

# WHERE THE RUBBER MEETS THE ROAD:

## TRANSITIONING ACADEMIC RESEARCH INTO REGULATORY REQUIREMENTS



### PART ONE

#### CROSS-TALK BETWEEN ACADEMIC GENOTOXICITY RESEARCH AND REGULATORY GENOTOXICITY ASSESSMENT

13:00 - 13:15

Reflections on the commonalities and differences between academic and regulatory genotoxicity studies  
Speaker: TBD

13:15 - 13:35

Overview of consortia efforts to improve genotoxicity data for regulatory use  
Speaker: TBD

13:35 - 13:55

Statistics and Experimental Design: Similarities and Differences Between Regulatory and Academic Studies  
Speaker: David Lovell (St. Georges Medical School, University of London)

13:55 - 14:15

Use of academic and regulatory studies for regulatory decision making  
Speaker TBD

14:15 - 14:35

Genotoxicity in marine organisms, assessing the potential impacts of offshore oil and gas activities on the marine environment.  
Confirmed speaker: Steven Brooks (NIVA)

Genotoxicity assessments in both wild fish and field transplanted mussels that live on and around offshore oil and gas installations in the North Sea, have been performed to assess the health status of the populations and to determine the potential impacts of oil and gas activities on the marine environment. Application of three genotoxicity biomarkers (comet, micronuclei and DNA adducts) in marine organisms will be presented and discussed.

14:35 - 15:00

Break

## HESI WORKSHOP



HESI.



ROVINJ, CROATIA

MONDAY  
SEPTEMBER 23<sup>RD</sup> 2024

13:00 - 16:30

THIS WORKSHOP AIMS TO ADDRESS THE CURRENT USE OF **GENOTOXICITY** STUDIES IN **REGULATORY APPLICATIONS** AND HIGHLIGHT HOW ACADEMIC RESEARCH HAS MOVED REGULATORY SCIENCE FORWARD.

THE FIRST PART OF THE SYMPOSIUM WILL COVER **REGULATORY USE** OF GENOTOXICITY STUDIES, **CURRENT PERSPECTIVES** ON AND THE CURRENT STATUS OF VARIOUS CONSORTIA EFFORTS REGARDING DATA QUALITY.

THE SECOND HALF OF THE WORKSHOP WILL PRESENT RECENT **SUCCESS STORIES** OF GENOTOXICITY ASSAYS AND APPROACHES WITH ORIGINS IN ACADEMIA THAT HAVE EITHER **SUCCESSFULLY BEEN OR ARE ON THE ROAD TOWARDS REGULATORY USE AND ACCEPTANCE.**

THIS SYMPOSIUM WILL FEATURE SPEAKERS FROM ACROSS THE ACADEMIC, INDUSTRY AND REGULATORY DISCIPLINES TOWARDS FOSTERING **COLLABORATION AND KNOWLEDGE EXCHANGE** BY BRIDGING RESEARCH INTO TRANSLATION AND APPLICATION.

### CO-CHAIRS:

CONNIE L. CHEN (HESI)  
&  
MARIE VASQUEZ (HELIX3)



### PART TWO

#### FROM ACADEMIC ORIGINS TO THE REGULATORY ARENA: SUCCESSES AND CURRENT CHALLENGES

15:00 - 15:20

PigA: Lifecycle and lessons learned  
Speaker TBD

15:20 - 15:40

Duplex Sequencing: The roadmap for error-corrected next gen sequencing  
Tentative Speaker: Aaron Boswell (TwinStrand)

15:40 - 16:00

ToxTracker  
Confirmed speaker: Inger Brandsma (Toxys)

16:00 - 16:30

Quantitative-based Genotoxicity Risk Assessment  
Speaker TBD



Hrvatsko genetičko društvo  
Croatian Genetic Society



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