PHYTEX CUSTOMER DRUG DEVELOPMENT JOURNEY

DOCUMENTATION & INFORMATION SUPPLIED BY CLIENT TO MOVE THROUGH PROCESS

- Consideration of API supplier
  - Alternative supplier required
  - Consumer market identified
  - Locating of suppliers
  - Supplier short-list
  - FDA DMF Registry search
  - Online search
  - Due diligence
- Project stage details
  Customer questionnaire
  Target market
  Dev. Supply requirements
- Drug Product (DP)
  Sponsor
  CMO Details
- PO Placement
  Shipping details
  Letter of Use
- Sample Analysis Feedback
  Method qualification
  API suitability in Drug Product
  DP Stability Trials
- Onsite Audit
  NDA/ANDA Preparation
  DP controlled Trials
- NDA/ANDA Filing
  Sec 1.1-14,
  2.3, 2.7,
  3.2.P.1-8,
  3.2.R.P,5.2-3

INITIAL ENQUIRY | **CDA SIGN OFF** | **SAMPLE PROVIDED (25-100G)** | **SUPPLIER / CUSTOMER QUALIFICATION** | **CLINICAL TRIALS (3 x XX KG) SUB. BATCHES (3 x XX KG)** | **IND / NDA / ANDA LODGMENT**

DUE DILLIGENCE | **QUALITY ASSESMENT** | **TECHNICAL REVIEW** | **COLLABORATE DEVELOPMENT** | **APPLICATION & APPROVAL**

MOVE TO COMMERCIAL SUPPLY

- R&D Pricing
  Payment terms & details
  Shipping/Logistics
  Quality Overall Summary
  Required Statements
- US agent details
- Additional Tech info
  Method Transfer
  Product specific info
- CT Pricing
  Mfg Scheduling & Lead Time
  Shipping/Logistics
  Open Filing info (2.3.S & 3.2.S.1-7)
  Tech development collaboration
- Filing Support
  API Tech info
  DP Sponsor LofA Submission
  DMF Maintenance & updates
  Annual Reporting
- Company introduction
  Gen. product spec sheet
  Gen CofA
  Regulatory credentials/certs

PHYTEX COMMITMENTS TO MOVE THROUGH PROCESS

Our core focus is on ***reliability*** in addition to ***close collaboration*** with customers in critical and technical challenges in product formulation, application process, clinical trials and expansion.

Security of supply is underpinned by strong supplier partnerships.