

ESTP Newsletter 2018 (2)



Editor Zuhal Dincer (zuhal.dincer@covance.com)

President's Column

Dear ESTP members,

Winter time is over and spring is coming, what a great opportunity for things to do you always wanted to do!

I would like to remind you on the ESTP election, which will be take place this year. The information about the election will be sent out in May by e-mail. Please take the chance to support the Society!

This year, we have a number of meetings and congresses, you could participate:

In February we had already the Classic Examples, held at the Hanover Veterinary School, and very well organized by Thomas Nolte and others. The scientific and social program was again outstanding and a lot of people met in Hannover. Many thanks to all for organizing this great meeting!

In May, another "Adversity Workshop" will take place in Berlin and some places for the audience are still available to register. Do not miss the opportunity to discuss with the experts from industry, academia and regulatory authorities.

In September, traditionally the ESTP Congress is organized in Copenhagen this year and the registration is now open for this event. We expect another scientific high class congress and you should not miss it!

The SFPT and STP have their annual meetings in Montpellier in May and in Indianapolis in June respectively. Please visit the meetings of these Societies!

The ESTP already set up the SOC for the upcoming meeting in 2019 in Germany. The place will be the nice city of Cologne (Sept 17 – 20, 2019). We are still looking for enthusiastic people willing to take responsibility and to be a member of a creative team. If you are interested to

participate in the SOC, please send an email to the chair of the SOC Björn Jacobsen or myself:

bjoern.jacobsen@roche.com

sibylle.groeters@basf.com

I am always happy to receive direct feedback from the membership and I am glad to answer your questions! The spring time finally arrived in Europe and I hope you can enjoy the first sun with an ice cream and a smile on your face!

Best regards,
Your Chairman

Sibylle Gröters
ESTP Chairman

sibylle.groeters@basf.com



Inhaled Biologics White Paper - an Update and Thank You -

The concept of delivering biologics – whether they be proteins, peptides, antibodies (or fragments thereof) or DNA oligomers – by the inhaled route has great appeal due to the opportunity to deliver locally high concentrations into the lung with the possibility of avoiding systemic toxicity. However, this has met with limited success (so far) with few products reaching the market place. Notable exceptions include the inhaled insulins (Exubera & Afrezza) and inhaled DNase (Pulmozyme) to treat diabetes and cystic fibrosis respectively.

The past few years however have witnessed renewed interest in this route of delivery with most of the major pharmaceutical companies currently developing inhaled biologics programmes. This has been reflected in several toxicology and pathology conferences in 2017 showcasing inhaled biologics as part of their core agenda. The discussion at these conferences was vigorous, collegial and well received as it became increasingly apparent to pathologists and toxicologists alike that the response of the lung to biologics was even more complex and poorly understood than for low molecular weight molecules. In addition, the relative novelty of inhaled biologics meant that understanding was limited around what could be classed as a “typical” response to a proteinaceous material in the lung, all of which might hamper the route to clinical trials.

It was with this background that the BSTP devoted its annual scientific meeting to the topic of ‘Inhaled Biologics’ in November 2017 and perhaps not unsurprisingly, delegate discussion led to the suggestion of a White Paper to help understand this complex area of biology. It was from these relatively humble beginnings that we began the task of building a group to deliver one or two white papers that would address both the pathology and toxicology challenges arising from this route of delivery.

During the first quarter of 2018 an industry wide survey was submitted to the BSTP, ESTP, STP, AIT (Association of Inhalation Toxicologists) and BioSafe Societies to gather volunteers and poll available experience. The results were very encouraging (probably reflecting the underlying need within the industry). All the major pharmaceutical companies responded positively, and despite not having all the results back yet, we have more than 40 volunteers gathered from all corners of the industry – pharma, CROs and consultants. No doubt this figure will increase over the coming weeks. We also can report from the initial analysis of the survey that we have representative examples of all the major modalities and all the common toxicology species (including a few exotics ones too!). Thank you to all who have responded, volunteering their time, experience and (hopefully)

information on their case studies – this is very much appreciated!

The real work now of assembling the working groups and putting pen to paper starts! No doubt the discussion will be lively and informative. From a pathology perspective, we are hoping that we’ll unravel some of the layers of complexity surrounding the response of the lungs to inhaled biologics. If we achieve this then both sponsors and regulators will be in a better position than where we stand today, with the opportunity to make more informed judgements on findings that start from a common position of understanding. From a toxicology perspective, we are hoping to discuss and review the specific challenges that come with dosing biologics and the different approaches and limitations in resolving these, and thus facilitate the conduct of high quality inhalation toxicology studies.

Best regards

Inhaled Biologics White Paper Group

Peter Hall (Peter.Hall@ucb.com)

Frank Brennan

Annick Cauvin

Karyn Colman

Sherri Dudal

Renaud Fleurance

Jo Kilgour

Alison Wolfreys



The 6th ESTP International Expert Workshop 16th – 17th May, 2018

Dear ESTP Members

The 6th ESTP International Expert workshop will elaborate criteria for pathologists to assess adversity of thyroid follicular cell hypertrophy/hyperplasia, taking into account the differentiation between direct and indirect mechanisms and their implication for risk assessment.

