

# Commercial Ready Roadmap

*All the steps to get you on the road to commercialization*

## 9-12 months before approval

- Commercialization Roadmap Development
- Pre-Commercial Design Initiatives



## 6-9 months before approval

- ERP Selection Complete
- RACI and Process Development
- Distribution/Revenue Plan



## 2-4 months before approval

- System Controls & Responsibilities Determined
- Costing Method Selected
- Item Master Definition
- System Validation Strategy



## 6 months before approval

- ERP Implementation Kickoff
- CMO Commercial Contracts Finalization
- Future State IT Architecture



## 1-2 months before approval

- ERP/Systems Go-Live
- Integrations to 3<sup>rd</sup> Parties



## PDUFA/approval

- Begin Capitalization (Cost Accounting)
- Commercial Sales Commence

