

University Council Athens, Georgia 30602

October 2, 2009

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#### Dear Colleagues:

The attached proposal to offer a non-thesis option under the major in Pharmacy (M.S.) will be an agenda item for the October 9, 2009, Full University Curriculum Committee meeting.

Sincerely,

David E. Shipley, Chair

University Curriculum Committee

cc:

Dr. Arnett C. Mace, Jr.

Professor Jere W. Morehead



College of Pharmacy

March 31, 2009

Dean Maureen Grasso University of Georgia Graduate School 320 E. Clayton St., Suite 400 Athens, Georgia 30602-4401

Dear Dean Grasso:

Enclosed please find a proposal on behalf of the College of Pharmacy to add a Non-Thesis Option for the M.S. in Pharmacy (with an emphasis in Pharmaceutical and Biomedical Regulatory Affairs). This option has been approved by the College of Pharmacy Regulatory Affairs Advisory Board 9 yes, 0 no; the College of Pharmacy Graduate Education Council 7 yes, 1 no; the College of Pharmacy Faculty Council 9 yes, 0 no and the College of Pharmacy Faculty 39 yes, 1 no.

Thank you for your consideration of this proposal.

Sincerely,

Svein Øie, PhD

Dean

**Enclosure** 

Cc: Dr. Paul Brooks

## Proposal to Add a Non-Thesis Option for the M.S. in Pharmacy (with an emphasis in Pharmaceutical and Biomedical Regulatory Affairs) Offered by the University of Georgia College of Pharmacy

#### Submitted to:

Dr. Maureen Grasso Dean, The Graduate School The University of Georgia

#### Prepared by:

Dr. Paul Brooks
Graduate Coordinator, Pharmaceutical & Biomedical Regulatory Affairs
College of Pharmacy
The University of Georgia

#### Approved by:

Dr. Svein Øie Dean, College of Pharmacy The University of Georgia

#### **Basic Information:**

<u>Proposed Change</u>: Addition of a non-thesis option to the M.S. in Pharmacy (with an emphasis in Pharmaceutical and Biomedical Regulatory Affairs).

Proposed Starting Date: Semester following final approval.

## Votes:

- UGA College of Pharmacy Regulatory Affairs Advisory Board (12-01-09)	9 yes, 0 no
- UGA College of Pharmacy Graduate Education Council (2-16-09)	7 yes, 1 no
- UGA College of Pharmacy Faculty Council (3-11-09)	9 yes, 0 no
- UGA College of Pharmacy Faculty (3-25-09)	39 yes, 1 no

#### Background:

Regulatory Affairs (RA) professionals are employed in industry, government and academia and provide a range of services related to the regulation, development, manufacturing and marketing of pharmaceuticals, medical devices, in vitro diagnostics, biologics, biotechnology, nutritional products, cosmetics, and veterinary products. RA professionals come from diverse backgrounds and usually have experience in other careers before transitioning into a career of regulatory affairs. Often, they have worked in the fields of medicine, nursing, pharmacy, engineering, clinical laboratory science, research or healthcare manufacturing. Currently there is no standard undergraduate or terminal degree for Regulatory Affairs Professionals; however, according to the Regulatory Professional Society (RAPS), more than half have an advanced degree, most often in a scientific or technical field. Moreover, since the discipline of regulatory affairs continually needs new and increasingly

sophisticated talent, there is a growing expectation for advanced education and credentialing. RAPS provides a credentialing program, Regulatory Affairs Certified (RAC), for those professionals who successfully pass a rigorous comprehensive examination covering the federal regulations (US) and/or designated international regulations.

The University of Georgia (UGA) College of Pharmacy offers both a graduate-level certificate program in Regulatory Affairs, and a Master's of Science (M.S.) degree in Pharmacy, with an emphasis in Regulatory Affairs. The graduate certificate provides a foundational core for individuals who wish to transition into entry level regulatory affairs positions. The M.S. degree assures a strong professional background needed to succeed in administrative positions and specialized areas required of this handson profession. These graduate education offerings are geared for working professionals and as such are planned to be taken on a part-time basis. Classes are designed to allow individual flexibility, yet provide a standard academic structure to advance student learning from one semester to the next. The graduate certificate and the M.S. program require separate application processes and admission criteria. Currently, the M.S. program of study includes the completion of a research-based thesis. This proposal is to request the addition of a non-thesis option for students who do not plan to pursue research intensive positions nor complete a Ph.D., and instead plan to work in competitive practice-based settings within global pharmaceutical and biomedical industries and healthcare related agencies.

