERIENCE (cont.)

1997 - 2000 KMI/PAREXEL, LLC, Aliso Viejo, CA (cont.)

Regional Sales Specialist (November 1998 to March 2000)

While continuing to support the President and the Chairman, participated as a core member of the Sales Support Group (SSG), a team formed to define and implement the sales/marketing strategy. Essential in building and maintaining client relationships. Hands-on participation with the development of sales-support activities to increase business penetration. Advised Senior Management of opportunities and direction for sales and marketing.

Assistant to the President and the Chairman (March 1997 to November 1998)

While supporting the founders of KMI, in all duties, exercise discretion and independent judgment with regard to establishing priorities, setting tasks, and determining how a task should be done; keeping company information confidential; interacting with clients and other KMI employees; and performing personal tasks for the founders.

RELATED EXPERIENCE

Proficient in leading software programs including: GMPware™ (Validation Protocol Generation software); EMSS (Environmental Monitoring Software System); Microsoft PowerPoint, Excel, Outlook, Word, Projects, Publisher, FrontPage, Visio and Access; and ACT!, Maximizer and Goldmine (client databases).

EDUCATION**Framingham State College, Framingham, MA**

Business Administration Studies (Evenings 1997 - 1998) -- GPA 3.6/4.0

Broome Community College, Binghamton, NY

Business Administration Studies (Evenings 1995 - 1996) -- GPA 3.9/4.0

Elmira Business Institute, Elmira, NY

Two-Year Executive Secretarial Program -- graduating with honors (1984 - 85)

ADDITIONAL TRAINING

“Principles and Practices in the Aseptic Processing of Small Volume Parenterals”

“Identification and Characterization of Microorganisms Using Molecular Methods”

“Environmental Monitoring Software System” training program

HONORS

Phi Theta Kappa Member, Mu Eta Chapter

National Honor Society; National Dean's List

PROJECTS/ACCOMPLISHMENTS

- Assistant coordinator of Aseptic Processing Training Program
- Member of development team originated to write cGMP software Training Guides and User Manuals
- Performed Quality Assurance testing of cGMP software pre-commercial release
- Contributed to the development and implementation of company's hiring process
- Assisted in the coordination of company's all-employee annual training program
- Established a new office one week ahead of a four-week plan through effective project planning
- Served as a team member of four key groups: Sales Support Group, Recruiting Strategy Group, Knowledge Capture Group and Employee Communications Team
- Selected to represent companies at tradeshow and job fairs
- Selected as the administration member of a business merger implementation team and assisted in the executive coordination of the program
- Supported the ahead-of-schedule completion of a Manufacturing Resource Planning (MRP II) System through detailed project tracking and coordinated training of key users
- Responsible for implementing and maintaining Internet and Intranet websites
- Developed educational material and trained employees on using Microsoft Office software
- Developed and documented policies and procedures

PROFESSIONAL MEMBERSHIPS

- Parenteral Drug Association (PDA)
- International Society of Pharmaceutical Engineers (ISPE)

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