



The Chapel, one of the first Greek Revival structures in Athens and one of the University's most prominent and popular landmarks. (University of Georgia, Paul Efland).

# PHAR 6900: Expanding Regulatory Experience

By Allison Lowry, RAC and David W. Mullis Jr., PhD, RAC

The increasing demands regulatory professionals face to stay current with industry trends and regulatory changes may seem daunting. Similarly, young professionals are challenged to increase their professional skills and demonstrate added value to employers by enhancing their credentials.

Reviewing industry journals and periodicals, attending FDA workshops and professional meetings and participating in RAPS and other professional associations are just some of the keys for success in the regulatory profession. Graduate-level education has become increasingly common and can provide opportunities for professionals to enhance and advance their careers in regulatory affairs.

Although working professionals are considered nontraditional students in most academic settings, the University of Georgia's (UGA's) graduate education programs are tailored specifically for working regulatory and clinical trials professionals and are designed to be taken on a part-time basis. Courses are delivered via distance education programs geared for working professionals.

For its instructors, the UGA program utilizes a mix of current industry professionals as a way to keep the curriculum relevant. Developing opportunities for students



to gain real-world experience and apply the theory learned in coursework is a priority for the program. The search for an experiential learning opportunity led to an innovative regulatory internship program with a local pharmaceutical company, Atlanta-based Sciele Pharma Inc.

Sciele, like other industry employers, finds recruiting qualified and experienced regulatory professionals difficult, even in a major metropolitan

area like Atlanta. The competition for experienced regulatory talent, coupled with the limitations of local resources, makes internship programs extremely attractive for Sciele and an important recruitment tactic to attract highly skilled candidates for technical positions. Its internship program allows Sciele to grow talent locally, identify early career talent and build bench strength within the organization while giving students valuable hands-on work experience. Sciele's Talent Acquisition department led the joint effort to formalize the regulatory internship with UGA.

## Achieving Industry and Academic Goals

The internship arrangement is based on the Experience Training Program required for UGA doctor of pharmacy students, who are placed in a variety of field settings to gain practical experience and fulfill advanced pharmacy practice experience

## Table 1. UGA Regulatory Affairs Internship Course Objectives and Expected Learning Outcomes

- Provide a practical, supervised experience for the application of federal regulations to biomedical industries
- Provide a practical, supervised experience for the application of professional standards, ethics and laws regulating biomedical industries
- Stimulate independent critical thinking
- Reinforce curriculum content through experiential learning
- Clarify personal career goals and interests
- Facilitate professional development
- Promote importance of good communications skills
- Provide an experience that will lead from internships to careers
- Build long-lasting relationships with industrial partners

requirements for academic credit. UGA and partner companies and organizations enter into a memo of understanding (MOU) that governs unpaid five-week rotations. Modeling the regulatory framework after the traditional and highly structured PharmD program provided the framework and structure for a comprehensive graduate level internship.

A student can earn three semester credit hours toward UGA's master of science degree in regulatory affairs after completing 120 direct contact hours at the pharmaceutical company, along with up to 20 hours of off-site time typically spent in writing a summary and presenting the experience to the course preceptor. Translating these academic requirements into Sciele's desire for concentrated work effort and close supervision resulted in an internship schedule of four days per week for a five-week period.

Sciele's regulatory affairs department defined a scope (see **Table 3**) for the internship project

that would provide a learning opportunity for the student and also benefit the company. Limited customization of the scope is possible to match the interests of the individual intern while continuing to benefit the company.

### Roles and Responsibilities

A comprehensive MOU clarifies roles and responsibilities, sets expectations among all parties and is worth the time and effort to get an experiential learning program started in the right direction from the beginning. UGA and Sciele's legal departments jointly developed an MOU outlining clear and explicit responsibilities and expectations of all parties—UGA, Sciele, the student, the corporate supervisor and the faculty preceptor. All parties worked to develop nondisclosure provisions in the MOU to protect the proprietary nature of the student's work.

Regarding use and disclosure of Sciele's protected health information, the intern must agree to keep in confidence all medical, health (including mental health), financial, regulatory and social information pertaining to particular clients or patients. Although not a Sciele employee, the student must agree to comply with all policies and procedures of the company, including those governing the use and disclosure of individually identifiable health information under federal law, specifically 45 CFR parts 160 and 164.

