

Biotechnology Specialty Section

Summer 2024 Newsletter

SOT | Society of
Toxicology



Jason Pinkstaff
PhD, DABT, ERT



President's Message

Dear BTSS members,

Thank you for this great opportunity to serve as the Biotechnology Specialty Section (BTSS) President for the 2024–2025 term.

As we transition to a new term, I would like to congratulate the BTSS Executive Committee and membership on a successful 2023–2024 term and promise to work to continue this momentum into the 2024–2025 term. At the SOT Annual Meeting in Salt Lake City, Utah, BTSS sponsored three sessions and co-sponsored a networking event for students and early career professionals. There was also a great turnout for the BTSS reception which featured a short presentation by Dr. Katy Frasier on cell therapies. Furthermore, at this year's BTSS reception, we presented our annual awards to well-deserving recipients. A special thank you to our outgoing president, Tod Harper for his tremendous leadership during the 2023–2024 term. I also want to thank our other departing officers for their great contribution to BTSS over the past year: Nicola Stagg (Past President), Rene Vinas (Secretary/Treasurer), and Jessica Sims (Senior Councilor).

The 2024–2025 Executive Committee team members, Ed Dere (Vice President), Herve Lebrech (Vice President-Elect), Ashwini Phadnis (Secretary/Treasurer), Adhithiya Charli (Senior Councilor), Lauren Lewis (Junior Councilor), Yunjia Lai (Postdoctoral Representative), and Rajat Gupta (Graduate Student Representative) and I are very excited to continue the important mission of BTSS. In the 2024–2025 term we will:

- 1) Encourage members to recognize their accomplishments (to be highlighted in newsletters) and to nominate members for annual BTSS awards;
- 2) Continue mentoring and to provide guidance and support for scientists seeking to initiate a career in the biotechnology field;
- 3) Deliver no less than two scientific webinars on diverse biotechnology topics; and
- 4) Prepare for the 2025 SOT Annual Meeting in Orlando, Florida! We hope to see everyone there.

Best Regards,
Jason Pinkstaff, PhD, DABT, ERT, RAC
President, Biotechnology Specialty Section

Volume 15, Issue 1

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Newsletter Editors:

Yunjia Lai
Rajat Gupta

Interested in contributing to future BTSS newsletters? We would love your input! Please contact Yunjia Lai at yl5001@cumc.columbia.edu or Rajat Gupta at rajatgupta@ucla.edu

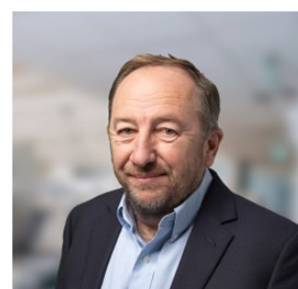
BTSS Executive Board 2024-2025



President
*Jason Pinkstaff,
PhD, DABT, ERT
Pfizer*



Vice President
*Edward Dere,
PhD, DABT
Genentech*



Vice President-Elect
*Hervé Lebrech,
PharmD, PhD, DABT
Sonoma Biotherapeutics*



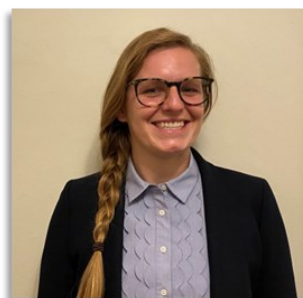
Past President
*Tod Harper,
PhD, DABT
Amgen*



Secretary/Treasurer
*Ashwini Phadnis Moghe,
PhD, DABT
Boehringer Ingelheim*



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*Adhithiya Charli,
PhD
Biogen*



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*Yunjia Lai,
PhD
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Grad Student Rep
*Rajat Gupta, MS
PhD Candidate
University of California, Los Angeles*



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Exiting 2023-2024 BTSS Officers

The BTSS-sponsored events at the 63rd Society of Toxicology Annual Meeting held in Salt Lake City, Utah, were a great success.

We would like to thank our incredible team from the **2023-2024** year!

- **President:** Tod Harper
- **Vice President:** Jason Pinkstaff
- **Vice President-Elect:** Edward Dere
- **Secretary/Treasurer:** René Viñas
- **Senior Councilor:** Jessica Sims
- **Junior Councilor:** Adhithiya Charli
- **Postdoc Representative:** Yunjia Lai
- **Grad Student Representative:** Rajat Gupta

Renew Your Membership

Membership dues and donations are important sources of funding that are critical to support the BTSS mentoring activities, awards, workshops, and other activities to keep our Specialty Section active. If you have not already done so, please **renew your BTSS membership ASAP**. In addition to funding our activities, it will ensure that you are able to vote in the upcoming BTSS officer election and that you receive our emails.

Donations & Finances

On behalf of the BTSS Executive Board and members, we would like to thank the recent generous donations from Pfizer, Amgen, and LTZ Therapeutics to our Specialty Section.



LTZ
Therapeutics

If you or your organization is able to [make a financial contribution](#), it will help ensure BTSS representation within SOT for years to come.

Please reach out to our Treasurer, Dr. Ashwini Phadnis Moghe, for more info:
ashiwini.phadnis_moghe@boehringer-ingenheim.com

BTSS Financials:

Net assets as of May 2024: \$11,677

Award Recipients of SOT 2024

2024 BTSS Award Winners



**Candace Longoria,
PhD, CSCS**

Rutgers, State University of New Jersey

Battelle Postdoctoral Award



Rajat Gupta

University of California, Los Angeles

Student Achievement Award



**Leslie Valencia,
PhD**

Genentech

Best Paper Award



Punnap Saha

University of California, Irvine

Student Achievement Award



No Candidates Applied

**Boehringer
Ingelheim Award for
Excellence in
Biotherapeutic Safety**



**Natasha Caitlin,
PhD, DABT**

Pfizer

Young Investigator Award

Introducing BTSS Awards

2025 BTSS Awards

Award deadlines are approaching! Please visit the [BTSS website](#) to nominate and apply.

