



E-Health service provider | Medical software developer |
Have a novel health cellular App ? |
Have a unique digital-health technology ?



- ✓ Want to register your medical software with FDA and obtain a CE mark?
- ✓ Want to establish ISO 13485 and 21 CFR 820 quality systems?
- ✓ Looking for the best FDA and CE regulatory strategy for your solution?
- ✓ Need support with GDPR, HIPAA and ISO 27001 regulations?
- ✓ Need to complete a Risk Assessment?
- ✓ Need Quality Assurance and ISMS services?

We will support and guide you from design to global final marketing approval



About us

Bio-Chem Ltd. (2007) is a **leading global** consultancy company in the **Bio-Med** and the **E-Health** industries.

Based in Israel and **working worldwide**, **Bio-Chem** has been specializing **for more than a decade** in multidisciplinary **consulting for the Medical Device**, Pharmaceutical and **Health** sectors.

With the advent of **digitalization, big data, and ML/AI developments**, similar changes are taking place in the health sector as well.

Bio-Chem is on the cutting edge of these changes and we are here to **support Hi-Tech technologies entering the Bio-Med industries**.

Bio-Chem is fully **committed** to a **high standard** of service, with **maximum flexibility** to accommodate client needs. We have a proven track record showing our capabilities in managing **complex and multi-disciplinary projects** while adapting solutions to the unique needs of each client.

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

Our consulting services

- Development & commercialization strategy
- Preparations toward regulatory inspections
- Quality System Regulation
- ISO 13485, ISO 13495, FDA 21 CFR 820
- ISO 14001, ISO 27001 & ISO 27799
- Global regulatory strategy
- DMR, DHF, technical file
- Product market analysis
- Software validation
- Pen testing
- Clinical trials & pathology
- Risk Assessment
- Health & Medical technologies
- Industry needs mapping
- Design Control
- HIPAA, SOC2, PHI & GDPR
- Regulatory policies
- Product submission to the FDA
- CE marking
- Hospitals & ER
- Data integrity
- Risk management
- Courses & training
- Verification & Validation (V&V)
- Physician & hospitalization consulting

What do our customers think

"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 •

"I am writing to recommend the services of Bio-Chem team members have been working with Teva Medical for 3 years as our consultants.

The professional knowledge, services and attention to detail of Bio-Chem helped keep our company on track during this challenging time.

I feel confident in recommending Bio-Chem's consulting services."

Doron Ravtal | Quality System Manager, Teva •

"I met Eran Yona and Bio-Chem when I was the GMP plant engineer at Sigma-Aldrich. Bio-Chem supplied GMP and validation consulting in preparation for an FDA inspection.

Eran and the team's work demonstrated their professionalism and commitment to the success of the audit, and they succeeded in achieving fruitful cooperation in the company in order to efficiently perform the required work during a relatively short time.

I have no doubt that many pharma and medical companies can gain value from Bio-Chem's services."

Hovav Amram | Plant Engineer Manager, Sigma-Aldrich •

"Eran Yona performed quality and GMP audits as well as supplier and subcontractor ISO 13485 audits in the framework of a suppliers qualification process our company performed.

We received from Eran and Bio-Chem team professional excellence, deep knowledge of cGMP and ISO, service orientation and a fast response to everything we needed.

The audit documentation reports were provided to us within a short time period. Questions that we raised were answered quickly and with a high level of detail and precision.

I would be happy to work with Eran Yona again in the future on any project that is needed."

Georgy Laskov | QP Zoetis •

"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 owner of Bio-Chem Engineering 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 regulation."

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

"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

PHILIPS

MEDISPEC

Medtronic

GILEAD
Creating Possible

Medinol
Ingenuity for life

emedgene

SGS

Valtech

West

fairtality

DEPOMED

MediLine

Yissum

Jaff

MEDIMOR

MediLine



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

Over 20 years of multidisciplinary experience in the pharmaceutical industry and R&D.

"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

