

Quality Requirements Specifications

December 1, 2003

Oracle Consulting Group (OCG) is dedicated to providing quality consulting services to your firm. Part of that dedication is our commitment to providing the following **Quality Requirements Specifications** to your firm. These **Quality Requirements Specifications** include:

1. **OCG** commits to promptly notifying your firm of any changes in our products or services which may affect the quality of your firm's products or services, to ensure your firm's ability to determine the affect, if any, of those changes to their products or services.
2. **OCG** commits to provide your firm with the opportunity to review, edit, and approve any output document which will become an integral part of your firm's regulatory or production records.
3. **OCG** pledges to provide the contractually committed consulting services in a manner that provides your firm with **OCG's** "best efforts" quality service. Any consulting service output document which is reviewed by the FDA and found to be defective, deficient, or incomplete, shall be reviewed and assessed for FDA's concerns and expectations, and, whenever appropriate, revised or redone to meet that FDA expectation at no cost to each your firm. However, if that FDA finding is the result of your firm's providing incomplete, inaccurate, or otherwise erroneous information to **OCG**, any output document revision or rework, mutually agreed, shall be billed to that your firm.
4. **OCG** recognizes the importance of the Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) and the Center for Devices and Radiological Health (CDRH) to your firm, and agrees to routinely monitor both of these FDA Centers for draft policies, draft regulations, draft guidelines, new final policies, new regulations, new guidelines, **Federal Register** notices, and workshop notices that impact your firm.
5. **OCG** recognizes the importance of the Federal Laws related to the Food and Drug Administration (FDA), and agrees to retain copies, be familiar with their content, and the relationship of these Federal Laws to your firm's operational and manufacturing environment:

Federal Food, Drug, and Cosmetic Act, as Amended, 21 USC '321 et. seq. Major amendments include:

- a. Medical Device Amendments of 1976.
- b. Safe Medical Devices Act of 1990 (SMDA).
- c. The FDA Export Reform and Enhancement Act of 1996
- d. The FDA Modernization Act of 1997

Within the Federal Food, Drug, and Cosmetic Act, specifically:

- a. Section 501, Adulterated Drugs and Devices
 - b. Section 502, Prohibition of Misbranding
 - c. Section 503, Exemptions and Consideration for Certain Drugs, Devices, and Biological Products
 - d. Section 510, Registration of Producers of Drugs and Devices
 - e. Section 513, Classification of Devices Intended for Human Use
 - f. Section 514, Performance Standards
 - g. Section 515, Premarket Approval
 - h. Section 516, Banned Devices
 - i. Section 519, Records and Reports on Devices
 - j. Section 520, General Provisions Respecting Control of Devices Intended for Human Use
 - k. Section 522, Postmarket Surveillance
 - l. Section 555, Corrective Actions, Cessation of Dissemination
 - m. Section 563, Classification of Products
 - n. Section 704, Inspections
 - o. Section 801, Imports and Exports
6. **OCG** recognizes the importance of the FDA's Center for Devices and Radiological Health (CDRH) and/or Center for Biologics Evaluation and Research (CBER) to your firm, and agrees to retain copies of the following FDA regulations, guidelines and documents (among others), be familiar with their content, and the relationship of these regulations, guidelines and documents to your firm's operational and manufacturing environment:

Regulations:

