

From: "Nan Matthews" <rmas@themattgrp.com>
Subject: **December 2nd RMRAS Meeting**
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Rocky Mountain Regulatory Affairs Society (RMRAS)

Wednesday, December 2, 2009

3:30 pm – 4:00 pm Registration and Networking

4:00 pm – 5:00 pm **Regulatory Changes in the European Market**

For our December 2009 meeting, Rocky Mountain RAS is pleased to present Bob Clark of Medical Device Regulatory Advisors. .

Be prepared for changes in European regulations affecting medical devices and IVD products. Broad revisions to the MDD 93/42/EEC Medical Device Directive have been enacted and become effective March 2010. These changes could require revision of your technical files and might require additional documentary or clinical evidence to maintain your CE Mark status. **This can affect you even if your product has not changed!**

Learn how these changes could affect your European marketing strategy and how to prepare for them before the March 2010 deadline.

Speaker Bio

Bob is the founder of Medical Device Regulatory Advisors in Golden, Colorado, an international consulting firm offering professional expertise in regulatory affairs and quality assurance. His professional background encompasses over 30 years of medical product development, manufacturing, quality assurance, and regulatory affairs, encompassing a broad spectrum of diagnostic and therapeutic devices, as well as some bulk API pharmaceutical and drug packaging products.

Bob is a member of the Regulatory Affairs Professional Society (RAPS) and a senior member of the American Society for Quality (ASQ). He has authored industry articles on various aspects of regulatory affairs and quality systems, and has presented training and educational materials at various national and international medical industry seminars. Bob is EU Regulatory Affairs Certified (RAC EU)

Please RSVP to rmas@themattgrp.com

Location:

Koebel Library, 5955. S Holly Street, corner of Orchard and Holly, Centennial, CO 80121. Phone: 303-220-7704.

Directions

Take I-25 south to Orchard, exit west off Orchard to Holly Street. The library is on the corner of Holly and Orchard. Drive past Holly and turn left into the parking lot behind the library. Come in the main entrance and take a left to our meeting room.

[For further directions, go to www.arapahoelibraries.org]