AURIGENE

PHARMACEUTICAL SERVICES

Process Development

Phase appropriate development to meet the customer needs as well as the regulatory requirements.

Early-phase development | Late-phase development | Process optimization | QbD and DoE | Analytical development | Analytical validation | Process validation | Life-cycle management

/AurigenePharma

/aurigenepharmaceuticalservices

/AurigenePharmaceuticalServices

www.aurigeneservices.com

contactapsl@aurigeneservices.com

North America: +1 617 821 0595

European Union: +32 471 808710

Key highlights

- Safety and scalability
- Process efiiciency
- Increased throughputs
- Sustainaible manufacturing process
- Large supply chain network

Early phase

- Phase approprite development with faster turnaround time
- Dedicated team for early phase development and manufacturing
- Chromatographic capability
- Experience in handling complex and new chemistry
- Polymorph and salt screeening capabilities
- Integrated DS+DP capabilities

Late phase

- Process optimization based on DoE, QbD
- Analytical validation
- Process validation
- Polymorph screening and optimization
- Particle engineering capability
- Quality and regulatory support

Why Aurigene Pharmaceutical Services?

1. Phase-appropriate development
2. Legacy of developing 500+ APIs
3. Horizontal capabilities like polymorph screening, material science, QbD, PAT tools
4. Network of multiscale R&D, non-GMP and GMP manufacturing facilities
5. Ability to handle various types of chemistry and technology platform
6. Value added services – regulatory and IP
7. US FDA approved R&D and manufacturing facilities

/AurigenePharma
/aurigenepharmaceuticalservices
/AurigenePharmaceuticalServices
www.aurigeneservices.com
contactapsl@aurigeneservices.com
North America: +1 617 821 0595
European Union: +32 471 808710