

Dietary Supplement/Pharma- Producer Playbook



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Table of Contents

- I. **Buyer Persona: "Supplement Sally" 1**
 - Background.....1
 - Demographics.....1
 - Identifiers.....1
 - Goals.....1
 - Chalanges1
 - What Can We Do 2
 - Objections..... 2
 - Marketing Message..... 2
 - Elevator Pitch 2
- II. **Initial Meeting Questions 3**
- III. **Setting the Pre-Close 4**
- IV. **Delivering the Rules of Engagement 5**
- V. **Risk Assessment 5**
- Dietary Supplement/Pharma FYI 9**



I. Buyer Persona: "Supplement Sally"

Background:

Demographics:

Identifiers:

Goals:

Challenges:

Dietary Supplement/Pharma- Producer Playbook



What Can We Do:

Objections:

Marketing Message:

Elevator Pitch:



II. Initial Meeting Questions

1. Can you provide a brief overview of the types of supplements or pharmaceuticals your company focuses on?

2. Are you currently insured? Why did you choose your current broker?

3. What are the aspects you appreciate about your current insurance relationship?

4. What do you wish your current broker did better?

5. How are you handling regulatory challenges and requirements?

6. Do you have any pending or past litigations or recalls?

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7. Can you share any experiences you've had with claims, whether they were resolved effectively?

8. What are your immediate and long-term goals for your business?

9. What challenges are you currently facing that you believe an insurance solution could remedy?

10. How would you describe your risk tolerance?

III. Setting the Pre-Close

"If we can solve your challenges and provide comprehensive coverage within your budget, are you willing to move forward with us?"



Identifying Decision-Maker and Budget:

1. Who is the decision-maker for selecting an insurance partner?
2. Can you give a ballpark figure of your insurance budget?

IV. Delivering the Rules of Engagement

"We will need to conduct a detailed risk assessment to provide the most accurate and tailored coverage solutions. Would you be the primary contact for these discussions?"

V. Risk Assessment

Comprehensive Company Profile:

1. Company Name:	
2. Location(s) and Billing Address(es):	
3. FEIN (Federal Employer Identification Number):	
4. Website:	
5. Decision Maker's Name(s) and Contact Info:	

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6. Annual Sales:	
7. Annual Payroll:	
8. Property Value:	
9. Key Employees:	
10. Subsidiaries or Affiliated Companies:	
11. Previous Insurance History:	
12. Current Risk Management Measures:	
13. Mergers and Acquisitions:	

In-Depth Coverage Risk Assessment:

<p>1. Regulatory Compliance:</p> <ul style="list-style-type: none">• How do you keep up-to-date with FDA and other relevant regulations?• Do you have a compliance officer or legal team?



2. Product Liability: <ul style="list-style-type: none">• Details of any past, pending, or anticipated recalls.• Protocols in place for quality control.
3. Supply Chain: <ul style="list-style-type: none">• Procedures for vendor selection and evaluation.• Measures for securing the supply chain against disruptions.
4. Intellectual Property: <ul style="list-style-type: none">• Inventory of patents, trademarks, copyrights, and proprietary technology.• Measures to safeguard against IP infringement.
5. Cyber Liability: <ul style="list-style-type: none">• Description of cybersecurity protocols.• Past incidents of data breaches and responses.
6. General Liability: <ul style="list-style-type: none">• Instances of on-site accidents, visitor injuries, or property damage.• Safety measures in place, like signage and first-aid.



7. Employee Safety: <ul style="list-style-type: none">• Description of safety training and protocols.• OSHA compliance measures and reports.
8. Business Interruption: <ul style="list-style-type: none">• Detailed crisis management and disaster recovery plans.• Backup suppliers and service providers in case of disruptions.
9. Director & Officers Liability: <ul style="list-style-type: none">• History of legal actions against company leaders.• Protocols for ethical governance and financial disclosures.
10. High-Value Equipment: <ul style="list-style-type: none">• List and values of high-cost machinery and technology.• Preventive maintenance schedules and safety features in place.
11. International Operations: <ul style="list-style-type: none">• Risks associated with foreign operations or sales.• Compliance with international laws and regulations.



