



Blue Pharma Engineering Group Consultancy

Experience is very valuable,
we are ready to share and
progress together !

www.bpegconsultancy.com



BPEG Danışmanlık Tic. Ltd. Şti.
(BPEG Consultancy Trade Limited Company)
Blue Pharma Engineering Group

ABOUT US

Istanbul, TURKEY

Mission

To present experiences in the best way for the benefit of the industry, to share them together and to keep them alive wherever they are needed

Vision

To create awareness and added value in the most efficient way with domestic and international activities, to be a leader in this regard

Activities

Contractor, Greenfield Project, Production, Quality Assurance, Qualification & Validation, Project Management, Machine Design, Training, Audit, Agency

MANAGING DIRECTOR



Mr. Deniz ALKANAT
Managing Director

Contact

- +90 530 378 5443
- alkanat.deniz@bpegconsultancy.com
- <http://www.linkedin.com/in/bsc-chem-eng-deniz-alkanat-b4831119>
- <https://www.linkedin.com/company/bpeg-consultancy-trade-limited-company/>

Education

- Computer Science (Software & Hardware)
Tuzla Technical High School-TÜRKİYE
- Chemical Engineering, BSc
(Pharmaceutical Production Technologies)
Istanbul University-TÜRKİYE

Experience

~ 27 Years professional working life

2024 - : BPEG Consultancy Trade Limited Company (Managing Director)

2019 - 2024 : World Medicine Pharmaceutical – Tekirdağ/TÜRKİYE (Factory Director)

2013 - 2019 : Onko Koçsel Pharmaceutical - Kocaeli/TÜRKİYE (Production Group Manager, Factory Director)

2010 - 2013 : Deva Pharmaceutical - Kocaeli/TÜRKİYE (Production Manager, Vice Factory Director)

2006 - 2010 : Sanovel Pharmaceutical – İstanbul/TÜRKİYE (Production Chief)

2003 - 2006 : İdol Pharmaceutical – İstanbul/TÜRKİYE (Quality Assurance Chief, also Qualification & Validation)

2002 - 2003 : Fako Pharmaceutical API Site – İstanbul/TÜRKİYE (Production Chief)

1998 - 2001 : İdol Pharmaceutical – İstanbul/TÜRKİYE (Production Chief)

Skills

Production, Quality Assurance, Qualification-Validation, Project Management, Greenfield Project, Training, Audit

Members

- TSE-ISO Main Delegate, Cleanroom Technologies Society, Cleanroom News Adviser Committee, TMMOB Chemical
- Engineer Chamber, Turkish Standard Institute, ISO 14644/Technical Committee 209/WG 11

FIELD of ACTIVITY

- Contractor & Project Management
- Machinery & Equipment
- Design & Cleanroom
- Validation & Qualification
- Process & Operation
- Audit & Review
- Personnel & Training
- Budget & Cost
- Agency



CONTRACTOR & PROJECT MANAGEMENT



Design of Area and Process

- Operational Compliance
- cGMP(Good Manufacturing Practise) Compliance
- Product Specific Compatibility

Investment Feasibility

- New Facility Feasibility; CapEx, OpEx
- Current Facility Feasibility; Operational and Technical Analysis

Management

- Following and Inspection of ;
 - Factory Installation
 - Factory Revision
- Project Management

CONSTRUCTOR & PROJECT MANAGAMENT



Specific Technology and Operations

- **Oncology / High Potent Product Manufacturing**
 - Sterile Injectable (vial, ampoule, prefilled syringe, cartridge)
 - Non-Sterile Liquid (suspension, solution)
 - Solid (capsule, tablet, powder)
- **BFS Product Manufacturing**
 - Sterile Liquid (eye drop, inhaler)
 - Sterile Injectable (IV solution, ampoule)
- **Hormone / Steroid Product Manufacturing**
 - Sterile Liquid (eye drop)
 - Sterile Injectable (vial, ampoule, prefilled syringe, cartridge)
 - Non-Sterile Liquid (suspension, solution, nasal)
 - Solid (capsule, tablet, powder)
- **Inhaler Product Manufacturing**
 - Sterile Liquid (suspension, solution) & Solid (capsule, powder)



