Providing regulatory experience for students

# The BRAMS Practicum

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# BRAMS program curriculum

Program launched in 2008

45 credits

Courses cover regulatory, quality assurance, and clinical topics for drugs, devices, and biologics, plus technical writing

## Practicum

A 9-credit multi-quarter “course” providing practical regulatory experience

# What is the BRAMS practicum?

## Course description

The Biomedical Regulatory Affairs practicum provides a practical experience for students, allowing them to develop or expand skills in shepherding new medical products (drug, device, and biologic) through regulatory, clinical, and quality assurance aspects.  Students work on projects of their choice under the guidance of a preceptor from the practicum site.

# Designing the BRAMS practicum

How do we provide a practical regulatory experience of consistent scope to a group of students with varying backgrounds and availability?

Issues

- Protection of confidential information
- Provision of supervision and guidance
- Student availability
- Student background

# Confidentiality

UW is a public institution and subject to “sunshine” laws.
How do we protect confidential information?

- Students may be privy to confidential information at the practicum site. They sign confidentiality agreements.
- Coursemasters are not allowed to sign confidentiality agreements with practicum sites. They do not receive any confidential information.

# Supervision

Projects cover a broad scope of regulatory, clinical and quality-related activities.  The BRAMS faculty is small and many instructors are consultants—we do not provide direct project supervision.

## How do we arrange supervision?

Project supervision and guidance is provided by a mentor (preceptor) at the practicum site. The preceptor must have sufficient experience with the project topic to provide appropriate mentoring.

# Student availability

Many regulatory activities involve reviewing on-line resources, synthesizing ideas, and writing about them. Much of that can be done on the student's own time, with occasional meetings with the preceptor or other staff at the practicum site.

BRAMS practicum projects are variable.

- Some require little presence on site
- Some require moderate presence on site
- Some require the student to make use of on-site resources.

Project requirements as well as topic are important for matching a student with a project.

# Student background

Some students already have experience in the medical products industry; others have limited experience.

How do we make projects appropriate for students with varying backgrounds?

BRAMS practicum projects vary in topic and complexity.

An appropriate project is one which provides experience relevant to the career stage and desired career direction of the student. Students with experience do more advanced projects than those at early stages.

To keep projects similar in scope, preceptors are asked to design something that should take 150-200 hours to complete.

# Practicum organization

Practicum has two parts

**regulatory experience** (5 credits): must produce useful work product. Evaluated by preceptor feedback

**project documentation** (4 credits): must demonstrate good understanding or regulatory issues and good technical writing skills

Planning (2 credits)
Find a project
Brief proposal (form)
Workplan (form) and Gantt chart
Implementation (5 credits)
Updates (form)
Reporting (2 credits)
Final report
Presentation (20 min + questions)

Student proposes 3-5 learning objectives in the workplan. Achievement of the objectives is discussed in the final report and presentation.

# Expectations for a practicum project

- The student will develop new skills or significantly expand existing skills.
- The project will focus on a particular regulatory task or topic.
- The project must be relatively central to regulatory affairs, i.e., not a project that has only a minor regulatory component.
- The project must include student review of relevant regulatory resources and application of those resources to the project.
- The student must be directly involved in regulatory tasks.
- The student must generate a work product (usually a document or documents) that is of use to the host organization.
- The practicum project is expected to be of scope to require 150-200 hours of effort, including time spent reviewing regulatory resources and creation of the work product(s). This does not include preparation of documentation for the BRAMS program (brief proposal, workplan and Gantt chart, updates, final report, and presentation).

# University of Washington

## Examples of practicum topics

- Development of regulatory strategies
- Preparation of (parts of) applications and reports for regulatory agencies
- Development of audit materials and plans; carrying out audits
- Revision of materials in response to new and revised regulations, guidelines, standards
- Development of training materials
- Assistance with regulatory issues related to organization mergers