# UW Department of Pharmacy Faculty Meeting Agenda

**Monday, August 17th - 09:00 to 11:00 am**

**Venue:** Zoom  
**Conference URL:** https://washington.zoom.us/j/860946066  
**Zoom Phone Number:** +1 197 247 1195  
**Meeting ID:** 860 946 066

<table>
<thead>
<tr>
<th>Topic/ Business</th>
<th>Presenter</th>
<th>Appro. time</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Welcome and Announcements</td>
<td>White</td>
<td>10 min</td>
<td></td>
</tr>
<tr>
<td>2. Approval of Minutes (June 2020 meeting) [Vote requested]</td>
<td>White</td>
<td>2 min</td>
<td></td>
</tr>
<tr>
<td>3. Curriculum Committee – The Book Club: Timely Topics for Health Professionals [Vote Requested]</td>
<td>Chan/Dawson</td>
<td>10 min</td>
<td></td>
</tr>
<tr>
<td>4. BRAMS Appointment – Joshua Kim, Affiliate Assistant Professor [Vote Requested]</td>
<td>Stergachis</td>
<td>10 min</td>
<td></td>
</tr>
<tr>
<td>5. Discussion: Future of the PharmD – Physician Assistant (Master of Clinical Health Services) Concurrent Degree Program</td>
<td>Stergachis</td>
<td>30 min</td>
<td></td>
</tr>
<tr>
<td>6. Space Update</td>
<td>White</td>
<td>20 min</td>
<td></td>
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<tr>
<td>7. EE Update</td>
<td>Danielson</td>
<td>20 min</td>
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<tr>
<td>- APPE</td>
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<td></td>
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<tr>
<td>o Hiring for APPE Program Manager</td>
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<td>o Collective process for developing Purple Curriculum APPE course syllabi/apps</td>
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<td>- IPPE</td>
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<tr>
<td>o Displacements and Replacements</td>
<td></td>
<td></td>
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<tr>
<td>- WIP1/WIP2</td>
<td></td>
<td></td>
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<tr>
<td>o See report (WIP1)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>o Final stages of recruitment (WIP2)</td>
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<td></td>
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<tr>
<td>8. Other Business</td>
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</tbody>
</table>
# DOP Faculty Meeting Minutes
## June 15th, 2020

<table>
<thead>
<tr>
<th>DOP Faculty Meeting</th>
<th>9:00 am</th>
<th>H371</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Meeting called by:</strong></td>
<td>H. Steve White</td>
<td></td>
</tr>
<tr>
<td><strong>Notes by:</strong></td>
<td>Meghan Turner</td>
<td></td>
</tr>
</tbody>
</table>

### Attendees


- **Absent:** R. Allen, B. Devine, A. Bouge, R. Firebaugh, A. Goo, P. Odegard, T. O'Sullivan, J. Plein, S. Sullivan, J. Wilson-Norton

- **Staff Present:** S. Ahmed, A. Camp, M. Gano, P. Hedtke, M. Kimura, L. Truong, M. Turner

### 1. Welcome/ Acknowledgements/ Announcements

#### 10 min  
**White**

Steve White opens, welcoming everyone to the meeting. To begin, Steve thanks everyone who helped with graduation last Friday. The event looked very different this year, being held virtually for the first time.

A number of announcements were made at the All School meeting a few days ago and over the weekend. Importantly, the School does not yet have complete instructions or clarity on what the budget is going to look like, and probably will not until the end of the month. Once the numbers are sent down to the University from the state, we will have a better idea of how to move forward. While many of our neighbors are struggling financially, thankfully our School does not depend entirely on state funding. We will know more as the state passes on its guidance on to the University. Currently, UW is being asked to model 15% reductions. With this in mind, it is no surprise that the University has advised that there will be no merit increases for faculty and staff. Hiring is also being restricted to essential positions only, and there are purchasing and travel restrictions still in effect. However, on a positive note, those receiving promotions will receive their anticipated raises. Steve acknowledges Ryan Hansen and Jennifer Chang who have both been promoted to Associate rank.

