

### Core Competencies

- Formulation Development
- Process Validation
- CMO Transfer
- Due Diligence
- Person in Plant
- CMO Selection
- GAP Analysis
- Project Management
- Process Scale-up

### Products

- Covera®
- Ditropan XL®
- Kadian®
- Concerta®
- Invega®

### Professional Summary

Mr. Michailaros provides over 21 years of drug product expertise with both oral and solid processes, and product development and manufacturing. He specializes in difficult technical formulation and manufacturing challenges and products with unique requirements, including controlled release, zero-order release, abuse deterrence, pediatric formulations, oral disintegration. In addition, he has developed, and optimized products including controlled release tablets, abuse deterred capsules, pediatric formulations, solid and liquid filled capsules, suspensions, inhaled products, and transdermals.

Mr. Michailaros has helped author regulatory submissions in the EU as well as in the US and has worked extensively with international vendors. He has extensive experience in project management, scale-up, tech transfer and validation, lean manufacturing, six sigma/process excellence, design of experiments (DOE), chemistry manufacturing and controls (CMC) regulatory submission authoring, capital projects and third-party manufacturing management.

- Led Product Launch teams for time sensitive milestones,
- Authored development protocols, reports, and CMC sections for regulatory filings,
- Experience in regulatory CMC strategy for drug development,
- Production troubleshooting of pharmaceutical oral solid dosage forms.

Before joining DSI, Mr. Michailaros was Senior Engineer, Validation and Commercial Technical Services at Teva Pharmaceuticals as well as Johnson & Johnson. He has served DSI clients for over ten years. He earned a chemical engineering degree from Lehigh University and a mini MBA in Management Essentials from Rutgers University.

### Education

B.S.	Chemical Engineering	Lehigh University
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# Kyriakos Michailaros

## Head of Drug Product Services

### **Professional Experience**

#### **Design Space Inpharmatics, LLC**

**2008 - Present**

##### **Head of Drug Product Services**

- Worked with over 15 clients on drug products across a wide range of therapeutic areas including oncology, pain, rare disease, cardiovascular, neurological and neurodegenerative disease, contraceptives, psychological and behavioral disorders, and hormones,
- Experienced with unique functionalities and manufacturing technology including controlled and zero-order release tablets, multi-layered tablets, spray drying, chewable tablets, orally disintegrating tablets, taste masking, liquid oral solutions and suspensions, parenterals, functional coating, solvent coating, laser drilling, vision systems, abuse deterred bead filled capsules, abuse deterred tablets, liquid filled capsules, contraceptive patch,
- Developed delivery systems for small molecules, actives with poor solubility and absorption, peptides, proteins, hormones, supplements, and pro-drugs,
- Managed drug product development, formulation and process development,
- Selected and managed third party vendors on behalf of clients domestically and internationally,
- Worked with client to develop a direct compression tablet product and close a partnership deal in excess of \$80 million.

#### **Teva**

**2009-2011**

##### **Senior Engineer, Validation and Commercial Technical Services/Engineer**

- Formulated and developed manufacturing processes for creams, gels, liquids and solid dose products,
- External transferred 5 topical products within scope of a CBE-30 regulatory filing,
- Implemented process improvements for manufacture of liquid and semisolid products.

#### **King Pharma (Alpharma)**

**2006-2009**

##### **Senior Process Engineer, Project Manager**

- Managed group of four engineers and two technicians,
- Oversaw build out and qualification of a new pilot plant,
- Successfully developed, scaled-up, and validated two controlled release film coated pellet formulations.

#### **Johnson & Johnson (Alza)**

**2004-2006**

##### **Senior Process Engineer**

- Supported scale-up, validation, and commercial production, for osmotic controlled release tablets,
- Authored protocols, reports, white papers, investigations,
- Successfully developed, scaled-up, and validated two controlled release film coated pellet formulations.



# Kyriakos Michailaros

## Head of Drug Product Services

### Teva, Process Engineering

2000 - 2004

#### Engineer, Team Leader for New Product Launches

- Successfully led five cross functional product launch teams,
- Launched four topical semisolid products in a faced paced timeline oriented environment,
- Transferred high volume allergy drug from Sellersville PA to Kfar Saba Israel,
- Developed and validated manufacturing processes for eleven products.

### Aventis, Parenteral Clinical Supplies

1999 - 2000

#### Engineer

- Manufactured parenteral batches for toxicological and clinical supplies while maintaining a sterile research and manufacturing facility.

### Skills

Pre-formulation	Manage CMO
Oral solid/semi solid formulation	Topical, lotions, transdermal
Transdermal formulation	Immediate release oral
Insoluble drug formulation	Extended/modified oral release
Capsule fill	Inhalation
Tableting	Oral liquid
Lyophilization	Parenterals
Inhalation	Scale up
Tablet coating	Lyo process development/optimization
Liquid fill capsule	Process control/validation
Oral liquids	Experimental design/DOE
Topical ointment/lotions/transdermal	FMEA Analysis
CTM pack/label	Product image design
CTM shipping	Secondary pack/label

### Products

Covera®	Concerta®
Ditropan XL®	Invega®
Kadian®	Sudafed 24 ®
Loratadine Tablets	Amphetamine Mix ER
Lisinopril Tablets	Bupirone Tablets
Lisinopril with Hydrochlorothiazide Tablets	Enalapril Tablets



# Kyriakos Michailaros

## Head of Drug Product Services

Megestrol Suspension  
Mupirocin Ointment  
Fluoxetine Liquid  
Fluoxetine Tablets 10 mg  
Olanzapine Orally Disintegrating Tablets 5 mg  
Oxycodone HCl Tablets  
Hydrocodone HCl Tablets  
Oxycodone HCl with Acetaminophen Tablets  
Hydrocodone HCl with Acetaminophen Tablets  
Citalopram Tablets  
Haloperidol Tablets  
Sildenafil Tablets  
Valsartan Tablets  
Ketoconazole Cream  
Clobetazole Propionate Gel  
Lovastatin  
Dexpramipexole

Enalapril HCTZ Tablets  
Fluphenazine Oral Solution  
Propoxyphene Napsylate with Acetaminophen  
Risperidone Tablets  
Quetiapine Fumarate  
Amphetamine Mix ER  
Ortho Evra Patch ®  
Nicoderm Patch ®  
Lixivaptan  
Recombinant Salmon Calcitonin  
Betrixaban  
XOMA 985 Tablets  
Plenadren Tablets  
Amino Acid Blends  
TWIRLA ®  
Dextromethorphan HBR