- Code of Federal Regulations, Title 21, Part 11 - Electronic Records; Electronic Signatures
- Code of Federal Regulations, Title 21, Parts 200 - 299, and specifically, 21 CFR 211, Current Good Manufacturing Practice for Finished Pharmaceuticals
- Code of Federal Regulations, Title 21, Parts 600 - 799, and specifically, Subchapter F - Biologicals, 21 CFR 600 - 640.
- Code of Federal Regulations, Title 21, Parts 800 - 1299, and specifically, 21 CFR 801 Labeling.
- Code of Federal Regulations, Title 21, Parts 800 - 1299, and specifically, 21 CFR 803 Medical Device Reporting.
- Code of Federal Regulations, Title 21, Parts 800 - 1299, and specifically, 21 CFR 806, Corrections and Removals.
- Code of Federal Regulations, Title 21, Parts 800 - 1299, and specifically, 21 CFR 807 Establishment Registration and Device Listing for Manufacturers and Distributors of Devices.
- Code of Federal Regulations, Title 21, Parts 800 - 1299, and specifically, 21 CFR 809 In Vitro Diagnostic Device Requirements.
- Code of Federal Regulations, Title 21, Parts 800 - 1299, and specifically, 21 CFR 812, Investigational Device Exemptions.
- Code of Federal Regulations, Title 21, Parts 800 - 1299, and specifically, 21 CFR 814 Premarket Approval of Medical Devices.
- Code of Federal Regulations, Title 21, Parts 800 - 1299, and specifically, 21 CFR 820 Quality System Regulations.
- Code of Federal Regulations, Title 21, Parts 800 - 1299, and specifically, 21 CFR 821 Medical Device Tracking Requirements.
- Code of Federal Regulations, Title 21, Parts 800 - 1299, and specifically, 21 CFR 860 Medical Device Classification Procedures.
- Code of Federal Regulations, Title 21, Parts 800 - 1299, and specifically, 21 CFR 861 Procedures for Performance Standards Development.
- Code of Federal Regulations, Title 21, Parts 800 - 1299, and specifically, 21 CFR 862 Clinical Chemistry and Clinical Toxicology Devices.
- Code of Federal Regulations, Title 21, Parts 800 - 1299, and specifically, 21 CFR 864 Hematology and Pathology Devices.
- Code of Federal Regulations, Title 21, Parts 800 - 1299, and specifically, 21 CFR 866 Immunology and Microbiology Devices.
- Code of Federal Regulations, Title 21, Parts 800 - 1299, and specifically, 21 CFR 895 Banned Devices.

Computers and Software:

- FDA Policy for the Regulation of Computer Products (Draft),
- Glossary of Computerized System and Software Development Terminology, August 1995, FDA
- Guidance for Industry, Computerized Systems Used in Clinical Trials, April 1999, Draft Guidance, June 18, 1997
- Computerized Devices/Processes Guidance - Application of the Medical Device GMP to Computerized Devices and Manufacturing Processes
- Computerized Systems Used in Clinical Trials, April 1999, FDA
- Guidance for Industry, General Principles of Software Validation, Draft Guidance, Version 1.1, June 9, 1997, CDRH
- Review of 510(k)s for Computer Controlled Medical Devices #K91-1, Feb 27, 1997, ODE, FDA
- Guidance for Off-the-Shelf Software Use in Medical Devices, Draft Document, June 4, 1997, CDRH
- ODE Guidance for the Content of Premarket Submission for Medical Devices Containing Software, Draft Document, September 3, 1996, CDRH
- Guidance Concerning Conversion to FDA-Reviewed Software Products, November 13, 1995, CBER
- FDA/NLM Software Policy Workshop, September 3-4, 1996

Design Controls:

- Do It By Design - An Introduction to Human Factors in Medical Devices, CDRH
- Design Control Guidance for Medical Device Manufacturers, March 11, 1997, OC, CDRH
- Design Control Inspectional Strategy Report Evaluation, CDRH

Federal Register Notices:

- The Food and Drug Administration's Development, Issuance, and Use of Guidance Documents, Vol. 62, No. 39, p. 8961
- 21 CFR Part 803, et al., Medical Device User Facility & Manufacturer Reporting, Certification and Registration, Delegations of Authority; Medical Device Reporting Procedures, Final Rules, Vol. 60, No. 237, pp. 63577 - 63606
- 21 CFR Part 810, Medical Device Recall Authority, Final Rule, Vol. 61, No. 225, pp 59004 - 59022

Inspections:

- Guide to Inspections of Quality Systems, August 1999, ORA, CDRH
- Medical Device Manufacturer's Survey Evaluation of FDA Quality System / Good Manufacturing Practice Inspections
- Inspection of Medical Device Manufacturers; Final Guidance for Industry and FDA, Feb 7, 2001, OC, CDRH
- QSIT (Quality System Inspection Technique) Inspection Handbook, ORA

International Standards:

- Guidance on the Use of Standards in Substantial Equivalence Determinations, March 12, 2000, ODE, CDRH
- Required Elements for a Declaration of Conformity to a Recognized Standard,
- Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices, May 1, 1995, ODE, CDRH
- Recognition and Use of Consensus Standards; June 20, 2001, ODE, CDRH
- Medical Electronic Equipment, Part 1: General Requirements for Safety, IEC 60601-1, and Amendment 1, 1991-11 and Amendment 2, 1995-03

Labeling:

- Device Labeling Guidance #G91-1, ODE, CDRH
- Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers, April 19, 2001, Labeling Research and Policy Development Branch, CDRH
- Human Factors Principles for Medical Device Labeling, Sept 1, 1993, CDRH
- Identification of Manufacturer of Medical Devices, Draft, June 23, 2003, CDRH
- Labeling – Regulatory Requirements for Medical Devices (FDA 89-4203), Division of Small Manufacturers Assistance (DSMA), CDRH
- Review of Final Draft Medical Device Labeling #91-4, CDRH
- Write it Right, August 1993, DSMA, CDRH

Medical Device Reporting:

- Medical Device Reporting: An Overview, April, 1996, CDRH
- Medical Device Reporting for Manufacturers, March 1997, Division of Small Manufacturers Assistance, CDRH
- Medical Device Reporting - Alternative Summary Reporting (ASR) Program, Oct 19, 2000, CDRH

Premarket Notifications or 510(k)s (among many others):

- Deciding When to Submit a 510(k) for a Change to an Existing Device, January 10, 1997, CDRH
- Premarket Notification: 510(k) - Regulatory Requirements for Medical Devices, Division of Small Manufacturers Assistance, August 1995, CDRH
- Background Information on Reclassification and 515(i) Submission, October 27, 1997, CDRH
- Determination of Intended Use for 510(k) Devices B Guidance for Industry and CDRH Staff, January 30, 1998, CDRH
- ODE Guidance for the Content of Premarket Submission for Medical Devices Containing Software, Draft Document, September 3, 1996, CDRH
- A New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications, March 20, 1998, CDRH

Product Development Protocol:

- Contents of a Product Development Protocol, Guidance for Industry, July 27, 1998, CDRH

Registration and Listing:

- Establishment Registration and Medical Device Listing,
- Instructions for Completion of Medical Device Registration and Listing Forms FDA 2891, 2891a and 2892, CDRH
- Changes requiring Foreign Firms to Register, List their FDA regulated products and identify a U.S. Foreign Agent, effective November 2001

7. **OCG** recognizes the importance of the International Organization for Standardization (ISO) and its ISO 9000 series of international standards. **OCG** retains copies of the following ISO 9000 standards and ISO 10011 Guidelines for Auditing Quality Systems (among others), is familiar with their content and their relationship to ART attempting to obtain ISO 9000 certification or retaining ISO 9000 certification:
 - ANSI/ISO/ASQC Q9001-1994, Quality Systems - Model for Quality Assurance in Design, Development, Production, Installation, and Servicing.
 - ANSI/ISO/ASQC Q9002-1994, Quality Systems - Model for Quality Assurance in Production, Installation, and Servicing.
 - ANSI/ISO/ASQC Q9000-3-1991, Quality Management and Quality Assurance Standards - Guidelines for the Application of ANSI/ISO/ASCQ 9001 to the Development, Supply, and Maintenance of Software.
 - ANSI/ISO/ASQC Q10011-1-1994, Guidelines for Auditing Quality Systems - Auditing.
 - ANSI/ISO/ASQC Q10011-2-1994, Guidelines for Auditing Quality Systems - Qualification Criteria for Quality System Auditors.
 - ANSI/ISO/ASQC Q10011-3-1994, Guidelines for Auditing Quality Systems - Management of Audit Programs.

8. **OCG** recognizes the importance of the maintaining membership in a variety of professional organizations and associations to maintain professional skills. **OCG** pledges to maintain membership in the following organizations and associations, among others, for that purpose:
 - American Society for Quality (formerly American Society for Quality Control), (ASQ)
 - Regulatory Affairs Professional Society (RAPS)
 - Association for the Advancement of Medical Instrumentation (AAMI)