

PDA Journal of Pharmaceutical Science and Technology



PDA/FDA Virus & TSE Safety Conference

Kurt Brorson

PDA J Pharm Sci and Tech **2016**, 70 93

Access the most recent version at doi:[10.5731/pdajpst.2016.001095](https://doi.org/10.5731/pdajpst.2016.001095)

EDITORIAL

PDA/FDA Virus & TSE Safety Conference

In this issue, we present a summary of the 2015 PDA Virus and TSE Safety conference held in Cascais, Portugal. Starting in the mid-1990s, this conference series has discussed the state-of-the-art regarding regulatory aspects, virus testing and detection, virus reduction by the manufacturing process, and risk assessment and mitigation for viral safety of biotech and plasma-derived medicines. The risk of contamination of biologicals/biopharmaceuticals by TSE agents and how to mitigate this risk is traditionally discussed in the final day of the PDA/FDA Virus & TSE Safety Conference. The yearly conference alternated between Europe and the United States and has been an excellent networking opportunity for dialogue and sharing experience between industry—manufacturers of biotherapies/contract research organisations—and health authority representatives.

The Program Committee all this time has been led or co-led by Dr. Hannelore Willkommen, first as a representative of the Paul Erlich Institut and later as an independent consultant. I have had the immense privilege to work with her as co-chair when the meeting was held every other year in the United States since 2001. The meeting under her stewardship has always been packed with important scientific information related to virus safety and intense discussions between world-class subject matter experts. It is no coincidence that the field of virus safety has moved from being a black box in the 1990s to a well understood, almost an

engineering, discipline in 2016; Hannelore and this conference series was instrumental. This provides the public great confidence in the safety of the biotech medicines they need for urgent disease such as cancer and inflammatory conditions.

With these accomplishments as a background, Hannelore is retiring and will be saying bon voyage to the conference series. With the structure set in place by Hannelore, the conference is positioned for success year after year going forward. The committee's plan is to take a one year breather and then move the conference series to a three year cycle starting in 2017: year one in the US, year two in Europe, and then a hiatus in year three. Johannes Blumel from the Paul Erlich Institut, a veteran of the program committee, will be the new EU co-chair.

In addition to serving with Hannelore as co-chair of the PDA Virus and TSE Safety Forum, I have also had the honour of serving as an associate editor of the *PDA Journal* since 2009. Because I now must focus on new roles and responsibilities at the FDA, it is time for me to pass the baton to a new associate editor. I've learned a lot about different aspects of pharmaceutical science as an associate editor and really appreciate the opportunities the PDA has given me, including this one. The *PDA Journal* is now a very strong journal because of the leadership of our Editor-in-Chief, Dr. Govind Rao; the Journal is also poised for success year after year going forward.

doi: 10.5731/pdajpst.2016.001095

Kurt Brorson
Office of Biotechnology Products, CDER

PDA Journal of Pharmaceutical Science and Technology



An Authorized User of the electronic PDA Journal of Pharmaceutical Science and Technology (the PDA Journal) is a PDA Member in good standing. Authorized Users are permitted to do the following:

- Search and view the content of the PDA Journal
- Download a single article for the individual use of an Authorized User
- Assemble and distribute links that point to the PDA Journal
- Print individual articles from the PDA Journal for the individual use of an Authorized User
- Make a reasonable number of photocopies of a printed article for the individual use of an Authorized User or for the use by or distribution to other Authorized Users

Authorized Users are not permitted to do the following:

- Except as mentioned above, allow anyone other than an Authorized User to use or access the PDA Journal
- Display or otherwise make any information from the PDA Journal available to anyone other than an Authorized User
- Post articles from the PDA Journal on Web sites, either available on the Internet or an Intranet, or in any form of online publications
- Transmit electronically, via e-mail or any other file transfer protocols, any portion of the PDA Journal
- Create a searchable archive of any portion of the PDA Journal
- Use robots or intelligent agents to access, search and/or systematically download any portion of the PDA Journal
- Sell, re-sell, rent, lease, license, sublicense, assign or otherwise transfer the use of the PDA Journal or its content
- Use or copy the PDA Journal for document delivery, fee-for-service use, or bulk reproduction or distribution of materials in any form, or any substantially similar commercial purpose
- Alter, modify, repackage or adapt any portion of the PDA Journal
- Make any edits or derivative works with respect to any portion of the PDA Journal including any text or graphics
- Delete or remove in any form or format, including on a printed article or photocopy, any copyright information or notice contained in the PDA Journal