

## **APIs and Intermediates**

The CDMO Division of KD Pharma excels in the production of drug intermediates and API drug substances. We offer our customers the full spectrum of drug services:

- R&D development material for preclinical studies
- Pilot plant for phase I, II and III supplies
- Large scale production of metric ton amounts for commercial supply

We excel in rapid scale up and multi-step synthesis with a proven track record of successful custom productions for a number of global pharmaceutical companies.



## Basis of Our Success:

- Agile, right sized company = experienced work force able to quickly implement chemical synthesis and adjust for the needs of process scale-up
- Flexible production trains with adaptable configuration avoiding bottlenecks
- Right first time and continuous improvement culture
- Excellent quality system and regulatory track record

## KD Pharma's Position on Intellectual Property:

Simply: You pay for it, you own the IP.

## API Examples for the US, European and Japanese Markets:

Case study 1:

- 10 step synthesis
- Key technologies: Hazardous reagents, heterocyclic chemistry
- All steps were validated
- Production/validation on 1.3 mt scale API completed in 7 months

Case study 2:

- 11 step synthesis with the need to control several stereocenters
- Carbohydrate and heterocyclic chemistry including high pressure catalytic hydrogenation (50 bar)
- Largest scale done before: 10 kg
- Production / validation on 1'000 kg scale in 11 months from scratch
- Demonstrated cost reductions over time

Let's discuss your specific manufacturing challenges today! Contact us at: **CDMO@kdpharmagroup.com** 



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