12. Transportation and Logistics:

- Risks associated with shipping products or raw materials.
- Insurance coverage for fleet or outsourced transportation services.

13. Contractual Liabilities:

- Description of standard contracts with vendors, clients, and subcontractors.
- Provisions for indemnification and hold harmless clauses.

Dietary Supplement/Pharma FYI

DRUG STORES

Category: Retail Stores

SIC CODE: 5912 Drug Stores and Proprietary Stores

NAICS CODE: 456110 Pharmacies and Drug Retailers

Suggested ISO General Liability Codes: 12374, 12375

Suggested Workers Compensation Codes: 8045

Description of operations: Drug stores sell prescriptions and over-the-counter medications. Compounding pharmacies prepare drugs individually for customers. Operations can range from the small pharmacy that only fills prescriptions to retail stores that offer pharmacy services along with the sale of sundries to huge superstores that sell all varieties of general merchandise. While many drug stores are standalone businesses, some are located within a clinic, grocery store, hospital, nursing home, or physician's office. Delivery service may be available. Some drug stores have walk-in clinics offering health care services, including administering vaccines, medication regimen reviews, or sports physicals. Medical supplies and equipment rentals may be part of the operations. Some will offer a variety of services with little or no relationship to drug sales, such as beauty shops, key duplication, lunch counters or cafeterias, or shoe repair. Alcoholic beverages may be sold for off-premises consumption. Drug stores can be locally owned



or part of a regional or national chain or franchise. Some sell their products over the internet, although the FDA requires the customer to have a valid prescription. The Telephone Consumer Protection Act (TCPA) requires retailers to obtain express written consent from customers before sending text spam ads or robocalls.

Property exposure is moderate. Ignition sources are generally limited to electrical wiring, heating and cooling equipment. Packaging materials and many plastic items will add to the fire load. If there are oxygen tanks, the exposure to fire increases as these can explode. Storage of oxygen tanks should be away from heat sources. If a fire should occur, the loss could be substantial as the FDA requires most drug and alcohol stocks exposed to fire or smoke to be destroyed due to the possibility of contamination. If cooking is done, grills and deep fat fryers must have automatic fire extinguishing protection, hoods and filters. There should be fuel shut-offs and adequate handheld fire extinguishers. The kitchen must be kept clean and grease free to prevent fire spread. Theft is a significant exposure due to the amounts of narcotics and other popular street drugs, liquor, and tobacco products in the store. Individual items may be shoplifted. Appropriate security measures must be taken, including physical barriers to prevent entrance after hours and an alarm system that reports directly to a central station or the police department. Business interruption exposure can be high if alternative facilities are unavailable after a loss.

Inland marine exposures are from accounts receivable if the store offers credit, computers to transact sales and monitor inventory, signs, and valuable papers and records for customers' and vendors' information. Backup copies of all records, including computer files, should be made and stored off premises. Outdoor signs can be struck by lightning or vehicles, be blown over in heavy wind, or collapse due to the weight of ice and snow. There may be goods in transit if items are delivered to customers or between stores.

Crime exposures are from employee dishonesty and theft of money and securities from holdup or safe burglary. Background checks, including criminal history, should be conducted on any employee handling money. There must be a separation of duties between persons handling deposits and disbursements and reconciling bank statements. Receipting, inventory monitoring, and regular auditing are important. Money should be removed from cash drawers at regular intervals and moved to a safe away from the door. Irregular drops should be made to the bank during the day to prevent substantial cash accumulations. Narcotics should be inaccessible to customers and non-pharmacy employees and under constant surveillance to reduce the possibility of inventory shortage.

