Medical Equipment Case Study:

Includes:
Opportunity Marketing Piece
Skills Survey
Candidate Scorecard

Contact:
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POSITION
Associate Director, Regulatory Affairs - Devices

LOCATION
Round Lake, IL

For more information contact:
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Baxter

Company Information

Baxter International Incorporated develops, manufactures and markets products that save and sustain the lives of people with hemophilia, immune disorders, cancer, infectious diseases, kidney disease, trauma, and other chronic and acute medical conditions. As a global, diversified healthcare company, Baxter applies a unique combination of expertise in medical devices, pharmaceuticals and biotechnology to create products that advance patient care worldwide.

As one of the most respected companies in healthcare, Baxter is committed to being recognized and trusted worldwide, a preferred partner in improving the quality of and access to healthcare, an innovator in science and technology, the leader in its markets, a high-quality investment, a rewarding place to work and develop, and a socially responsible member of the communities in which it operates.

Since Baxter’s founding in 1931, the company has been responsible for many medical breakthroughs we take for granted today. Baxter has played a leading role in the development of modern intravenous (IV) therapy, hemophilia treatment, kidney dialysis and other critical therapies.

Baxter products are used in a variety of facilities: hospitals, kidney dialysis centers, doctors’ offices, nursing homes, rehabilitation centers, clinical and medical research laboratories, and in homes under physician supervision.

A global presence and infrastructure is one of Baxter’s key strengths. In 2007, half of Baxter’s sales, a total of $11.3 billion, and more than half of its 46,500 employee workforce were from outside the United States. With manufacturing facilities located throughout the world, Baxter’s philosophy of manufacturing locally allows the company to better manage production, costs and pricing.

R&D is also performed at centers around the world including facilities in Austria, Belgium, France, Japan and the United States. Research and development (R&D) is essential to Baxter’s growth and their investment has grown steadily over the last four years.

North America Baxter has many facilities in the United States and Canada including Arkansas, California, Florida, Illinois, Indiana, Maryland, Mississippi, New Jersey, North Carolina, Ontario, Quebec, and Puerto Rico. Baxter’s headquarters are located in Deerfield, Illinois, approximately 20 miles north of Chicago.

More Information:
www.baxter.com
Europe Baxter has significant presence in Europe with manufacturing and research facilities in more than a dozen countries including Austria, Belgium, Czech Republic, France, Germany, Ireland, Italy, Malta, Poland, Spain, Switzerland, Tunisia, Turkey, and the United Kingdom.

The Latin America region includes Baxter manufacturing and distribution facilities in Argentina, Brazil, Chile, Colombia, Costa Rica, the Dominican Republic and Mexico.

In Asia Pacific, Baxter has had a significant presence for nearly 40 years. As of July 2006, Baxter employed about 6,000 people and operated 11 manufacturing plants in the region. Given the vast geography and dynamic development of the diverse markets, Baxter Asia Pacific operates in the structure of five sub-regions namely Japan, China, North Asia, Australia/New Zealand and India/Southeast Asia.

**Baxter’s Culture**

They place strong emphasis on shaping their workplace culture by defining the Shared Values, Competencies and Personal Attributes that are necessary for employees to be successful. By setting common expectations for how they approach their work every day, their employees know what they can and should expect from themselves and from one another…and how they can achieve great results. They call these their Baxter Leadership Expectations, which are for every employee, everywhere at Baxter.

**Professional Development**

An important responsibility of an organization is to create opportunities for people to live their dreams. Baxter offers a range of training and development programs along with competitive compensation and benefits. The company views ongoing employee learning and skill development as critical to its future success. Baxter also supports a healthy balance between work, personal and family life, and recognizes that every individual’s diverse background and experiences contribute to the organization’s success.

**Commitment to Sustainability**

Baxter views sustainability as a long-term approach to balancing its business priorities with social, economic and environmental responsibilities. This includes using financial resources wisely, operating in a sound and ethical manner, giving back to their communities, responding to the needs of victims of natural and man-made disasters, expanding access to healthcare, protecting the environment and providing a safe and healthy workplace for employees – all of which make Baxter a rewarding place to work.
Position Information

**Associate Director, Regulatory Affairs – Devices**

**Location of Position:**
Round Lake, IL

**Position Description**
This position is in the Global Regulatory Affairs (GRA) organization that supports Baxter’s Medication Delivery Division. The successful candidate will be responsible for global regulatory activities associated with new product development and on market support of disposable single use medical devices and custom intravenous and specialty products. Knowledge of software controlled medical devices, software accessories and interfaces, is a plus.

