

Corporate Structure, Business Plans and Financing	Research and Development	Pre-Clinical Development	Technology Review, Rights and Ownership	Intellectual Property Strategies	Clinical Development for Drugs/Devices	Marketing Plans	Regulatory Filings and Approval For Drugs and Biologics	Veterinary Products	Dietary Supplements	Medical Devices	Diagnostics	Competition, Antitrust & Generic Pressure	Compliance, Enforcement Initiatives & Litigation
<p>Choosing the best corporate structure</p> <ul style="list-style-type: none"> Limited liability companies corporations Other structures to consider both within and outside the U.S. <p>Selecting a Board, a Management Team and Key Advisors</p> <ul style="list-style-type: none"> Hiring key executives Establish a Board of directors Establish an Advisory Board Obtain Directors and Officers Insurance coverage Consider "Key Man" insurance on certain individuals who are key to the company's growth <p>Funding</p> <ul style="list-style-type: none"> Angel financing Strategic investors Subsidies and grants When obtaining funding, consider: <ul style="list-style-type: none"> long term business goals dilution of equity when bringing in new investors the effects on future licenses and deals any change in control issues. <p>Business Plans</p> <ul style="list-style-type: none"> Secure intellectual property Plan for outsourcing such as clinical trials, manufacturing and distribution Define the market for your technology Identify who else is in the same market space and differentiate your technology Define financing: needs in terms of capitalization need, burn rate, and expected returns on investment 	<p>Proof of conception and reduction to practice</p> <ul style="list-style-type: none"> Notebooks Corroboration Document retention policies <p>Invention Review Procedures</p> <ul style="list-style-type: none"> Invention disclosure and internal patent review process Issues regarding assignment of IP rights from individual or employed inventors Collaboration among multiple entities Joint inventorship Employee Invention Act implications <p>Publication issues</p> <ul style="list-style-type: none"> Managing scientific publications to avoid loss of IP rights Choice of publication Time between submission and publication <p>Business implications when government funds are used in research and development of the product or process</p> <ul style="list-style-type: none"> Baye-Dole U.S. government intervention rights Foreign Government rights to forced licensing Foreign Government rights to seize patents for public use NIH and related research contracts can create IP ownership issues 	<p>Assays</p> <ul style="list-style-type: none"> Toxicity Protein binding Test in animals Pre-phase I Research agreements Material exchange Human testing University/PI confidentiality agreements Management of intellectual property rights Ownership of data Publication rights <p>Drug formulations</p> <ul style="list-style-type: none"> Oral Parenteral Transdermal Immediate release Enteric-coated/ Extended release Stability Bioavailability Inclusion of data into patent application Re-evaluation of continued product development Testing or use by government for government purpose Proof of concept Strategic timing of interactions with CDRH Upon completion of preclinical work, file IND <p>Assessing FDA/European Regulatory Authority Issues</p> <ul style="list-style-type: none"> Regulatory classification of drug product or medical device Effects classification on clinical development and corporate strategies Market exclusivities for orphan drugs and pediatric use 	<p>Internally developed technology</p> <ul style="list-style-type: none"> Technology review Scientific literature Patent literature Monitor of competitors' patent estates Determine whether a license is needed to further develop the technology Obtain both internal and external legal freedom-to-operate opinions when necessary Obtain assignments where needed <p>Acquired technology</p> <ul style="list-style-type: none"> Sources for such technology can be: <ul style="list-style-type: none"> Academic institutions Other corporate entities Entrepreneurs <p>Acquisition issues</p> <ul style="list-style-type: none"> Ability to sublicense Exclusivity Worldwide rights to use versus geographic territories Ownership of new inventions and improvements Royalties and milestones <p>Protecting Non-Patented Technology and Property</p> <ul style="list-style-type: none"> Identify trade secrets