Blue Pharma Engineering Group Consultancy

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

ABOUT US

- Company Name: **BPEG Danışmanlık Tic. Ltd. Şti.**
  Blue Pharma Engineering Group
- Founding : January 2024, İstanbul
- 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
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www.bpegconsultancy.com

https://www.linkedin.com/company/bpeg-consultancy-trade-limited-company/

FIELD of ACTIVITY

- CONTRACTOR & PROJECT MANAGEMENT
- MACHINE & 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 Managment

CONTRUCTOR & PROJECT MANAGEMENT

➢ 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 Liquide (eye drop, inhaler)
  - Sterile Injectable (IV solution, ampoule)

- ✓ **Hormone / Steroid Product Manufacturing**
  - Sterile Liquide (eye drop)
  - Sterile Injectable (vial, ampoule, prefilled syringe, cartridge)
  - Non-Sterile Liquid (suspension, solution, nasal)
  - Solid (capsule, tablet, powder)

- ✓ **Inhaler Product Manufacturing**
  - Sterile Liquide (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

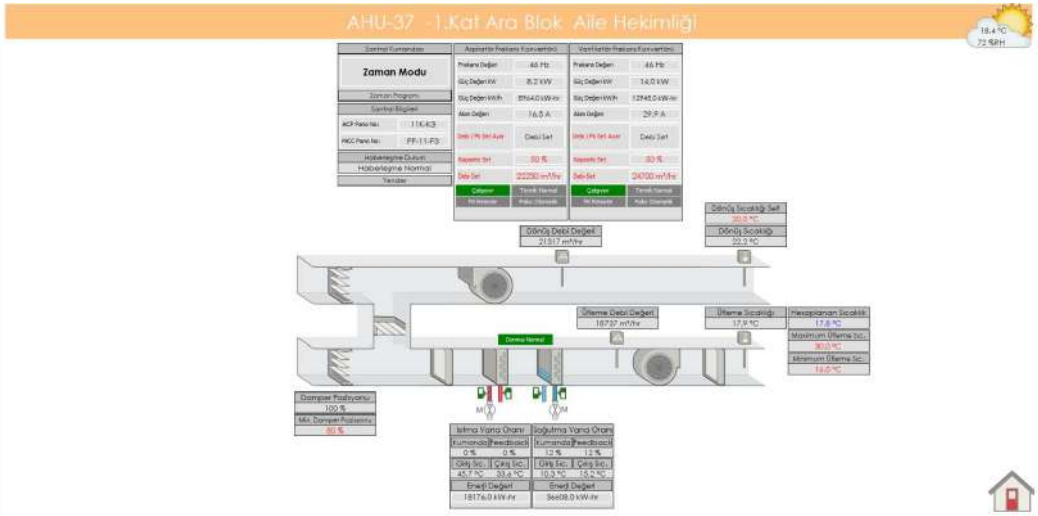
➢ Machinery and Equipment Purchase Support

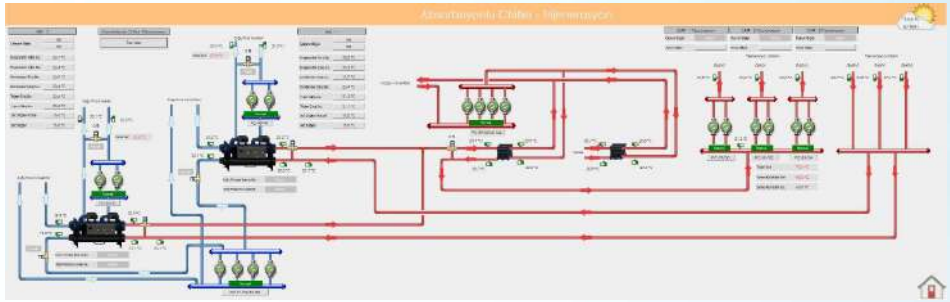
- ✓ Holding Technical Meeting
- ✓ Evaluation Machine and Equipment
- ✓ Attendance Commercial Meeting

