DIAMOND CO.

Pharma Compliance Script Pack for EHR Audits

Here's the **complete improved version** of your *Pharma Compliance Script Pack for EHR Audits*, with a clearer structure, concrete examples, and actionable templates/checklists:

Pharma Compliance Script Pack for EHR Audits

Free, downloadable PDF guide for auditors, consultants, and regulatory specialists

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1. Overview

This script pack provides **ready-to-use templates, checklists, and examples** to streamline EHR audits in the pharmaceutical industry. Covers:

- **FDA 21 CFR Part 11** (EHR security & integrity)
- **HIPAA** (privacy & data protection)
- **State-specific regulations** (e.g., California's SB 1386)
- **Common audit pitfalls** (with resolution templates)

Format: Single PDF (10–15 pages) with:

- Fill-in-the-blank templates
- Checklists for pre-audit prep
- Sample interview scripts
- Evidence collection guides

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2. Detailed Contents

A. Pre-Audit Checklist

Before starting an audit, verify:

✅ **Regulatory scope** (FDA, HIPAA, state laws)

✅ **Audit team roles** (Lead Auditor, Scribe, IT Observer)

✅ **EHR system documentation** (vendor manuals, SOPs)

✅ **Data access permissions** (user roles, audit logs)

Template:

```
[ ] Confirm audit scope with client (e.g., "FDA 21 CFR Part 11, HIPAA")
[ ] Schedule pre-audit meeting with IT team
[ ] Request EHR system access (username, permissions)
[ ] Review prior audit reports (if available)
```

B. Audit Scripting Templates

1. Interview Guide (SOPs)

Example:

```
**Topic:** EHR Security Controls
**Questions:**
1. Who has administrative access to the EHR system?
2. How are passwords managed (e.g., complexity, expiration)?
3. Describe your incident response plan for data breaches.
```

2. Evidence Collection Checklist

Example:

```
[ ] Screenshots of EHR user roles
[ ] Printouts of audit logs (last 30 days)
[ ] Copies of signed SOPs
[ ] Vendor documentation (e.g., EHR security certifications)
```

C. Compliance Reminders

Deadlines & Reporting:

- **FDA 21 CFR Part 11:** Annual review of EHR controls
- **HIPAA:** Annual risk assessment due by [date]
- **State laws:** California's SB 1386 (EHR transparency) reporting due [date]

D. Case Study Examples

Example 1: Failed Audit (EHR Security)

- **Issue:** No audit trail for EHR changes.
- **Resolution:** Implemented automated logging (screenshots provided).

Example 2: HIPAA Violation

- **Issue:** Unencrypted PHI in emails.
- **Resolution:** Enforced email encryption policy (template attached).

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3. Distribution Plan

A. Landing Page (Example: Carrd/Webflow)

Headline: "*Free EHR Audit Scripts for Pharma Compliance Pros*"

CTA: "*Download Now*" (email + name required)

Post-Download: Offer a **bonus checklist** (e.g., "Top 5 EHR Audit Mistakes").

B. Promo Channels

- **LinkedIn:** Post in groups like "*Pharma Compliance Professionals*" (target 500+ members).
- **Email:** Send to lists like HIMSS or AHIMA (subject: "*Streamline Your EHR Audits*").
- **Slack/Discord:** Share in channels like "*Pharma IT Compliance*".

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4. Metrics & Monitoring

Goal: 100+ signups in 24 hours.

Kill Rule: If <50 signups, pause and refine messaging.

Boost Rule: If 1 signup = $1 revenue (e.g., upsell later), clone the campaign.

Maintenance:

- Weekly: Track downloads, user feedback.
- Quarterly: Update scripts for new regulations (e.g., FDA's 2025 EHR updates).

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5. Next Steps (Action Plan)

Task	Owner	Deadline
Design PDF scripts	[Name]	Week 1
Build landing page	[Name]	Week 2
Launch LinkedIn post	[Name]	Week 3
Monitor signups	[Name]	Ongoing

Status: Ready for execution. Proceed with design and launch.

Venture ID: `2f302c14-219f-4afa-b43b-c11c39a304cb`

Task ID: `2a6ebf25-2a5b-4f9f-b66e-68a592bf2106`

This version is **clearer, more actionable, and structured for immediate use**.
