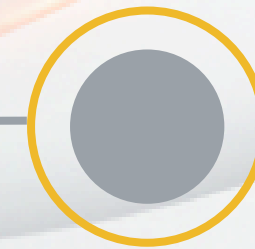
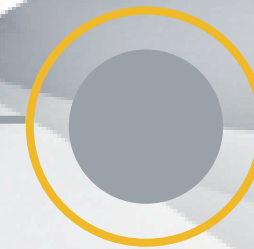
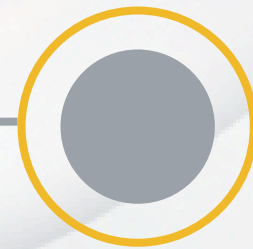
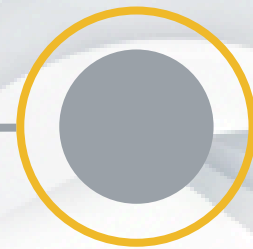
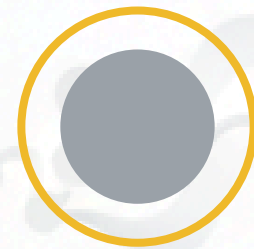
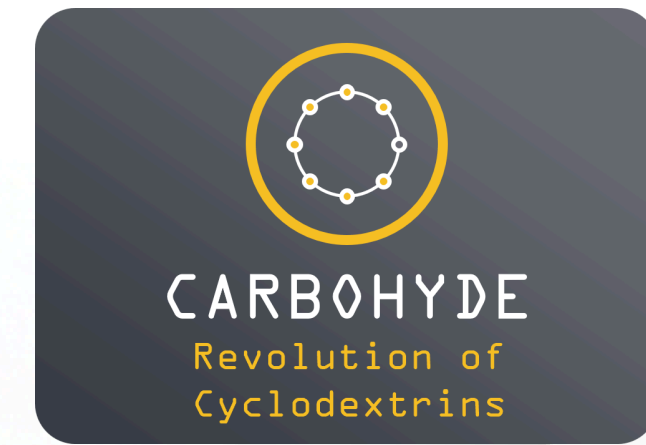


# From lab bench to industrial manufacturing

CDMO Project Management & CMC Services

One partner. One plan. Full control



## Strategy & Planning

- CMC strategy
- CDMO selections
- Risk assesment

## Development & Analytics

- Formulation
- Method development
- Characterization

## Scale-up & Tech tranfer

- Process optimization
- Pilot batches
- Packaging

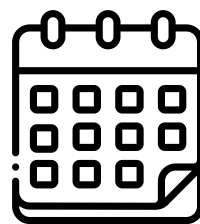
## GMP manufacturing

- Validation batches
- Clinical batches

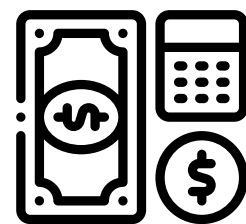
## Commercial Readiness

- Documentation
- Regulatory support
- Stability testing

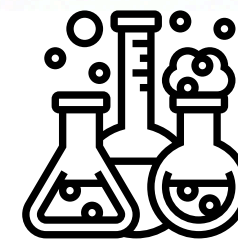
## Why clients work with us



Faster development timelines



Controlled cost and scope



Scientifically grounded decisions



Audit- and authority -ready process

tamas.vargadi@carbohyde.com

# End-to-End Drug Development Services

## Project Management + Expert CMC Support



### Program Setup & CDMO Management

CMC development strategy (preclinical → clinical → commercial)  
Target Product Profile and quality strategy alignment  
CDMO selection, RFI/RFQ/RFP and vendor governance  
Integrated project management (timeline, cost, risk)  
Single client-side point of coordination

### Drug Substance (API) Development & Manufacturing

Route scouting and process development  
Scale-up from laboratory to pilot and GMP scale  
GMP API manufacturing (clinical and validation batches)  
API analytical method development and transfer  
Impurity profiling and control strategy

### Drug Product Development

Preformulation and solid-state characterization  
Formulation development and optimization  
Excipient compatibility and manufacturability assessment  
In-vitro performance testing (dissolution / release)  
GMP drug product manufacturing support

### Analytical, Stability & CMC Support

Analytical method development and validation (ICH Q2)  
Release testing and specification setting  
Stability-indicating methods and comparability analytics  
ICH stability studies and shelf-life assignment  
Stability trending, protocols and reporting

### Risk, Impurity & Bioanalytical Programs

Impurity identification and genotoxic impurity assessment  
Nitrosamine risk assessment and testing  
Container-closure interaction / E&L studies  
Bioanalytical method development (e.g. LC-MS/MS)  
PK/PD and ADME/DMPK support

### Quality, GMP & Regulatory Support

GMP compliance and QA interface management  
Quality agreements, deviations, OOS and change control  
Audit preparation and CDMO audit support  
CMC documentation for IND / IMPD / CTA submissions  
Regulatory agency Q&A and lifecycle management support