Premises liability exposure is high due to the number of visitors to the store. Waiting areas should be provided as some customers may be sick or have impaired mobility. There should be good lighting and adequate aisle space to prevent slips and falls. All



goods should be kept on easily reached shelves, so customers do not pull items down on themselves. Stock dropped on floors by customers must be retrieved promptly. Shattered glass from broken items must be cleaned up quickly. Floor coverings must be in good condition with no frayed or worn spots on carpet and no cracks or holes in flooring. Steps and uneven floor surfaces should be prominently marked. Sufficient exits must be provided and well marked, with backup lighting systems in case of power failure. The rental of medical equipment can result in additional injuries to customers who already have health problems. Equipment must be inspected and maintained after each use. Excellent housekeeping is required to prevent the spread of infectious diseases. Parking lots and sidewalks need to be in good repair with snow and ice removed and generally level and free of exposure to slips and falls. If the business is open after dark, there should be adequate lighting and appropriate security for the area. There should be a disaster plan in place for unexpected emergencies. Personal and advertising injury exposure can arise from allegations of copyright or trademark infringement, defamation, discrimination, invasion of customers' privacy should confidential medical information be released to unauthorized sources, and from apprehending and detaining suspected shoplifters, which may result in allegations of assault and battery, false arrest or detention, unauthorized or intrusive searches, or wrongful ejection from the premises. The use of closed-circuit camera systems prevents such incidents from evolving into a "he said, she said" situation. Shoplifting procedures must be fully understood and utilized by all employees.

Products and professional exposures are tied together. The training, experience, background, and expertise of anyone handling and dispensing drugs need a thorough review. A pharmacist must properly supervise pharmacy technicians. Compounding pharmacists may limit activities to adding flavorings to medications or may develop drugs for specialized use by a doctor's patient. Physician's instructions identifying the medication, dosage, and frequency of use must be followed. A denial of service claim may arise should a pharmacist refuse to fill a legally-prescribed medication. Some states now require pharmacists to review a patient's medical history before filling a prescription to avoid adverse reactions due to a combination of the patient's medications or possible allergic reactions to a new medication. Most states require that only healthcare professionals with appropriate credentials be permitted to issue prescriptions. However, recent legislation in some states has opened prescription writing to druggists, substantially increasing the exposure to loss. Some drugstores now offer limited health care services, including screenings and vaccine administration. If performed by an employee, proper licensure is required. If performed by a vendor, certificates of insurance showing professional liability are required. If liquor is sold, employees must be trained to verify that customers are not underage and recognize signs of intoxication.

Automobile exposure may be limited to hired nonownership for employees running errands. If delivery services are provided, all employees driving vehicles must have



appropriate licenses and acceptable MVRs. Vehicles must be regularly maintained with records kept.

Workers compensation exposure is moderate due to employees standing for long hours, using computers, and restocking, which requires lifting and placing items on shelves. Continual standing can result in musculoskeletal disorders of the back, legs, or feet. Trips, slips, and falls are common, as are cuts and punctures from broken glass. When work is done on computers, employees are exposed to eyestrain, neck strain, and repetitive motion injuries, including carpal tunnel syndrome. Lifting can cause back injury, hernias, sprains, and strains. Employees should be provided with safety equipment, trained on proper handling techniques, and have conveying devices available to assist with heavy lifting. Shelves should be easily accessible for storage. Stepladders should be available. Housekeeping in storage areas is vital to prevent trips and falls. Cleaning workers can develop respiratory ailments or contact dermatitis from working with chemicals. In any retail business, hold-ups are possible. Employees should be trained to respond in a prescribed manner. Cooking operations can result in cuts, slips, falls, and burns. Delivery drivers may be subject to robbery if they transport high-value street drugs.

Minimum recommended coverage:

Business Personal Property, Business Income and Extra Expense, Accounts Receivable, Computers, Signs, Valuable Papers and Records, Employee Dishonesty, Money and Securities, General Liability, Employee Benefits, Professional, Umbrella, Hired and Nonownership Auto, Workers Compensation

Other coverages to consider:

Building, Earthquake, Equipment Breakdown, Flood, Leasehold Interest, Real Property Legal Liability, Spoilage, Goods in Transit, Computer Fraud, Forgery, Active Shooter, Cyberliability, Employment-related Practices, Liquor Liability, Business Auto Liability and Physical Damage, Stop Gap Liability