#### **Program Modification:**

All students enrolled in the masters program, whether thesis or non-thesis, must complete the 30 semester hour graduate core curriculum (see Program of Study - Appendix 1). In addition, relevant thesis (research) or non-thesis (application-based) requirements must be met and are summarized below. Note: A chart that compares course requirements for the Graduate Certificate, the M.S. with Thesis, and the proposed M.S. with Non-Thesis Option is included as Appendix 2.

After completing at least 17 hours of core coursework, each student must declare either the thesis or non-thesis option. This decision will be made in concert with the student's advisor and in discussion with program faculty. Those who select the thesis option will follow the routine "Masters Student Thesis Guide" (http://www.rx.uga.edu/main/home/reg affairs/pdfs/Guide for MS.pdf). These students must complete and receive thesis-directed committee approval for at least 6 additional research/thesis semester hours beyond the 30 hr core curriculum, including:

- PHAR 7000 (Masters Research); at least 3 hrs
- PHAR 7300 (Masters Thesis); at least 3 hrs
- Pass an oral defense of the Thesis, administered by the student's committee (according to the current Masters Students Thesis and Defense Guidelines).

Students pursuing the <u>non-thesis option</u> must complete and receive non-thesis-directed committee approval of a focused area of study/exploration, consisting of at least 9 additional semester hours beyond the 30 hr core curriculum. The concentration of courses and experiential learning is intended to better prepare the student for the job market and includes:

- 3 hrs of additional elective(s) or other appropriate courses related to the student's career objective (e.g., pharmaceutical, device, biological, FDA operations, international regulations, animal health).
- 3 hrs of an applied project and/or internship related to the student's career objective.

- o PHAR 6800 (Applied Project in Regulatory Affairs) and/or
- o PHAR 6900 (Internship in Biomedical Regulatory Affairs)
- 3 hrs of Masters Seminar in Regulatory Affairs. This course will be an in-depth topical exploration in regulatory science that complements the applied project and/or internship (corequisite w/PHAR 6800 or 6900 & described below).
- Pass a comprehensive written examination, administered by the student's graduate advisory committee.

Non-Thesis Committee: Students who declare the non-thesis option will select an appropriate major professor, who is associated with the area of concentration for which the student is inclined to pursue. The major professor will serve as advisor to determine the final program of study, and help select a three or four person non-thesis Advisory Committee. At least two of the committee members, including the major professor, must hold a UGA College of Pharmacy faculty appointment and be an instructor in the program of study. The third committee member may be an appropriate outside expert in regulatory science. The Advisory Committee, in consultation with the student is charged with approving the student's Program of Study, determining the culminating applied project and/or experiential education component based on the needs of the student, coordinating the student's seminar, and administering and evaluating the final examination over the Program of Study.

Comprehensive Examination: A written comprehensive examination, administered during the student's last semester tests the student on four topical areas of regulatory affairs, determined by the student's advisory committee. This examination is designed to provide students with an opportunity to display a comprehensive understanding of the discipline of Regulatory Affairs. Students must be able to effectively integrate course work from their program of study into their responses to the questions. The comprehensive examination may not be taken prior to the last semester of course work. Students will apply to take the examination in advance, normally during the first two weeks of the semester/term in which they desire to take the examination. Each exam will be graded by at least two program faculty, and the student's answers will be assigned one of three grades: pass with distinction, pass, or fail. Students failing the comprehensive examination on the first attempt may retake it a second time. If a student fails the examination a second time, the student's committee shall decide if remediation of coursework is applicable and/or feasible, or if the student should be dismissed from the program.