After a series of preparatory teleconferences amongst experts, face-to-face meeting of this Expert Workshop will take place at Bayer AG, Müllerstraße 178, 13353 Berlin (Germany), on May 16-17, 2018. Online registration for the event has been extended till 20th April, 2018.

In addition to approximately 25 invited experts, including pathologists and toxicologists from international regulatory agencies, a limited audience (maximum: 40 persons) will be accepted to this expert discussion, which will comprise 'questions & answers' sessions.

The registration fee for this event includes lunch and coffee breaks on both days and will be **135 €**. Detailed information, including the detailed workshop program, and the online registration tool are available on the ESTP homepage:

<https://www.eurotoxpath.org/meetings/index.php?id=workshop6>

For any organizational questions or requests, please contact one of the workshop organizers. We are very much looking forward to another successful ESTP International Expert Workshop!

Best regards,

Wolfgang Kaufmann

wolfskauf@gmail.com

Barbara Lenz

barbara.lenz@roche.com

Xavier Palazzi

xavier.palazzi@pfizer.com

Gabriele Pohlmeier-Esch

gabriele.pohlmeier-esch@boehringer-ingelheim.com

**Annual Congress of the French Society of
Toxicologic Pathology (SFPT)
24th – 25th May, 2018**

Dear ESTP Members

The next congress of the French Society of Toxicologic Pathology (SFPT) will take place on the 24th-25th May 2018 in Montpellier, Southern France. This year, the scientific presentations will focus on a hot topic:

Digital Pathology:

Insights on scientific and regulatory aspects

The presentations will be held in English. Registration is open until 7th May 2018 and the SFPT will be happy to welcome sister societies colleagues.



Looking forward to seeing you in the meeting

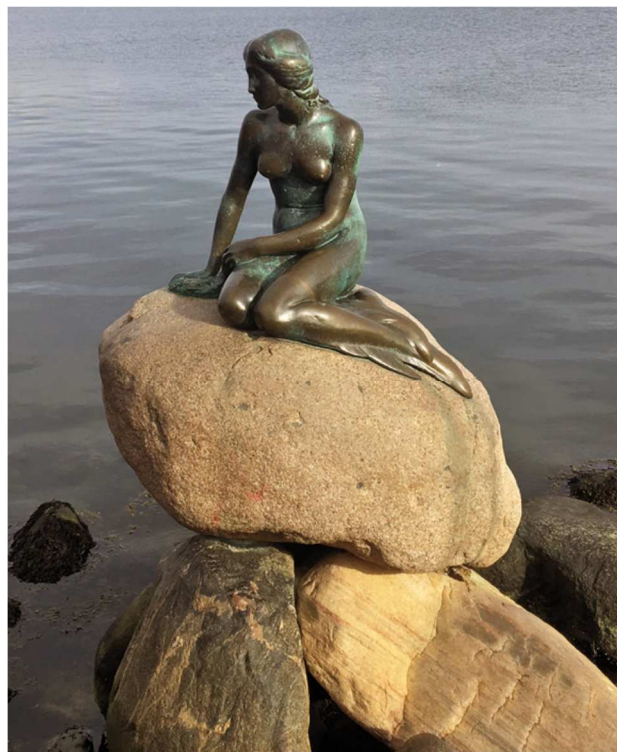
Beatrice Gauthier

beatrice.gauthier@galderma.com

**2018 ESTP Annual Congress
in Copenhagen this September**

Dear ESTP Members

This is a reminder that the registration site for the ESTP 2018 Annual Congress from September 11-14th in Copenhagen, Denmark is now open!



We have recruited over 20 world-leading experts to speak on the theme of the meeting:

Adipose Tissue and Central Nervous System in Metabolic and Neurodegenerative Diseases including Biology, Toxicologic Pathology and Investigative Techniques

<https://www.eurotoxpath.org/meetings/index.php?id=congress2018>

We especially would like to point out that the deadline for submitting abstracts for case presentations from the podium or posters is May 31, 2018. The deadline for the early registration at a discounted price is June 30, 2018.

Don't forget there is also a stand-alone, half-day workshop Nonclinical Safety Assessment of Stem Cell Based Therapies co-sponsored by the International Academy of Toxicologic Pathology (IATP) and ESTP which will emphasize the nonclinical development strategies and challenges of this emerging therapeutic modality.

September is a delightful time to experience the end of the Scandinavian summer and we hope to see you soon in the "hygge" city of Copenhagen.

Best regards,
Local Hosts and Chairs of the Scientific Organizing Committee

Ingrid Sjögren

InSj@NovoNordisk.com

Kevin Keane

KnKe@NovoNordisk.com

Mikala Skydsgaard

MqSy@NovoNordisk.com

Upcoming Elections for the ESTP Executive Committee

Dear ESTP Members

I would like to remind you that, according to our constitution, elections for the ESTP Executive Committee (EC) will be conducted soon by means of an electronic voting procedure.

You had already been asked to nominate candidates for these EC positions.

The voting period will start soon, presumably on May 9th, 2018, and will be announced to the membership by email.

At our next Annual General Assembly in Copenhagen, we will endorse the results of the elections.

Best regards

Gabriele Pohlmeier-Esch

ESTP Secretary

gabriele.pohlmeier-esch@boehringer-ingenelheim.com