BPEG
BLUE PHARMA ENGINEERING GROUP

Blue Pharma Engineering Group Consultancy

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

Deniz ALKANAT

Managing Director / Member of Cleanroom Technologies Society of Turkey / ISO 14644 TC209-WG11 Delegate

With Production, Qualification & Validation,
QA, Greenfield Project Management Background

www.bpegconsultancy.com

Tecrübe çok değerlidir.

Paylaşmaya ve birlikte ilerlemeye hazırız!

Misyonumuz;

Tecrübeleri endüstrinin faydasına en iyi şekilde sunmak, birlikte paylaşmak ve ihtiyaç duyulan her yerde yaşatmak.

Vizyonumuz;

Yurt içi ve yurt dışı faaliyetlerle en verimli şekilde farkındalık ve katma değer oluşturmak, bu konuda lider olmak.

Tecrübe, bilim temeli ile başarı için vazgeçilmez bir kaynaktır. Biz, BPEG Danışmanlık olarak bu gerçeği benimseyerek, ilaç endüstrisinde faaliyet gösteren veya temizoda operasyonları olan firmalara kapsamlı danışmanlık hizmetleri sunan öncü bir kuruluşuz. Uzun yıllara dayanan deneyimimizle sektördeki uzmanlığımızla harmanlanmış şekilde, müşterilerimizin başarılarını operasyonel süreçlerinde mükemmelliği hedefleyerek artırmak için destek oluyoruz.

Birlikte, başarıya giden yolda önemli adımlar atmak için hazırız. Müşterilerimizin mevcut ve gelecekteki zorluklarını anlamak ve bunlara uygun çözümler üretmek analitik bakış açımızın temelidir. Endüstri trendlerini yakından takip ediyor ve müşterilerimize bu değişen peyzajda öncü olmaları için gerekli bilgi ve farkındalıkları sağlıyoruz.

BPEG Danışmanlık olarak, sadece müşteri memnuniyetini değil, aynı zamanda sektöre ve ülkemize olan katkımızı da ön planda tutuyoruz. Etiğe ve kaliteye olan bağlılığımızı korurken, iş ortaklarımıza güvenilirlik prensibi ile hizmet veriyoruz.

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Contact Information

Business e-mail: alkanat.deniz@bpegconsultancy.com;

Education and Experience Summary

I graduated from the Computer Department of technical high school and then I graduated from Istanbul University, Department of Chemical Engineering. During the undergraduate education, I had pharmaceutical production technology sections.

I began my career in the pharmaceutical industry 27 years ago. Mainly, I specialized in sterile production/aseptic dosage operations, liquid and solid dosage operations, quality assurance, validation, qualification, new facility building and design. Also, I am expert for selection and evaluation of manufacturing equipment. Additionally, these processes are also valid for medical empty glass ampoule and vial production.

Main Skills

- Building the team for new facility for technical operations and organization skills
- Experience in the action of leading a team and an organization, also ability to work on cross-functional departments
- Technical Experience in Project Management and design in Pharmaceutical Industry for Sterile, Non-Sterile Liquid/Semi Solid and Solid Product
- Experience in regulatory inspections and CMO inspections according to formal authorized guidance of US FDA, EU cGMP, PIC/S, WHO and supporting guidance of PDA, ISPE, ISO
- Qualification of Equipment and Validation of Systems for Sterile, Non-Sterile/Semi Solid and Solid Product, Water Systems
- Risk Assessment of all pharmaceutical cleanroom areas, processes and systems
- Design of single-use sterile materials and aseptic connections to use and apply in aseptic processing
- In aseptic processing concept, BFS technology, isolator technology for compounding-filling-freeze drying and sterility test isolator
- In high potent solid doses form, containment system for dispensing and solid manufacturing lines
- Leadership for all factory divisions
- Productivity of all processes, cost calculation, cost reduction studies
- Having new product portfolio to make a pre-audit and evaluation of manufacturer current conditions according to the agreement in order to take bulk vaccines, recombinant antibody

and protein products to make fill & finish processing of influenza vaccine and recombinant EPO (Erythropoietin) in Turkey. Such as Biopharmaceutical Manufacturing Factories in China (Hualan Bio), in Korea (Green cross). Also before to manage fill & finish processing of filgrastim as first pilot production at Sanovel in Turkey.