#### Justification and Need for the Non-Thesis M.S. Option:

There are several reasons why a non-thesis M.S. option is justified and needed for this specialized program of study:

1. Employers need and recruit regulatory professionals who have advanced training, application, and practical experience to take on the complex and hands-on work of interpreting, implementing, and monitoring FDA regulatory compliance for their medical products. These are a complex set of skills that do not involve original academic research. According to the Regulatory Professional Society (RAPS), experience and applied course work is the key asset for RA professionals. Thus, substitution of thesis research with applied projects and experiential training for the non-thesis option makes graduates valuable and marketable for specific types of positions in life science industries. These include managing regulatory and quality control personnel, performing advanced auditing of regulatory systems, interpreting and

applying national and international regulations to product lines, ensuring compliance with applicable regulations, consulting with regulatory authorities and other regulatory agencies to develop guidance strategies, and compiling and assuring proper product reports to the FDA and other global regulatory agencies. For these students, the experience of completing a research study for a thesis is less valuable than taking additional course work along with a guided application project or internship, directed by a faculty practitioner.

- 2. Offering an M.S. with both a thesis and non-thesis option will allow the college to more-effectively compete for students. Applied projects and experiential training for the non-thesis option makes graduates valuable and marketable for specific types of positions in life science industries. That is why twelve of the fourteen identified similar degree programs in the country (all but UGA and Massachusetts College of Pharmacy) offers a non-thesis option or is solely offered as non-thesis masters program (see Listing of Regulatory Affairs Masters Programs Appendix 3). These programs include those with whom UGA directly competes for students like Temple University (~36 hrs for non-thesis), San Diego State University (~ 32 for non-thesis), Northwestern University (~33 hrs for non-thesis) Johns Hopkins University (~35 hrs for non-thesis), and University of Florida (~ 30 hrs for non-thesis). As you can see from Appendix 3, the non-thesis requirements for these programs entail completion of a similar project or internship and/or a comprehensive examination. Our proposed program meets or exceeds the requirements of these competitive institutions for the similar degree.
- 3. There is established precedent at the University of Georgia for non-thesis M.S./M.A. degrees. Among others, non-thesis options are available for the M.S. in Exercise Science, Statistics, Bioinformatics, Housing and Consumer Economics, and Physics; and, for the M.A. in Mathematics, Journalism and Mass Communication, and Kinesiology.
- 4. This proposed modification has been voted on and approved by the University of Georgia College of Pharmacy's Graduate Education Committee and the College of Pharmacy faculty at large. Moreover, it has been reviewed and endorsed by the Regulatory Affairs Advisory Board, which is a separate group of industry and academic leaders that provides guidance and recommendation on curriculum development, program enhancements, and industry work force needs. A listing of Regulatory Affairs Advisory Board members is attached.

#### Job Prospects:

There is an immediate and rapidly growing need for experts who can interpret, apply, and monitor federal and international regulations of pharmaceuticals, biologics, medical devices, combination products, animal health products, and nanomedicine. Reasons for the striking demand of regulatory experts include increases in the:

- 1. Complexity of applied regulatory requirements for biomedical products like monoclonal antibodies, transgenic derived biologics, and genomic interpretations;
- 2. Sophistication of delivery systems through devices and at the molecular level;
- 3. Outsourcing of biomedical manufacturing to places throughout the world, which often have less stringent regulatory standards;
- 4. Public demand for safety and efficacy accountability of biomedical products; and,
- 5. Public and private demand to get products to the market as soon as possible.

The 2009, UGA Terry College Selig Center's Analysis of Georgia's Life Sciences Industry identified Regulatory Affairs to be among the top ten very important and/or critical issues relevant to Life Science Companies' growing operations, start-ups, and re-locations in Georgia. Georgia businesses see this area as critical to the operation and growth of their industries in Georgia. In addition, Battelle Memorial Institute assisted the State of Georgia and the Georgia Research Alliance (GRA) in developing a strategic framework to guide Georgia's investments in support of the bioscience sector. The project included an economic analysis of Georgia's bioscience base, a benchmarking analysis, an assessment of Georgia's bioscience core competencies, and completion of a Georgia bioscience strategic framework. Data from this project indicate that regulatory affairs is a high demand field and an ample talent pool in this area is needed to attract and retain competitive bioscience companies.

Based on the RAPS Scope of Practice & Compensation Study - 2008, Advanced Education and Regulatory Affairs Certification (RAC) has been shown to correlate to higher compensation for professionals in entry- to mid-level positions, and increases steadily at higher levels. Professionals with advanced credentials are expected to possess a strong applied background that requires strategy development, risk assessment and management; monitoring and communicating change in the regulatory environment as well as global communication. These practical aspects of the job are highly desired by employers. The non-thesis option will engage the students in real-world application, practice development and experiential learning needed for career success.

