What is happening? The fall semester is nearly over. I hope you have all been enjoying your courses. Many of you are taking electives or required courses from other programs (courses that do not have the RA prefix).

You will start to see a department name change that we have been planning for a while. “Health Product Regulation” does not appropriately recognize our Clinical Research program and its students. So the department name is changing to “Regulatory and Clinical Research Management”. You can see the new name highlighted in the title of this newsletter. Over the next semester, you will see the name roll out in websites, brochures, catalogs, etc.

The term “Management” comes from a department vision.

The RCRM program prepares students so that three to five years after receiving an MS, RCRM alumni are in management, supervisory, or strategic professional positions.

What has not changed? The program and curriculum are the same. The diploma still says Master of Science (in Latin, of course). Our program’s graduate degree has always been Master of Science without designation of program or track.

Two courses have been renamed to better describe the course content. RA 601 is changing its name from Overview of the Health Product Industry to Overview of the Medical Product Industry. RA 602A is changing its name from Overview of Health Product Regulation to Overview of FDA Regulation.
Spring enrollment is open!

Many of you have already taken advantage of the on-line enrollment capability. Please enroll soon! Early enrollment allows us to plan better. Better planning means we can lock in better rooms and equipment and means that faculty members can plan their schedules.

Late breaking news

If you tried to enroll in this spring’s HP 601 recently, you may have been wait-listed. A second session is being planned. All who enroll should be able to take the course. Both sessions will be given Tuesday evenings.

Re-evaluation of HP 600 Biostatistics

HP 600 Biostatistics has been taught twice. The instructors, Profs Laura Mignone Burke and Lisa Fardy have suggested some ways to make the course better. Changes include:

- In spring 2011 the class will be given in the physical classroom only. There will be no virtual classroom option. By fall 2011, we hope to have developed a more effective distance learning method. Stay tuned for that.

  The program policy is to provide every course with a distance option at least once per year. We continue to work to meet that policy.

- In spring 2011 each class will be divided into a 90 minute classroom session and a 90 minutes computer lab session. With computer exercises in the college lab and during class time, there is no need for students to purchase statistics software in order to complete assignments.

- Prerequisite knowledge of basic statistics is strongly encouraged. (An undergraduate course in statistics may be a prerequisite in the future.)

Students enrolling in HP 600 for this spring will be contacted with more details.

Come prepared to the first spring class!

Regis College IT has expedited the process of entering students into the Regis email system, into Moodle, and into Connect Pro classes.

Now that students will be on the systems, RCRM put the first day of class to better use. Students will be expected to prepare for the first class. The Moodle class site may have reading or other assignments due at the first class.

Announcements will be posted on Moodle by Friday before the first class, that is, by January 14, 2011. Instructors are asked to use their Moodle site forum to push announcements to students. To be safe, students should make a point to go to their Moodle class sites on Friday, January 14.

Check Moodle the Friday before classes start.
### Spring and summer 2011 course schedules

Please see Regis Access for all courses.

#### Spring 2011
- **RA 601** Overview of the Medical Product Industry (previously Overview of the Health Product Industry), Tuesdays, 6-9 pm, Regis campus, virtual classroom capable.  
  Instructor: Ed Burke

- **RA 602A** Overview of FDA Regulation (previously Overview of Health Product Regulation), Wednesdays, 6-9 pm, Regis campus, virtual classroom capable.  
  Instructor: Michael Drues

- **RA 603A** Pharmaceutical Product Regulation, Thursdays, 6-9 pm, Marlborough, virtual classroom capable.  
  Instructor: Robert Yocher

- **RA 605** Field Experience, individual projects. Contact Profs. Chas Burr or Lisa Fardy for more information.

- **RA 609** Clinical Trial Management, Thursdays, 6-9 pm, Regis campus, virtual classroom capable.  
  Instructor: Prof. Lisa Fardy

- **RA 610** Medical Product Reimbursement, Wednesdays, 6-9 pm, Regis campus, virtual classroom capable.  
  Instructor: Erica Bisguier

- **CO 613** Writing in the Professional Workplace. Wednesdays, 6-8:30 pm, no virtual classroom, hybrid course.  
  Instructors: Barbara Mintz and Mary Ann Hart

- **HP 600** Biostatistics, Wednesdays, 6-9 pm, Regis campus, no virtual classroom this semester.  
  Instructor: TBA

- **HP 601** Health Ethics and Law, Tuesdays, 5:30-8 pm, Regis campus, virtual classroom capable.  
  Instructors: Juliette Shih and Prof. Mary Ann Hart

#### Summer 2011
- **RA 604A** Medical Device Regulation, Thursdays, 6-9 pm, Marlborough, virtual classroom capable.  
  Instructor: Prof. Chas Burr

- **RA 616** Project Management, Wednesday, 6-9 pm, Regis campus, virtual classroom capable.  
  Instructor: Tina Karunaratne
A change in Clinical Research Management Graduate Certificate requirements

Last year Graduate Certificate requirements changed to accommodate new course offerings. We need to tweak the requirements for the Clinical Research Management Graduate Certificates. (N.B., this change only affects new students. Students in the program can continue with the requirements in effect when they started.)

