



Medical Device CEO | QA | Engineering |  
R&D | Operation | V&V manager ?



- ✓ Want to establish a clean room based on FDA/ICH requirements?
- ✓ Want to register you device in the FDA/CE?
- ✓ Need QA/Engineering/Validation retainer services?
- ✓ Need to prepare for external audits from the FDA, NB or IMOH?
- ✓ Want to establish a ISO 13485/CFR 820 QMS?

**We will be happy to offer you our consulting services**

## About us

**Bio-Chem Ltd. (2007)** is a leading **global consultancy** company in the Bio-Med industry.

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

**Bio-Chem** is fully committed to its client and provides **high-standard service** with maximum flexibility.

It has proven capabilities in **managing complex and multi-disciplinary projects** while adapting solutions to the **unique needs of every client**.

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

## Our consulting services

- Quality Management System
- Quality System Regulation
- Quality System audits
- Medical Device design review
- ISO 13485, ISO 17025, ISO 14001
- ISO 27001 & ISO 27799
- DMR, DHF, DHR, Technical file
- Verification & Validation
- Medical Devices prototype
- Medical technologies
- Medical Device classification
- CE marking, MDD, MDR
- Combination products
- Cleaning & Sterilization
- Process Engineering
- Design Control
- Pre-audits readiness
- Risk Management
- Courses & Training
- Projects Management

## 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 •**

"Eran from Bio-Chem supported and counseled Medimor Ltd. during its transformation from an antenna manufacturing company named "Galtronics" to one of the leading subcontractors in Israel for development and production of medical equipment and medical devices.

Bio-Chem led the planning of the clean rooms at a higher-than-usual standard, supervised building and testing, and the qualification and validation of the clean rooms, system and equipment. The project included GMP training and for employees who did not originally have any background in the bio-med field. I enjoyed working with Eran and the Bio-Chem team.

They performed excellent, professional work and demonstrated high levels of commitment throughout the project, while keeping to the highest standards and accommodating the customer's requests and meeting their expectations.

Eran and Bio-Chem completed the project tasks at the required level of quality, while keeping to challenging and tight deadlines, with responsibility and within time and budget constraints."

**Ofer Sagi | Quality Engineering Manager, Johnson & Johnson •**

"Eran and Bio-Chem's team were instrumental in assisting the group I manage to complete qualification activities prior to, during and after important audits by regulatory bodies.

The Bio-Chem team was engaged mostly in cleaning processes validation, equipment validations and various utility validations, in order to achieve the desired progress and to improve the levels of quality we requested."

**Amitai Itzhakov | Process Technology Specialist, Omrix •**

"I was happy to work with Eran and the Bio-Chem team. They are reliable and very professional in the pharma and medical fields. They provide all our requirements under one roof, which simplifies the regulatory process.

With Eran's many years of experience, I was impressed by his ability to advise you on almost all aspects of biotech, pharmaceuticals and medical devices."

**Stephen Shattenstein | QA/RA, AB Dental •**

"The and Bio-Chem team and Eran Yona executed a large operational excellence and efficiency improvement



project at our pharmaceutical manufacturing and compounding facility.

The project included review and mapping of several critical, complex operational processes, most of which are performed in clean rooms.

The project was completed in the most professional manner by Bio-Chem, and demonstrated vast knowledge in the area of operational excellence and efficiency. The recommendations given by Bio-Chem were practical and greatly helped us to implement the efficiency process.

I very warmly recommend Eran Yona and the services of Bio-Chem."

**Guy Meirovich | Medical Risk Compliance, Neopharm •**

"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 •**

## From our clients list

**PHILIPS**

**MEDISPEC**

**Medtronic**

**GILEAD**  
Creating Possible

**Medinol**  
Ingenuity for life

**CollPlant**  
Powering Regenerative Medicine

**SGS**

**Valtech**

**West**

**COLBAR**  
LifeScience Ltd.

**DEPOMED**

**MediLine**

**Jaff**

**Yissum**  
Israel University Technology Transfer

**MEDIMOR**

**MediLine**



**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

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