#### **Impact on Current Students:**

There would be no adverse impact on current students enrolled in the program of study. The 21 students currently enrolled in this masters program will have the option of switching to the non-thesis track, depending on their career goals. We anticipate that if the program is approved for implementation Fall 2009, at least 10 students will request a change to the non-thesis option. At least fifty percent of future students are anticipated to enroll in the M.S. non-thesis option.

#### **New Courses and Financial Impact:**

Only one new course will be required to implement a non-thesis option for the M.S. The course, Masters Seminar in Regulatory Affairs will be an in-depth topical exploration in regulatory science and will require the student to demonstrate expertise in a specialized practice area related to regulatory affairs. This course will complement the applied project and/or internship and collectively will provide the student with a sufficient knowledge base and the skills needed to apply their original work in regulatory affairs to a specialized setting. Using critical thinking processes and appropriate oral and written communication, the students will be guided by their faculty committees to engage with their peers to critically analyze, refine and creatively apply their project finding and/or internship experiences to contemporary biomedical regulatory practice.

The course will be taught by existing program faculty and no new funds are required.

Appendices:

- (1) Program of study that includes the proposed non-thesis option
- (2) Course requirement comparisons for graduate Certificate, the M.S. with Thesis, and the proposed M.S. with Non-Thesis Option
- (3) Listing of Regulatory Affairs Masters Programs
- (4) Regulatory Affairs Advisory Board members



## Master of Science in Pharmacy (With an Emphasis in Regulatory Affairs)

#### Core Courses (27 semester hours):

- PHAR 6010 Pharmaceutical, Biotechnology, and Device Industries (4 sem hrs)
- PHAR 6020 Food and Drug Law (3 sem hrs)
- PHAR 6030 Current Good Manufacturing Practices (4 sem hrs)
- PHAR 6100 Quality Control and Quality Assurance (3 sem hrs)
- PHAR 6120 Process Control and Validation (3 sem hrs)
- PHAR 6130 FDA Applications for Drugs, Biologics, Devices & Animal Health Products (4 sem hrs)
- PHAR 7100 Biostatistical Applications for Pharmaceutical & Biotech Industries (3 sem hrs)
- PHRM 7230 Ethical Issues in Research (3 sem hrs)

#### **Elective Courses (minimum of 3 semester hours):**

- PHAR 6200 Clinical Trials Design and Management (4 sem hrs)
- PHAR 6210 Project Management in Clinical Trials (3 sem hrs)
- PHAR 6310 Good Clinical Practices for Drugs, Biologics & Medical Devices (3 sem hrs)
- PHAR 6320 Understanding the Role and Function of the FDA (3 sem hrs)
- Comparative Global Regulations (3 sem hrs)
- Critical Issues in Regulatory Sciences (3 sem hrs)
  - ⇒ Topics vary: In depth regulatory analysis of regulatory issue or regulated industry

#### Thesis Option (minimum of 6 semester hours):

- At least 6 semester hours of thesis hours including,
  - o PHAR 7000 (Masters Research); at least 3 sem hrs
  - o PHAR 7300 (Masters Thesis); at least 3 sem hrs
- Pass an oral defense of thesis.

#### Non-Thesis Option (minimum of 9 semester hours) – Pending approval:

- At least 3 sem hrs of additional elective(s) from list above or other appropriate course via POD
- At least 3 sem hrs:
  - o PHAR 6800 (Applied Project in Regulatory Affairs) and/or
  - o PHAR 6900 (Internship in Biomedical Regulatory Affairs)
- At least 3 sem hrs of Masters Seminar in Regulatory Affairs Pending approval
- Pass a comprehensive written examination.