Steve invites Lingtak Chan and Doug Black to share their thoughts on the work needed on electives. Currently we are losing an estimated 600 hours of elective credits over the last two quarters. Lingtak shares the primary focus of the Curriculum Committee, which is to ensure that there are enough elective courses for the students. Currently most of the students have registered for next quarter’s courses, and 2/3 of the elective courses are within the SOP. The number of slots vs. the number of credits needed both look okay for now, and winter registration has not yet started. However, due to the preparation for graduation, we have not looked into the detail of the data. The suggestion for those offering elective courses with a virtual or online component is to increase enrollment capacity. Also, if you have any plans of initiating new elective courses for the winter and spring quarter we would welcome that move as well.

### 2. Approval of Minutes

#### 2 minutes  
**White**
**Discussion**

The DRAFT Meeting Minutes of the May 2020 faculty meeting were presented to all prior to the meeting for review.

**Motion to Approve:**

First: Zach Marcum  
Second: Don Downing

**Vote**

<table>
<thead>
<tr>
<th>Eligible: 39</th>
<th>Yes: 29</th>
<th>No: 0</th>
<th>Abstain: 0</th>
<th>Absent for Vote: 10</th>
</tr>
</thead>
</table>

Note: Votes included from those present at the meeting and via email response.

**Action and by:**

The minutes will be noted as FINAL and posted to the intranet.

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### 3. Return to Work, Research

**White**

A lot of work has gone into returning to work plans, first focusing on return to research, and then offices for faculty and staff. Research plans have been reviewed and approved by department and school leadership. Regarding returning to work for faculty and staff, please look for a draft procedural outline through email by the end of the week. Included will be steps for attestation, general planning, rules regarding social distancing, sanitizing spaces before and after use, and limitations on in-person occupancy of locations such as conference rooms.

**Discussion:**

UW is requiring Back-to-work COVID-19 safety training available online. A link will be sent out in the near future, please plan to take this training before returning to the office. Once complete, both the faculty/staff member will receive an email confirmation. Supervisors will also receive employee completion notifications.

For those planning to come to campus in the near future, please remember to fill out your daily symptom-free attestation in Workday. Assistant Dean Kelly Campbell has set up daily reminders for critical staff. Also, as a reminder, face coverings are required at all times when in common areas or when working with others around campus. However, you can remove your face covering when you are in your office or in your lab by yourself.

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### 4. Discussion: Learnings from Remote Teaching – Quarter Debrief

**All Spring Quarter Course masters**

**Discussion:**

An open discussion takes place amongst the faculty, sharing take-aways from the shift to remote teaching, areas of difficulty and of success. Steve thanks everyone who taught remotely this past quarter, especially for making the adjustments made to make remote learning such a success.

---

### 5. Washington Rule Re-Write Update

**Bacci**
### Discussion:

Jenny Bacci provides new legislative and regulatory updates from WSPA. Jenny shares that the majority of these updates are the multi-year project that PQAC has been undergoing around re-writing for pharmacy practice. These new rules go into effect on July 1st. This is a pretty major overhaul, intended to remove outdated and overly prescriptive rules. There is a lot more room for allowance of professional judgement. This will be an adjustment though. Please see links in the June 2020 materials and agenda for additional details.

#### 6. Experiential Education

<table>
<thead>
<tr>
<th>10 min</th>
<th>Danielson</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discussion</td>
<td>Jennifer Danielson provides a brief update from the Experiential Education team. It is the time of year that we take a look at what has happened over the year, especially in terms of placing students. The APPE numbers are down a bit in General Medicine rotation for year 2020-2021, certainly due in part to COVID-19 and sites not being able to guarantee what they are able to provide in terms of availability. A less concerning factor is that more students are participating in longitudinal or LEAP program, which include General Medicine rotations. Jen advises this is somewhat of a concern for the team, and they are monitoring the situation closely. Also of note is the capacity for the IPPE program. It was very different this year, as this summer is when we have two classes of students doing hospital IPPes. The EE team was very pleased that the health system partners were willing to step up and take on additional students. Looking at WIP placements, just enough WIP1 placements were made, and the team already has 75-80% of WIP2 placements arranged.</td>
</tr>
</tbody>
</table>

#### 7. 5 and 10 Presentation

<table>
<thead>
<tr>
<th>10 min</th>
<th>Cirrincione</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discussion</td>
<td>Lauren Cirrincione presents his research on Renal Function in Transgender Women.</td>
</tr>
</tbody>
</table>