### Finding the Right Fit

UGA master's candidate Matt Rycyk saw the internship at Sciele as a way to gain valuable industry experience leading to additional career opportunity, as well as broadening his knowledge

## Table 2. Program Challenges

- Identifying a discrete project for the internship to ensure an optimal learning experience for the student
- Recruiting from a student pool of working professionals in a competitive marketplace
- Developing acceptable and mutually beneficial selection criteria
- Scheduling
- Maintaining confidentiality and adherence to company and academic policies
- Establishing evaluation criteria with involvement from all parties

## Table 3. Sciele Regulatory Affairs Intern Project Scope

Assist Regulatory Affairs with compilation of a New Drug Application (NDA) or a supplemental New Drug Application (sNDA) that includes a clinical component and manufacturing / CMC changes. Objectives include:

- Preparing a checklist or updating an existing checklist, detailing requirements needed for an NDA (or sNDA) that complies with federal regulations and eCTD (electronic Common Technical Document) software, when applicable
- Researching regulations to determine requirements for the submission
- Using the checklist and research results, interview individuals from respective departments (Clinical, Technical Affairs, Quality Assurance, Supply Chain, Marketing, Promotional, Labeling and Project Management) to gather information on requirements from their departments to fulfill applicable sections of the NDA/sNDA
- Preparing a GAP analysis or an equivalent report as needed to determine submission needs
- Preparing project plans
- Participating in activities such as label preparation, change controls, evaluating promotional review and compiling sections of the eCTD submission

and experience base.

“I worked in medical devices for a year and because of the internship opportunity, I decided it would be good to round out my experience with some pharmaceutical experience to make myself more marketable when I finish my master’s degree,” said Rycyk.

“I also wanted the experience of working for a larger company. Regulatory strategy is based around business decisions as well as the regulations. You don’t get that experience working with small firms with limited budgets and resources. It’s the kind of experience you get when you are actually on the job; it can’t be taught in the classroom.”

### Conclusion

Experiential learning programs that are jointly sponsored by academia and industry are a way for regulatory affairs professionals to expand their technical skills and broaden their experience by learning on the job. As part of a larger degree program, these internship opportunities are a mutually beneficial educational experience, providing students with real-world experience and giving employers access to potential employees who are well-versed in regulated healthcare areas. ■

#### Authors

**Allison Lowry, RAC**, is senior manager of regulatory affairs at Sciele Pharma, Inc. She has more than 10 years’ experience in the pharmaceutical industry, primarily involved in regulatory submissions. She can be reached via email at [alowry@sciele.com](mailto:alowry@sciele.com). **David W. Mullis Jr., PhD, RAC**, is director of the University of Georgia’s Regulatory Affairs and Clinical Trials Graduate Education Program. Mullis is also president of Mullis & Associates, Inc. He is a founding member of the

Atlanta chapter of the Regulatory Professional Society and can be reached at [dmullis@rx.uga.edu](mailto:dmullis@rx.uga.edu).

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**Sciele Pharma Inc.** is a pharmaceutical company specializing in sales, marketing and development of branded prescription products focused on cardiovascular disease, diabetes, women’s health and pediatrics. Founded in 1992 and headquartered in Atlanta, Georgia, Sciele Pharma employs more than 1,000 people. Sciele Pharma Inc. is a wholly owned subsidiary of Shionogi & Co. Ltd.

**The University of Georgia’s Regulatory Affairs Graduate Education Program** inaugurated students January 2005. To date, 32 students have received certificates in regulatory affairs from the program, and the first students to receive a master’s degree in pharmacy with an emphasis in regulatory affairs for completing the 38-hour program will graduate this fall.

## Table 4. MOU Components

An agreement that “parties will work together to maintain an environment of quality learning experiences,” which includes:

- Definition of mutual responsibilities
- Description of the recruitment and selection process
- Company responsibilities—appropriate supervision of the student; identification of a liaison with the university; participation in the evaluation of the intern; protection of student information
- Student responsibilities—adhere to administrative policies, standards and practices of the company; maintain confidentiality; protect intellectual property; possess professional insurance
- Faculty supervisor—maintain confidentiality; protect student record information