



Blue Pharma Engineering Group Consultancy

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

- ❑ **Company Name:** **BPEG Danışmanlık Tic. Ltd. Şti. (BPEG Consultancy Trade Limited Company)**
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
- ❑ **Contact** : Mr. Deniz ALKANAT / Managing Director
+90 530 378 5443
alkanat.deniz@bpegconsultancy.com

www.bpegconsultancy.com

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

Deniz ALKANAT

- ❑ 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/Technical Committee 209/WG 11
- ❑ Contac : +90 530 378 5443
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- **CONTRACTOR & PROJECT MANAGEMENT**
- **MACHINE & EQUIPMENT**
- **DESIGN & CLEANROOM**
- **VALIDATION & QUALIFICATION**
- **PROCESS & OPERATION**
- **AUDIT & REVIEW**
- **PERSONNEL & TRAINING**
- **BUDGET & COST**
- **AGENCY**



➤ 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



➤ 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)



➤ 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

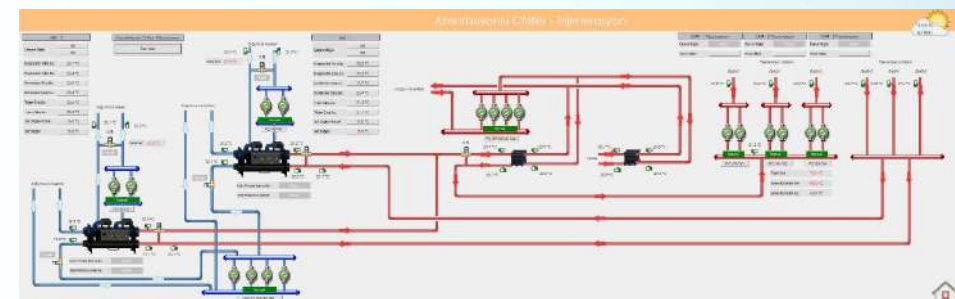
- ✓ Operational Compliance
- ✓ cGMP Compliance
- ✓ Product Specific Compatibility

