



Oracle Consulting Group

Company Profile

General Overview

Oracle Consulting Group is a Tucson, Arizona-based firm specializing the quality system consulting activities to U.S. and foreign firms:

- Regulated by the U.S. Food and Drug Administration (FDA)
- Meeting various international medical device regulatory requirements
- Who have adopted or are implementing one of the ISO 9000 quality standards
- Foreign firms that require an official U.S. Agent and/or an Official Correspondent
- Who require client or marketing surveys

Mission Statement

Our mission is to provide cost-effective quality system consulting and U.S. Foreign Agent services that meet each client's current, near-term, and long-term needs.

Establishing a Relationship

We typically start our discussions after executing a Non-disclosure Agreement to provide you the protection you deserve in our discussions. We can also provide our Quality Policy.

If appropriate, we follow our initial discussions with a tailored Consulting Service Agreement (CSA) and Quality Requirements Specification (QRS) document. The CSA and QRS will provide each client with the information they need to make an intelligent, informed decision on the ability of Oracle Consulting Group to meet their quality system consulting service needs. Don't forget, the FDA may review your decision.

Product/Service Overview

Oracle Consulting Group provides the following services:

- Preparing medical device manufacturers for FDA regulatory compliance and device submissions.
- Providing U.S. Agent and Official Correspondent services to foreign firms.
- Assisting firms for their implemented ISO 9000 quality system conformance.
- Providing firms with tailored client and market surveys.
- Assisting firms with their "due-diligence" for potential acquisition of medical device manufacturers, that is, a regulatory status assessment of the prospective acquisition to reveal their FDA compliance status.

Client Tailored Consulting Service Agreement

After execution of a Non-disclosure Agreement, we invite potential clients and existing clients to discuss their quality system consulting needs with us. That dialogue will allow Oracle Consulting Group to tailor each Consulting Service Agreement and Quality Requirements Specification specific to those needs.

Competitive Advantages

Oracle Consulting Group pledges to provide cost-effective quality system consulting services and ensure that clients remain in-charge of our consulting services throughout the term of agreed services.

Technology Capabilities

Oracle Consulting Group provides on-site and our office-based FDA and quality system consulting services. We are reachable by phone, FAX, internet web site and email.

Our consulting service projects are managed by milestone-based management documents that help firms control both the project and process. Our service output documents are provided to clients in the word processing application and version of their choice.

Recent Company News

In April 1999, our managing consultant, Gordon Harnack had a book published by the American Society for Quality's **Quality Press**. The book is titled "**Mastering and Managing the FDA Maze: Medical Device Overview**" and is a management and training aid for medical device manufacturers. The book is available from ASQ's **Quality Press**, Amazon.com, most other booksellers or Oracle Consulting Group.

Gordon is working on several other "**Mastering and Managing the FDA Maze**" books with management and training aids for other elements of FDA compliance.

Client Benefits

Our clients benefit from our consulting services through:

- Their management and control of each project and process.
- Our cost-effective approach to quality system consulting.
- Our constant feedback and assessment of the project and the process to ensure client satisfaction.
- Our 24 hour a day accessibility, by phone, FAX or email, and to our web site <http://www.fdamaze.com>

Summary

Oracle Consulting Group welcomes inquiries and questions about our consulting services. We will honestly assess your quality system needs and tailor a proposal specific to those needs. We know that you will be satisfied with both the process and the output products of our services.

Call Gordon Harnack, Managing Consultant, at 1-520-825-0555, FAX 1-520-825-0556 or visit our web site at <http://www.fdamaze.com>, or email us at <info@fdamaze.com>.

Our solutions only look expensive!