and business know-how Develop Noncompete Agreements with key individuals Copyrights and Trademarks <ul style="list-style-type: none"> Trademark proprietary names or slogans Copyright original writings Obtaining global protection through regulatory filings including filings with the USPTO and Madrid Protocol 	<p>Portfolio management</p> <ul style="list-style-type: none"> Costs for preparing and filing applications in various countries Assess value and payment of maintenance fees Assess piracy <p>Type of application to be filed</p> <ul style="list-style-type: none"> Utility, design, and plant variety protection patents Provisional and non-provisional PCT applications <p>Data collection</p> <ul style="list-style-type: none"> <i>In vitro</i> data <ul style="list-style-type: none"> Binding, substrate cleavage, enzyme, cell-based assays <i>In vivo</i> data <ul style="list-style-type: none"> Animal testing in small mammals and primates Clinical trials <p>Claiming subject matter</p> <ul style="list-style-type: none"> Compound <i>per se</i> Methods of synthesis Compositions and combinations Formulations <ul style="list-style-type: none"> Mode of administration Dose, timing, amount Devices to administer Methods of treatment Research tools and kits <p>Patent term management</p> <ul style="list-style-type: none"> PTO activities <ul style="list-style-type: none"> Terminal disclaimers Patent term adjustments Patent term extensions FDA activities <ul style="list-style-type: none"> Pediatric extensions Orphan drug designations <p>Life cycle management</p> <ul style="list-style-type: none"> New treatments Isomers, salt forms, pro-drugs, formulations, dosage forms <p>Monitoring for infringing products</p> <p>Enforcing patents/IP rights</p> <p>Trademarks</p> <ul style="list-style-type: none"> International Nonproprietary Names creation & approval Submissions of trade names to FDA 	<p>Sponsor Concerns</p> <ul style="list-style-type: none"> File IND/IDE Quality Assurance/Control Contract Research Organizations (CRO) Design/Protocol <ul style="list-style-type: none"> Number of Subjects Special Populations Pediatric Rules Compensation Adverse Drug Reaction (ADRs) Multicenter Trials <p>Investigator Issues</p> <ul style="list-style-type: none"> Qualifications Randomization and Unblinding Informed Consent Adverse Event Reports Conflicts of Interests <p>IRB Issues</p> <ul style="list-style-type: none"> Approval <ul style="list-style-type: none"> Minimize Risks Reasonable Risk – Anticipated Benefits Selection of Subjects Informed Consent Suspension or Termination of Approval HIPAA concerns <p>Clinical Trials – For Drugs</p> <ul style="list-style-type: none"> Phase I – (Human Pharmacology) <ul style="list-style-type: none"> Tolerance Pharmacokinetics Pharmacodynamics Drug Activity Phase II – (Exploration) <ul style="list-style-type: none"> Targeted Indication Dosage Design Endpoints Methodologies Phase III – (Confirmation) <ul style="list-style-type: none"> Efficacy Safety Profile Establish dose-response Phase IV – (Use) <ul style="list-style-type: none"> Benefit/Risk Special Populations and Circumstances Refine Dosing <p>- For Devices</p> <ul style="list-style-type: none"> Significant Risk v. Non-significant Risk Pre-IDE Meetings Monitoring, Record Keeping and Reporting Requirements 	<p>Elements of Marketing Plan</p> <ul style="list-style-type: none"> Designing the label as a driver for the marketing initiatives Product name selection <ul style="list-style-type: none"> Regulatory agency approval of drug name Trademark selection Product branding <ul style="list-style-type: none"> Shape Color Packaging Taste Smell Feel Internet presence <ul style="list-style-type: none"> Website design and maintenance Designing domain names Driving business to your web site Optimizing visibility in search engines Business commerce features <p>Avoid Common Marketing & Advertising Mistakes</p> <ul style="list-style-type: none"> Putting Claims of Excellence or Gold Standard Use of Unapproved Material Misbranding/Mislabeling <p>Geographic segments</p> <ul style="list-style-type: none"> Partnering considerations E.U., U.S., and Asian markets Consideration of the best market Effect of foreign trial data for E.U./U.S. market <p>Unfair competition issues including specific legal and industrial restrictions</p> <p>Confidential access to client data</p> <p>E.U. national patent oppositions/ worldwide oppositions/E.U. and U.S. interferences</p> <p>Quantify costs for