MACHINERY & EQUIPMENT

➢ HVAC System

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





MACHINERY & EQUIPMENT

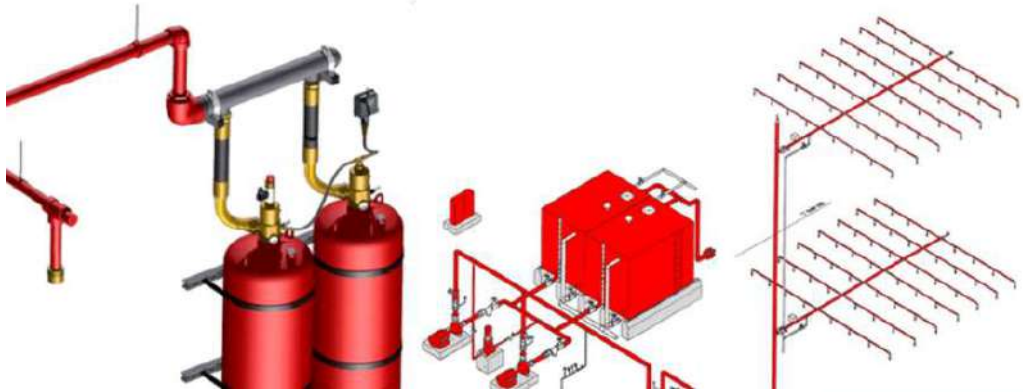
Utility System

- ✓ 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



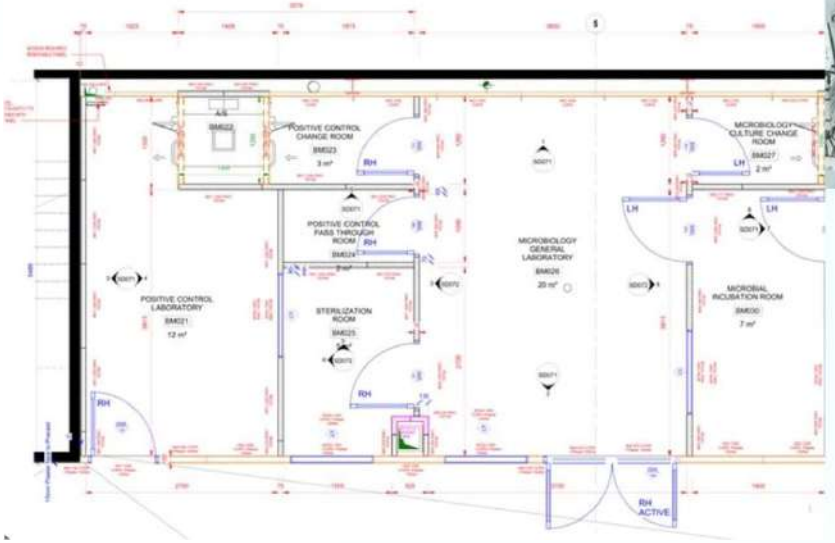
DESIGN & CLEAN ROOM

Design & Analysis

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

Clean Room

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



VALIDATION & QUALIFICATION

➢ DQ (Design Qualification)

