



Bio-Med Entrepreneur | CEO | QA/RA |
R&D or Biz-Dev manager ?



- ✓ Want to establish FDA/IMOH/EMA Certified lab?
- ✓ Wondering which technology is best for your needs and budget?
- ✓ Need QA/Engineering/R&D retainer services?
- ✓ Need to prepare for external audits from the FDA, EMA or IMOH?
- ✓ Want to establish a GMP/GLP/ISO 17025 quality system?
- ✓ Want to register your product in the FDA/CE?

We will be happy to offer you our consulting services

About us

Bio-Chem Ltd. (2007) is a leading **global consulting company** in the Bio-Med industry. Based in Israel and working worldwide, Bio-Chem has been specializing for **more than a decade** in multidisciplinary consulting for the pharmaceutical, biotechnology and medical devices sectors, we have the **expertise and know-how to get the job done.**

Bio-Chem fully commits to provide its clients with **high-standard service.** It has proven capabilities in **managing complex and multi-disciplinary projects** while adapting solutions to the **unique needs of every client**, with maximum flexibility.

Bio-Chem has a strong record of accomplishment and more than 500 clients worldwide, of which **90% are returning customers.**

Our consulting services

- Scientific/business introduction pager
- Business plan
- CMC writing
- Investment & funding strategy
- Product market analysis
- Development and commercialization strategy
- Potential partnerships consultancy and support
- Documentation procedures and training based on GLP
- Clinical risk assessment, risk management and GCP
- Applications to the chief scientist funding program
- Choosing outsourced and in-house activities
- Global regulatory strategy
- Laboratory quality system
- Scientific trials, studies plan and protocols
- Preparations and training towards due-diligence
- Reliable & robust trials set up
- Patents application support
- Clinical trials protocols writing
- Clinical trials support
- Laboratory & clean room design
- Laboratory equipment and system
- Testing & qualifications
- New Bio-Pharma process development
- Employees training
- Preparations towards external regulatory inspections
- Process engineering, design & scale-ups
- GMP/FDA/Eu. compliant clinical trials
- Aseptic and sterile manufacturing
- Drug substance and drug product stability

What do our customers think

"Eran Yona and Bio-Chem led Tiltan Pharma in the area of production and validation for several formulations over a number of years. They were very professional and instrumental in the preparation for production of clinical lots as well as in the actual production work in the clean rooms. Eran did it all with a smile, even after long (sometimes very long) hours of work and when facing non-trivial process challenges."

Dan Goldstaub | Clinical Research Director, MSD •

"Following the completion of a 4 year mega-scale project to develop a new product, I had the opportunity to work with Eran and the Bio-Chem team on the design control file for the new product. Eran led us through the full process with very clear and coherent guidance. Eran and the team showed us the way through the mass of documentation collected throughout the whole project, from initiating the new product requirements, to the completion of the product validation, to the final delivery of the manufacturing line to the plant operation facilities.

I warmly recommend Eran as a skilled professional in the field of compliance and regulatory documentation."

David Molcho | R&D Manager, Albaad-Fem •

"I enjoyed working with Eran and Bio-Chem.

They performed excellent professional work, while keeping to the study plans defined at the start of the various projects, submitted the project deliverables on time, for a large number of manufacturing process engineering and validation projects."

Dr. Shimon Amsalem | Chief Scientific Officer, Pharma •

"We used Bio-Chem for a GMP inspection at one of our TEVA manufacturing sites.

The auditor was professional and experienced.

The GMP inspection was performed in a thorough and businesslike manner. Thank you very much!"

Dr. Gali Guzikevich | Sr. Director GMP QA, Innovative R&D, Teva •

"Eran Yona and Bio-Chem have many years of experience in the pharma industry, from the design stages, construction of production sites, and validation and manufacturing to GMP standard. In all our interactions with Bio-Chem, the objectives were met and I was very satisfied with their recommendations and practical suggestions.

Eran assisted the companies I was involved with to overcome manufacturing and regulatory obstacles."

Dr. Adrian Harel | CEO, Medicortex Finland Oy •

"To the Bio-Chem team: Working with you was professional and businesslike, as well as engaging and pleasant.

Thank you for your support throughout the period we worked together, and we are happy to recommend Bio-Chem as an excellent and professional consulting company."

Dr. Yael Koresh | VP QA, Minipac •



"Many thanks to Eran Yona and the Bio-Chem staff. The company was invited on short notice to our new facility to support an FDA inspection. The job was done professionally while meeting very tight and rigid deadlines. We worked with a professional team with lots of patience and courtesy. I am happy to recommend Bio-Chem as an excellent and professional consulting company."

Simha Vazana | QA Manager, Phibro

From our clients list

OPKO
Biologics

FERRING
PHARMACEUTICALS

SGS

Bonus
BioGroup

TEVA

Yisum
Tel Aviv University Technology Transfer

KAMADA
High Quality Pharmaceuticals

Pluristem

DEPOMED

GILEAD
Creating Possible

sartorius

IBI

CollPlant
Pioneering Regenerative Medicine

MERCK

NeuroDerm

J&J



Eran Yona, B.Sc., MBA
Bio-Chem's founder & CEO

Over 20 years of multidisciplinary experience in the medical device and software industries.

"A successful project is a winning combination of 3 things: challenge, responsibility, and people."

To achieve your next challenge - contact us

Eran Yona
Founder and CEO

+972-(0)52-2777744

eran@bio-chem.co.il

Administration Manager

+972-(0)51-5001353

+972-(0)72-2337710

info@bio-chem.co.il

 **BioChem**

www.bio-chem.co.il