

SPARK EUROPE WEBINAR SERIES 2021

Wednesdays
at 16.00 CET

SPARK
TEL AVIV



SPARK Europe
Education

SPARK TEL AVIV Educational Meeting

**Drugs – from discovery to market:
regulatory strategy, submission
package and marketing approval**
Sara Blumenstein Ph.D.

Wednesday, March 2nd, 2022 at 4–5 pm (CET) 5–6 pm (Jerusalem) | Online Webinar

- **Type of drugs and biologics:** Describing the different drugs and biologics regulated by FDA and EMA
- **Regulatory Pathways:** Summarizing the various regulatory pathways to approve drugs and biologics in the US and Europe
- **Drug development process:** Describing the drug development stages from discovery to quality, pre-clinical and clinical development to marketing approval
- **Additional topics:** Regulatory strategy, interactions with the regulator, expedited Programs
- **Examples:** Review of drugs and biologics examples approved by the FDA and EMA in the recent years

Dr. Sara Blumenstein is the Pharma and Biotechnology Regulatory Section



Manager at Gsap providing regulatory support to pharma and biotechnology firms in the development of drugs and biologics. Dr. Blumenstein has over 20 years' experience in Biotechnology and cell therapy fields. Sara has managed the R&D and QC groups at ProChon Biotech and was responsible for improving a cell therapy cartilage repair product marketed in Israel which was also undergoing clinical study under IND. Sara was also a project manager in KSC labs and designed an immunotherapy product based on mesenchymal stem cells. From 2014 to 2016 she served as a quality and regulatory consultant at Gsap and since 2016 Sara serves as the Pharma Regulation section manager at Gsap. She received her B.Sc. with distinction from Ben Gurion University, Beer-Sheva, M.Sc and Ph.D from the Weizmann Institute of Science, Rehovot in the field of biochemistry, and was a Post-Doctoral fellow in the field of human DNA repair at the Weizmann Institute of Science.



Online via Zoom – Please register [here!](#)

The webinar is open to all interested people from SPARK associated organizations. Registration to the webinar is required (Registration link: <https://tau-ac-il.zoom.us/meeting/register/tZ0udumqrDsqGdUs0pTkC11p9cWDkFwOfwTg>)

After registering, you will receive a confirmation email containing information about joining the meeting.

The organizers reserve the right to change and update the topics and speakers

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