Choosing a CDMO
for Your Reformulation Needs

RECRO®

Reformulating an oral solid dosage (OSD) product can be a challenging process. Choosing a CDMO that has the right combination of experience, equipment, and technology is imperative. Here are some points to consider when choosing a CDMO for your drug product reformulation project.

POINTS TO CONSIDER AND QUESTIONS TO ASK:	RECRO'S CAPABILITIES:
Experience Does the CDMO have a long history of working with modified release formulations? What is the depth of knowledge and tenure of the team working on your project?	**Experience** • Lengthy history with modified release formulation approaches for OSD forms • Over 40% of employees have more than 10 years at the facility • 43% of the product development team have Ph.D.s
A Focus on Oral Solid Dosage Forms Many CDMOs work with different dosage forms. Is the CDMO focused on staying current with oral solid dosage technologies?	**The CDMO specializes in:** • Simple to complex formulations • Modified release technology • Phase-appropriate analytical approaches • Controlled substances • High potency compounds • Flexible-scale clinical through commercial manufacturing and packaging • Integrated regulatory support starting with a product's conceptualization and continuing through commercialization and post-approval product lifecycle management
Start to Finish Capabilities Working with the same CDMO from product development through commercial manufacturing can save time and yield cost savings. Does your CDMO's capabilities span the product development value chain – from concept to commercialization?	**Capabilities Across All Areas** • Flexibility in scale allows support for products with smaller batches sizes (e.g. for orphan indications) and for those requiring large-scale production • Extensive expertise from early feasibility and product development to clinical and commercial manufacturing and packaging • Effective communication and partnering between development and commercial teams result in efficient scale-up and tech transfer activities
Regulatory Having the experience and resources to work with the FDA, DEA, and international regulatory authorities is essential. What is your CDMO's track record regarding inspections and audits? How many times have they been visited by regulators? What was the outcome?	**Regulatory Expertise** • 20+ years of experience with DEA controlled substances • 20+ years of successful face-to-face FDA meetings • 7 product launches

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