



CEO | QA | Engineering | R&D  
Operation | Validation manager ?



- ✓ Want to establish a facility that will be approved by the FDA and EMA?
- ✓ Wondering which technology is best for your needs?
- ✓ Need QA/Engineering/Validation retainer services?
- ✓ Need to prepare for external audits from the FDA, EMA or IMOH?
- ✓ Want to establish a GLP/GMP quality system?

**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 specialized for **more than a decade** in a multidisciplinary consulting for **pharmaceutical, biotechnology**, medical device, cosmetic and dietary supplement industries.

**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

- GxP & Quality Assurance
- New facilities design
- Manufacturing technology
- New product development
- ISO 27001, ISO 27799
- ISO 14001, ISO 17025, ISO 22000
- QP & QPPV services
- CMC file
- Verification & Validation
- Quality System
- Audits & inspections
- Data Integrity
- Process engineering
- Staff training & courses
- Validation & QA contracting
- Risk management
- Regulation & submissions
- Pre-audit readiness
- Courses & training
- EHS



## What do our customers think

"Eran Yona of Bio-Chem assisted Kamada with a cross-contamination risk assessment project. Eran led a comprehensive risk assessment in different departments at the plant, brought some special problems to our attention, and followed up to implement several GMP issue improvements. The entire assessment was very successfully completed within the defined timelines."

**Dr. Moshe White | QA Project Manager, Kamada •**

"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 •**

"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 not doubt that many pharma and medical companies can gain value from Bio-Chem's services."

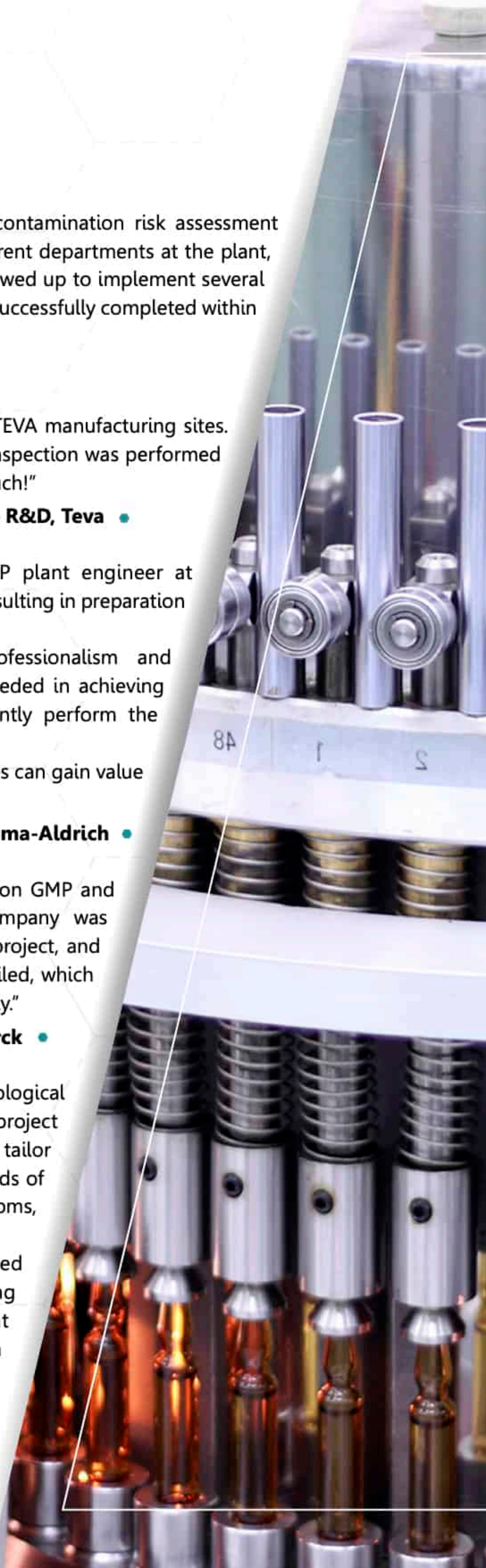
**Hovav Amram | GMP Plant Engineering Manager, Sigma-Aldrich •**

"Eran Yona and the Bio-Chem team consulted for Merck on GMP and Validations for an FDA regulatory inspection. The company was professional and service-oriented throughout the entire project, and all the documentation supplied was well written and detailed, which allowed us to complete the project on time and successfully."

**Inbal Kapry Barel | QA & Validation team leader, Merck •**

"I've worked with Bio-Chem for the last three years on a biological manufacturing process scale-up; this tech transfer project included commissioning, installation and qualification of tailor made equipment, which was built to meet the unique needs of the manufacturing process, building of ISO6 level clean rooms, validation and qualification of clean rooms.

Eran Yona and the Bio-Chem team were deeply involved in the project, particularly during engineering testing and qualification stages (commissioning), equipment validation for critical systems, and in the verification and validation processes.





They performed at a high level, and provided documentation in compliance with requirements for the system and the manufacturing processes of two types of sterile bio-pharmaceutical products, manufacturing processes, control systems and automation, for the critical control and automation programs and systems of the project.

It required active intervention and keeping to challenging and tight timeline, and in compliance with the regulations, done responsibly and within the limits of the schedule and budget."

**Yaki Sidis | Operation Manager, Johnson & Johnson •**

"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 professional excellence, deep knowledge of cGMP and ISO, service orientation and a fast response to everything 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 •**

## From our clients list



**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



[www.bio-chem.co.il](http://www.bio-chem.co.il)