Courses and credit hours listed above are subject to change. For more information, please visit our website: <a href="http://www.rx.uga.edu/main/home/reg\_affalrs/index.htm">http://www.rx.uga.edu/main/home/reg\_affalrs/index.htm</a>. May 2009

# Comparison of Requirements for Graduate Certificate, M.S. with Thesis, and Proposed M.S. with Non-Thesis Option in Pharmaceutical and Biomedical Regulatory Affairs offered by The University of Georgia College of Pharmacy

Characteristics	Graduate Certificate in Regulatory Affairs	Current M.S. in Regulatory Affairs with Thesis	Proposed M.S. in Regulatory Affairs with Non-Thesis
Semester Hours	14 hrs	36 hrs min	39 hrs min
Core	PHAR 6010 Pharma, Biotech	PHAR 6010 Pharma, Biotech	PHAR 6010 Pharma, Biotech &
(14 hrs)	& Device Industries (4 hrs)	& Device Industries (4 hrs)	Device Industries (4 hrs)
	PHAR 6020 Food & Drug	PHAR 6020 Food & Drug Law	PHAR 6020 Food & Drug Law
	Law (3 hrs)	(3 hrs)	(3 hrs)
	PHAR 6030 Current GMPs	PHAR 6030 Current GMPs	PHAR 6030 Current GMPs
	(4 hrs)	(4 hrs)	(4 hrs)
	PHAR 6100 QC & QA (3 hrs)	PHAR 6100 QC & QA (3 hrs)	PHAR 6100 QC & QA (3 hrs)
Additional Core		PHAR 6120 Process Control &	PHAR 6120 Process Control &
(13 hrs)		Validation (3 hrs)	Validation (3 hrs)
		PHAR 6130 FDA Apps: Drugs,	PHAR 6130 FDA Apps: Drugs,
		Biologics, Devices & Animal	Biologics, Devices & Animal
		Products (4 hrs)	Products (4 hrs)
		PHAR 7100 Biostats Apps for	PHAR 7100 Biostats Apps for
		Pharma & Biotech Industries	Pharma & Biotech Industries
		(3 hrs)	(3 hrs)
		PHRM 7230 Ethical Issues in	PHRM 7230 Ethical Issues in
		Research (3 hrs)	Research (3 hrs)
Electives		Current approved electives or	Current approved electives or
(3-6 hrs min)		others by POD (3 hrs min)	others by POD (6 hrs min)
Thesis vs Non-		PHAR 7000 Masters Research	PHAR 6800 Applied Project in
Thesis	·	(3 hrs min)	Regulatory Affairs (3 hrs min)
(6-9 hrs min)	•		and/or
			PHAR 6900 Internship in
			Biomedical Regulatory Affairs
			(3 hrs min)
		PHAR 7300 Masters Thesis	Masters Seminar in Regulatory
		and Oral Defense of Thesis	Affairs and Comp. Written
		(3 hrs min)	Examination (3 hrs min)

### **REGULATORY AFFAIRS MASTERS PROGRAMS**

Source: RAPS.org, as of 01/2009.

MS Program	Total # HRs Required	Thesis/Non-Thesis option
Johns Hopkins University Baltimore, MD  Master of Science degree in blotechnology with a concentration in regulatory affairs Master of Bioscience in Regulatory Affairs	10 courses 6 core courses, 3 electives and 1 practicum	Non-Thesis Only  410.679 Practicum in Bioscience Regulatory Affairs (Open only to Students in MS BSRA)  This integrative case-based course will focus on applying knowledge gained from previous courses in the MS Bioscience Regulatory Affairs program to actual cases from the U.S. Food and Drug Administration. For each case, students will assume the role of either a regulatory specialist, an FDA reviewer or senior-level policy-maker, or other involved stakeholders, such as a consumer group or an advocacy group. Students will be expected to research, evaluate, and present scientifically and legally justifiable positions on case studies from the perspective of their assigned roles. Students will present their perspectives to the class and be asked to debate the Issues with the other students from the perspective of their assigned roles. The major responsibility of the students in this course will be to make scientifically and legally defensible recommendations and to justify them through oral and written communication.
Keck Graduate Institute Claremont, CA  Master of Bioscience (MBS) with emphasis in Clinical Regulatory Affairs	12 courses	Non-Thesis Only  "Team Masters Project" is required - An Interdisciplinary team of students, working for several months – supervised by a KGI faculty member and in collaboration with a corporate organization – delivers results on the project identified by the company. Work occurs at KGI w/ occasional trips to company.
Long Island University—Arnold and Marie Schwarzt College of Pharmacy Brooklyn, NY  Master of Science with a specialization in Drug Regulatory Affairs	30-33 sem hrs	Thesis – 30 credits, of which 6 are research and thesis Non-Thesis – 33 credits plus written comprehensive exam
Massachusetts College of Pharmacy Boston, MA  Master of Science in Drug Regulatory Affairs and Health Policy	30 sem hours	Thesis Only

