QA RA Compliance Connection, Inc.

P.O. Box 448 * Odessa, FL 33556 * (813) 784-8457 * www.qaracc.com

QMS REQUIREMENTS TRAINING

for the Medical Device Industry

Date: April 28-29, 2010

Time: 8:30 AM to 5:00 PM

Medical device manufacturers looking to sell product in the U.S. are mandated to implement and comply with the FDA's Quality System Regulation (QSR) codified under 21 CFR Part 820. Further, manufacturers looking to remain competitive and/or expand their distribution into other countries such as Europe and Canada, are often required to comply with ISO 13485 requirements. This 2-day course provides an in-depth review and perspective of the FDA QSR and ISO 13485 requirements.

This class is ideal for individuals responsible for developing, implementing, complying, managing and auditing an organization's QMS. Interactive discussion and mock exercises will assist participants in understanding and applying the requirements.

Highlights

- **QMS Introduction**
- **Benefits of Compliance**
- **ISO's Process Approach**
- **FDA's Quality System Inspection Technique (QSIT)**
- **Key Terms & Definitions**
- **QMS Requirements Review**
- **FDA 483 Observation Examples**
- **General Auditor/Inspector Questions**
- **Interactive discussion and real world application through mock exercises**
- **Tips for Compliance**
- **FDA Enforcement Actions**

REGISTER NOW!

SAVE $100 off the $995 registration fee by registering before 3/28/2010

CONTACT:

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SEMINAR/HOTEL INFO:

The seminar will be held at the:
Hilton Tampa Airport Westshore
2225 North Lois Avenue
Tampa, FL 33607
Tel: (813) 874-5008 Fax: (813) 872-0603

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