MACHINERY & EQUIPMENT

Technical Support and Analysis

- Needs - Capacity Analysis
- Single Machine Technical Analysis
- Line Technical Analysis
- Auxiliary Equipment
- Cleanroom Environment Monitoring System
 - Airborn Particle (non viable)
 - Air Sampling (viable microorganism)

Machine Design Optimization

- Operational Compliance
- cGMP Compliance
- Product Specific Compatibility

Machinery and Equipment Purchase Support

- Holding Technical Meeting
- Evaluation Machine and Equipment
- Attendance Commercial Meeting

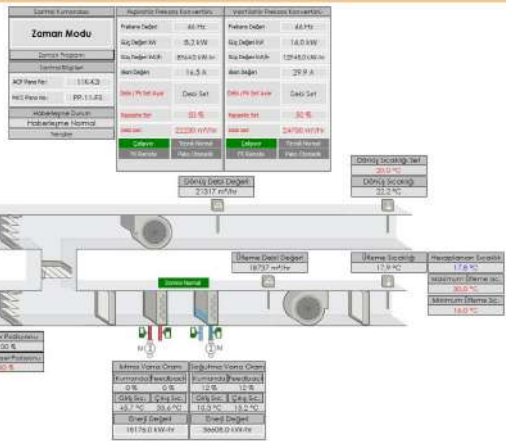


MACHINERY & EQUIPMENT

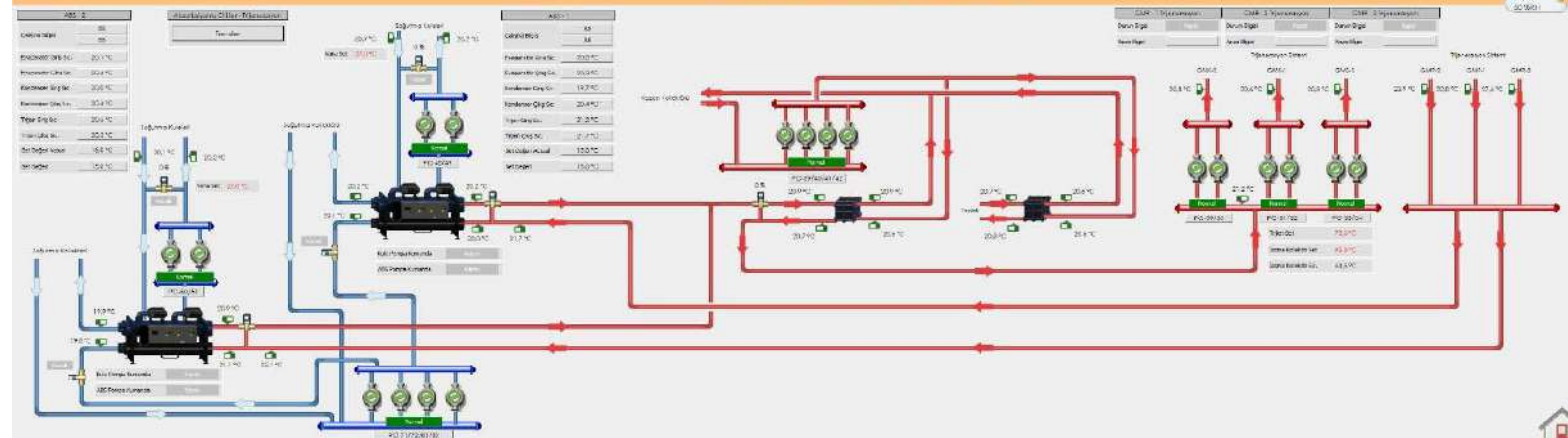
HVAC System

- Needs - Capacity Analysis
- HVAC Design with 3D
- BMS & EMS System
- Infrastructure;
 - Electrical Cabling
 - Utility Connections