marketing ; including in funding plans</p>	<p>Up on completion of Clinical Development</p> <ul style="list-style-type: none"> Filing the NDA Chemistry – Manufacturing - Controls Pharmacology and Toxicology Parmacokinetics and Bioavailability Microbiology Clinical Data Statistical Data <p>Developing relationships early with authorities</p> <p>FDA Orange book issues</p> <ul style="list-style-type: none"> Patent listings Patent term extensions under 35 U.S.C. § 156 Pediatric extensions Orphan drug designations Orphan drug status/Humanitarian Device Exemption <p>Foreign regulatory agency issues</p> <ul style="list-style-type: none"> E.U. substitution issues Supplementary patent certificates (E.U.) <p>Centralized procedure vs. mutual recognition procedure for specific products</p> <p>Accelerated approval Effective utilization of the relevant FDA Centers and Ombudsman's office Unexpected demands for military or national security purposes</p> <p>Non Approvable Letters</p> <ul style="list-style-type: none"> Engaging in administrative process to correct the identified concerns <p>Biologic License Applications</p> <ul style="list-style-type: none"> Safety, Purity and Potency Submission to CDER or CBER <p>Convergence Technology</p> <ul style="list-style-type: none"> Drug & device combined Deciding regulatory route 	<p>File Investigational New Animal Drug (INAD) with the FDA</p> <ul style="list-style-type: none"> Labeling Requirements Qualification of Investigators Collection of Data Accountability of Drug Shipments Accountability of Treated Animals Pre-Submission Conference <p>New Animal Drug Application (NADA)</p> <ul style="list-style-type: none"> Phased Review and Direct Review Environmental Assessment Freedom of Information Summary Labeling <p>New Animal Drug Application Technical Sections</p> <ul style="list-style-type: none"> Public Safety <ul style="list-style-type: none"> Mutagenicity Studies Feeding Studies Reproductive Study Teratology Study Special Studies User Safety Information Resistance Study Metabolism Studies Tissue Residue Depletion Studies Target Animal Safety <ul style="list-style-type: none"> Tolerance Study Reproductive Safety Study Animal Class Safety Study Special Cases (e.g., specific breeds) Environmental <ul style="list-style-type: none"> Categorical Exclusion Environmental Introduction and Fate Studies Environmental Effects Studies Environmental Assessment Effectiveness <ul style="list-style-type: none"> Target Species Study Laboratory Animals Study Field Investigation Bioequivalence <i>In Vitro</i> Study Manufacturing Chemistry <ul style="list-style-type: none"> Methods and Controls Stability Data 	<p>Definition of Dietary Supplement</p> <ul style="list-style-type: none"> A oral product containing a "dietary ingredient" intended to supplement the diet Dietary Ingredient – one or combination of: <ul style="list-style-type: none"> A Vitamin A Mineral A Herb or other Botanical An Amino Acid A dietary substance supplementing diet by increasing total dietary intake A concentrate, metabolite, extract, or constituent <p>Notification of New Dietary Ingredient</p> <ul style="list-style-type: none"> Premarket Approval <ul style="list-style-type: none"> 75 Days Name and Address of Manufacturer or Distributor Name and Latin Binomial Name Description of Dietary Supplement Level of New Dietary Supplement Conditions of Use Recommended History of Use or Other Evidence of Safety <p>Necessary Label</p> <ul style="list-style-type: none"> Identify as "Dietary Supplement" Descriptive Name of Product Name and Place of Business List of Ingredients Net Controls of Product Supplemental Facts Panel <ul style="list-style-type: none"> Identify each Dietary Ingredient Other Ingredient Statement <p>Claims of DS</p> <ul style="list-style-type: none"> No Claims as Treatment, Prevention or Cure Health Claims <ul style="list-style-type: none"> Health Claims – Authoritative Statement Qualified Health Claims Nutrient Content Claims Structure-Function Claims Disclaimer 	<p>Correct Classification of Devices</p> <ul style="list-style-type: none"> Class I <ul style="list-style-type: none"> General Controls Premarket Notification (510(k)) Exemptions Class II <ul style="list-style-type: none"> Special Controls Exemptions Class III (PMA) <p>Premarket Notification Issues</p> <ul style="list-style-type: none"> 510(k) Requirements Exemption <ul style="list-style-type: none"> Custom Devices Distributors and Repackagers Class I and