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

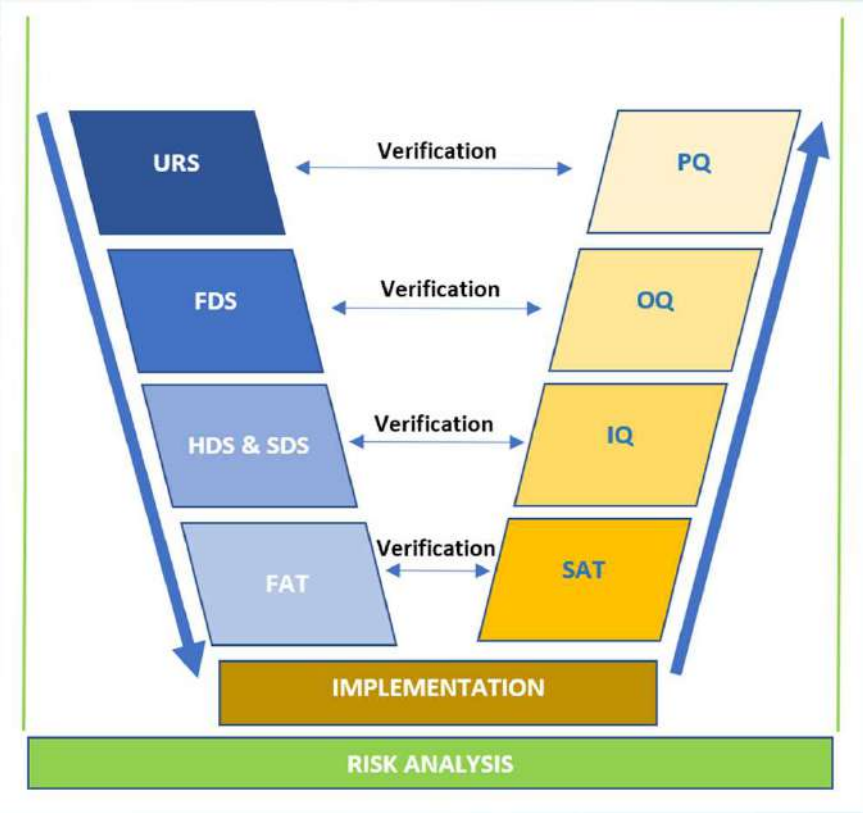
➢ Machine & Line Acceptance Test

- ✓ 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

Validation & Qualification Flow



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 setup

Training

- ✓ cGMP Training
- ✓ CCS - Contamination Control Strategy
- ✓ PUPSIT(Pre-Use Post-Sterilization Integrity Testing) application
- ✓ Cleanroom Concept & Behaviour & Aseptic Techniques
- ✓ Theoretical&Practical training (HVAC, water system, production and quality operations)
- ✓ R&D Product design to operation compliance,
- ✓ BFS(Blow Fill Seal) or FFS(Form Fill Seal) Technology&Operations
- ✓ Isolator Technology&Operations
- ✓ Containment Technology&High potent product operations
- ✓ Qualification&Validation applications for machine&system, cleanroom
- ✓ Sterilization&Practical applications
- ✓ *(… Specific training based on the request subject …)*

PERSONNEL & TRAINING

Training

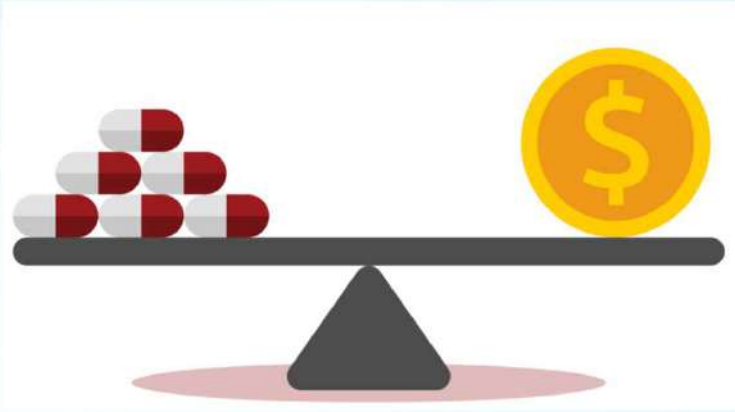
Trainings Based on EU cGMP Guidelines Annexes;

