Gsap
Integrative Impact
A Family of Companies

We help companies by accelerating the development of safe and effective pharmaceutical and medical device products for patients worldwide.

Gsap group: led by Dr. Sigalit Ariely-Portnoy for over a decade provides best in class, value-added services

OUR VALUES

Gsap group strives for:

Professionalism
With extensive knowledge, understanding, working skills and an integrative view on the biomedical arena.

Cooperation
Working together with our customers as partners on their journey.

Responsibility
We are committed to the solution we offer.

Enthusiasm
We love our work and care about the outcome.

Management
We help our customers manage all activities for early development to marketing approval.

Integrative Impact
Our values and rich experience in multiple professional domains, enables us to have a significant impact, ensuring that our customers meet their goals.

OUR CUSTOMERS

Gsap group provides services to:

- A variety of Israeli and international customers
- Large pharma and medical devices corporations
- Product Manufacturers
- Small and medium-sized companies
- Entrepreneurs & VCs
- Start-ups
- Academics and universities
- Hospitals and medical centers
- Technological incubators and accelerators

OUR EXPERTS

Gsap group experts are knowledgeable, enthusiastic and highly experienced in the industry

Curiosity, self-learning, flexibility and management skills are our most valuable qualities

Many of our experts hold Master and Ph.D degrees

Prior to joining Gsap, our employees have occupied key positions in the pharmaceutical, medical device and biotechnology industries

Since the foundation of the company, the team has gained experience in several hundreds of industrial projects

INDUSTRIES

- Medical Devices
- Pharmaceutical *(including biotechnology)*
- Advanced Therapies *(Cell therapies and Immunotherapy)*
- Medical Cannabis
- Healthcare *(hospitals and medical centers)*

Gsap Integrative Impact

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OUR SERVICES

Gsap group provides a variety of services that enable our customers to have, in one place, all they need to bring their product from concept to reality. These services include:

QUALITY

- Quality Culture implementation
- QMS procedures
- Training
- Internal Audits
- Electronic QMS (e-QMS)
- Total quality management services
- Design controls
- Risk management
- Supplier controls
- GMP
- Production controls
- Statistical techniques
- Preparations for 3rd party audits

CLINICAL

- End to End CRO services
- Clinical study design and planning
- Protocol and study document preparation
- Feasibility and sites identification
- Regulatory submissions and contracts
- Full clinical study management and execution
- Monitoring & EDC services
- Biostatistics
- Interim and final reports preparation

PHARMACY

- Certified Qualified Person
- Batch release services
- Drug management

TRAINING

- Communities and forums
- Courses and seminars
- Internal organizational training
- Online courses and webinars

REGULATION

- Regulatory strategy
- Regulatory package preparation and submission
- Communication with regulatory authorities such as FDA/EMA and Israeli Ministry of Health (MOH)
- Product verification and validation activities
- Management and project support from concept through to regulatory approvals

ENGINEERING, VALIDATION, CALIBRATION

- Project Management
- Validation life-cycle
- Facility Design
- Clean-room validation
- Systems & Equipment Qualification Process validation
- TMV
- Gap analysis
- Temperature Mapping
- ISO 17025 Calibration
- CSV

PRE CLINICAL

- Preclinical safety and efficacy study design to support clinical studies and regulatory submissions
- Gap analysis
- Study design review
- Study protocol and report preparation
- Monitoring studies at the selected CRO

GRANT & TECHNICAL WRITING

- Guidance on product development strategy
- Consultation on grant selection
- Assessment of grant eligibility
- Pre and full proposals preparation
- Budgeting, competitive environment and sales projections
- Investor presentations
- Technical writing

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Since 2009, Gsap is highly involved in the biomed industry. Our level of expertise, our values and reputation ensure Gsap's strong presence in different segments of this industry.

ALMOND®
keeps you up to date

Almond is an electronic tool for managing your company's QMS while ensuring compliance with regulatory requirements, including 21CFR Part 11 for electronic records & signatures.

Almond was established after many years consulting and accompanying the development process for numerous biomed with Gsap.

SE

SE Pharma provides Validation, Calibration and temperature monitoring along the supply chain of medicines and medical devices. Our clients enjoy the highest levels of professional services, quality standards and hands-on experience. Accredited by ISRAC for ISO/IEC 17025:2017.

Gstudy

Innovative center for training and learning for Pharmaceutical, Advanced Cell and Gene Therapy, Medical Device and Medical Cannabis Industries.

The center is based on knowledge sharing between participants and the professional knowledge of our best experts. Our goal is to promote and improve the professional excellence of employees in the medical industry worldwide.

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