PHARMACEUTICALS & BIOTECHNOLOGY CORPORATE CLIENT INTAKE QUESTIONNAIRE:

REPORTING CLOCKS RUN IN DAYS. Serious and unexpected adverse events, product quality field alerts, controlled substance losses, and recall decisions all carry short deadlines. Do not include patient identifiers or unpublished clinical data on this form — we will arrange a secure channel after a confidentiality agreement is in place.

CONFIDENTIAL. This questionnaire covers corporate legal work and capital markets advisory for pharmaceutical and biotechnology businesses — innovator and generic manufacturers, biotechnology companies, contract manufacturers, product license holders, distributors and retailers, and veterinary and preventive product companies. Complete the sections that apply. If a question does not apply, write "N/A."

NAME OF THE CLIENT:

[__] Legal Entity Name: _____

DBA / product or brand names: _____ Year founded: _____

Entity type:

- [__] Corporation
- [__] LLC
- [__] Partnership
- [__] Public company
- [__] Subsidiary of a parent
- [__] Foreign parent or operations

State of formation: _____ EIN (last 4): _____

Establishment registration no.: _____ Syndicate Plan Member ID: _____

Contact person & title: _____

Address: _____

City: _____ County: _____ State: _____ Zip: _____

Phone: _____ Email: _____

Annual revenue: $ _____ Employees: _____

PART 1 — YOUR BUSINESS

1.1 Type of business:

- [__] Innovator / brand manufacturer
- [__] Generic manufacturer
- [__] Biotechnology company
- [__] Contract manufacturer (CDMO)
- [__] Active ingredient manufacturer
- [__] Product license holder
- [__] Distributor / wholesaler
- [__] Repackager or relabeler
- [__] Retailer or pharmacy
- [__] Veterinary products
- [__] Preventive products & vaccines
- [__] Therapeutic products
- [__] Over-the-counter products
- [__] Compounding facility

1.2 Product types:

- [__] Small molecule
- [__] Biologic
- [__] Biosimilar
- [__] Vaccine

[__] Cell or gene therapy [__] Controlled substances

[__] Combination products [__] Diagnostics

1.3 Describe your products, pipeline, and current stage: _____

_____

_____

PART 2 — SERVICES NEEDED

Entity, Governance & Filings:

[__] Formation or incorporation [__] Entity conversion / restructuring

[__] Operating agreement / bylaws [__] Corporate resolutions

[__] Annual reports & business filings [__] Foreign qualification

[__] International incorporation [__] Business licenses & permits

Regulatory & Marketing Applications:

[__] Marketing application strategy for drugs, biologics & devices [__] Pathway & exclusivity analysis

[__] Establishment registration & product listing [__] Emergency use authorization & follow-up strategy

[__] Labeling & package insert review [__] Promotional & advertising review

[__] Off-label communication policies [__] Adverse event reporting & pharmacovigilance

[__] Recalls, field alerts & corrections [__] Inspection response & warning letters

Clinical Research & Development:

[__] Clinical trial agreements & site contracts [__] Investigator & consultant agreements

[__] Institutional review & consent documents [__] Privacy & authorization requirements for research

[__] Data integrity & records requirements [__] Trial registration & results posting

[__] Research collaboration & sponsored research agreements [__] Material transfer agreements

Manufacturing, Quality & Supply Chain:

[__] Good manufacturing and laboratory practice compliance [__] Quality agreements

[__] Contract manufacturing & fill-finish agreements [__] Active ingredient & raw material supply agreements

[__] Supply chain security & serialization [__] Distributor agreements

[__] Import, export & customs requirements [__] Controlled substance registration & recordkeeping

[__] Supply chain disputes [__] Global supply continuity planning

Pricing, Government Programs & Compliance:

[__] Government price reporting obligations
[__] Medicaid, Medicare & veterans program requirements
[__] 340B program compliance
[__] Payer, PBM & group purchasing contracts
[__] Patient support & copay program review
[__] Sales & marketing compliance program
[__] Anti-kickback & referral analysis
[__] Transparency & payment reporting
[__] False claims exposure review
[__] Speaker, advisory board & consultant arrangements

IP, Licensing & Capital Markets:

[__] Patents & freedom to operate
[__] Patent listing & exclusivity strategy
[__] Licensing & technology transfer
[__] Trademarks & brand protection
[__] Trade secrets & know-how
[__] State & international product licensing
[__] Capital markets consultation & private placements
[__] Exchange listing (OTC, Nasdaq, NYSE, international)
[__] Mergers, acquisitions & asset sales
[__] Royalty monetization & milestone financing

