Compliance in Life Sciences

WHAT IS COMPLIANCE IN LIFE SCIENCES?

"Compliance" = Following the rules

In life sciences, compliance means:

1. **Following all laws and regulations** set by government bodies (like FDA, EMA).
2. **Protecting patients' rights and safety**.
3. **Keeping accurate records** (can't fake data or miss reporting).
4. **Getting informed consent** before enrolling a patient.
5. **Maintaining privacy** (HIPAA in the U.S., GDPR in Europe).

Examples of compliance areas:

- GxP: Good Clinical Practice (GCP), Good Manufacturing Practice (GMP)
- 21 CFR Part 11: U.S. FDA rule for electronic records
- Adverse Event Reporting: Must report any side effects within strict time limits.

🧠 In Salesforce, this is where:

- **Audit trails**
- **Consent capture**
- **Automated workflows**
- **Case management**
  are used to stay compliant.

In the **life sciences industry**, “compliance” means **meeting strict legal and ethical standards** when conducting clinical trials, manufacturing drugs, handling patient data, and communicating with healthcare professionals (HCPs).

Violating these rules can lead to:

- Product recalls
- Fines
- Loss of license
- Even patient deaths (if critical data is mishandled)

COMMON REGULATORY STANDARDS

1. GxP ("Good Practices")

“GxP” = umbrella term for **Good [x] Practices** — here are two key types:

Type	Meaning	Purpose
GCP (Good Clinical Practice)	Rules for conducting ethical, safe clinical trials	Protect patients and ensure accurate trial data
GMP (Good Manufacturing Practice)	Rules for manufacturing drugs/devices safely	Ensure consistent quality, avoid contamination

2. 21 CFR Part 11 (FDA, USA)

- A U.S. **FDA regulation for electronic records and electronic signatures**.
- Ensures that systems storing health data:
    - Are **secure**
    - Maintain **audit trails**
    - Can verify who did what and when
    - Prevent **data tampering**

Applies when using systems like Salesforce for storing clinical or patient data.

3. Adverse Event Reporting

- Life sciences companies must **report any serious side effects (adverse events)** within specific timelines (e.g., 24–72 hours).
- If a patient faints or dies, the company must:
    - Capture all info quickly
    - Report it to the regulator (e.g., FDA, EMA)
    - Track follow-ups

HOW SALESFORCE ENSURES COMPLIANCE

Salesforce Life Sciences Cloud (built on Health Cloud) includes **tools and capabilities** that help companies meet these rules.

1. Audit Trails

What it is: A record of every action taken in the system — like edits, deletions, approvals.

🔒 **Used for:**

- 21 CFR Part 11
- GCP/GMP compliance
- Inspections and audits

📌 **In Salesforce:**

- Field history tracking
- Shield Platform Encryption + Event Monitoring (adds full audit logs)
- Can track user actions for compliance audits

2. Consent Capture

What it is: Getting the patient's or HCP's **informed consent** to collect and use their data.

🔒 **Used for:**

- GCP (clinical trials)
- GDPR (Europe)
- HIPAA (U.S.)

📌 **In Salesforce:**

- Consent Management Objects:
    - Consent Records
    - Data Use Purpose
    - Authorization Forms
- Pre-built UI in Life Sciences/Health Cloud
- APIs to sync consent from EHR or external systems

3. Automated Workflows

What it is: System rules that **automatically route tasks**, generate alerts, and enforce protocols.

🔒 **Used for:**

- Adverse event reporting deadlines
- Patient journey tracking
- Case escalation (e.g., for serious side effects)

📌 **In Salesforce:**

- Flow Builder
- OmniStudio
- Scheduled Notifications, Alerts
- Approval Processes (for legal reviews or regulatory sign-off)

4. Case Management

What it is: Managing complex issues like:

- Adverse event reporting
- Medical inquiries
- Investigational drug requests

🔒 **Used for:**

- Track resolution timelines
- Record actions taken
- Route to right team (Medical Affairs, Safety, etc.)

📌 **In Salesforce:**

- Case object + custom record types
- Life Sciences Data Model supports:
    - Adverse Event Case
    - Medical Inquiry Case
    - Patient Support Case
- SLA monitoring (e.g., alert if deadline is missed)

🔄 Example Flow: Adverse Event Reporting in Salesforce

Here's how it looks in practice:

1. **HCP reports a side effect** (via portal or rep)
2. **Case is created automatically** in Salesforce
3. **Consent is verified**
4. **Workflow routes it to safety team**
5. **Team investigates & records findings**
6. **Audit log tracks all actions**
7. **Report is sent to FDA or EMA via integration**
8. **Follow-ups tracked in same case**

All this ensures full compliance with **GxP + 21 CFR + safety reporting laws**

.🔚 Summary Table

Regulation	What it Requires	Salesforce Feature
GCP	Trial ethics, consent, accurate data	Consent Capture, Audit Trails, Workflow
GMP	Safe manufacturing	Audit Trails, Compliance Tracking
21 CFR 11	Secure e-records, e-signatures	Shield, Audit Logs, Signature Flows
Adverse Events	Timely side effect reporting	Case Management, Alerts, SLA Timers