

Co – Development project (Business Case example)



BUSINESS MODEL PRE-REGISTRATION

PREFORMULATION / FORMULATION



Galenic Development

SCALE - UP



* Tech transfer
* Analytical methods transfer (API/Finished product)

VALIDATION BATCHES



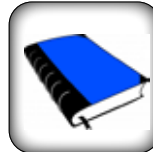
* Production of validation batches
* Stability Studies

REGULATORY



Bio equivalence

REGULATORY AFFAIRS



Dossier compilation

Partner:
(at cost)
+
Rovi:
(at cost)

API
+
GD

50/50 %

API
+
Pilot equipment
Laboratory

50/50 %

API
+
Production
and analysis

50/50 %

API
+
Bioeq.

50/50 %

DMF
+
Dossier compilation
& Fees

50/50 %

COST

BUSINESS MODEL POST-REGISTRATION

COMMERCIAL MANUFACTURING



Industrial batches

API
+
Manufacturing

50/50 %

DOSSIERS



* Licensing out dossiers
* Down Payment

50 %

50 %

INCOMES MANUFACTURING



* Marked up CoGs

15 % over API CoGs

15 % over manf. cost

TRANSFER PRICE



Margin

50 %

50 %

PROFIT

COST - PROFIT SHARING 50/50 % (VIRTUAL JOINT VENTURE)