➤ Machinery and Equipment Purchase Support

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



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



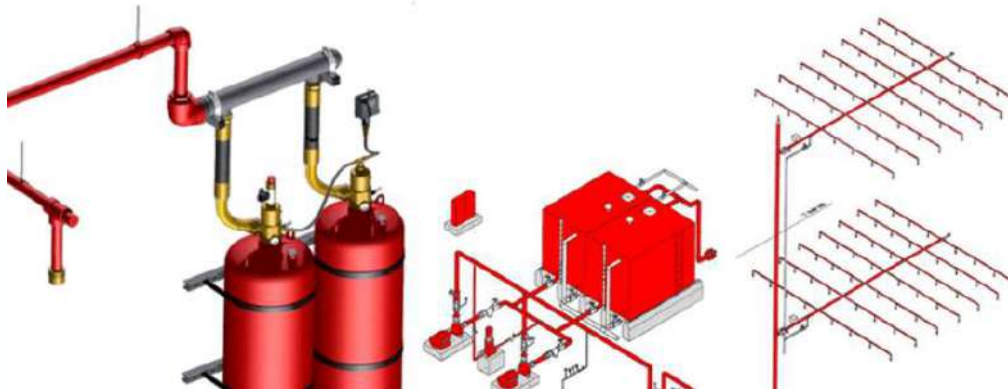
➤ Utility System

- ✓ 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



➤ Fire Fighting System

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



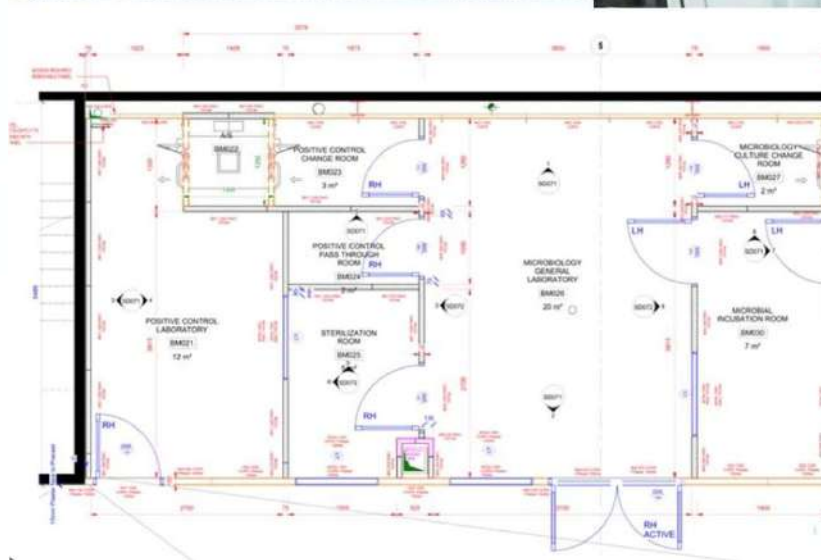
➤ Design & Analysis

- ✓ 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



➤ DQ (Design Qualification)

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

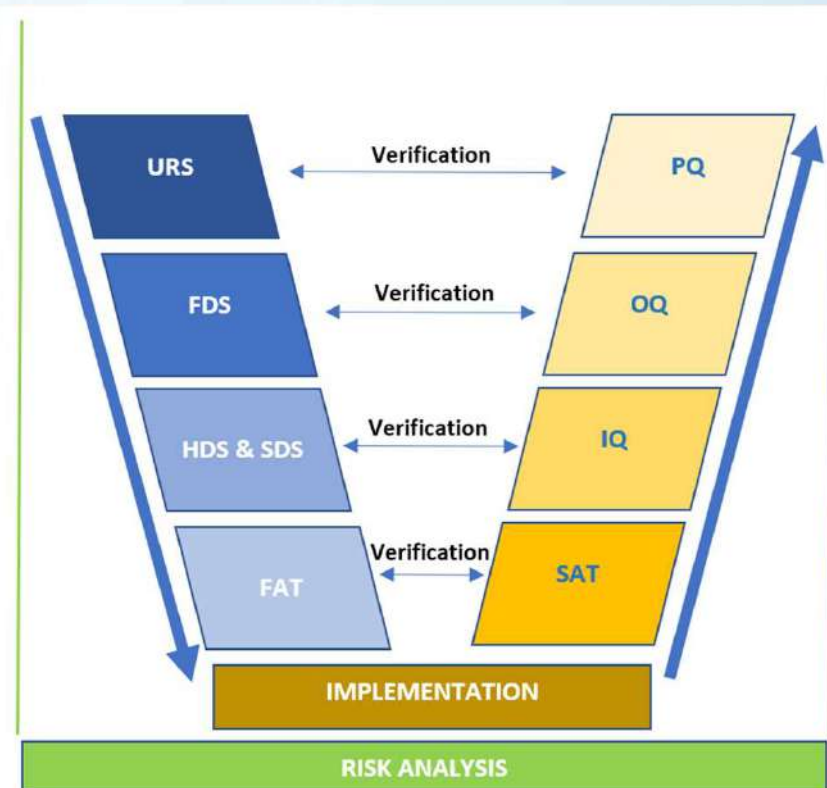
➤ Machine & Line Acceptance Test

- ✓ 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

- ✓ 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



➤ 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

- ✓ Personnel Technical Evaluation
- ✓ Team Set-up

➤ Training

- ✓ cGMP Training
- ✓ CCS - Contamination Control Strategy
- ✓ Process Validation
- ✓ Cleaning Validation
- ✓ 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 Commercial Operation Compliance,
- ✓ BFS(Blow Fill Seal) or FFS(Form Fill Seal) Technology&Operations
- ✓ Isolator Technology&Operations
- ✓ Containment Technology & High Potency Product Operations
- ✓ Qualification & Validation Applications for Machine & System, cleanroom
- ✓ Sterilization & Practical Applications
- ✓ (... Specific training based on the request subject ...)