AHU-37 -1.Kat Ara Blok Altle Hekimliği



Absorbsiyonlu Çiller - Trijenerasyon



MACHINERY & EQUIPMENT

Utility System

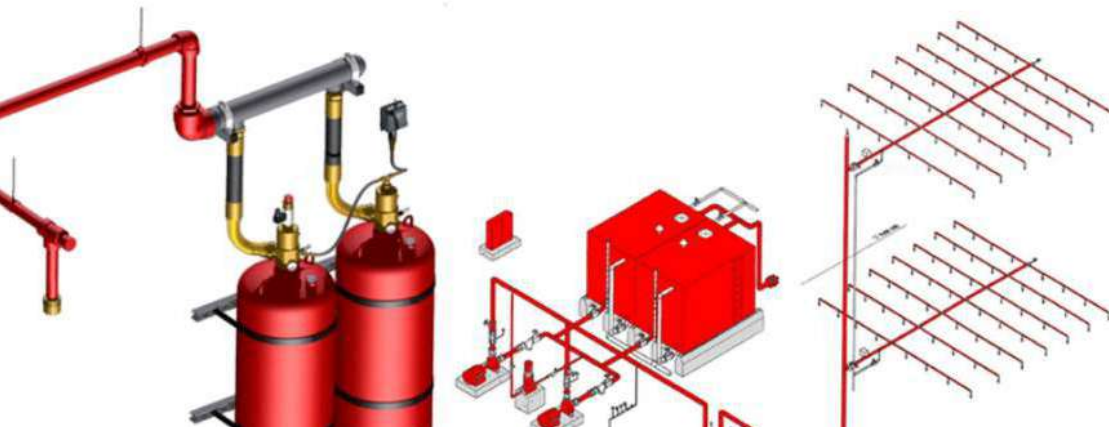
- Technical Specification Preparation Support
- Needs - Capacity Analysis
- Energy Power & UPS (uninterruptible power supply)
- Pharmaceutical Water Systems and Pure Steam
- Compressed Air & Process Gas (nitrogen etc.) Distribution System
- Cooling & Heating System
 - Chiller, Cooling Tower, Adiabatic, Hybrid and Air Blast
 - Cooler
 - Boiler
 - Plant Steam



MACHINERY & EQUIPMENT

Fire Fighting System

- Fire Detection Systems
- Fire Suppression Systems
- Fire Extinguishers
- Passive Fire Protection