The Certificate still requires only four courses. However, RA 603A and RA 604A will no longer count toward those four courses. The revised Clinical Research Management Graduate Certificate requirements are:

- RA 601 Overview of the Medical Product Industry
- RA 602A Overview of FDA Regulation
- RA 609 Clinical Trial Management
- Your choice of:
  - RA 608 Clinical Research Methods
  - RA 616 Project Management

For comparison, the unchanged Regulatory Management Graduate Certificate Requirements are:

- RA 601 Overview of the Medical Product Industry
- RA 602A Overview of FDA Regulation
- RA 615 Risk Management and Quality Systems
- Your choice of:
  - RA 603A Pharmaceutical Product Regulation
  - RA 604A Medical Device Regulation

If you have questions, talk with your advisor: Lisa Fardy for Clinical Research Management or Chas Burr for Regulatory Management.

Tentative Two Year Schedule

Students and faculty have had a difficult time planning because there have been no long term schedules on which they could rely. HPR has developed some principles for course scheduling, which in turn have led to the following tentative schedule.

It must be tentative because things happen. It includes RA courses, which HPR directly controls, and required courses for the MS HPR, which HPR can influence. It does not include other electives. Perhaps in the future.

Principles:

- When more than 20 students per year take a course, offer it twice per year.
- Split courses between Regis campus and remote sites.
- Most students start in the fall or spring semester. Hold the Overview courses (RA 601 and RA 602A) in these semesters. Remote site in the fall. Regis in the spring, when undergraduate seniors are likely to take the course.
- Elective RA courses likely to draw undergraduate seniors should be given in the spring semester.
- Offer a distance option at least once per year for each course.
- Each track requires three unique courses. Offer one each semester (fall, spring, summer) until student numbers justify a second session.
- Try to spread required non-RA courses evenly over the three semesters.
- Work with non-RA program directors to spread the schedule and to have distance options for required courses and popular electives.

See the tentative schedule on the next page.
## Tentative Two Year HPR Schedule

<table>
<thead>
<tr>
<th>Type</th>
<th>Course</th>
<th>SP 11</th>
<th>SS 11</th>
<th>FA 11</th>
<th>SP 12</th>
<th>SS 12</th>
<th>FA 12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overview</td>
<td>RA 601</td>
<td>REG</td>
<td>MRL</td>
<td>REG</td>
<td>MRL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overview</td>
<td>RA 602A</td>
<td>REG</td>
<td>MRL</td>
<td>REG</td>
<td>MRL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PR track</td>
<td>RA 603A</td>
<td>MRL</td>
<td></td>
<td>REG</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PR track</td>
<td>RA 604A</td>
<td>MRL</td>
<td></td>
<td>REG</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PR track</td>
<td>RA 615</td>
<td>REG</td>
<td></td>
<td>REG</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CR track</td>
<td>RA 608</td>
<td>REG</td>
<td></td>
<td>REG</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CR track</td>
<td>RA 609</td>
<td>REG</td>
<td></td>
<td>REG</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CR track</td>
<td>RA 616</td>
<td>REG</td>
<td></td>
<td>REG</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Requirement</td>
<td>CO 613</td>
<td>REG</td>
<td>REG</td>
<td>REG</td>
<td>REG</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Requirement</td>
<td>HP 600</td>
<td>REG</td>
<td>REG</td>
<td>REG</td>
<td>REG</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Requirement</td>
<td>HP 601</td>
<td>REG</td>
<td>REG</td>
<td>REG</td>
<td>REG</td>
<td>REG</td>
<td></td>
</tr>
<tr>
<td>Requirement</td>
<td>RA 605</td>
<td>IND</td>
<td>IND</td>
<td>IND</td>
<td>IND</td>
<td>IND</td>
<td></td>
</tr>
<tr>
<td>Elective</td>
<td>RA 610</td>
<td>REG</td>
<td></td>
<td></td>
<td></td>
<td>REG</td>
<td></td>
</tr>
</tbody>
</table>

**Key:**
- **MRL** = Marlborough site
- **REG** = Regis College campus
- ? = No commitment yet for non-RA course
- **IND** = Independent project

**Notes:**
- **SS 11** = Summer session 2011 (most RA courses begin in first summer term)
- **FA 11** = Fall 2011
- And so on for the other semesters
Are you thinking about Field Experience?

RA 605 Field Experience is the course in which you get experience working with a health product company or clinical research organization. You work with a supervisor in a host company or organization on a project of value to the host and with valuable experience for you. For more information, please contact Chas Burr.

Even if you are not planning to take Field Experience, please contact Chas Burr if your company might have an opportunity for a Field Experience intern.

Chas Burr, Graduate Program Director, Regulatory and Clinical Research Management
charles.burr@regiscollege.edu
781-768-7008 (office)
781-789-1646 (cell)
781-723-2422 (efax)