Meeting is Adjourned.
NEW COURSE APPLICATION

Template

Contents

Course Information ................................ ................................ ................................ ................................ .......... 1
Proposal Information ................................ ................................ ................................ ............................... 3
Credits.................................................................................................................................................. 4
Activities and Hours................................ ................................ ................................ ................................ 4
Evaluation Details................................ ................................ ................................ ................................ ........ 5
Distance Learning ................................................................................................................................. 5
Grading System ..................................................................................................................................... 6
Scheduling ............................................................................................................................................. 6
Learning Objectives ............................................................................................................................. 7
Curricular Relationship ......................................................................................................................... 7
Supporting Documents......................................................................................................................... 9

Course Information

<table>
<thead>
<tr>
<th>Prefix (Required)*</th>
<th>PHARM</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Course Number (Required)*</th>
<th>XXX</th>
</tr>
</thead>
<tbody>
<tr>
<td>Must be 3 digits Max 3 characters</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Department</th>
<th>Pharmacy</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>College/School</th>
<th>Pharmacy</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Campus</th>
<th>Seattle</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Course Title (Required)*</th>
<th>The Book Club: Timely Topics for Health Professionals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do not use &quot;&amp;&quot; symbol in the course title. Please spell out the word (&quot;&amp;&quot; is OK for the abbreviated title).</td>
<td></td>
</tr>
<tr>
<td>Max 120 characters</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Abbreviated Title (Required)*</th>
<th>THEBOOKCLUB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Must be ALL CAPS Max 20 characters</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>First Effective Quarter/Year (Required)*</th>
<th>Fall 2020</th>
</tr>
</thead>
</table>
New Course Application – Template

<table>
<thead>
<tr>
<th>Last Effective Quarter/Year</th>
<th>(leave blank)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Course Description</td>
<td>Through active learning methods and group discussion, students and faculty will share their perspectives understanding and explore book topics related to interprofessionally relevant and timely topics on social justice, health disparities, and health care, including the annual UW Health Sciences “Common Book”.</td>
</tr>
<tr>
<td>Recommended Preparation</td>
<td>None</td>
</tr>
<tr>
<td>Course Prerequisites</td>
<td>None</td>
</tr>
</tbody>
</table>

General Education Requirements

| Area of Knowledge: Individuals and Societies (I&S) |
| Area of Knowledge: The Natural World (NW)       |
| Area of Knowledge: Visual, Literary and Performing Arts (VLPA) |
| Diversity (DIV)                                 |
| English Composition (C)                         |
| Quantitative and Symbolic Reasoning (QSR)       |

Prerequisite Changes

This request is for a prerequisite change only which does not involve any other department’s courses.

- [ ]

Enforce cancellation of registration if prerequisites not met (for undergraduate courses only)

- [ ]

Enforce prerequisites for undergraduates only (classes 1 - 4)

- [ ]
New Course Application – Template

Elective Lists
Add course to the following approved major/minor/option elective lists. Max 255 characters

Doctor of Pharmacy

Anticipated Student Type

<table>
<thead>
<tr>
<th>Undergraduate Majors/Minors</th>
<th>Undergraduate Non-Majors</th>
<th>Non-Matriculated Students</th>
<th>Graduate Students</th>
<th>Professional Students</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

Anticipated Enrollment

50

Proposal Information

This proposal is accompanied by one or more related add, drop or change proposals that need to be processed together.

Justification (Required)*

Explain why this course is being proposed including its relationship to your overall curriculum. Is this course part of a broader curricular initiative? If so, please explain.

The Book Club, inclusive of the Common Book and other selected books, fosters reading and shared learning for health professions students on topics relevant to health care and the role of health professionals and scientists including cultural awareness, social justice, health care, health disparities, self-care, health promotion and teamwork.

Administrative Contact Information (Required)*

Add the name of the department administrative contact who should be contacted in the case of any questions with this proposal. Start by typing in the contact’s last name and select from the list of
New Course Application – Template

suggestions. Be sure to "Share" the proposal with this person as well so they will have access to edit the proposal prior to submission.

Ms Patricia Hedtke, Department of Pharmacy Program Coordinator. Tel: 221-5342

_author(s)_

Indicate the names of the people who participated in authoring this course proposal. (Optional)

Karan Dawson, PhD, Peggy Odegard, PharmD, others as identified

<table>
<thead>
<tr>
<th>Credits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fixed</td>
</tr>
<tr>
<td>Multiple</td>
</tr>
<tr>
<td>Range</td>
</tr>
</tbody>
</table>

Multiple, Range or 0 Credit Comment

If multiple, range, or 0 credit, how will the number of credits be related to the amount of student effort?

