

## MINUTES OF THE PHARMACEUTICAL INTEREST GROUP MEETING AT THE 2018 SETAC NORTH AMERICA CONFERENCE HELD ON MONDAY 5 NOVEMBER, 4:30-5:30

### 26 Attendees:

Jane Staveley (Exponent); Lucie Bielska (Masaryk University); Lucia Skulcova (Masaryk University); Paul DeLeo (Integral Consulting); Rai Kookana (Commonwealth Scientific and Industrial Research Organisation); Roel Evens (SETAC); Matthieu Duchemin (Envigo); Michael Lee (Eli Lilly); Roger Meyerhoff; Jerold Teeter (Elanco); Jay Harriman (BIAH Health); Rose Huang (Boehringer Ingelheim Animal); Liz Miller (University of Wisconsin – Madison); Vijay Kannapan (Georgia Pacific LLC); Eric Silberhorn (US Food and Drug Administration / Center for Veterinary Medicine; US FDA / CVM); Holly Zahner (US FDA/CVM); Wesley Hunter (US FDA/CVM); Jim Meador (NOAA Fisheries); Jake Wilhelm (Integral Consulting); John Nicoletta (AbbVie); Donna Davila (AbbVie); Amy Soli (AbbVie); Joanne Elmoznino (Pfizer); Jim Laursen (US FDA/ Center for Drug Evaluation and Research; CDER); Sarah Jane Follett (Health Canada); Julie Chateauvert (Health Canada).

### 1 Welcome – Introductions

### 2 Update on selection of new Chair at SETAC Europe

A PhIG meeting was held in Rome and about 30 people attended. During this meeting, new steering committee volunteers were named. Volunteers were chosen to ensure representation from business, academia and government from all SETAC regions. Steering committee members serve a 3 year term. The current members are:

- Gerd Maack (Chair)
- Jason Snape (Vice-Chair)
- Mike Williams (Past-Chair)
- Thomas Backhaus
- Laura Carter
- Chris Van den Eede
- Wesley Hunter
- Sigrun Kullik
- Ruth Marfil-Vega
- Jane Staveley
- Todd Davidson

### 3 SETAC North America (Sacramento) Sessions co-sponsored by the Pharmaceutical Interest Group (PhIG)

This year the PhIG co-sponsored the following sessions:

- 1) Monday 1:00 – 4:15 pm: *Exposure Assessment and Modeling for Ecological risk Assessment of Veterinary Pharmaceuticals and Pesticides* / Co-sponsored with the Exposure Modeling Interest Group
- 2) Thursday 1:00 – 4:15 pm: *Environmental Assessments for human and Veterinary Pharmaceuticals – Evolving Regulations* / co-sponsored with Endocrine Disruption Testing and Risk Assessment Interest Group

### 4 Recap of PhIG meeting in Rome (SETAC EU)

A variety of speakers discussed initiatives related to antimicrobial resistance (AMR).

Jason Snape (EU SETAC, PhIG Vice-Chair) gave a keynote speech on the topic of AMR. His talk was recorded and is available online here: <https://www.youtube.com/watch?v=zBerTEAIEok>

Members of the PhIG Steering committee attended the Dug Organism Toxicity Testing Standardisation (DOTTS) Group meeting. This group has been very active in the past (e.g., developed standard test guidelines). There is currently a proposal with the European Medicines Agency (EMA) for a higher tier

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field study. However, the status of this proposal is currently unknown, and advancements may be delayed due to the EMA's move to the Netherlands.

### 5 Discuss website updates

The web page for the PhIG is online. Anyone can sign up online to become part of the group, including SETAC non-members.

The PhIG could benefit from content updating on the website. For example, links to current projects, updates from regulatory agencies, etc., can be shared with the Steering Committee for upload to the website.

### 6 Brainstorm ideas for future activities/directions

The PhIG took part in many activities over the years (e.g., sponsoring a special issue of Environmental Toxicology & Chemistry). Now, the PhIG is in transition phase and the group needs to determine what direction to take next.

An Interest Group Summit was held earlier on Monday November 5 during which Chairs of the various interest groups got together and received updates from SETAC (attended by Wesley Hunter). This summit is a platform to share concerns and to try to find momentum from collaboration. People discussed challenges and provided ideas, namely encouraging the interest groups to:

- Examine challenges to advance the science
- Find areas where we can advance science (e.g., enhance communications between sectors, collaborate on authorship of papers, sponsor issues of journal, initiate new sessions, create training courses, collaborate with external entities, develop special events, workshops, special symposia, and build tools and databases, etc.)

SETAC wants interest groups to know that:

- There is a SETAC career center that can be leveraged by organizations
- A science corner exists on the SETAC website to house everything in one place (e.g., review articles, podcasts, etc.)
- The 8<sup>th</sup> World Congress will take place in Singapore in 2020

The Global Horizon Scanning project, which grew out of a paper by Boxall et al. 2012<sup>1</sup>, is trying to identify research needs for a better understanding of adverse impacts of stressors on environmental sustainability. The top questions for North America from the Global Scanning project can be found here: <https://www.setac.org/general/custom.asp?page=GHSResults>

Thoughts from PhIG meeting attendees on potential future directions for the interest group:

- A good starting point would be to see how the questions compare between the Global Horizon Scanning project and the Boxall paper (for example, a poster presented at SETAC world Congress in Orlando matched the questions to workgroups in US federal agencies).

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<sup>1</sup> Boxall, Alistair BA, et al. "Pharmaceuticals and personal care products in the environment: what are the big questions?." Environmental Health Perspectives 120.9 (2012): 1221-1229.

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- There is a need to for a standardized method(s) for testing AMR in the context of environmental risk assessments
- We do not have drinking water limits for pharmaceuticals, but we do have it for food (e.g., meat and eggs). Perhaps more work can be done to determine regulatory drinking water limits for pharmaceuticals.
- There is a big push to try to reduce # of vertebrates in testing
- A major challenge is sound management of pharmaceuticals in Asia. We should think about reaching out to our colleagues in Asia to encourage them to be involved in the PhIG.
- The PhIG should reach out to other interest groups to discuss potential collaborations

Anyone with additional thoughts is invited to contact the PhIG membership through the SETAC online portal or to communicate directly with Wesley Hunter or Jane Staveley.

#### **7 New business**

- The Steering Committee will look into the possibility and feasibility of having conference calls (either quarterly or at mid-year) to ensure continuity within the PhIG
- The SETAC EU abstract submission deadline is coming up (November 28). The following session is relevant to the PhIG:
  - New insights into chemical exposures over multiple spatial and temporal scales (Co-chairs: Alistair Boxall, Charlotte Wagner, Rainer Lohmann, Jason Snape)  
A description is available here: <https://helsinki.setac.org/time-schedule/scientific-programme/tracksessions/>
- Update from IPIE – The annual meeting takes place on November 14. The SUM database will provide high level access to properties of API of data that has been collected. This can be accessed here: <http://i-pie.org/ipiesum/>
- If you want to proposed a session and have it sponsored by the PhIG, get in touch with the Steering Committee!