HUMAN HEALTH RISK ASSESSMENT 16:963:510

Course Directors:

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Course Description: The human health risk assessment course is designed to provide an introduction to the theory and practice of risk assessment in toxicology. Xenobiotic exposure is ubiquitous at home, in the workplace, and in the environment. Conducting risk assessment in toxicology requires a thorough understanding of pharmacology, pharmacokinetics, of all organ systems, and of the limitations and strengths of the different models used to assess the toxicity profile of chemicals. It also requires to be able to conduct exposure assessment. Risk assessment is an integral component of risk analysis which also includes risk management, and risk communication. While this course focuses on the technical aspects of former, risk management and risk communication will also be briefly introduced to contextualize risk assessment. Participants will be responsible for all of the in-class material during the 2-day intensive 'bootcamp', and then will be responsible for individually documenting a risk assessment for an environmental chemical that will be assigned randomly. There will be three monthly 'check-ins' during which specific progress towards the term paper will be assessed and where guidance will be provided.

Course Objectives: The purpose of this course is to provide the learner with a basic understanding of fundamental risk assessment in toxicology. At the end of the course, the participants should be able to make a determination as to whether a hazard pose an unacceptable risk to public health and to formulate recommendations to risk managers. The course will emphasize on the four classical steps of risk assessment (hazard identification, dose-response, and exposure assessment which culminate in the risk assessment). Students will also develop their skills in the critical review of data, and adequately documenting each step of the risk assessment process. In class, new up and coming risk assessment approaches will also be introduced.

Upon completion of this course, the learner is expected to:

- I. Understands the concepts of hazard and risk, risk assessment, and risk analysis
- II. Know the four classical steps of the risk assessment process
- III. Demonstrate critical analysis of a toxicological study
- IV. Differentiate key assumptions and uncertainties between non-cancer and cancer dose-response models
- V. Be able identify the most appropriate point of departure based on hazard identification and dose-response assessment
- VI. Be capable of extrapolating from non-clinical species to human
- VII. Have a working understanding of the principles of exposure assessment
- VIII. Develop a scientifically supportable and well documented risk assessment paper

SCHEDULE

| Bootcamp Day 1 | |
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| 9:00-9:15 | Introductions, Program Overview, and Learning Objectives |
| 9:15-10:45 | Risk Analysis: Risk Assessment, Risk Management, and Risk Communication |
| 10:45-11:00 | Refreshment Break |
| 11:00-12:30 | Risk Assessment: Hazard Identification and Dose Response (non-cancer) |
| 12:30-13:30 | Lunch Break |
| 13:30-15:00 | Risk Assessment: Hazard Identification and Dose Response (cancer models) |
| 15:00-15:30 | Refreshment Break |
| 15:30-17:00 | Data quality, weight of evidence, and point-of-departure (hands-on group exercises) |
| Bootcamp Day 2 | |
| 9:00-10:30 | Exposure pathways and toxicokinetics refresher |
| 10:30-10:45 | Break |
| 11:00-12:30 | Exposure assessment, a tiered approach |
| 12:30-13:30 | Lunch Break |

| Extrapolation, variability, susceptibility, and uncertainty |
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| Refreshment Break |
| Is it okay or not? Documenting and completing a risk assessment |
| Concluding remarks, assignments |
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| Critical analysis of a toxicology study (hand-in paper) Annotated bibliography expectations / discussion on term paper |
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| Presentation of risk assessments |
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