Northeastern University, School of Professional and Continuing Studies Boston, MA	40 quarter hours (~27 sem hrs)	Non-Thesis Only
Master of Science in Regulatory Affairs		
Northwestern University School of Continuing Studies Chicago, IL	11 units, including a leadership course	Non-Thesis Only
Master of Science in Quality Assurance and Regulatory Science	readership course	Capstone Project - The final course in the MQARS program is an independent project in which students integrate the knowledge they have gained in the curriculum with a topic of relevance to their professional goals. Working with MQARS faculty, students conduct research while also contributing something of practical value to the field. The capstone project counts as one unit of credit.
Regis College	11 courses, 33 sem hrs	Non-Thesis Only
Weston, MA		<b>_</b>
Master of Science in Health Product Regulation		Field experience project required
San Diego State University	40 quarter hours (~27	Thesis and Non-Thesis Options
(Center for Bio/Pharmaceutical and Biodevice Development)	sem hrs)	Tricala and Hor-Tricala Optiona
San Diego, CA		Thesis – 40 units including 6 are research and thesis
Master of Science in Regulatory Affairs		Non-Thesis - 40 units including applied project and exam
St. Cloud State University	10 courses	Non-Thesis Only
St. Cloud, MN	10 Courses	
Master of Science in Regulatory Affairs and Services, focus medical devices		Required culminating project
St. Johns University	30-33 sem hours	Thesis and Non-Thesis options
New York, NY		
Mantada la alcamana della tratta della del		Thesis – 30 hrs.
Master's in pharmacy administration with a specialization in Pharmaceutical Marketing and Regulatory Affairs/Quality Assurance		Non-Thesis – 33-36 hrs. plus written comprehensive exam
Temple University	12 courses, 36 sem hrs	Thesis and Non-Thesis options
Philadelphia, PA	12 Wuises, 30 Seili (118	Linasia aiku Moli-Titasia upitotia
Master of Science in Quality Assurance/Regulatory Affairs		Non-Thesis students must pass a written comprehensive exam
University of Florida	30 sem hours	Non-Thesis Only
Gainesville, Florida		•
Master of Science in Pharmaceutical Regulatory Affairs		Coursework only – no culminating experience
University of Southern California	36 quarter hrs (~ 25	Non-Thesis Only
Los Angeles, CA	sem hrs)	
Master of Science in Regulatory Science		Six-unit "Directed Field Research Project/Internship" required

#### Regulatory Affairs Advisory Board

Robert G. Boehmer, J.D., UGA Associate Provost for Institutional Effectiveness & Professor of Legal Studies

Paul Brooks, Pharm.D., Assistant Dean, Division of Outreach & Nontraditional Education, UGA College of Pharmacy

Tony Capomacchia, Ph.D., Associate Professor, Department of Pharmaceutical & Biomedical Sciences, UGA College of Pharmacy

J. Griffin Dovle, J.D., University of Georgia Director of Federal Relations

Gary Dykstra, Director, Biomedical Continuing Education and Strategic Planning UGA College of Pharmacy

George Francisco, Pharm.D., Associate Dean, UGA College of Pharmacy

Patty Fritz, Vice President, Regulatory Affairs, UCB Pharma, Inc.

Johnna Hodges, Regulatory Affairs Graduate Education Programs, UGA College of Pharmacy

Robert T. McNally, Ph.D., President, Nutek BioMedical, LLC

Randolph P. Martin, M.D., FACC, Associate Dean for Clinical Development, Professor of Medicine, Emory University School of Medicine

Alan G. Minsk, J.D., Partner & Leader Food & Drug Practice Team Arnall Golden Gregory LLP

Chris Moder, ICAPP Program Director, University System of Georgia and The University of Georgia

David Mullis, Ph.D., RAC, Director, Regulatory Affairs Graduate Education Program, UGA College of Pharmacy

Ellen de Brebander, Ph.D., Chief Scientific Officer and Global Head of Research and Development, Merial, Ltd.

Randall Tackett, Ph.D., Professor, Department of Clinical and Administrative Pharmacy, UGA College of Pharmacy

Barbara Wood, Director, Southeast Region, Food and Drug Administration