

RCRI receives ISO 9001:2000 certification

RCRI is very proud to announce that this past January, we received our ISO 9001:2000 certification.

The ISO 9001:2000 standard, released in December 2000 as the successor to ISO 9000:1994, is an internationally recognized quality management system (QMS) standard developed by the ISO (International Organization for Standardization). ISO is a network of national standards institutes from more than 140 countries working in partnership with international organizations, governments, industry, business and consumer representatives.

"We are committed to maintaining our quality systems at the highest available standards. ISO 9001:2000 certification assures our clients that we are providing high quality services," said Steve Norsted, Ph.D., President and Chief Executive Officer of RCRI. "To meet the registration requirements, companies must implement and document QMS processes involving staff training, product design and processes, materials and services purchasing, and product service delivery," said Jennifer Marrone, Executive Vice President of RCRI.

RCRI chose to apply for ISO 9001:2000 certification to demonstrate to customers that our quality management system provides confidence in the conformance of our products and services to established or specified requirements. We intend to consistently provide products and services that meet applicable statutory, regulatory, as well as customer requirements. In addition, we strive to continually improve our quality management system. Continual improvement is a process of increasing the effectiveness of our organization to fulfill our mission and quality objectives, and enhance customer satisfaction.

Through our quality management system, RCRI personnel work to thoroughly understand customer needs, and then apply the appropriate resources to meet the customer's specifications and exceed their expectations. During the process of providing services the scope of the project may expand. RCRI will work to adapt to the clients' evolving requirements, to document these changing requirements, and adapt delivery of services to meet these requirements.

Various internal processes are utilized by RCRI to link and control activities and resources which must be managed to achieve the desired outputs. The Quality Management Principles in ISO 9001:2000 (customer focus, leadership, involvement of people, process approach, system approach to management, continual improvement, factual approach to decision making) are used by RCRI to improve and strengthen our quality management system.

One of the benefits of the process based quality management system will be improved customer satisfaction. Customer feedback along with various external and internal sources of data (such as effective internal auditing and management review of system performance) is valuable in order for RCRI to improve the performance of our processes and the overall quality management system. As part of RCRI's quality processes, customer satisfaction surveys will be sent at each project milestone.

Should you have comments regarding your experiences with RCRI, please contact Juli Stabile, Director of Business Development at jstabile@rcri-inc.com or 952-746-8080.



ISO 9001:2000
FM 89594

For more information on ISO certification, visit the ISO website at www.ISO.org.

New Appointments at RCRI

RCRI is delighted to announce the appointments of Tito Aldape to Vice President of Regulatory Affairs and Quality Systems, Andy Anderson to Senior Regulatory Project Director, and Juli Stabile to Director of Business Development.

Tito Aldape, MS

Vice President of Regulatory Affairs & Quality Systems

Tito Aldape brings over 20 years of experience and an outstanding track record of industry and regulatory involvement to this new position at RCRI. He has previously held significant positions with MicroFlex Medical Corporation, Baxter Healthcare, Allegiance Healthcare, and Alcon Laboratories. Aldape leads the regulatory and quality departments while also serving as Principal Advisor to further support client needs. "Tito's unique combination of expertise in regulatory and quality, along with his project management and business development experience bring a strategic, senior level consultative role to RCRI" said David Meyer, Chief Operating Officer at RCRI. "His experiences add a new layer of specialized services for RCRI clients."



Andy Anderson, PhD, RAC

Senior Regulatory Project Director

Andy brings over 25 years of strategic regulatory and clinical research experience to RCRI. He has held significant positions with CNS, Inc., including Vice President of Product Development, Regulatory, Clinical Affairs, and R&D. Andy has extensive experience working with U.S. and international regulatory agencies for product registrations. "Andy provides experienced leadership and expertise in the development of domestic and international regulatory strategies for submissions and market release of medical products," said David Meyer, Chief Operating Officer at RCRI. "His array of experience is rare and invaluable to our clients."



Juli Stabile, BA

Director of Business Development

Juli Stabile brings 8 years of outstanding business development experience to RCRI. She previously held leadership positions with Johnson & Johnson in sales and marketing. "Her long-standing track record of successful business development, project management and sales for Johnson & Johnson speaks to her focus on company growth and customer satisfaction" said David Meyer, Chief Operating Officer at RCRI. "This expertise is critical during a time of increasing outsourcing and consulting needs by the medical products industries." Stabile stated, "I am delighted to assume leadership of the department at such a key point in the company's development."