**Responsibilities:**
- Independently lead global regulatory strategy development, planning, and implementation for multiple complex programs and platforms
- Participate in identification of risk areas and develop alternative courses of action including anticipation of regulators responses through scenario planning and development of contingency plans
- Guide and influence technical groups in areas of product development, labeling and promotion. Participate in potential and established third party efforts (i.e. Due diligence activities, joint ventures, etc)
- Initiate and maintain appropriate communication within the RA function and represent Regulatory Affairs with business units and other functions
- Implement policies to ensure ongoing compliance of regulatory requirements
- Develop and implement regulatory strategy aligned with business strategy
- Assess impact of new regulations and implement appropriate changes as well as lead development of company policy and positions on draft regulation and guidance
- Responsible for negotiating and decision making with regulators and stakeholders with complex and high-risk projects
- Provide direct supervision of individuals including mentoring, performance management and staffing decisions
- Represent Baxter externally at appropriate industry associations
- May act as primary contact with regulatory authorities including the planning and leadership of meetings
- May participate in management of budgets

**Requirements:**
- Excellent verbal communication, presentation, and facilitation skills
- Negotiation, risk management and problem solving skills
- Demonstrated success in leading and coaching others, meeting established schedules, and resolving technical and operational challenges in a matrix environment
- Ability to identify risks, make decisions independently and escalate issues when necessary
- Demonstrated ability to mentor and work with hardware and software engineers in the design control regulation, software guidance, and compliance standards space
- Ability to independently identify compliance risks and escalate when necessary
- Ability to lead and coach others
- Bachelor’s degree in scientific discipline, with a minimum of 3-5 years direct experience in US regulatory submissions for hardware/software medical device regulatory submissions. Engineering degree or advanced degree (MS, PhD) a plus
- International regulatory experience/exposure preferable
- Experience in disposable hardware/software medical device development, regulations, standards, and current industry practices
- Experience in managing direct reports
Round Lake, IL

**Area Information**

Lake County, IL is situated on the shore of Lake Michigan between Chicago and Wisconsin. It is home to over 644,000 residents, some of whom live in highly developed urban centers while others live in beautiful rural communities.

One such community is the Village of Round Lake. It’s located in central Lake County and is about 50 miles west of Chicago. They are conveniently located along Metra’s Milwaukee District North Line. Round Lake is approximately a 50-70 minute drive from O’Hare International Airport.

Round Lake offers a wide variety of activities and facilities for its residents to enjoy. They include Renwood Golf Course, the new Sports Center, the Prairie Grass Nature Museum, Community Theatre, outdoor pool/aquatic center, Fitness Plus fitness center, Child Development Center, Teen Center, Senior Center and acres of picturesque parklands.

The population of Round Lake is approximately 11,000 residents and the median household income is about $58,000. The village is currently served by several school districts, Round Lake Unit District #116, Grant High School District #124, Big Hollow District #38, Grayslake Elementary District #46, and Grayslake High School District #127. Round Lake provides a diversity of housing options from older neighborhoods where the median house value is $160,000 to newer neighborhoods of attached single family and single family homes.

Round Lake boast a quiet, small town atmosphere with the benefits of a close metropolitan area. Just a few of Chicago’s featured attractions beside the exquisite dining and shopping are: Cellular Field and the Chicago White Sox, Wrigley Field and the Cubs, the United Center with the Chicago Bulls, Six Flags Amusement Park, Lamb’s Farm, and the Lake County Fairgrounds.

**More Information:**

www.eroundlake.com
Baxter
Associate Director, Regulatory Affairs - Devices

For more information contact:
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Prmcjj_@ropella.com

If you have open positions in your organization, give us a call and put our people and our process to work for you.
Skill Survey for: Associate Director, Regulatory Affairs

Please type your answers in blue.

Name: 

Date: 

1. Outline University Degree(s) with date(s): 
   (Please provide the Name, the Location and the Phone # of each Institution AND YOUR BIRTHDATE so we can conduct degree confirmation check.)

2. Describe your direct experience & number of years in new product development of disposable single use medical devices, custom intravenous and specialty products.

3. What type of software control medical devices or products have you worked on/with?

4. Outline your 510K background and experience.

5. Describe your biggest “Project” that required significant project management skills.

6. Outline your people management experience. How many people have you managed and what are/were their position titles?
7. If asked one of these questions during an interview, how would you answer?
   a. Why are you looking to change jobs?
   b. What is it that has motivated you to consider this position?