- ANNEX-1 MANUFACTURE OF STERILE MEDICINAL PRODUCTS
- ANNEX-2A MANUFACTURE OF ADVANCED THERAPEUTIC MEDİCİNAL PRODUCTS
- ANNEX-2B MANUFACTURE OF BIOLOGICAL MEDICINAL SUBSTANCES AND PRODUCT
- ANNEX-3 MANUFACTURE OF RADIOPHARMACEUTICALS ANNEX-4 MANUFACTURE OF VETERINARY MEDICINAL PRODUCTS OTHER THAN IMMUNOLOGICALS (OUT OF SCOPE)
- ANNEX-5 MANUFACTURE OF IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCTS
- ANNEX 6 MANUFACTURE OF MEDICINAL GASES
- ANNEX 7 MANUFACTURE OF HERBAL MEDICINAL PRODUCTS
- ANNEX 8 SAMPLING OF STARTING AND PACKAGING MATERIALS
- ANNEX 9 MANUFACTURE OF LIQUIDS, CREAMS AND OINTMENTS
- ANNEX 10 MANUFACTURE OF PRESSURISED METERED DOSE AEROSOL PREPARATIONS FOR INHALATION
- ANNEX 11 COMPUTERISED SYSTEMS
- ANNEX 12 USE OF IONISING RADIATION IN THE MANUFACTURE OF MEDICINAL PRODUCTS2.217
- ANNEX 13 MANUFACTURE OF INVESTIGATIONAL MEDICINAL PRODUCTS
- ANNEX 14 MANUFACTURE OF MEDICINAL PRODUCTS DERIVED FROM HUMAN BLOOD OR PLASMA
- ANNEX 15 QUALIFICATION AND VALIDATION
- ANNEX-16 CERTIFICATION BY THE AUTHORISED PERSON AND BATCH RELEASE
- ANNEX 17 REAL TIME RELEASE TESTING AND PARAMETRIC RELEASE
- ANNEX-18 BASIC REQUIREMENTS FOR ACTIVE PHARMACEUTICAL INGREDIENTS (PART 2)
- ANNEX 19 REFERENCE AND RETENTION SAMPLES
- ANNEX 20 QUALITY RISK MANAGEMENT

BUDGET & COST

➢ 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

➢ Iskra PIO d.o.o. / SLOVENIA

- ✓ **ISOLATOR, SAFETY CABINET, SAMPLING CABIN, CLEANROOM DECONTAMINATION GENERATOR, 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

➢ 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/

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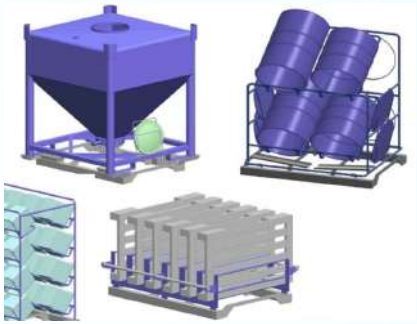
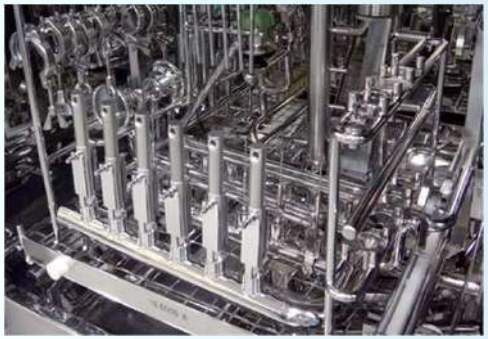
https://amsonic-hamo.com/wp-content/uploads/2021/03/Hamo_P-Line_E_2021_03_03.pdf





➢ 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/

➢ MK-Versuchsanlagen / GERMANY

- ✓ **GLOVE LEAK TESTER, TRANSNFER SYSTEM ALPHA PORT&BETA PORT LEAK TESTER, PORTS, GLOVES, METAL-FREE CLEANROOM EQUPMENT-PANEL-CABINET**

In 1988 Founding of MK Versuchsanlagen und Laborbedarf, which focuses on the construction of biotechnological plants on a pilot plant scale for research purposes. Eexpansion of the production facility in Gruenberg. Development of pharmaceutical testing systems and first standardization of metal-free workspaces. The production plant and management are relocated to Muecke-Merlau. This results in expanded its production and development areas to 2200 m² with the construction of a special facility. Developed its own hardware and software products for MK systems and pharmaceutical products. With its own software, it produces the fastest and most stable solution for its customers. Finally, in 2011, the technical department for electrical engineering / microelectronics was expanded.

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

https://www.youtube.com/watch?v=_WP3mBqNCPo

BPEG

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

www.bpegconsultancy.com