2.1 Describe your most urgent matter and objective: _____

_____

_____

2.2 Deadline (submission, response, launch, closing): _____

PART 3 — PRODUCTS & REGULATORY STATUS

Product / Candidate	Type	Application Type & Number	Stage	Territory

3.1 Are establishment registration and product listings current? [__] Yes [__] No

3.2 Are any applications pending, or are responses to agency questions due? [__] Yes [__] No

3.3 Do you hold or seek an emergency use authorization? [__] Yes [__] No

3.4 Are products marketed under a monograph or without an approved application? [__] Yes [__] No

3.5 Have you received inspection observations, warning letters, or import alerts? [__] Yes [__] No

If yes, explain: _____

_____

3.6 Have there been recalls, field alerts, or market withdrawals? [__] Yes [__] No

If yes, explain: _____

_____

PART 4 — QUALITY, PHARMACOVIGILANCE & SUPPLY CHAIN

Program Area	In Place	Needs Update	Missing
Quality system & good manufacturing practice compliance	[__]	[__]	[__]
Quality agreements with manufacturers & suppliers	[__]	[__]	[__]
Supplier qualification & audits	[__]	[__]	[__]
Batch records & data integrity controls	[__]	[__]	[__]
Adverse event intake & reporting procedures	[__]	[__]	[__]
Product complaint handling	[__]	[__]	[__]
Recall & field alert procedures	[__]	[__]	[__]
Serialization & supply chain security	[__]	[__]	[__]
Controlled substance security & suspicious order monitoring	[__]	[__]	[__]
Import & export documentation	[__]	[__]	[__]

4.1 Do you manufacture, or use contract manufacturers? [__] Yes [__] No

If yes, explain: _____

_____

4.2 Do quality agreements allocate regulatory responsibilities? [__] Yes [__] No

4.3 Do you handle controlled substances, and are registrations and quotas current? [__] Yes [__] No

4.4 Have there been losses, thefts, or diversion incidents? [__] Yes [__] No

4.5 Are single-source ingredients or facilities a supply risk? [__] Yes [__] No

PART 5 — CLINICAL RESEARCH

5.1 Are clinical studies underway or planned? [__] Yes [__] No

Phases, sites & sponsor role: _____

5.2 Are site agreements, budgets, and indemnities documented? [__] Yes [__] No

5.3 Are consent forms and privacy authorizations reviewed for each protocol? [__] Yes [__] No

Research involving identifiable health information requires authorization or an approved waiver, and sponsors should confirm site obligations in writing.

5.4 Are trials registered and results posted as required? [__] Yes [__] No

5.5 Do you use contract research organizations or academic collaborators? [__] Yes [__] No

5.6 Are data integrity, monitoring, and audit procedures documented? [__] Yes [__] No

PART 6 — COMMERCIAL, PRICING & FRAUD AND ABUSE

6.1 Distribution channels:

[__] Direct to wholesalers
[__] Specialty pharmacy
[__] Retail pharmacy
[__] Hospital & health system
[__] Government purchasers
[__] International distributors
[__] Direct to consumer

6.2 Do you participate in government pricing or rebate programs? [__] Yes [__] No

Government price reporting obligations carry certification requirements and significant penalties for inaccurate reporting.

6.3 Do you offer patient assistance, copay, or free goods programs? [__] Yes [__] No

6.4 Do you pay physicians as speakers, advisors, consultants, or investigators? [__] Yes [__] No

6.5 Are payments to providers tracked and reported as required? [__] Yes [__] No

6.6 Is promotional material reviewed before use, with a documented process? [__] Yes [__] No

6.7 Any investigative demand, subpoena, or whistleblower complaint? [__] Yes [__] No

Syndicate provides advisory and compliance support; representation in investigations and litigation is handled by counsel of record.

PART 7 — IP, LICENSING & CAPITAL MARKETS

7.1 Do you own or license patents covering your products? [__] Yes [__] No

7.2 Are patent listings or exclusivities part of your strategy? [__] Yes [__] No

7.3 Are there patent challenges, notices, or infringement claims pending? [__] Yes [__] No

If yes, explain: _____

_____

7.4 Do you license products in or out, and are milestones and royalties tracked? [__] Yes [__] No

Existing Debt / Investment	Lender or Investor	Amount $	Terms	Secured By

7.5 Capital sought: $ _____ Purpose: _____

7.6 Capital strategy:

[__] Research & development
[__] Clinical program funding
[__] Manufacturing scale-up
[__] Commercial launch
[__] Working capital
[__] Growth equity or venture capital
[__] Public offering or listing
[__] Sale of the company or a product

PART 8 — PEOPLE, DISPUTES, DOCUMENTS & CERTIFICATION

8.1 Employees: _____ Contractors: _____ States / countries with workers: _____

8.2 Is immigration sponsorship needed for scientists or regulatory staff? [__] Yes [__] No

8.3 Current disputes:

- [__] Product liability or injury claim
- [__] Supply or manufacturing dispute
- [__] Distributor or payer dispute
- [__] Patent or IP dispute
- [__] Government investigation
- [__] Regulatory enforcement
- [__] Employment claim
- [__] Collections
- [__] None

8.4 Is a non-disclosure agreement required before documents are shared? [__] Yes [__] No

Please provide the following, if applicable. Check each item available. Do not include patient identifiers or unpublished study data.

- [__] Formation & governance documents
- [__] Ownership / cap table
- [__] Financial statements & projections
- [__] Applications, approvals & correspondence
- [__] Labeling & promotional materials
- [__] Quality & manufacturing agreements
- [__] Clinical trial & research agreements
- [__] Distribution & payer contracts
- [__] Patent filings & license agreements
- [__] Agency notices & inspection records

Certification:

I declare that the information provided in this questionnaire is true, correct, and complete to the best of my knowledge, that I am authorized to provide it on behalf of the business named above, and that it does not include patient identifiers. I understand this information is provided to Syndicate Subscription Legal Plans in confidence for the purpose of evaluating and scoping this engagement.

Signed and dated this ____ day of _____, 20___

Signature: _____

Print Name: _____

Title: _____

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Your information will be reviewed within one hour.