1 credit per annual participation in the course book, a new book topic each year

_repeatable credit_

Course is Repeatable for Credit

Yes – this course may be taken annually with 1 credit applicable for each annual common book title activity/learning up to 4 credits maximum OR

**Activities and Hours**

In-classroom Instructional and Additional Hours (Required)

One credit represents an approximate time commitment of 3 hours per week.

| Hours/Week |  |
New Course Application – Template

<table>
<thead>
<tr>
<th>Lecture</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Quiz Section</td>
<td></td>
</tr>
<tr>
<td>Seminar</td>
<td>1</td>
</tr>
<tr>
<td>Laboratory</td>
<td></td>
</tr>
<tr>
<td>Studio</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
<tr>
<td>Non-instructional Hours</td>
<td>2</td>
</tr>
<tr>
<td>TOTAL</td>
<td>3</td>
</tr>
</tbody>
</table>

Explanation and Justification for "Other" Instructional Hours

Evaluation Details

Evaluation Details (Required)

How will students be evaluated for credit or grades? Provide specific information on assignments, projects, exams, etc. and relative % for each area. Max 1000 characters

<table>
<thead>
<tr>
<th>Activity</th>
<th>Percent of Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>In-Class Assignments/Activities</td>
<td>40%</td>
</tr>
<tr>
<td>Homework Assignments</td>
<td></td>
</tr>
<tr>
<td>• Project/Class Prep</td>
<td>40%</td>
</tr>
<tr>
<td>• Reflection</td>
<td>20%</td>
</tr>
<tr>
<td>Total</td>
<td>100%</td>
</tr>
</tbody>
</table>

Distance Learning

Seattle Campus: A course or sections of a course in which students can participate fully without being physically present on campus must be designated as a “DL” course or section. Attach a syllabus for the DL course as well as the in-classroom syllabus, if both are planned. See FCAS website for specific “DL” designation criteria: https://www.washington.edu/cms/faculty/files/2014/05/DL-guideline.pdf

Bothell/Tacoma Campuses: See Campus Curriculum Committees on guidelines for DL review/approval.
New Course Application – Template

This is a proposal to add Distance Learning designation to the course.

N/A

This is a proposal to renew Distance Learning designation (3 year review).

N/A

Grading System

Grading (Required)*

<table>
<thead>
<tr>
<th>Standard or Credit/No Credit grading</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Credit/No credit grading only</td>
<td>X</td>
</tr>
</tbody>
</table>

Sequenced (Hyphenated) Courses

A sequenced (hyphenated) course is one in which the same course, or a series of courses, do not receive a final grade until the series has been completed. Please indicate position in sequence.

[ ] of [ ]

Prior course in the sequence is

Scheduling

Quarters Offered

<table>
<thead>
<tr>
<th>Quarters</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Autumn, Winter, Spring, Summer</td>
<td>X</td>
</tr>
</tbody>
</table>

Odd or Even Years

<table>
<thead>
<tr>
<th>Odd or Even Years</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Only even years</td>
<td></td>
</tr>
</tbody>
</table>
New Course Application – Template

Instructor Name
Enter UW instructors if you would like their name to appear in the catalog. Start by typing in the instructors last name and select from the list of suggestions.

Learning Objectives

Learning Objectives (Required)

Learning Outcomes

1. In a group format, engage in discussion and dialogue to explore critical and timely topics through the use of books and other supporting materials, including the UW Health Sciences Common Book option, when prioritized

2. Share experiences, related to the book topics, in small group format to explore and develop personal understanding of the issue and gain appreciation for differing perspectives

3. Facilitate awareness and dialogue about opportunities for personal, community/societal, and policy development through shared discussion and dialogue

4. Reflect on how selected book topics apply in one’s life and where increased sensitivity or attention to this topic could be helpful personally

5. Explore alternative approaches to learning and self-development through possible activities such as the use of music, art, drama, writing, and other creative activities.

Curricular Relationship

List all curricular relationships associated with this course application. It is the responsibility of the initiating unit to do a good-faith review of existing courses to identify affected units. This application will automatically route to the identified units for review and comment. Failure to identify the affected departments here will delay action on this application.

Offered Jointly With - NA
New Course Application – Template

Same course from two or more units. All courses within a joint loop satisfy prerequisite and program requirements.

