



NAME:

COMPANY:

PHONE:



PHARMACEUTICAL CHEMISTRY DEVELOPMENT

DRUG DEVELOPMENT RISK ASSESSMENT SCORECARD

OVERVIEW

Pharmatek's Drug Development Risk Assessment Scorecard allows managers to get a dashboard view of critical aspects in their specific oral drug development program. The Scorecard is defined by 8 key categories where project managers are able to evaluate the risk associated with their project. Once the components of risk are understood, strategies can be implemented to mitigate some of this potential risk going forward.

DIRECTIONS

For each category on the Scorecard, assess its risk based on the potential complexity it brings to your drug development program. Each category is given a numeric score of 0, 1, or 2 using the scale below.

- 0- Low Risk
- 1- Standard Risk
- 2- High Risk

SCORING

The risk score for each category is summed to generate a Total Score. The Total Score is then Used to quantitatively assess the Overall Project Risk for any given drug development program using the guideline below.

Total Score	Overall Project Risk
0-4	Low
5-8	Standard
9-16	High

Go to www.pharmatek.com/scorecard for more information on risk mitigation strategies and representative scoring models.

Category	Definition	Risk Score
Biopharmaceutics Classification System	<ul style="list-style-type: none"> ▪ I (Soluble and permeable) ▪ II (Not soluble but permeable) ▪ III (Soluble but not permeable) ▪ IV (Not soluble or permeable) 	
API Supply	<ul style="list-style-type: none"> ▪ Quantity and quality of research, non GMP and GMP batches of API ▪ Timing of API availability is key ▪ Considerations: -Crystalline or Amorphous -Polymorphs 	
API Stability	<ul style="list-style-type: none"> ▪ Solid State (oxygen, moisture, light, heat) ▪ Solution (aqueous pH range) ▪ Stability-indicating analytical method required 	
Highly Potent/Cytotoxic	<ul style="list-style-type: none"> ▪ APIs characterized as highly potent or cytotoxic require special handling, limiting vendor selection and increasing development costs ▪ Consult Pharmatek or other qualified banding system, such as Safebridge 	
Dosage Strength	<ul style="list-style-type: none"> ▪ Appropriate for Phase I ▪ Outside 1mg to 250mg may require additional formulation considerations 	
Formulation	<ul style="list-style-type: none"> ▪ Strategy: Staged formulation development approach or commercial formulation? ▪ What is the proposed FIM dosage form: PIC, PIB, dry blend, or solubility enhancing formulation 	
Quality of CMC Leadership	<ul style="list-style-type: none"> ▪ Source of CMC strategies to support all development needs such as: quality, timing, scientific scope, and cost 	
Timing	<ul style="list-style-type: none"> ▪ The development timeline leading to the proposed IND filing date. 	
Total Score		