DESIGN & CLEANROOM

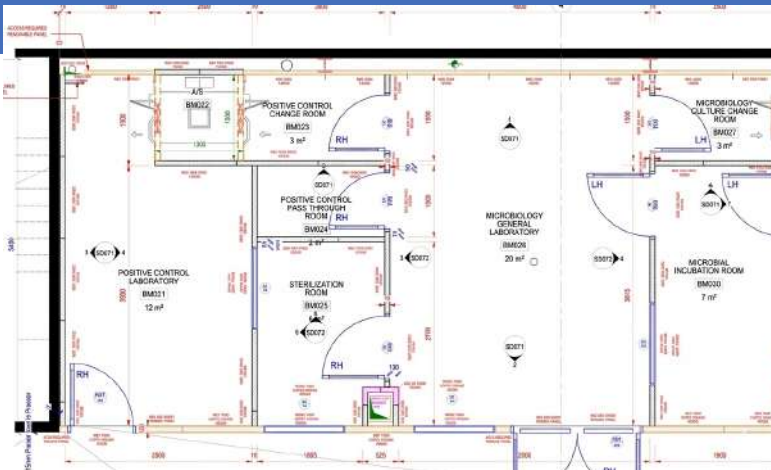


Design & Analysis

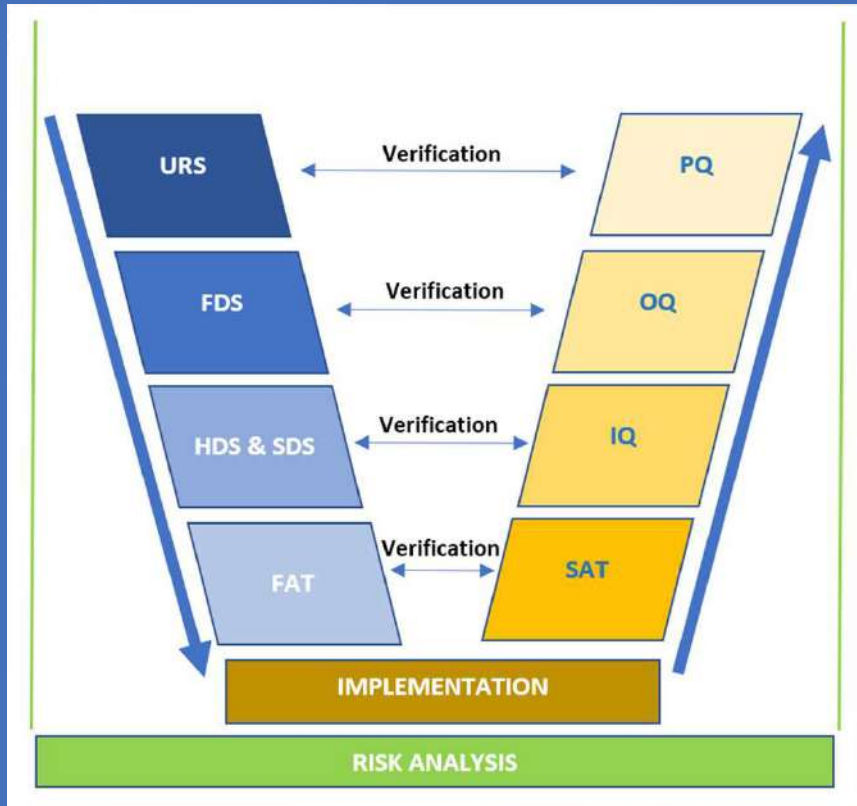
- Needs - Capacity Analysis
- Basic Concept Design
- Detail Design
- Operational Compliance
- cGMP Compliance
- Energy Saving Compatibility
- ISO 3 - ISO 8 Requirements

Cleanroom

- URS Preparation Support
- Room Book Support
- Auxiliary Equipment Analysis
- Supply Different Industry Cleanrooms
 - Pharma & Biotech
 - Semiconductor
 - Food & Drink
 - Medical Device



VALIDATION & QUALIFICATION



Validation & Qualification Flow

DQ (Design Qualification)

- URS (User Requirement Specification) Preparation and Review
- FDS (Functional Design Specification) Preparation and Review
- HDS & SDS (Hardware & Software Design Specification) Review

Machine & Line Acceptance Test

- FAT (Factory Acceptance Test) Preparation and Application Support
- SAT (Site Acceptance Test) Preparation and Application Support

Start-up & Re-Qualification

- IQ (Installation Qualification) Preparation and Application Support
- OQ (Operational Qualification) Preparation and Application Support
- PQ (Performance Qualification) Preparation and Application Support

PROCESS & OPERATION



Process

- Process&Machine Review and Design
- PUPSIT (Pre-Use Post-Sterilization Integrity Testing) system design
- cGMP&Product Based Risk Analysis
- OHSE (Occupational Health, Safety & Environmental) Based Risk Analysis

Operation

- cGMP&Operation Based Risk Analysis
- GAP Analysis

Operational Excellence

- Lost Time Analysis
- Set-Up Process Analysis
- Operation Optimization Analysis
- Yield Analysis (OEE), 5S and Lean Manufacturing Analysis



AUDIT & REVIEW



Internal Audit

- Production
- Technical services
- Quality assurance
- Quality control
- Warehouse

External Audit

- API (Active Pharmaceutical Ingredient) Supplier
- Excipient Supplier
- Primary Material Supplier
- Secondary Material Supplier

