



Get projects done.



Kymanox Process Operations Services

Linking Development and Manufacturing

Process knowledge and **process design** are central to Kymanox's Process Operations services. We align our approach with the principles of **Quality by Design** and use professional **project management** methodologies. With expertise in **upstream** and **downstream bioprocessing** technologies, we apply best practices for both the initial **setup** and ongoing **management** of process operations. **Planning** and **risk management** are employed early in the drug development program to avoid costly troubleshooting down the road. Our team has **proven, successful experience** in:

- **Technology transfer** and **scale-up** for Phase III and commercial processes
- Process **troubleshooting** and optimization
- Process design from bench to **commercial** scale
- Creation of upstream and downstream **development strategies**
- **Feasibility** and business assessments including cost modeling
- CMO **person-in-the-plant** representation
- **Resource, budget** and **capacity** planning for development and manufacturing
- **Fast-track** preparation and execution of **cGMP campaigns**
- Planning and managing of clinical and commercial drug product **supply chains**
- Process **mapping** and process **modeling**
- **PAT, Six Sigma, and LEAN** implementations
- Hands-on **execution** and **supervision** of **start-up** cGMP manufacturing
- Technical and quality **audits** at prospective CMOs

Synergy with other Kymanox Services

Kymanox holds a **360° view** of process operations; we augment our activities with the following capabilities:

- **Engineering** and **Manufacturing Science**
- **Automation** and **Controls**
- **Training**
- **Quality, Compliance** and **Regulatory**

Integrating Science with Business and Compliance

With a focus on **cGMP-compliant** and **financially viable** processes, Kymanox helps its clients avoid costly and often irreversible missteps. Together with our clients, we help select the optimal **processing methods, equipment** and **components** from early development through commercial cGMP manufacturing.

Contact Kymanox

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