8. This position will be located in Round Lake, IL. Are you currently a commutable distance from the site or will you need to relocate?

9. If you will need to relocate, do you have any unusual relocation issues or requirements? If so, please list them.

10. If we were to speak to your current boss when doing reference checks, how do you believe he/she would describe your performance, your strengths and weaknesses?

References
Please provide three to six references. The first priority is past bosses, then employees, then peers.

Example: Bob Smith, currently – Director of Purchasing at ABC Chemical 412-123-4567, Email: bob.smith@abcchem.com.
Was Purchasing Manager, my direct boss, while I was Sales Rep. at ABC Chemical.

We will NOT contact any references until after completing the interview process and not without notifying you first.

1) 
2) 
3)
Our scorecard is a form you complete on every candidate you have now screened as a potential fit. If you can tell that some of the candidate’s are probably C level in a superficial overview in comparison to others you set those aside now and grade the rest. The scorecard will help you objectively weigh all the Must Haves and even the preferences in such a way that at the end of using the scorecard process you can be pretty sure who the A plus candidates are, who the A candidates are, and who the B candidates are. Then we focus on scheduling for the A’s.

<table>
<thead>
<tr>
<th>Attribute</th>
<th>A/B/C</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Education</td>
<td></td>
<td>A = BS, MS or PhD in Chem or Chem E</td>
</tr>
<tr>
<td></td>
<td></td>
<td>B = BS in Chem or Chem E</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C = only BS in something other than above</td>
</tr>
<tr>
<td>2. Exp with new product dev of disposable single use medical devices, # of years</td>
<td></td>
<td>A = Yes, 5 plus</td>
</tr>
<tr>
<td></td>
<td></td>
<td>B = Somewhat, 3-5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C = No, less than 3</td>
</tr>
<tr>
<td>3. Exp with software control medical devices or products</td>
<td></td>
<td>A = Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>B = Somewhat</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C = No</td>
</tr>
<tr>
<td>4. Exp and background with 510K</td>
<td></td>
<td>A = Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>B = Somewhat</td>
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<td></td>
<td></td>
<td>C = No</td>
</tr>
<tr>
<td>5. Exp in projects that require significant management skills</td>
<td></td>
<td>A = Yes</td>
</tr>
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<td></td>
<td></td>
<td>B = Somewhat</td>
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<tr>
<td></td>
<td></td>
<td>C = No</td>
</tr>
<tr>
<td>6. Exp in a management role</td>
<td></td>
<td>A = Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>B = Somewhat</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C = No</td>
</tr>
<tr>
<td>7. Relocation to Round Lake, IL</td>
<td></td>
<td>A = Yes, no issues and/or lives in the area</td>
</tr>
<tr>
<td></td>
<td></td>
<td>B = Some issues but nothing major</td>
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<tr>
<td></td>
<td></td>
<td>C = Will have major issues relocating</td>
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<tr>
<td>8. Compensation: 140K to 160K with bonus 20%</td>
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</tbody>
</table>
Our scorecard is a form you complete on every candidate you have now screened as a potential fit. If you can tell that some of the candidate’s are probably C level in a superficial overview in comparison to others you set those aside now and grade the rest. The scorecard will help you objectively weigh all the Must Haves and even the preferences in such a way that at the end of using the scorecard process you can be pretty sure who the A plus candidates are, who the A candidates are, and who the B candidates are. Then we focus on scheduling for the A’s.

<table>
<thead>
<tr>
<th>A = 130K to 150K</th>
<th>B = 100K to 120K or 165K to 175K</th>
<th>C = below 100K or over 180K</th>
</tr>
</thead>
</table>

9. Job Changes/Stability

<table>
<thead>
<tr>
<th>Total Number of Job changes:</th>
<th>Total number of yrs working:</th>
<th>Average number of yrs at each job:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>A = Avg. yrs = 5-10</td>
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<tr>
<td></td>
<td></td>
<td>B = Avg. yrs = 3-5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C = Avg. yrs &gt;3</td>
</tr>
</tbody>
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Grading Point System:

<table>
<thead>
<tr>
<th>A’s = 4</th>
<th>B’s = 3</th>
<th>C’s = 2</th>
<th>Bonus Points = 1</th>
</tr>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Now add up the numerical value of each grade and then divide by the total number of grades</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Total Points</th>
<th>Divided by ___ grades = Avg. Grade</th>
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