Review

- Technical Infrastructure Systems (HVAC, Water System etc.)
- cGXP Operations

* *The process is carried out based on EU GMP, PIC/S, FDA, WHO guidelines etc.*

PERSONNEL & TRAINING

Personnel

- Personnel Technical Evaluation
- Team Set-Up

Training

- Sterile Manufacturing and Sterile Product R&D Processes
- Isolator Technology and Operations; Sterile Manufacturing, High-Potency Products and Quality Use
- Aseptic Filling Processes; FFS (Form Fill Seal), BFS (Blow Fill Seal), PFS (Pre-Filled Syringe), Cartridge, Ampoule, Vial Production Technologies
- PUPSIT (Pre-Use Post-Sterilisation Integrity Testing) System Design and Applications
- Qualification and Validation Applications in Equipment and Systems
- Cleanroom Operation, Aseptic Techniques and Personnel Behaviour
- Facility and Cleanroom Design Approach
- Facility Critical Systems; HVAC, Water System, Infrastructure Systems Operation and Design Approach
- Sterilisation Techniques and Practical Applications
- Aseptic Process Simulation (Media Fill) Design and Applications
- Cleaning Validation
- Process Validation
- Contamination Control Strategy (sterile, solid, liquid, semi-solid forms)
- FMEA Risk Analysis and Root Cause Analysis (with case studies, specific topics are selected from all departments)
- Process and Line Efficiency Approach, Cost-Effective Processes (sterile, solid, liquid, semi-solid forms / design, time, consumption, budget, materials, products, etc.)
- GMP Training (Basic or Advanced Level)
- Containment Technology & High Potency Product Operations
- Qualification & Validation Applications for Machine & System, Cleanroom
- (... Specific training based on the request subject ...)



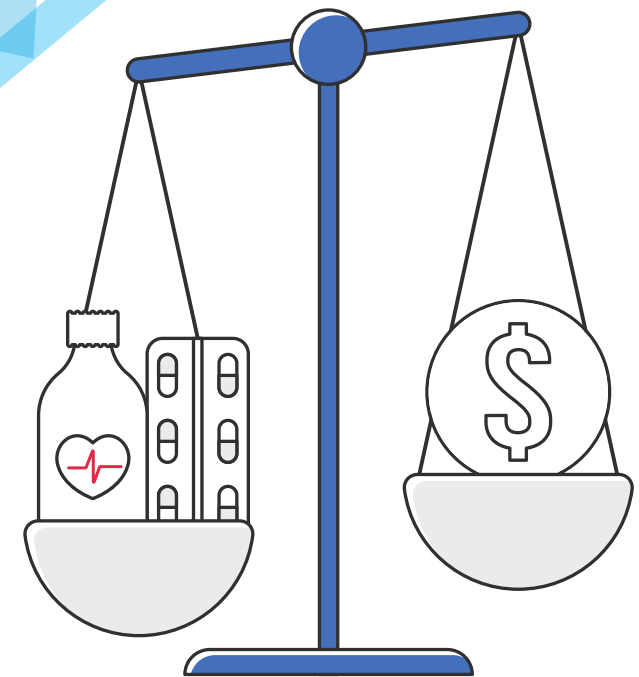
Process & System

- Energy Cost Reduction Analyzes
- Operational Cost Reduction Analyzes
- Operating Cost Reduction Analyzes
- Cost Reduction with Qualification and Validation Optimization

Product & Production & Technical & Quality Based

- Cost Reduction with Process Design Analysis
- Primary and Secondary Packaging Materials Cost Reduction
- Physical, Chemical and Microbial Sampling Risk Analysis
- Cost Reduction with Consumable Analysis
- Capacity Increase and Cost Reduction with Yield Analysis (OEE)
- Cost Reduction with 5S and Lean Manufacturing Applications

BUDGET & COST



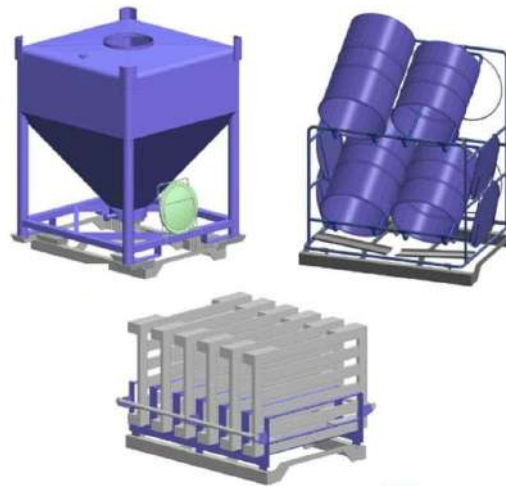
AMSONIC-HAMO / SWITZERLAND CLEANING TECHNOLOGY

The AMSONIC-HAMO Group, with roots dating back to 1957, is headquartered in Switzerland. With production facilities and R&D laboratories in Germany, Switzerland and France, AMSONIC-HAMO has considerable experience and reputation in its fields of activity, offering individual solutions based on the highest quality requirements.

