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Emerging Life Sciences Companies

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Chapter 26

Key Contract Provisions for
Supply and Manufacturing Agreements

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KEY CONTRACT PROVISIONS FOR SUPPLY AND MANUFACTURING AGREEMENTS

The following outline sets forth key contract provisions that the parties should consider when negotiating and drafting supply and manufacturing agreements.

Coordination—Establishment of Supply Team

- A. Scope
 - 1. Requirements; output; exclusivity
 - 2. Commitment to supply/allocation of supply (in case of supply shortage)
 - 3. Subcontractors
 - a. Identities to be disclosed to purchaser
 - b. Approval required by purchaser
 - c. Terms consistent with supply agreement
 - d. Subcontractor oversight program
 - e. Change of subcontractor
 - 4. License grant
 - a. Use of technology to supply
 - b. Grant back—rights to inventions
 - c. Right to sublicense to contractors
 - d. Reservation of rights
 - 5. Change of supplier—supplier may assign contract to an affiliate or third party
 - a. Subject to approval by purchaser
 - b. Guarantees by supplier that assignee will abide by terms of supply and/or technical agreements
- B. Forecasting and ordering
 - 1. Initial forecast (binding/nonbinding)

2. Long-range forecasts (binding/nonbinding)
 3. Rolling forecasts; firm orders
 - a. Period of time encompassed by forecast
 - b. Excess of firm order above previous forecast. (What are supplier's obligations with respect to firm orders of material that exceed previous forecasts? With respect to prior firm orders?)
 4. Order size; lead time—state minimum and maximum orders
 5. Purchase orders
 - a. Acceptance/rejection by purchaser
 - b. Information to be included
 - (i) Order size
 - (ii) Delivery date
 - (iii) Request for additional terms
 6. Safety stock
- C. Sourcing of raw materials
1. Appropriate supplier contracts—supplier and its affiliates and subcontractors shall establish appropriate contracts with suppliers of raw or key materials and shall make reasonable efforts to ensure stability of its sources of supply
 2. Inventory management processes—supplier shall implement and, as necessary, update inventory management processes and procedures reasonably designed to ensure that supplier has on hand, when necessary, key raw materials
 3. Establishment of second sources of supply—supplier shall have on hand inventories of raw materials to meet specific demand for advanced periods of supply
 4. Establishment of secondary sources of supply
- D. Product labeling and packaging
1. Initial layout and package insert (should suppliers have input?)
 2. Changes to labeling and packaging
 - a. Cost of changes
 - b. Timeliness of changes
 3. Patent marking
 4. Packaging standards

- a. Specifications established by purchaser (possibly a quality agreement)
 - b. Regulatory specifications
 - c. Additional standards subsequently agreed to by the parties
5. Validation—packaging and labeling equipment
 6. Inspection—purchaser, or third party appointed by the purchaser, shall have the right to inspect the equipment (state frequency of inspection)
 7. Packaging and labeling equipment

Storage and Segregation of Product Inventories

A. Shipping and delivery

1. Shipping and delivery dates—to be provided by purchaser. Subject to lead-time requirements. To be supplied with orders?
2. Terms of delivery
 - a. Method of delivery
 - b. Allocation of risk
 - c. Incoterms 2000
3. Shipping costs related to transportation and costs of naturalization
 - a. Who will pay?
 - b. Reimbursement procedures
4. Shipment/retention of samples
5. Shipping documentation
 - a. Bill of lading
 - b. Certificate of conformance/certificate of analysis
6. Shelf life
7. Retention of samples

B. Inspection and acceptance

1. Inspection by purchaser/testing of shipment samples
 - a. Detectable defects—damages that are apparent are to be reported to supplier within specified period of time of receipt of shipment (generally 10–30 days). Must notify supplier within short period of time after discovery of defect.
 - b. Nondetectable defects (latent defects)—use of quality control/testing procedures by purchaser to discover defects that are not readily apparent