➤ Training

✓ Trainings Based on EU cGMP Guidelines Annexes;

- ANNEX-1 MANUFACTURE OF STERILE MEDICINAL PRODUCTS
- ANNEX-2A MANUFACTURE OF ADVANCED THERAPEUTIC MEDICINAL 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 PRODUCTS^{2.217}
- 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

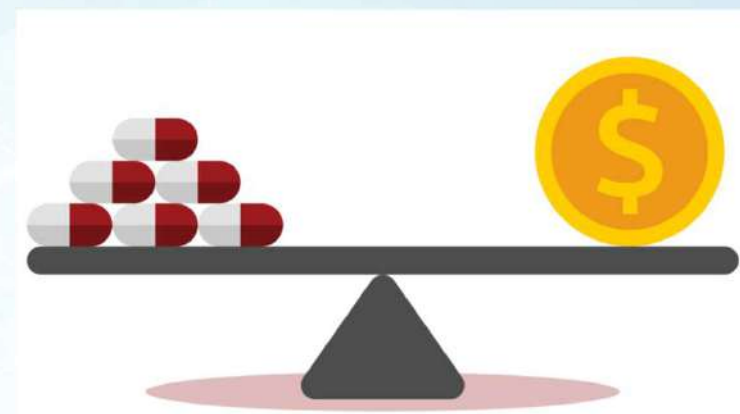


➤ Process & System

- ✓ 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



➤ **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**

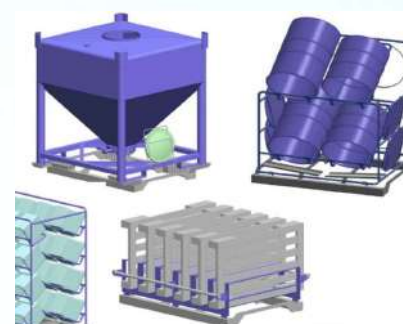
- Product contact parts (needle, hose, pump, pipe etc.)
- IBCs, drums, pallets

* **Medical & Precision Industries**

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

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

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

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

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



➤ **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>



➤ **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/>



➤ The Companies we serve under cGMP



DAR ESSAYDALI Pharmaceutical / TUNUSIA
<https://daessaydali.com/en/>



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

Türkiye Cumhuriyeti Sağlık Bakanlığı, TİTCK – Türkiye İlaç ve Tıbbi Cihaz Kurumu / TÜRKİYE
<https://www.titck.gov.tr/>



TURK İlaç ve Serum San. A.Ş. / TÜRKİYE
<https://www.turkilac.com.tr/en/>



Lisure Science (Suzhou) Co., Ltd / CHINA
<https://www.lisure.com/en/>

➤ The Companies we serve under cGMP



Kızılay İlaç A.Ş. / TÜRKİYE
<https://www.kizilayicecek.com.tr/en>



BİLİM İlaç San. ve Tic. A.Ş. / TÜRKİYE
<https://www.bilimilac.com.tr/en>



BiEM İlaç San. ve Tic. A.Ş. / TÜRKİYE
<https://www.biemilac.com.tr/en/>



NOVARTIS, IDL Holland B.V. / HOLLANDA
<https://www.novartis.com/>

➤ The Companies we serve under cGMP



Gensenta İlaç, Eczacıbaşı Grubu / TÜRKİYE
<https://www.gensenta.com.tr/en/>

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



Deva İlaç – Kartepe Tesis / TÜRKİYE (Large-Scale Facility Revision)
<https://www.deva.com.tr/en/>



Onko-Koçsel İlaç – Gebze Tesis / TÜRKİYE (New Facility Instalation as a Greenfield Project)
<https://www.onkokocsel.com/en>



WORLD MEDICINE
Pharmaceutical Company

World Medicine İlaç – Çerkezköy Tesis / TÜRKİYE (New Facility Instalation as a Greenfield Project), <https://www.worldmedicine.com.tr/en>



Badalli Boş Cam Ampul ve Flakon Üretim Tesis – Çerkezköy / TÜRKİYE (New Facility Instalation as a Greenfield Project), <https://www.badalli.com.tr/en/>



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