

**From:** "Nan Matthews" <rmras@themattgrp.com>  
**Subject:** **Industry Speakers Needed**  
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BioMARC, The Regional Training Center for Product Translation at CSU, would like to invite RMRAS members to participate in their new seminar series in collaboration with the Fitzsimons BioBusiness for both Small Molecules/Biologics/Vaccines and Medical Devices in two separate sessions for pre/non-clinical testing and clinical trials.

The presentations are scheduled for February 22-23, 2010, and the proposed agenda for the pre/non-clinical testing section is listed below.

If you are interested in being a speaker/presenter, please submit your resume and the topic you would like to cover to Deanna Scott [contact information below] by the week of January 4. Speakers will be selected the week of January 11<sup>th</sup>.

**Preclinical Aspects of Product Translation for Small Molecules/Biologics/Vaccines, February 22, 2009:**

(Day long seminar series about an hour for each topic)

- 1) Overall Pre/Non-Clinical Testing Requirements for Regulatory Submissions
  - a. Reference to FDA Guidance for Industry "M3 Nonclinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals "
- 2) Pre-clinical Trial Design
- 3) Animal Modeling
- 4) Toxicology
- 5) Statistical Analysis
- 6) Regulatory Requirements
- 7) Translation of Pre/Non-Clinical Data to Humans

**Preclinical Aspects of Product Translation for Medical Devices and Diagnostics, February 23, 2009:**

(Day long seminar series about an hour for each topic)

- 1) How to Determine the Pre-Clinical Trial Requirements for Regulatory Submissions
- 2) Pre-clinical Trial Design
- 3) Animal Modeling
- 4) Biocompatibility
- 5) Statistical Analysis
- 6) Regulatory Requirements
- 7) Translation of Pre/Non-Clinical Data to Humans

**For more information or additional details, please contact**

[Deanna Scott, M.S. RAC, Director](#)

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