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Jointly Offered Course Departments

For each course listed under Offered Jointly With, enter the related department here. Start by typing in the department name and select from the list of suggestions.

| N/A |

Overlapping Courses

Significant content overlap of existing courses within or between UW campuses. Students only receive credit for one course. Does not necessarily satisfy prerequisite and program requirements for units involved.

| N/A |

Overlapping Course Departments

For each course listed under Overlapping Courses, enter the related department here. Start by typing in the department name and select from the list of suggestions.

| N/A |
New Course Application – Template

Equivalent Courses
Same course across two or more UW campuses. Courses satisfy prerequisite and program requirements for all units involved.

N/A

Equivalent Course Departments
For each course listed under Equivalent Courses, enter the related department here. Start by typing in the department name and select from the list of suggestions.

N/A

Potentially Affected Colleges, Schools, or Departments
Similar course content covered in one or more potentially affected units within or between UW campuses. Start by typing in the department name and select from the list of suggestions.

N/A

Supporting Documents

File/Description
Attach a course syllabus/outline and reading list if this course will be offered for more than one quarter. If you are submitting a syllabus, please ensure it is compliant with FCAS Syllabus Guidelines and attendance is not listed as an evaluation type.
July 30, 2020

H. Steve White, PhD
Chair, Department of Pharmacy, School of Pharmacy, UW

Re: Letter of recommendation for Joshua Kim, MS, as Affiliate Assistant Professor of Pharmacy

It is my great pleasure that I write this letter of support for Joshua Kim’s appointment as Affiliate Assistant Professor of Pharmacy. With Tom Hazlet’s retirement, the Biomedical Regulatory Affairs Program (BRAMS) is in immediate need of an instructional faculty member who specializes in medical devices and in quality systems. Joshua Kim is highly qualified to be course-master Pharm 517, “Product Development and Manufacturing Systems,” and co-instructor for Pharm 516, “Introduction to Biomedical Regulatory Affairs.” These are critical, core courses for both the BRAMS MS degree and Certificate program.

Joshua is a graduate of BRAMS having earned his MS in 2017. He earned his BS in Biochemistry and Molecular Biology from University of California, Davis (6/2006). Notably, Joshua earned the Regulatory Affairs Certification (RAC) – Devices, an important and well-recognized achievement in this field of biomedical regulatory affairs.

Joshua presently serves as Senior Regulatory/Quality Specialist for EKOS Corp (A BTG International Company). There he provides quality and regulatory guidance to internal project teams and international regulatory teams. His duties include developing and implemented regulatory strategies across a broad array of projects, including new product development. His achievements there include successfully submitting premarket notifications to FDA via the Special 510(k) process resulting in their clearances and interactions with regulatory agencies. His previously held positions in regulatory affairs and/or quality were with Solta Medical, Inc., Immune Design Corp, and Genentech.

His teaching experience to-date includes multiple presentations on quality metrics for quality management, developing and delivering instructional material on new test methods, and mentoring a BRAMS MS student who successfully completed her practicum. For the latter, his responsibilities included helping the student scope and refine her practicum project to ensure it provided focused learning opportunities while meeting practicum requirements. His experience as a preceptor illustrates his ability to work with students towards academic goals. Moreover, Joshua’s experience in leading, training, and mentoring those around him translates well to our instructional needs.

Several faculty associated with BRAMS, including me, interviewed and have met with Joshua. In summary, Joshua Kim will be a valuable addition to BRAMS and I support his appointment with my highest level of enthusiasm. Thank you for your consideration.

Sincerely,

Andy Stergachis, PhD, BPharm
Professor of Pharmacy and Global Health
Interim Director, Biomedical Regulatory Affairs Program
Executive Summary
12 years of successful experience within the regulated healthcare industry. Lead by example in achieving corporate goals and project timelines. Developed new processes to comply with regulatory changes made by domestic and international organizations. Trained and mentored peers by acting as a Quality subject matter expert. This provided additional resources for transitions to new regulatory requirements without the added cost of new hires. Ardently supported processes improvements in order to create a collaborative and transparent environment within the department.