* Pharma & Life Science

- Product contact parts (needle, hose, pump, pipe etc.)
- IBCs, drums, pallets

* Medical & Precision Industries



<https://amsonic-hamo.com/>

https://amsonic-hamo.com/wpcontent/uploads/2019/11/Hamo_PG800_1300_E_2017_10_09.pdf

https://amsonic-hamo.com/wp-content/uploads/2021/03/Hamo_PLine_E_2021_03_03.pdf



MARTIN CHRIST GEFRIERTROCKNUNGSANLAGEN GmbH / GERMANY FREEZE DRYER

Martin Christ brand is a world leader in the development and manufacture of freeze dryers with over 75 years of experience. The product portfolio includes laboratory units, pilot systems and production systems as well as vacuum concentrators for an extremely wide range of applications and process requirements. Based in Osterode (Germany), the company group consists of Martin Christ Freeze Dryers and Sigma Laboratory Centrifuges.

As of 2023, by adding Motus Engineering GmbH & Co. KG to its structure, it offers excellent solutions with competent high-level GMP designs for Freeze dryer automatic loading and unloading systems.

- * Lyophilization
- * Automatic loading & unloading solutions



AGENCY

<https://www.martinchrist.de/en>

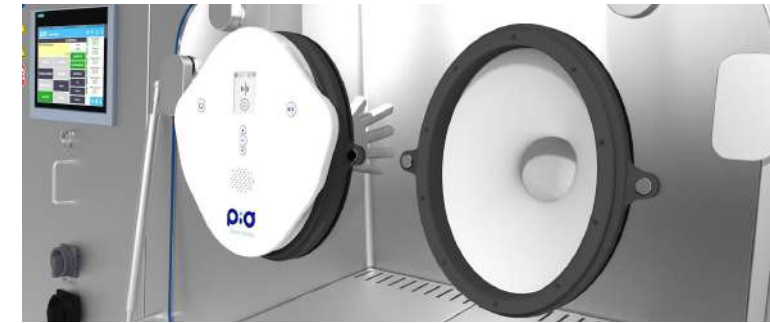
<https://www.motus-engineering.de/home>



Iskra PIO d.o.o. / SLOVENIA

ISOLATOR, GLOVE LEAK TESTER, SAFETY CABINET, SAMPLING CABINET,
MATERIAL HANDLING, SPECIAL PERSONNEL/MATERIAL AIRLOCK

Iskra PIO d.o.o., based in Slovenia and with more than 30 years of experience, is an approved supplier to global pharmaceutical companies, especially in Europe, with its high standard engineering designs based on cGMP requirements. It also performs additional activities such as "cleanroom, safety cabinet, isolator validation".



<https://www.iskra-pio.si/en>

<https://www.youtube.com/watch?v=ePx8-PTptD8&t=110s>

https://www.youtube.com/watch?v=fyK_H_fpLUk

<https://www.youtube.com/watch?v=CTktDefGeP8>

<https://www.youtube.com/watch?v=DyKwNPv9ohg>

BRAM-COR S.p.A. / ITALY

PHARMACEUTICAL WATER SYSTEM (WFI, PW, PS),
PROCESS VESSEL / SYSTEM, FILLING

BRAM-COR S.p.A., a company based in Parma/Italy, has considerable experience and reputation worldwide with equipment and systems installed in almost all continents.

- * Pharmaceutical Distillers and Water Systems Producing Purified Water (PW), Water for Injection (WFI) and Pure Steam (PS)
- * Pharmaceutical Formulation and Processing Systems for IV Solutions and Drugs Manufacturing
- * Pharmaceutical Filling and Packaging Systems for Pharmaceutical Products

<https://www.bram-cor.com/en/en-equipment>

<https://www.pharmaceutical-equipment.eu/>



RYCHIGER

RYCHIGER AG / SWITZERLAND

LIFE SCIENCE, PHARMA and DIAGNOSTICS

A journey began 105 years ago in various fields, and today Rychiger has established itself as a manufacturer of equipment for the pharmaceutical, medical, cosmetic and food industries.

