

**From:** "RMRAS Programs" <programs@rmras.org>  
**Subject:** What Needs to Be in a Product Submission - Oct 31 Audioconference  
**Date:** October 17, 2011 10:44:00 AM MDT  
**To:** "RMRAS Programs" <programs@rmras.org>

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Please join the Rocky Mountain Regulatory Affairs Society at **Regus Business Center in Westminster** to take advantage of discounted fees for the following teleconference from FOI.

(This discount is only available at Regus, not in your office. If you want to participate from your office, contact the Sponsor for full price rates.)

## What Needs To Be in a Product Submission: An FDA Reviewer's Perspective

Presented by *Joshua Sharlin, Ph.D.* (and FOI)

**Monday, October 31, 2011**

**11:00 am–12:30** audio conference / informal discussion with attendees and a private Q&A with instructor until around 1:15 pm

**Cost is \$100**

**Your registration is needed by October 25<sup>th</sup>. If there are fewer than 10 participants, this event will be cancelled.**

**Submissions:** You've finally completed your submission to FDA and are ready to send it in. What are FDA's reviewers going to think when they sit down with it? Are you sending in a submission that will delay (or even deny) your product's approval? This popular and practical presentation gives you valuable insight into how FDA reviewers think and work and advice on using that understanding to improve your own submission content and reduce approval anxiety.

The recommendations provided in this teleconference are valuable to drug, device, and biologic firms, offering pragmatic and easily implemented suggestions to improve your submissions.

For additional information about this audioconference see: <http://www.foiservices.com/tc-docs/moreinfo/oct3111.cfm>

**Cost:** The cost of this teleconference is **\$100.00**. (RMRAS group rate at Regus)

**Registration:** To register, please go to: [https://www.paypal.com/cgi-bin/webscr?cmd=\\_s-xclick&hosted\\_button\\_id=X6EHRBGXT5GWG](https://www.paypal.com/cgi-bin/webscr?cmd=_s-xclick&hosted_button_id=X6EHRBGXT5GWG)

Note: Your credit card will be charged at registration, but you will be fully refunded if the event is cancelled.

### **Location:**

Regus Business Center  
10955 Westmoor Drive, 4th Floor  
Westminster, CO 80021  
303-379-2100

**Follow the signs for the Golf Course and after you see the clubhouse, look for the building with the gazebo (approximately 0.9 miles from entrance of complex). (Warning: the building numbers are hard to see.)**

**Questions:** Questions can be addressed to: Georganne Brown, [gbrown@regulatoryrelief.com](mailto:gbrown@regulatoryrelief.com) or to [Webinars@RMRAS.org](mailto:Webinars@RMRAS.org)