- Taking active role in improvement of equipment manufacturers' design concepts with my experience and cGMP compliance background. Such as;
  - Additional drying line on CIP/SIP system in filling isolator for brand of Groninger / Germany
  - Sensor support design on main center of tablet compressing machine for brand of Fette / Germany
  - Inner design on main chamber in sterility test isolator for brand of Fedegari / Italy
  - P&ID design, electrical cable and pneumatic piping management for stainless steel solution preparation&filtration systems by foreign and local brands(Türkiye and Italy)
  - Eye drop filling machine design for brand of Romaco / Italy, I Dositecno / Spain and TM / Italy
  - Line consept design of syrup filling line to reach high capacity for brand of Romaco / Italy
  - Aseptic consept design of ampoule and vial filling machine for brand of Marchesini / Italy, I Dositecno / Spain
  - Buffer LAF design for all critical area on sterile filling lines for foreign brands

Project Management Summary

- **WORLD MEDICINE PHARMACEUTICAL / Çerkezköy – TEKİRDAĞ / TÜRKİYE – greenfield project**
  - Project investment budget 155 million USD
  - Installed capacity 1,3 billion boxes (without OEE),
  - Managed factory headcount is 850 people and max 1250 people in the future
  - Sterile and non-sterile product
  - EU GMP certified

  World Medicine Pharmaceutical Corporate Presentation Movie
  https://youtu.be/a4KsN16K1Ko?si=79dW1vEsgNfKJW6I

  World Medicine Pharmaceutical Facility, Tekno Hayat Program – NTV on Turkish TV
  https://www.youtube.com/watch?v=OJILdBTRuOI

- **BADALLI Empty Glass Container Manufacturing / Çerkezköy – TEKİRDAĞ / TÜRKİYE (group of WORLD MEDICINE PHARMACEUTICAL) – greenfield project**
  - Project investment budget 12 million EURO
  - Capacity 120 million ampoules, 30 million vials, extension capacity is 240 million ampoules (with OEE),
  - Managed factory headcount is 60 people and max 120 people in the future
  - Empty glass container as vial and ampoule for injectable product
  - ISO Std certified

  Badalli Corporate Presentation Movie (World Medicine Pharmaceutical Group Firm)
  https://www.youtube.com/watch?v=yhYzpm4-QXY

- **ONKO PHARMACEUTICAL / Gebze – KOCAELİ / TÜRKİYE – greenfield project**
  - Project investment budget 110 million EURO
  - Installed capacity 35 million boxes (without OEE),
  - Managed factory headcount is 155 people and max 250 people in the future
  - Sterile and non-sterile product (oncology and non-oncology)
  - EU GMP certified

  Onko Pharmaceutical Site, High Potent Manufacturing and Non-High Potent Manufacturing Plant
  https://www.youtube.com/watch?v=dcpcuTlMrXk

- **DEVA PHARMACEUTICAL / Kartepe – KOCAELİ / TÜRKİYE – factory revision project**
  - Project investment budget 40 million EURO
  - Installed capacity 10 million boxes (without OEE),
  - Managed factory headcount is 355 people and max 450 people in the future
  - Sterile product
  - EU GMP and FDA certified

  DEVA Pharmaceutical Corporate Presentation Movie
  https://www.youtube.com/watch?v=XRKrmUrY7nY

Experience

- 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, Deputy Factory Director

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

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

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

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

Education Information

- **Istanbul University (IU) -** Engineering Faculty, Chemical Engineering (*industrial toxicology and pharmaceutical production technologies)*
- **Tuzla Technical High School -** Computer Department for Hardware and Software

As Speaker at Seminar / Symposium / Exhibition

- **ISCC'22 International Symposium on Contamination Control for Three Presentations – Türkiye 2022**
  - Cleaning, Sterilization and Practical Applications
  - Ophthalmic Processing – Filling and the Differences from Other Aseptic Processing-Filling Technologies
  - Manufacture of Highly Potent Products with Isolator

- **Romaco Bologna Open House - Italy 2021**
  - **-** Ophthalmic Processing – Filling and the Differences from Other Aseptic Processing-Filling Technologies

- **Cleanroom Exhibition in Istanbul - Türkiye 2017**
  - Example Initiative Review; Important Decisions to Be Evaluated and Considered for The Period in Which The Facilities Have Been Operated from The Initial Design Stage

- **Cleanroom Exhibition in Istanbul - Türkiye 2016**
  - GMP and Sterile Application Knowhow Transfer from Pharmaceutical Operation to Stem Cell Laboratories

- **Pharma Congress in Dusseldorf - Germany 2016**
  - The Case Study as the Challenge of New Facility Building for High Potent Drugs Manufacturing

- **Wyndham Hotel in Istanbul - Türkiye 2015**
  - Sterilization and Practical Applications

As Writer an Article in Technical Newspaper

- **Article : New Facility Building as Onko Pharmaceutical**
  N1 of CleanroomNews at 16th -17th of pages / Türkiye - 2017
  www.cleanroomnews.org

- **Article : Using of Electrical Switch and Socket at Cleanroom**
  N3 of CleanroomNews at 9th of pages / Türkiye - 2017
  www.cleanroomnews.org

Memberchips

- Chamber of Chemical Engineers / Union of Chambers of Turkish Engineers and Architects
- Cleanroom Technologies Association
- CleanroomNews Newspaper Advisor Committee
- MTC 165: Cleanroom Technologies Mirror Committee
  - ISO/TC 209: Cleanrooms and Associated Controlled Environments
    - ISO / TC 209 / WG 11: Working Group Assessment of Suitability of Equipment and Materials for Cleanrooms (as one and first expert from Türkiye)