1. BTSS Battelle Postdoctoral Award in Biotechnology

This award will recognize a postdoctoral researcher whose work, as demonstrated in a poster or oral presentation at the SOT Annual Meeting, best exemplifies the mission of BTSS. A plaque of recognition and monetary prize (\$500) will be awarded to the winning nominee.

2. BTSS Best Paper Award

A monetary prize will be awarded to the authors of the best paper in the area of biotechnology, published in a peer-reviewed scientific journal.

3. BTSS Boehringer Ingelheim Award for Excellence in Biotherapeutic Safety

This award is intended to encourage research and training of graduate students and postdoctoral researchers in nonclinical safety sciences as applied to biotherapeutic products. Examples include (but are not limited to): biotechnology-derived proteins; gene therapies; vaccines; blood-derived products; imaging agents; molecular diagnostics; genetically-modified organics (crops, foods, and animals); biodegradable plastics; biofuels; biodefense; and bioremediation. The award recipient will be eligible for reimbursement of up to \$2,000 of expenses related to attendance at a biotechnology nonclinical safety-related conference or training course.

4. BTSS Career Achievement in Biotechnology Award

An engraved plaque will be awarded to a Senior Investigator whose body of work represents an outstanding achievement or contribution in the evolution of scientifically relevant approaches to and interpretation of toxicological aspects that are unique to biotechnology-derived products.

5. BTSS Outstanding Young Investigator Award

A monetary prize will be awarded to the Young Investigator who has made a significant contribution to the evolution of scientifically relevant approaches to and interpretation of toxicology aspects unique to biotechnology-derived products. The recipient must have less than 10 years of experience since obtaining his/her highest-earned degree. This award is NOT LIMITED only to those in academia.

6. BTSS Student Achievement Award

A monetary stipend will be awarded to two graduate students (\$500 each) who are presenting a poster at the SOT Annual Meeting and whose work exemplifies the mission of the Biotechnology Specialty Section.

Determination of all awardees will be by the members of the BTSS Award Committee.

Society of Toxicology 2025

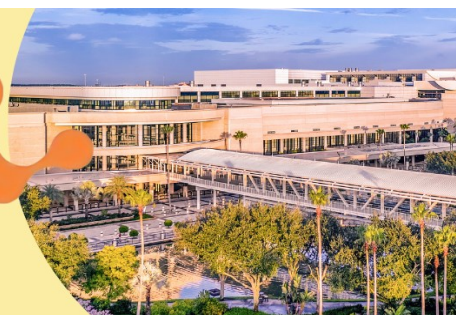


The 64th Society of Toxicology Annual Meeting & ToxExpo is coming up! Please be sure to mark your calendars:

- Early Bird [Registration](#) Deadline: January 24, 2025
- Standard [Registration](#) Deadline: February 21, 2025
- Final [Registration](#) Period: After February 21, 2025



Brings Toxicology to Orlando in 2025!

The image shows the SOT logo (S, asterisk, T) in blue on a yellow background. To the right of the 'T' is a stylized orange and blue graphic resembling a chemical structure or a network. Below the logo, the text 'Brings Toxicology to Orlando in 2025!' is written in orange.

Upcoming BTSS Webinar

Beyond MABEL: An integrative approach to first-in-human dose selection of immunomodulators by the Health and Environmental Sciences Institute (HESI) Immuno-Safety Technical Committee (ITC)

Administration of a new drug candidate in a first-in-human (FIH) clinical trial is a particularly challenging phase in drug development and is especially true for immunomodulators, which are a diverse and complex class of drugs with a broad range of mechanisms of action and associated safety risks. Risk is generally greater for immunostimulators, in which safety concerns are associated with acute toxicity, compared to immunosuppressors, where the risks are related to chronic effects. Current methodologies for FIH dose selection for immunostimulators are focused primarily on identifying the minimum anticipated biological effect level (MABEL), which has often resulted in sub-therapeutic doses, leading to long and costly escalation phases. The Health and Environmental Sciences Institute (HESI) Immuno-Safety Technical Committee (ITC) organized a project to address this issue through two complementary approaches: (i) an industry survey on FIH dose selection strategies and (ii) detailed case studies for immunomodulators in oncology and non-oncology indications. Key messages from the industry survey responses highlighted a preference toward more dynamic PK/PD approaches as *in vitro* assays are seemingly not representative of true physiological conditions for immunomodulators. These principles are highlighted in case studies. To address the above themes, we have proposed a revised decision tree, which expands on the guidance by the IQ MABEL Working Group (Leach et al. 2021). This approach facilitates a more refined recommendation of FIH dose selection for immunomodulators, allowing for a nuanced consideration of their mechanisms of action (MOAs) and the associated risk to benefit ratio, among other factors.

- October 16th 2024 from 12:00 Noon to 1:00 PM (US ET)
- Registration required: Click [here](#) to receive Zoom Link
- Click [here](#) for more on the SOT Calendar of Events

Member Spotlight Section

The BTSS leadership would like to solicit member accomplishments to highlight in our future newsletters! We are trying out a new way to engage with and recognize our members hard work and achievements within the biotechnology field. Please be on the lookout for future calls to spotlight our outstanding BTSS membership!

<https://www.toxicology.org/groups/ss/btss/join.asp>