- (purchaser generally given longer period of time to test products and discover additional defects)
- c. Failure to notify—subject to loss of rights with regard to defective products; purchaser must notify supplier within reasonable period of time of delivery of defective product
 - d. Disagreement regarding defective product—parties will submit samples taken from an allegedly defective batch for additional laboratory testing (performed by third party) to determine if shipment is in compliance with preestablished standards
2. Remedies
 - a. Replacement product
 - b. Out-of-pocket costs to purchaser associated with defective products
 - c. Disposal of defective products
 3. Risk of expiry
- C. Failure to supply
1. Shortages
 2. Maintenance during shortages
 3. Costs incurred as a result of failure to supply
 4. Research of rights
 5. Assumption of certain manufacturing activities by purchaser
- D. Product pricing
1. Mechanism for calculation
 2. Price adjustment and incentives
 - a. Index used for price adjustment
 - b. Year-end reconciliation based on forecast/order disparity
 - c. Sharing of cost efficiencies
 3. Payment terms
 - a. Wire instructions
 - b. Late payments
 4. Taxes
 5. Currency exchange

6. Products not subject to normal pricing mechanisms
 - a. Commercial samples
 - b. Clinical supplies
- E. Regulatory issues
 1. Quality/technical agreement
 2. Manufacturing facility inspections and audits
 3. Subcontractor inspections and audits
 4. Approval of new facilities/subcontractors
 5. Facility registrations and approvals
 6. Maintenance of batch documentation
 7. Use of appropriate test methods
 8. Procedures for process changes; notice and regulatory approvals
 9. Stability testing; sample retention
 10. Accident reports
 11. Annual reviews and reporting

Handling of Raw Materials and Wastes—Environmental Matters

- A. Effect of product discontinuance/recalls
 1. Ability to discontinue product
 - a. Allowable reasons for discontinuance
 - b. Failure to obtain regulatory approval
 - c. Financial penalties
 - d. Liability
 - e. Insufficient marketing opportunities
 2. Liability associated with product discontinuance
 3. Product recall
 - a. Recall attributable to supplier
 - (i) Notification of other party
 - (ii) Communication with regulatory authorities
 - (iii) Costs associated with recall

- (iv) Logistics of recall—control
 - (v) Remedies of purchaser
 - b. Recall attributable to purchaser
 - (i) Notification of other party
 - (ii) Communications with regulatory authorities
 - (iii) Costs associated with recall
 - (iv) Logistics of recall—control
 - (v) Remedies of supplier
 - c. No-fault recall
 - (i) Notification
 - (ii) Communication with regulatory authorities
 - (iii) Costs associated with recall
 - (iv) Logistics of recall—control
- B. Confidentiality and publicity
 - 1. Mutual obligations
 - 2. Existence and terms of agreement
 - 3. SEC filings
 - 4. Press releases
- C. Representations and warranties
 - 1. Basic corporate warranties
 - 2. Product warranties
 - a. Compliance with cGMPs, monographs, compendia, and so forth
 - b. Compliance with agreed-upon specifications, labeling requirements, and so forth
 - c. Not adulterated or misbranded
 - d. No disbarred employees/subcontractors used to manufacture
 - e. Good title; no liens or encumbrances
 - 3. Disclaimer of additional warranties

- D. Indemnification and limitations of liability
 - 1. Breach of representations and warranties
 - 2. Gross negligence or willful misconduct
 - 3. Procedures for third-party claims
 - 4. No liability for consequential and related damages
- E. Term and termination
 - 1. Term
 - a. For a defined period of years
 - b. Annual renewal unless terminated with at least two years' prior notice
 - 2. Termination
 - a. For material breach
 - b. For bankruptcy
 - c. By mutual consent
 - d. For convenience
 - 3. Return/destruction of confidential information
 - 4. Cross-default of other agreements
 - 5. Survival
 - a. Confidentiality
 - b. Indemnification and limitations of liability
- F. Miscellaneous
 - 1. Effect of change of control
 - a. By seller
 - b. By purchaser
 - 2. Assignment
 - a. By seller
 - b. By purchaser
 - 3. Bankruptcy protections
 - 4. Force majeure; allocation of capacity
 - 5. Insurance obligations
 - 6. Choice of law; dispute resolution