Education
B.S., Biochemistry and Molecular Biology University of California, Davis (6/2006)
M.S., Biomedical Regulatory Affairs University of Washington (8/2017)
RAC Devices 12/2019
RAC Drugs In Progress

Professional Experience
EKOS Corp (A BTG International Company) Apr 2018–Present
Sr. Regulatory/Quality Specialist
Provided quality and regulatory guidance to internal project teams and international regulatory teams.
Accomplishments
- Developed and implemented regulatory strategies across a broad array of projects, including new product development. Responsibilities included providing an initial regulatory assessment, reviewing/approving project documents (protocols, reports, etc.), and assessing any changes associated during the project.
- Successfully submitted premarket notifications to FDA via the Special 510(k) process resulting in their clearances. Responsibilities included handling questions from FDA, proactively communicating their status to various leadership teams, and communicating potential risks before and during FDA’s review.
- Interacted with regulatory agencies during the submission review process via email, teleconferencing, and video conferencing to address concerns related to design verification testing and indications for use.
- Served as the lead regulatory reviewer for Advertisement/Promotion pieces. This included developing and maintaining an approved claims matrix with the Marketing group. Responsibilities included providing regulatory insight to FDA’s position on how claims need to fit the cleared indications for use.
- Successfully submitted substantial change notifications to the notified body prior to the MDD-to-MDR blackout period. Responsibilities included periodic contact with the scheme manager to ensure timely review, fielding questions from their reviewers, and providing status updates to various leadership teams.
- Served as the primary reviewer for the clinical evaluation report (CER) for a sister company as it transitioned from MEDDEV 2.7/1 Rev 3 to Rev 4. Responsibilities included providing procedural updates to governing QMS documents and revising the CER to align with the new requirements in Rev 4.
Joshua Kim

- Developed on-boarding materials and digitized historical submissions, letter-to-files, and international licenses to aid in the knowledge transfer in order to ensure open access to all Regulatory team members.

V Scale Consulting, LLC May 2018–Present
Founder
Provided guidance to complex regulatory and quality management issues, helping clients solve their compliance problems.

Accomplishments
- Developed regulatory transition plans for clients. This included generating gap assessments and providing solutions that met the new requirements efficiently and expeditiously.
  - These transition plans included the move from ISO 13485 to ISO 13485/MDSAP as well as the transition from MDD to EU MDR.
- Developed regulatory strategy for new product transition to the EU MDR. This entailed understanding previous regulatory engagements with notified bodies and creating a path forward for a successful EU MDR transition.
- Provided US and EU guidance for new product introduction utilizing the FDA’s 513(g) process.

Solta Medical, Inc. Apr 2015–April 2018
Sr. Regulatory/Quality Specialist
Provided quality and regulatory guidance to internal project teams and international regulatory teams.

Accomplishments
- Served as the regulatory chair for a technical presentation with China’s FDA (CFDA). This resulted in a device approval which garnered $1M in sales the first quarter.
- Created new medical device submissions using an internationally recognized format. This resulted in a CE certification for the device allowing it to be placed into the EU market. This submission was also used for other regions and resulted in over a dozen approvals worldwide.
- Served as the labeling subject matter expert. Regulatory label requirements were addressed as part of the device characterization process instead of during verification/validation. This will result in better labeling verification prior to the pre-market submission.
- Implemented the regulatory-gated distribution process. This successfully stopped shipments from going to regions that did not have proper device approvals. The process generated annual reports which are used for management and product reviews.
- Successfully transitioned clinical evaluation reports to new European requirements. This resulted in no findings during our notified body surveillance audits.

Project Management
Managed regulatory-mandated projects in order to maintain compliance with domestic and international regulations.

Accomplishments
- Successfully managed the transition of all medical device licenses to align with the current legal owner. This involved understanding local regulatory requirements and managing the different review/approval periods to ensure supply chain continuity for the customers.
- Successfully implemented FDA’s Unique Device Identifier requirements on all medical devices.
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- Managing quality management certification process per required by the Medical Device Single Audit Program. Health Canada requires this certification in order to continue marketing devices within Canada. Successful completion is expected in June 2018.
- Managing the corporate transition to comply with EU Regulation (EU) 2017/745, colloquially known as the EU MDR. This affects both quality systems and product CE certifications. Successful implementation is expected by April 2020 for new product introductions and May 2023 for legacy product.
- Managing labeling updates for reprocessable devices to align with FDA’s guidance document, “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling.” This addresses labeling gaps with our reusable devices portfolio in both the US and EU markets.

Quality Associate II
Matured Quality Lab processes and qualified assays for Phase I clinical trial submissions to FDA and NIH.