Class II Devices <p>Premarket Approval Issues</p> <ul style="list-style-type: none"> Premarket Approval Application Amendments Supplements Humanitarian Device Exemption <p>Registration, Listing & Product Labeling</p> <ul style="list-style-type: none"> Establishment Registration Requirements <ul style="list-style-type: none"> Foreign Establishments Distributors Exemptions for Device Establishments Listing Requirements Labeling Requirements <ul style="list-style-type: none"> Intended Use Advertising <p>Investigation Device Exemption (IDE)</p> <ul style="list-style-type: none"> Investigation Exemption for IDE Significant v. Non-significant Risk Record Keeping Reporting <p>Manufacturing Controls</p> <ul style="list-style-type: none"> Design Production and Process Label and Packaging Handling and Storage Distribution <p>Report and Tracking Requirements</p> <ul style="list-style-type: none"> Death, Serious Injury of Malfunction Reports Removals/Corrections 	<p>Correct Classification of Diagnostics</p> <ul style="list-style-type: none"> Same Classification as Devices <p>Clinical Laboratory Amendments (CLIA)</p> <ul style="list-style-type: none"> Waiver Tests Moderate Complexity High Complexity <p>Premarket Notification</p> <ul style="list-style-type: none"> Product Name Established Registration Classification Special Controls or Performance Standard Summary or Statement Class III Certification and Summary Truthful and Accurate Statements Indication for Use Statement 510(k) Paradigm <p>Premarket Approval</p> <ul style="list-style-type: none"> Technical Sections Non-clinical Laboratory Studies Section Clinical Investigations Section <p>Labeling Requirements</p> <ul style="list-style-type: none"> Immediate Container, Inserts, and Outer Packages <ul style="list-style-type: none"> Proprietary Names Intended Uses A Statement of Warning Manufacturer's Identifiers Product Controls Quality Control Establishment Registration GMPS Medical Device Reporting <ul style="list-style-type: none"> Requirements for written MDR procedures MDR Event Files Individual Adverse Event Reports MDR Baseline Reports MDR Supplemental Reports Recall and Corrections and Removals <ul style="list-style-type: none"> Voluntary Recalls Mandatory Device Recalls Corrections and Removals 	<p>Competition</p> <ul style="list-style-type: none"> Patent infringement Trademark infringement Trade secret misappropriation Counterfeit issues <p>Antitrust</p> <ul style="list-style-type: none"> Licensing Refusals to license Exclusive licenses Grant backs Patent pools Mergers/Joint Ventures/Acquisitions Tying Bundling Pricing issues Resale price maintenance Group boycotts <p>FDA extensions</p> <p>ANDAs</p> <ul style="list-style-type: none"> Paper NDAs Salt or ester substitution <p>Monitoring for infringement</p> <p>State formularies and interchangeability</p> <p>What generics mean to market share</p> <p>Licensing</p> <ul style="list-style-type: none"> Co-marketing/ Joint Ventures Risks Contracts <p>Regulatory issues related to marketing and advertising</p> <p>Duty to warn/ labeling/First Amendment issues</p> <p>Disclaimers</p> <p>Privacy issues</p> <p>Advertising</p> <p>FDA and E.U. regulation of marketing, advertising, distribution and considerations</p> <p>Monitoring for infringing products</p> <p>Enforcing patents/IP rights</p>	<p>Hatch-Waxman issues</p> <p>Reimbursement mechanisms; rebate/AMP, best price, ASP</p> <p>Nominal price issues</p> <p>Fraud and abuse/ Anti-Kickback issues</p> <p>Guidance documents from the OIG, CMS, and the FDA</p> <p>Final Privacy & Security Rule Compliance</p> <p>Association's codes of conduct</p> <p>Building a strategy to comply with Medicare Modernization Act reporting requirements and setting of Average Sale Price</p> <p>Increase in Enforcement Activities with Misbranding</p> <p>Criminal Implications</p> <p>Litigation</p> <ul style="list-style-type: none"> Pricing Product liability Class actions Licensing disputes Unwinding joint ventures Suppliers/rebate arrangements Distribution arrangements Whistleblowers and <i>qui tam</i> suits Off-label promotions preemptions <p>International arbitrations</p> <p>Risk avoidance</p> <ul style="list-style-type: none"> Anticipating issues in clinical trials and license arrangements Adverse reaction procedures Document retention policies Defending product liability complaints Evaluating adequate label warnings <p>Compliance with Sarbanes-Oxley</p>

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