PHARMACEUTICALS

Category: Manufacturing

SIC CODE: 2833 Medicinal Chemicals and Botanical Products

2834 Pharmaceutical Preparations

2835 In Vitro and In Vitro Diagnostic Substances

2836 Biological Products, Except Diagnostic Substances

NAICS CODE: 325411 Medicinal and Botanical Manufacturing

325412 Pharmaceutical Preparation Manufacturing

Suggested ISO General Liability Code: 52341, 52342, 52343

Suggested Workers Compensation Code: 4825, 4611, 8045, 8047



Description of operations: Pharmaceutical manufacturers produce over-the-counter drugs such as antacids, antiseptics, cough drops or syrups, mild painkillers, vitamins, and prescription drugs, including controlled substances, which may be patent-protected or generic. Drugs are made from a variety of raw materials, which may be organic, chemical, or synthetic. Processes may include aeration, blending, coating, cooling, crushing, filtering, freezing, granulating, heating, milling, mixing, molding, pressurizing, or washing. The end product may take a variety of forms such as capsule, jelly, liquid, pill, powder, spray (aerosol or non-aerosol), suppository, or time-release patch. Cleanliness, purity, and the proper mix of ingredients are critical. Drugs can lose their effectiveness over time since bacteria, cancers, and viruses evolve and develop resistance to available treatments. Pharmaceutical manufacturers have laboratories engaged in ongoing product development, testing, and quality control. Products must pass rigid clinical trials before being approved by the Food and Drug Administration (FDA) for use by consumers.

Property exposure consists of an office, laboratories, production plants, and warehousing of raw materials and finished goods. Ignition sources include electrical wiring, heating and cooling equipment, overheating production machinery, buildup of static electricity, escape of fumes from storage tanks, and refueling of forklifts. Wiring must be grounded, adequate for peak demands, and meet all current codes. The large draft spaces in storage warehouses can contribute to the spread of a fire. Flammable lubricants and cleaning agents should be properly labeled, separated, and stored in approved containers. Bunsen burners and chemicals used in laboratories may ignite or explode. Smoking should be prohibited. Forklifts should be refueled in a separate, ventilated area away from combustibles. Some chemicals and final products may be spoiled by temperature change, humidity, dust or other factors. Due to the sterile conditions that must be maintained throughout the manufacturing process, even a small fire can result in a total loss to stock. Raw ingredients and finished stock are expensive, and may be targeted by thieves who anticipate profits from black market sales, particularly of controlled substances. If animals are used in testing, vandalism can result from protestors. Appropriate security controls should be taken including physical barriers to prevent entrance to the premises after hours and an alarm system that reports directly to a central station or the police department.

Business interruption exposure can be high due to lack of backup facilities, including expensive scientific equipment. A large loss can result in lengthy downtime for repairing or replacing equipment.

Equipment breakdown exposures include breakdown losses of processing systems, heating and cooling equipment, electrical control panels, and other apparatus. These should be properly maintained and records kept in a central location. Breakdown and loss of use to the production machinery could result in significant loss, both direct and under time element.



Inland marine exposures include accounts receivable if the manufacturer offers credit to customers, computers (which may include analytical equipment or computer-run production equipment), goods in transit, and valuable papers and records for customers' and suppliers' information, quality control testing results, and proprietary formulas used for drugs. Computer systems must have adequate security features to prevent unauthorized access due to industrial espionage or by hackers. Backup copies of all records should be made and stored off premises. Goods in transit may be damaged by fire, theft, collision and overturn, spillage, contamination or aerosol explosion. Some products require shipment in refrigerated vehicles to prevent spoilage. Trucks must be well maintained with any refrigeration units checked regularly.

Crime exposures are from employee dishonesty and theft of money and securities. Background checks should be conducted on all employees. The black market for pharmaceuticals, particularly controlled substances, makes many drugs and/or their raw ingredients targets of theft. Employees may act alone or in collusion with outsiders in stealing money, raw materials, trade secrets, or finished stock. There must be a separation of duties between persons handling deposits and disbursements and reconciling bank statements.

