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## Streamlining the Process of Bringing Products to Market in the Medical Device Industry, The Matzen Group Provides Multifaceted Guidance through Process, Product and People Development, Enabling Leadership Qualities on the Journey to Excellence



**Annette Matzen**  
 Owner

**BIO:** Ms. Matzen has over 25 years of experience working with management teams aligning operations with strategic initiatives; improving business processes & performance, mentoring and developing leaders, shortening product development cycle time, and expediting time to market.

Her career has included senior business unit leadership positions and global consulting assignments in the Aerospace and Medical Device Industries. Annette has worked with large multi-national corporations, locally managed cost centers, and new mergers & acquisitions.

Annette is an ASQ certified biomedical auditor with a BSEE and a BA in Mathematics. She has completed certification programs in Design for Six Sigma, Lean Manufacturing, Total Quality Management, and Honeywell (Baldrige-based) Quality System Auditing. She has been a mentor through the Minneapolis-based Menttium program since 2005.

### **About The Matzen Group:**

Provide multi-faceted guidance to the Medical Device Industry in the form of process, product and people development, quality system compliance, program management and interim leadership expertise. Be leaders on the journey to excellence.

### **Business Services Medical Devices**



**Interview conducted by:  
 Lynn Fosse, Senior Editor  
 CEOCFO Magazine**

**CEOCFO:** Ms. Matzen, would you tell us about The Matzen Group?

**Ms. Matzen:** We work primarily with medical device companies but also with businesses that manufacture combination products, such as drug/device products. We work with clients who are in the process of bringing products to market and have many regulatory requirements to meet. They are often struggling with getting their testing done, getting their documentation in order and preparing for the submission process. We help streamline that process and develop their organization's capability. What differentiates us in the market is our

ability to not only get our client's product approved, but also to build sustainable skills in their organization so the next time through they will be more efficient and effective.

**CEOCFO:** What are some of the areas that people miss when they are trying to get approval?

**Ms. Matzen:** Most of the time with smaller companies and continued certification of legacy products it is a matter of evolving Regulatory Agency expectations. The other is time and money. It takes a great deal of effort, test samples and testing to provide sufficient verification and validation evidence. Businesses are looking at the investment required and need to make careful choices on how they will establish a case for product effectiveness and safety. Today, the regulatory agencies expect statistically significant results to support product claims. Often, medical devices are developed by a group of highly intelligent scientists, not necessarily product developers. The transition from a great idea that works in a lab to a product that is safely marketed is hindered by a 'talent gap'. Smaller companies do not have the right talent to make that happen.

**CEOCFO:** How do you deal with the scientist turned entrepreneur that does not want to relinquish control and accept help?

**Ms. Matzen:** Because we are experienced product development engineers; we understand their language and their concerns. I have found throughout my career that what sets me apart is being a technical person who can also manage people

and bring a project together. Understanding someone on a technical level goes a long way in building trust and allows them to collaborate with you. Once you tell them what is necessary to get a product to market, they realize they do not want to do that kind of necessary work. So often, they are excited to find someone to do the work for them.

**CEOCFO:** What is your geographic range?

**Ms. Matzen:** We have had clients primarily in Canada and the U.S. My partner has worked in Japan and Scandinavia as well. The products we have approved are U.S. products going into Europe, Japan and other countries.

**CEOCFO:** How do you reach prospective customers?

**Ms. Matzen:** Primarily through references, word of mouth and networking. We have started pursuing higher visibility opportunities such as attending the BIO 2013 Conference in Chicago as part of the Minnesota Delegation. We have also recently updated our website and developed new marketing material. Several upcoming opportunities to conduct seminars will also help our exposure.

**CEOCFO:** Why is this the time to look for that heightened visibility?

**Ms. Matzen:** We are looking for a way to more uniquely position ourselves in the marketplace. There are large firms who have a cadre of consultants or contractors working for them of various abilities and dedication. Rarely are close, long-term relationships built using this model. That is not the

approach we are pursuing. We are developing an alternative model that resembles a collaboration of highly talented independent consultants who develop strong working relationships with their clients and are often long-term partners. We mutually reference and share our talents with this client community. Our presence is larger as a collective of talented people yet we allow the individual consultant/client relationships to build and grow.

**CEOCFO:** When speaking with prospective clients, what is the “aha” moment when they understand that they are getting a different quality of work than they would with a larger organization?

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**- Annette Matzen**

**Ms. Matzen:** Often, in speaking with our prospective clients they understand right away that we are going to build their team, improve leadership as well as technical and critical thinking skills. We talk to many clients who are interested and would like to invest more in building their teams but cannot afford the time or money for coaching and training, especially when there is so much ‘real’ work to do! This is why our model of actually doing necessary work while concurrently building skills in the teams and leaders we work with, is so beneficial. It is a great return on investment.

**CEOCFO:** What is the process for taking on a project?

**Ms. Matzen:** When you visit a company, talk with their leaders and meet the workers, you know immediately if you are going to be able to help them effect positive change or not. It is important that the leadership is aligned on objectives and understands the value we bring both in problem solving and people/process development.

**CEOCFO:** How is business?

**Ms. Matzen:** Business is really good now. There was a lull in the last year because of changes going on in the industry and lots of companies reorganizing.

**CEOCFO:** Why should the Matzen Group stand out to investors and people in the business community?

**Ms. Matzen:** We are unique because of our breadth of experience in highly regulated industries and our ability to effect sustainable, long-term improvement in our client’s performance. My partner and I both ‘grew up’ in a large highly respected corporation prior to moving into medical device consulting. We have decades of high caliber technical training and leadership development. When we come in and help companies—small, medium, or large—we have a foundation to build on and many lessons learned to apply to any given situation. The clients we are seeking want an immediate problem solved but they also want to build a talented workforce and work processes that will ensure their success long term.