Accomplishments
- Successfully qualified molecular biological assays in support of NIH and FDA submissions for an immunotherapy drug candidate.
- Created and reviewed Quality modules in CTD format for an IND submission and subsequent IND amendments. This included the Quality Overall Summary and Module 3. This resulted in no clinical holds issued by FDA for our clinical trial.
- Notified NIH of clinical trial progression as required by NIH Guidelines. This resulted in the successful initial clinical site initiation as well as follow-on sites.

Genentech Inc. Sep 2006–Sep 2010
Quality Associate II
Executed and reviewed a variety of validated assays used to release antibody- and enzyme-based drug products. Trained personnel on these assays to allow for >95% coverage.

Accomplishments
- Successfully managed testing campaigns which led to continuous reduction in testing and review times. This reduced the lot release time for drug substance and product lots.
- Served as the subject matter expert for lab investigations for initial out of specification (OOS) CAPAs. This prevented OOS lots from being released into distribution. These investigations also identified problematic manufacturing steps in lyophilized products.
- Demonstrated critical lab assays for FDA inspectors. This resulted in their better understanding of the assay in question as well as showcased the GMP-readiness of the department.
- Transitioned labs as part of the corporate 5S Initiative. This laid the groundwork for achieving the corporate Class A status in Operational Excellence. This also reduced the walking distance of lab associates by an average of 300 yards per assay.

References
Available upon request.
INFORMATION

Experiential Education  
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E-mail: py1ee@uw.edu  
SOP.UW.EDU

2019-2020 WIP1 Highlights

43 Health System Sites Committed

<table>
<thead>
<tr>
<th>Practice Site Type</th>
<th>Number of Sites</th>
<th>Number of Students</th>
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</thead>
<tbody>
<tr>
<td>Behavioral Health</td>
<td>3</td>
<td>8</td>
</tr>
<tr>
<td>Hospital</td>
<td>20</td>
<td>46</td>
</tr>
<tr>
<td>Infusion</td>
<td>9</td>
<td>18</td>
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<tr>
<td>LTC/Home Health</td>
<td>10</td>
<td>29</td>
</tr>
<tr>
<td>UW Dental</td>
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<td>6</td>
</tr>
</tbody>
</table>

107 PharmD Students

WIP1 Preceptor Performance

We are excited to share that this year’s WIP1 preceptors consistently demonstrated quality precepting behaviors to our students and students’ overall impression of their preceptors were excellent. We recognize your dedication!

On a scale of 5 = Always to 1 = Never, please indicate how consistently this preceptor demonstrated these 16 quality behaviors.

4.89 /5.00 All Preceptors (N=134)

On a scale of 4 = Excellent to 1 = Needs Improvement, please indicate your overall impression of the preceptor.

3.92 /4.00 All Preceptors (N=134)
Student Comments on Preceptor Roles and Qualities

**Coaching**
“My preceptor was able to coach me and guide me through some of the tasks. She allowed me to work things out on my own first and use my critical thinking skill.”

**Facilitating**
“She took time out of her day to make sure I felt welcomed and planned special activities to promote my learning.”

**Modeling**
“He showed what it is like to be a valued and integral member of the health care team.”

**Organization**
“My preceptor was very well organized with my tasks and very clear in what was expected from me. We would discuss the goals that the SOP would like for us to meet. And when we would not reach a specific goal, we would adjust our schedule in order to ensure that we would be able to manage to do so within the next visit.”

**Teaching**
“He is always happy to go back to the basics to teach about complex concepts that were concurrent with what we are learning in school. He pushed me out of my comfort zone to deliver an SBAR to other pharmacists so that I can continue gaining experience and overcoming the fear of public speeches. I appreciate his methods of teaching and I can see that he really cares about my learning experiences.”

Preceptor Feedback on Student Performance

“What’s going well?”

- “I like how the student comes in very engaged and ready to learn and also to help out when needed.”
- “Frequent updates, proposed activities and flexibility with students.”
- “Enjoy interacting with the students. I also appreciate the detailed schedule outlined by UW and additional resources that have been provided.”
- “Timely feedback from the school.”
- “Once the students became proactive about the goals of each visit it went quite well. They became quite independent.”

Plans for Improvement Based on Preceptor Feedback for 2020-2021

- To increase flexibility of learning activities in different practice settings
- To decrease preceptor time commitment in weekly evaluations
- To integrate learners into pharmacy workflow
- To prepare learners for practice experience