



PDA ISRAEL CHAPTER

Annual Meeting

Feb 13, 2025

President's Notes
Karin Baer



Who are we?

- The Israel Chapter of PDA is a non-profit organization founded in 1997.
- The Chapter's goal is to promote scientific and regulatory knowledge within the pharmaceutical community in Israel
- bringing together pharmaceutical manufacturers, suppliers, academy researchers, Consultants, and regulatory officials of the Israeli Ministry of Health
- to exchange regulatory and scientific information focused on quality of pharmaceutical products
 - latest regulatory guidance updates
 - Pharmacopoeia updates
 - FDA and other regulatory bodies new guidances

This goal is achieved through :

- seminars,
- **webinars,**
- discussion groups,
- task forces,
- Courses and conferences
- Etc.

- The organization is managed by an elected Executive Committee, Members of the Executive Committee, as well as lecturers in the organization events, all are **volunteers.**

- Different decisions were taken:
 - Become independent
 - Have our own mailing list
 - Upgrade the Website
 - Work directly with the graphic designer
 - Organize the webinars by ourselves
 - Work with production company per event
 - Sponsors to support and cover expenses as much as possible



- Since.....
- 5 Webinars with more than 150 participants each
- 2 Seminars -very succesfull!

.....And today the Annual meeting with approximately 150 participants!!!

- Basic fundamental GMP issues continue to be seen in FDA across the industry, despite the tools, technology, resources, policy, guidance documents, history of observations, warning letters and enforcement, training and industry groups.
- FDA's top Ten issues cited in 483s have not really changed over 20+years; ranking have shifted up or down, but it is still the same things!
- Similarly, Data Integrity [DI] is not a new concept. As the FDA said [Dr. Cavazonni] get away from paper!!
- “Reading an SOP is not a training” Alonza Cruse



PDA-FDA Meeting Washington Sept 2024

Some take aways....

- Have we forgotten about the patient? Have we forgotten who the patient is? Do we not realize we are the patient?
- “Cost of Quality” why do we not speak of cost of HR? The cost of SC? Of technical Services?
- Leadership sets the ton, is it the determiner of success?
- Leadership is responsible for issues -whether they know it or not!!
- Training, training, training. Designing the organization to be effective over the product lifecycle should be the goal, not just for the next quarter’s result!!
- FDA encourages to reach out to them, to talk, to ensure one understands their comments, observations!

FDA reorganizations:

1-ORABecomes OII

Michael Rogers explained the Office of Regulatory Affairs (ORA), responsible for conducting field inspections of all FDA-regulated facilities, will be renamed the Office of Inspections and Investigations (OII). Current ORA compliance officers will report to the compliance functions within the centers for biologics, drugs, devices, food safety and veterinary medicine. The reorganization takes effect on 1 October 2024.

The new OII will focus on inspections, investigations and imports as its core mission.

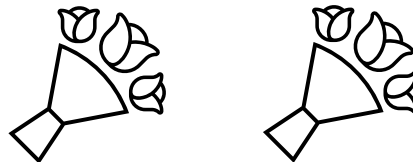


2-creation of Office of Enterprise Transformation

Another key aspect of the reorganization is the creation of the Office of Enterprise Transformation within the Office of the Commissioner to focus on key information technology transformation projects across the FDA.

Arnan Ben David has been elected to the PDA Journal Editorial Board (PDAJEB).

➤ first Israeli to be elected to this position



➤ Additionally, he is part of the task force responsible for updating Technical Report No. 3 - Validation of Dry Heat Processes Used for Depyrogenation and Sterilization.

➤ has proposed several significant updates aimed at shortening depyrogenation and sterilization cycles and lowering operating temperatures, which could result in substantial cost and energy savings and will allow facilities to use their existing equipment at much higher capacities.

The proposals are currently under review by the PDA Scientific Advisory Board (PDASAB.....)

כל הכבוד!!!





Thank you