Premises liability exposures are normally low unless aerosols are manufactured or stored on premises. Although tours may be conducted, access by visitors is usually limited and well-controlled due to the need for a sterile environment. Visitors may be injured by slips, trips, or falls, or may be exposed to toxic or caustic chemicals. All areas accessible to the public must be free of obstacles with floor coverings in good condition. The number of exits must be sufficient and well marked, with backup lighting in case of power failure. Parking lots and sidewalks need to be in good repair with snow and ice removed, generally level and free of exposure to slips and falls. Fumes, spills, or leaks from tanks may cause serious injury or property damage to neighboring properties. Pharmaceutical manufacturers generally have traveling sales representatives who visit drug store chains, doctor's offices, and trade shows. Large sales cases or exhibition materials may present tripping hazards that could result in injuries to customers or the general public. Personal injury exposures include allegations of breach of confidentiality, copyright or trademark infringement, or defamation if misleading statements are made about competitors.

Products liability exposures are severe due to the potential for bodily injury, including sickness and death, to consumers of finished products. Quality control at all phases of the operation from product development to packaging is critical to reducing injury exposure. Significant injuries or damage may follow from improper processing or mixing of ingredients, improper storage, during transport, or inappropriate packaging and labeling. Packaging should include information addressing possible side effects and inform consumers of action that should be taken in the event of an allergic reaction. The workplace must meet all FDA specifications for sanitary working conditions and be



arranged to prevent foreign substances from entering the processing area. Factors affecting risk include whether the medicine produced is available over the counter or by prescription only; whether it is an established medicine (such as aspirin) or is newly developed; and whether it is the result of the manufacturer's research only, or is supported by academic research. Lack of compliance with government regulations and controls may dramatically increase hazards, and may also make defense of claims difficult. There should be a plan for recalling defective products.

Professional liability exposure is extremely high and increases if the manufacturer fails to conduct thorough background checks to verify employees' credentials, education, and licensing. Incorrect interpretation of quality control test results may result in a product being sold that causes severe side effects. Exact protocols must be followed. Sterile laboratory environments must be maintained to prevent contamination.

Environmental impairment exposures are very high. Sudden or cumulative discharges of chemicals may contaminate air, surface or ground water, or soil. Storage and disposal procedures must adhere to all EPA and other regulatory standards. Processes themselves may cause thermal or noise pollution. If there are underground tanks, a UST policy will be required.

Automobile exposure is high if the manufacturer transports raw materials or finished products. Manufacturers generally have private passenger fleets used by sales representatives. There should be written procedures regarding the private use of these vehicles by others. Each driver should have an appropriate license and an acceptable MVR. Refrigerated trucks may be required to transport products that are sensitive to changes in temperature. All vehicles must be well maintained, with documentation kept in a central location. Transport of aerosols is hazardous because the products need to be kept at cooler temperatures. HazMat licenses may be required. Refrigerated trucks used for this purpose and the transport of other drugs sensitive to temperature changes should be well maintained to prevent overheating and explosion.

Workers compensation exposures are high. Injuries from production machinery are common, as are burns, cuts, puncture wounds, slips, trips, falls, foreign objects in the eye, hearing loss from machinery noise, and back injuries from lifting. If animals are used for testing, animal diseases may be transmitted to workers. Employees should be provided with safety training and protective equipment. Ergonomically designed workstations can prevent repetitive motion injury. Aerosol containers may explode and injure workers. Exposure to toxic and/or caustic chemicals can result in injury to eyes, lungs, or skin. Workers must be made aware of the potential side effects, including long-term occupational disease hazards, so they can be aware of warning symptoms and obtain treatment as early as possible. Drivers of forklifts and vehicles may be injured in accidents.



Minimum recommended coverage:

Building, Business Personal Property, Business Income with Extra Expense, Equipment Breakdown, Accounts Receivable, Computers, Goods in Transit, Valuable Papers and Records, Employee Dishonesty, Money and Securities, General Liability, Employee Benefits, Environmental Impairment, Professional, Umbrella, Hired and Nonownership Auto, Workers Compensation

Other coverages to consider:

Earthquake, Flood, Spoilage, Exhibitions, Cyberliability, Employment-related Practices, Underground Storage Tank, Business Auto Liability and Physical Damage, Stop Gap Liability