Rychiger AG, Rychiger Canada Inc., Rychiger Pharmatech AG, and Rychiger Poland sp. z o.o., along with its subsidiaries, provide services worldwide.

In 2007, the company established the Life Sciences sector as a new business segment.

- * Pharma machinery
- * Assembling drug delivery devices



AGENCY

<https://www.rychiger.com/machines/mda-5>

<https://www.rychiger.com/machines/z-lab>

<https://www.rychiger.com/machines?filter-industries=pharmadiagnostics>

ZALKIN / FRANCE

CAPPING SOLUTIONS

A Global Leader in Capping Innovation with more than 90 years of industry expertise, Zalkin is a worldwide leader in rotary and singlehead capping systems, decapping systems and complete integrated capping solutions.

As Cap & Closures: Plastic screw-on caps (flat, sport, flip top,...), Tethered caps (snap and screw), Aluminum Roll-On Pilfer Proof (ROPP) closures, Snap-on caps, Push-in caps (T-corks, stoppers, and plugs), Metal Twist-Off caps, Dosing pumps and trigger sprayers.

From high-speed rotary systems to lower-speed inline solutions, every Zalkin machine is engineered for performance, precision and flexibility. Our technologies are trusted for even the most challenging bottle and closure combinations, ensuring consistent, repeatable results and superior product quality.

* Capping Solutions (Pharmaceuticals, Dairy, Food For Special Medical Purposes, Beverage, Food, Cosmetics etc.)



<https://www.zalkincapping.com/industry/>

REFERENCES

The Companies we serve under cGMP



DAR ESSAYDALI Pharmaceutical

TUNUSIA

<https://daessaydali.com/en/>



T.C. SAĞLIK BAKANLIĞI
TÜRKİYE İLAÇ VE
TIBBİ CİHAZ KURUMU

**Ministry of Health of the Republic of
Turkey, TİTCK – Turkish Medicines and
Medical Devices Agency**

TÜRKİYE

<https://www.titck.gov.tr/>



TURK Pharmaceutical

TÜRKİYE

<https://www.turkilac.com.tr/en/>

LISURE

Lisure Science (Suzhou) Co., Ltd

CHINA

<https://www.lisure.com/en/>



**Red Crescent Beverage
(Kızılay İçecek A.Ş.)**

TÜRKİYE

<https://www.kizilayicecek.com.tr/en>



BİLİM Pharmaceutical

TÜRKİYE

<https://www.bilimilac.com.tr/en>

REFERENCES

The Companies we serve under cGMP



BiEM Pharmaceutical

TÜRKİYE

<https://www.biemilac.com.tr/en/>



NOVARTIS, IDL Holland B.V.

HOLLANDA

<https://www.novartis.com/>



NOBEL

Nobel Pharmaceutical

TÜRKİYE

<https://www.nobel.com.tr/en-us>



**İDOL İLAÇ DOLUM
SANAYİ VE TİCARET A.Ş.**

İdol Pharmaceutical

TÜRKİYE

<https://www.idol.com>



Gensenta Pharmaceutical

Eczacıbaşı Group

TÜRKİYE

<https://www.gensenta.com.tr/en/>



**Eker Dairy Products Food
Industry and Trade Inc.**

TÜRKİYE

<https://eker.com/>

REFERENCES

Companies where I have been involved in project management for facility renovation and new facility construction in my professional career



**Deva Pharmaceutical
Kartepe Factory**

TÜRKİYE (Large-Scale Facility Revision)

<https://www.deva.com.tr/en/>



**World Medicine Pharmaceutical
Çerkezköy Tesisi**

TÜRKİYE (New Facility Instalation as
a Greenfield Project)

<https://www.worldmedicine.com.tr/en>



**Onko-Koçsel Pharmaceutical
Gebze Factory**

TÜRKİYE (New Facility Instalation as
a Greenfield Project)

<https://www.onkokocsel.com/en>



**Badalli Empty Glass Ampoule and
Vial Production Site
Çerkezköy**

TÜRKİYE (New Facility Instalation as
a Greenfield Project)

<https://www.badalli.com.tr/en/>



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