



GARDNER LAW

MEDTECH | PHARMA

POLICY & PROCEDURE CHECKLIST

Indicate which policies, procedures, etc., you have, need, are optional or not applicable. Asterisk = foundational.

COMPLIANCE PROGRAM OPERATION	HAVE	NEED	OPT.	N/A	NOTES
*Policy – Compliance and Investigations					
*Policy – Interactions with Health Care Professionals					
Policy – Compliance Hotline					
Policy – Conflict of Interest					
Policy – Good Documentation Practices					
Policy – Responding to Governmental Inquiries/Audits					
Policy – Risk Assessment, Auditing and Monitoring					
Charter – Compliance Committee					
Charter – Compliance Program					
Code – Code of Conduct					
Checklist – Compliance Assessment					
Form – Code of Conduct Certification					
Form – Non-Compliance					
Guide – Customer Guide on Company Compliance Program					
Job Description – Compliance Officer					
Training – Compliance					
SALES & MARKETING	HAVE	NEED	OPT.	N/A	NOTES
*SOP – Promotional Review Committee					
SOP – Collaborative Marketing (Co-Marketing)					
SOP – Field Sales Exhibits and Displays					
SOP – Press Releases					
SOP – Social Media					
Policy – Case Coverage (OR conduct, credentialing)					
Policy – Distributor Qualification					
Policy – Product Evaluation					
Policy – Product Spoilage					
Policy – Regulatory Considerations for Presentations					
Policy – Samples					
Policy – Tradeshow Dos and Don'ts					
Desk Aid – Advertising and Promotional Considerations					
Desk Aid – OPDP Collateral Prep					
Agreement – Collaborative (Co-) Marketing					
Agreement – Equipment Loan or Rental					
Agreement – Field Compliance Acknowledgement					
Agreement – Product evaluation					
Agreement – Product Sales, Consignment, or Distributor					
Training – Advertising and Promotion					
ENGAGING HCPS & HCES	HAVE	NEED	OPT.	N/A	NOTES
*Policy – Anti-Corruption (Foreign Corrupt Practices Act)					
*Policy – Needs Assessment for HCP Consultants					
*SOP – Fee For Service (Consulting)					
*SOP – Grants and External Funding					



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Policy – Charitable Contributions					
Policy – Competitive Product					
Policy – Fair Market Value Assessment					
Policy – HCP Travel					
SOP – Advisory Boards					
SOP – Speaker Programs					
SOP – Physician Training					
SOP – Conducting and Supporting 3rd Party Programs					
Form – Needs Assessment					
Agreement – Fee for Service (HCP Consulting)					
Agreement – Grants and External Funding					
MEDICAL & CLINICAL AFFAIRS	HAVE	NEED	OPT.	N/A	NOTES
*SOP – Responding to Off-Label Requests					
SOP – Medical Review Committee					
SOP – Proactive Dissemination of Scientific Publications					
Form – Medical Information Request					
Letter – Medical Information					
Policy – Clinical Compensation					
Policy – Notices of Availability					
Policy – Medical Affairs					
Job Description – Medical Affairs Director					
Agreement – Clinical Trial					
Agreement – Research Arrangement					
Agreement – Physician/Investigator Initiated Trial					
TRANSPARENCY REPORTING	HAVE	NEED	OPT.	N/A	NOTES
*SOP – Transparency Reporting (muni., state, federal)					
REIMBURSEMENT & DISCOUNTING	HAVE	NEED	OPT.	N/A	NOTES
Policy – Field Reimbursement Staff					
Policy – Health Care & Economic Information					
Policy – Pricing & Discounts					
Policy – Reimbursement Information					
SOP – Patient Assistance Program					
PRIVACY	HAVE	NEED	OPT.	N/A	NOTES
*Policy – Global Privacy and Security Incident Response					
*Policy – Information Security Program					
*Policy – Protecting Patient Privacy					
*Policy – Website Privacy					
Policy – Data Classification					
Training – Privacy					
Agreement – Patient Authorization for PHI					
Agreement – Patient Consent & Release					
HIPAA	HAVE	NEED	OPT.	N/A	NOTES
Policy – Business Associate Agreements					
Policy – De-Identified Health Information and Limited Data Sets					



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Policy – Designated Record Set					
Policy – HIPAA Breach Notification					
Policy – Notice of Privacy Practices					
Policy – Patient Privacy Rights					
Policy – Personal Representatives					
Policy – Uses and Disclosures of Protected Health Information					
Letter – Business Associate Response					
Job Description – Privacy Officer					
Form – Notice of Privacy Practices					
Agreement – Business Associate					
Agreement – Data Use					
GDPR	HAVE	NEED	OPT.	N/A	NOTES
*Policy – Global Privacy Program Policy and Standard					
*Policy – Record of Processing Activities					
Policy – Global Records Retention					
Policy – Global Employee Privacy Statement					
Policy – Handling Data Subject Rights Requests					
Policy – Privacy by Design					
Policy – Privacy Notice(s)					
Policy – Standard Contractual Clauses					
Template – Data Protection Impact Assessment					
Agreement – Data Processing					
Job Description – Data Protection Officer					
PATIENT CONTACT/SUPPORT	HAVE	NEED	OPT.	N/A	NOTES
Policy – Patient Assistance Programs					
Policy – Interactions with Patient Organizations					
Policy – Patient Support Program (includes consent forms)					
FDA QUALITY & REGULATORY	HAVE	NEED	OPT.	N/A	NOTES
SOP – Complaints					
SOP – Corrective and Preventive Action (CAPA)					
SOP – Document Control					
SOP – Emergency Hazardous Waste Management & GLP					
SOP – Failure Investigation					
SOP – Field Action					
SOP – Inspections					
SOP – Master Files – Check-in/Check-out					
SOP – Qualification & Training					
SOP – Quality Records					
Policy – Electronic Records and Electronic Signature					
Manual – Quality					
Training – Quality System & cGMP					
Quiz – Quality System & cGMP					
OTHER	HAVE	NEED	OPT.	N/A	NOTES
Policy – Escalation Process					



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Policy – M&A Dos & Don'ts					
Policy – Travel & Entertainment					
Handbook – Employees					