Veterinary clinical pathology trainees benefit from toxicologic externship opportunities in the biopharmaceutical industry

For the second year in a row, the ASVCP has provided the Regulatory Affairs Committee (RAC) with funds to financially support veterinary clinical pathology residents to participate in externships in toxicologic clinical pathology in various industrial settings, which this year included 2 contract research organizations and one large multinational pharmaceutical company. The goal of this scholarship is 2-fold: First, to expose residents to the opportunities and challenges of clinical pathologists in the biopharmaceutical industry, and second, to increase knowledge and capabilities in laboratory animal and toxicologic clinical pathology. Three resident externs were able to be supported financially this year, up from 2 awardees in 2014.

Dr. Laura Black, a 3rd year clinical pathology resident at the University of Florida, spent 4 weeks at MPI Research in Mattawan, Michigan under the mentorship of Drs. Adam Aulbach, Caitlyn Carter, and Laura Cregar. Dr. Eric Fish, also a 3rd year clinical pathology resident at Auburn University, spent 2 weeks at Merck Research Laboratories in West Point, Pennsylvania under the guidance of Drs. Elizabeth Besteman and Mike Topper. Dr. Adi Wasserkrug Naor, another 3rd year clinical pathology resident at Kansas State University, spent 2 weeks at Charles River Laboratories in Reno, Nevada under the guidance of Drs. Angela Wilcox and Bill Siska.

All 3 externship recipients enjoyed their respective training experiences in toxicologic clinical pathology and found them to be valuable in numerous ways, including but not limited to, learning about laboratory animal specific clinical pathology that they are not routinely exposed to in an academic residency, developing toxicology skills that have broad utility in research and industry, and experiencing exposure to rewarding and intellectually stimulating careers outside of diagnostic and academic clinical pathology.

Dr. Black’s externship experience at MPI research included:

1. Topic discussions on Clinical Pathology report writing and interpretation for nonclinical toxicology studies, biomarkers and biomarker validation, hemocompatibility (in vitro hemolysis testing and interpretation), platelet aggregometry and platelet function testing, immunotoxicity, and bone marrow evaluation including species variations and test article-related effects.
2. Weekly toxicologic pathology rounds which focused on histopathology and gross findings, a weekly journal club, and lectures on diagnostic necropsy, pharmacologic formulation, and a sponsor presentation.
3. Attendance of integration meetings where the clinical and anatomic pathologists, toxicologists, and study directors discussed individual studies.
4. Analysis and interpretation of 6 nonclinical toxicology study cases (including CBC, biochemistry, urinalysis, coagulation, and biomarker data) in either a boards style or an industry format. These cases included a variety of species (mice, rats, dogs, nonhuman primates, and rabbits) and a variety of test articles. Reports were reviewed by the clinical pathologists and discussed during weekly chemistry rounds.
5. Additional activities included shadowing the laboratory technicians and reviewing work flow, QA/QC procedures for both GLP and non-GLP studies, and reporting of results. One day was spent with the clinical veterinarians and reviewing the care, housing, and enrichment of the animals.

For Dr. Fish, his specific training experience at Merck Research Laboratories included:

1. Individual and group data interpretation in hematology (including microscopic blood smear and bone marrow review), chemistry, urinalysis, coagulation, and biomarkers for a variety of species, including mice, rats, rabbits, dogs, and nonhuman primates.
2. Practice in writing and interpreting preclinical toxicologic clinical pathology reports and integration into the master study report in the context of in-life observations, gross and histologic lesions, and pharmacologic and toxicokinetic data.
3. Inclusion in global pathology meetings where anatomic and clinical pathologists shared findings, troubleshoot problems, and optimized study design and protocols.
Discussions on GLP study design, protocol and facilities requirements; QA/QC policies and procedures; and sources of and strategies to minimize preanalytic, analytic, and postanalytic bias and error in order to gain regulatory approval from the FDA and international regulators.

Interactions with research scientists about integrating novel biomarkers (troponins, NGAL, Cystatin C, microRNA, genomic and proteomic profiling, and more) into both the discovery and safety assessment phases of drug development.

Dr. Naor’s time at Charles River Laboratories included:

1. Interpretation of the data as a clinical pathologist, with particular respect to discussing points that may help to decide if a change is test article related, proposing mechanisms for the effect of the article by understanding the target, and synergizing these findings together. Interpretation included discussions of species-specific differences, biologic variation, and integration with histopathology findings to support the clinical pathology data.

2. Reading and discussing articles that may help making the decision if a change is an adverse or nonadverse effect.

3. Writing toxicology reports by interpretation of the data, followed by feedback.

4. Participation in a whole necropsy process of a specific experiment of both rodents and monkeys, ranging from the time samples were collected for histopathology to bone marrow cytology and flow cytometry, and other ancillary testing.

5. Visiting the animals’ facilities in order to be familiar with the environment the animals are held, the steps taken to ensure the animals get the treatment needed, and documentation and follow-up of animal welfare and health.

6. Participating in different integration meetings involving the clinical and anatomic pathologist, scientists, study directors, toxicologists, and the sponsors. The main goals of the different meetings included discussing problems and concerns, addressing changes that could be considered both before an experience is held, during a study or organization of the report, and communicating about results and their significance with the sponsors.

Based on 2 consecutive years of positive extern and sponsor experiences, the ASVCP and the RAC have committed to continuing this scholarship in 2016. Any clinical pathology residents who are interested in exciting careers in toxicology settings in the biopharmaceutical industry should consider applying for funding. Candidates must first contact a suitable company or organization to host them, and arrange for a specific date and time for the externship. Residents who have already completed a qualifying externship may also apply to defray the prior costs of travel and lodging. A list of potential participating organizations can be found at http://www.asvcp.org/stures/ExternshipContacts.cfm. The application is found on the ASVCP website at http://www.asvcp.org/stures/RACScholarship.cfm, and is due April 15, 2016.

The 3 trainees funded through the ASVCP–RAC this year all had exceptional experiences and express gratitude for the opportunities they were given. These externships have deepened their interest in careers in toxicologic clinical pathology in the biopharmaceutical industry, and allowed them to take the first step on the path toward that goal.

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Laura J. Black
College of Veterinary Medicine, University of Florida, Gainesville, FL, USA
klockow@gmail.com

Eric J. Fish
College of Veterinary Medicine, Auburn University, Auburn, AL, USA
EJF0007@auburn.edu

Adi Wasserkrug Naor
College of Veterinary Medicine, Kansas State University, Manhattan, KS, USA
adiw@vet.k-state.edu