RCRI Participates in RAPS Summit - Recommends Strategies for Streamlining Regulation of Combination Products

The regulatory pathway for a combination product can be very complex, including what is-and what is not-a combination product. It seems obvious, two different medical products combine to form a single "combination product," (drug-device, device-device, biologic-device or drug-biologic). The combination product consists of two independently approved, manufactured and distributed products where the labeling requires the products to be used together or "cross labeled." Yet, it is unclear which US Food and Drug Administration (FDA) centers would be responsible for which combination product(s).

There is concern that the US FDA needs to apply a more consistent and predictable approach toward regulation and review of combination products. As such, RCRI participated in a Regulatory Affairs Professionals Society (RAPS) summit conference to explore regulation of combination products.

A panel of senior regulatory executives, including an RCRI principal advisor, gathered input from participants. The summit's panel and participants recommended that:

- FDA modify its intercenter agreements to more clearly delineate each center's roles and responsibilities for handling (1) approvals of combination products, (2) modifications to existing combination products and (3) labeling review;
- Greater predictability from the process of combination product regulation exist;
- A common set of terms and definitions related to combination products be developed;
- Definitions of what is/is not a combination product be clarified; and
- Enhanced training in the complexities of combination products for both FDA staff and those involved in the medical product industry be provided.

The panel relied on the input of the summit participants in developing its draft recommendations document. The panel allowed RCRI and all the summit participants to review and comment upon the draft report. The final report was expected to be released by the end of April 2005, and it will be submitted to FDA offices and to the docket for the FDA/DIA Cross-labeling Workshop, "Combination Products and Mutually Conforming Labeling," on May 10, 2005. At this workshop FDA will seek stakeholder input on regulatory approaches to combination product labeling issues.

Updated 21 CFR Part 11 Guidance Document on FDA Website

In September 2004 the FDA released a draft update to the April 1999 guidance document titled "Computerized Systems Used in Clinical Trials." This update was created to harmonize the existing guidance with the change in scope to 21 CFR Part 11, Electronic Records; Electronic Signatures – Scope and Application guidance document, released in August 2003. As with the original "Computerized Systems Used in Clinical Trials" guidance document, the intent of the recently released guidance is to outline suggested precautions to ensure the accuracy, integrity, and reliability of clinical systems that rely on electronic record and signature data.

As a result of the agency's efforts to streamline 21 CFR Part 11, the focus of the new guidance suggests the use of a risk-assessment approach to determine the extent to which certain requirements may necessitate additional controls within a clinical system. In essence, the document enables you to interpret and apply the guidance, as appropriate, concurrent with analyzing and documenting your rationale via conducting a risk assessment.

Individuals looking for this guidance document can find it at the CDER website address: <http://www.fda.gov/cder/guidance/6032dft.htm>. [It should be noted that the guidance is only available via the search engine for the CDER page and has not been updated within the CDRH guidance documents.]

RCRI can assist you in both the interpretation and application of the guidance as well as the risk assessment process.

Future Topics to be Discussed?

Do you have ideas on future topics you would like for us to review or discuss in this newsletter? Need some pointers or advice? Please email your ideas, needs, or questions to info@rcri-inc.com. We might write a response in an upcoming newsletter.

Contact Information

Your comments, questions, and general feedback are very important to us. Please mail comments to us using the address located on the back of this newsletter, or send an email to info@rcri-inc.com. This newsletter is also available in electronic format on our website at www.rcri-inc.com or via electronic subscription. To subscribe, send a "subscribe" message to us at the address above. Your email address will remain confidential.

Mark your calendars

Please visit RCRI at the following conferences. (Mention this newsletter at one of these events and receive a prize!)

- FDA Science Forum, April 26-28, 2005
Washington D.C.
- Invest Northwest, April 26-27, 2005
Seattle, WA
- Alley Chats, May 5, 2005
St. Paul, MN
- MN Venture Capital Conference, May 9-10, 2005
Bloomington, MN
- MedTech Investing, May 11-12, 2005
Minneapolis, MN
- Executive Summit on Medical Device
Reimbursement, June 16-17, 2005
Washington D.C.
- Bio 2005, June 19-22, 2005
Philadelphia, PA

Our mission is to serve our clients with knowledge, integrity, and ingenuity

At RCRI, we are proud of our record in providing integrated CRO services to the medical device, IVD, combination drug, and bioscience industries.

Since our inception in 1999, RCRI has helped more than 150 companies worldwide, ranging from development stage start-ups to the largest Fortune 500 companies, translate their product plans into successful revenue generating business.

Whether it is a single task or a complex multi-faceted project, you can count on the highly qualified professionals at RCRI.

Please contact us to discuss how we can assist you.



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