



Healthcare — Life Sciences at a Glance

Summary Notes

How a medicine travels from a lab bench to a patient's hand: the players, the seven stages, the systems and standards behind them, and what IT and QA teams must get right.



Inside these notes

1. What life sciences is, and who's who
2. The seven stages of a medicine
3. Discovery, preclinical and clinical trials
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8. The QA view and the numbers to watch
9. Real-world scenarios, first week, glossary



Watch the full session

Scan to watch "Healthcare — Life Sciences at a Glance" on the Business Domain Connect YouTube channel, including the animated film of all seven stages.

youtube.com/@BusinessDomainConnect

What life sciences is, and who's who

Companies that research, develop, make and sell medicines and medical products. One fact shapes every IT system you will work on: life sciences is **regulated end to end**. Every step must be documented, approved and traceable.

Pharma

Medicines made from chemistry: tablets, capsules, injections. Includes generics.

Biotech

Medicines made from living cells: vaccines, insulin, antibodies, cell and gene therapy.

Medical devices

From a syringe to a pacemaker to a diagnostic kit, including software.

Service partners

CROs run trials for sponsors; CDMOs manufacture for them. India is a major hub for both.

A The players you'll hear about in every stand-up

PLAYER	WHAT THEY DO	WHY IT CARES
Sponsor	The pharma or biotech company that owns the medicine and carries the responsibility	Owens the data, the validation and the inspection risk
CRO	Contract research organisation: runs trials on the sponsor's behalf	Often operates the sponsor's systems, or its own
Investigator site	Hospital or clinic where patients take part, led by a principal investigator	Site staff enter data in the EDC; source records live here
Ethics committee / IRB	Independent body that protects trial patients	Approves each protocol and consent version
Regulators	FDA (US) · CDSCO, led by the Drugs Controller General (India) · EMA (EU)	Approve trials and products; inspect everyone
CDMO / manufacturer	Makes the product under GMP	MES, LIMS, ERP, batch records
Distributors & pharmacies	Move and dispense the product	Serialisation, cold chain, GDP
Payers	Decide coverage and price (see Payer at a Glance)	Market access and pricing data

The patient appears twice

Once in the trial, giving consent and reporting symptoms, and again after launch, as the person who reports a side effect. Both moments create regulated data.

The seven stages of a medicine

From a molecule to a medicine, and then watching it for life. It often takes **10–15 years** from discovery to approval, and roughly **9 in 10** drugs that enter clinical trials never reach patients. Until the day of approval, the data *is* the product.



What safety monitoring learns feeds the next discovery

A What a beginner should hold on to at each stage

#	STAGE	THE ONE THING TO REMEMBER	KEY SYSTEMS
1	Discover	A target linked to a disease; thousands of molecules screened to find one candidate	ELN, LIMS
2	Preclinical	Lab and animal tests under GLP decide whether it is safe enough to try in people	LIMS, study data
3	Clinical trials	Each phase answers a different question; database lock is the moment of truth	CTMS, EDC, IRT, eCOA, eTMF
4	Approval	All the evidence goes in a five-module eCTD; every later change is a new submission	RIM, eCTD publishing
5	Manufacture	Every batch must match the one you proved; QA releases it before it ships	MES/eBR, LIMS, ERP, QMS
6	Supply & commercial	A unique serial number per pack, a cold chain, and market access with payers	ERP, serialisation, CRM
7	Pharmacovigilance	Serious, unexpected reactions reported within 15 days; signals change the label	Safety database

Watch the animated film

The session ends with a three-minute animation of all seven stages. Watch it once before a pharma interview: it is the fastest way to remember the whole chain.

Discovery, preclinical and clinical trials

Find a molecule that could work, prove it is safe enough to try in people, then test it in people, in phases, with more patients each time.



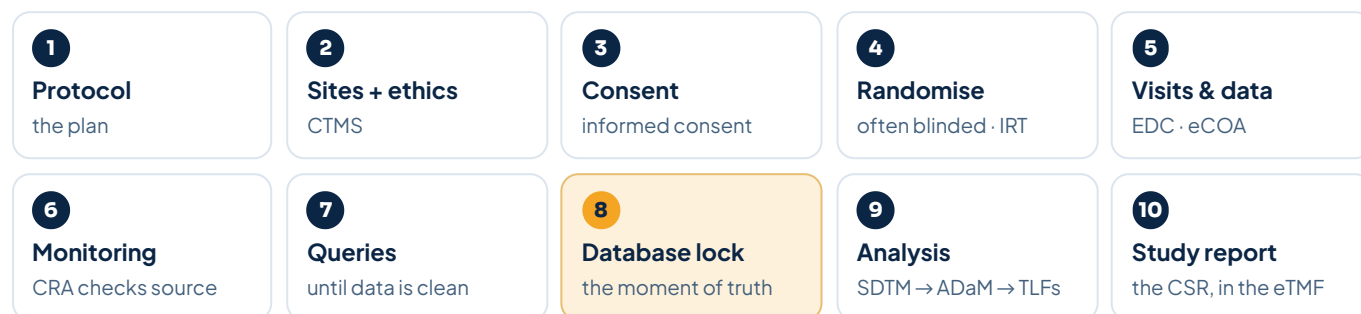
Animation: screening thousands of molecules to find one candidate



Animation: the three phases, then one trial end to end

PHASE	QUESTION	WHO AND HOW MANY	OUTPUT
Phase 1	Is it safe?	20–100, often healthy volunteers	Safe dose range
Phase 2	Does it work? Which dose?	A few hundred patients	Right dose, first signs of benefit
Phase 3	Better than today's care, at scale?	Hundreds to thousands, many countries	The evidence for approval
Phase 4	What happens in real-world use?	After approval	Rare side effects, long-term data

A Inside one trial: ten steps, and the system behind each

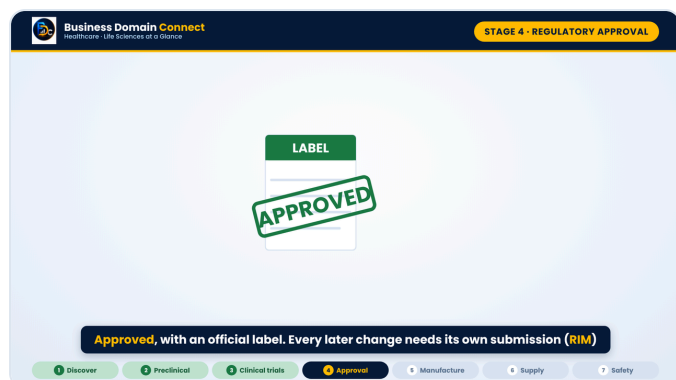


The rules behind stages 1–3

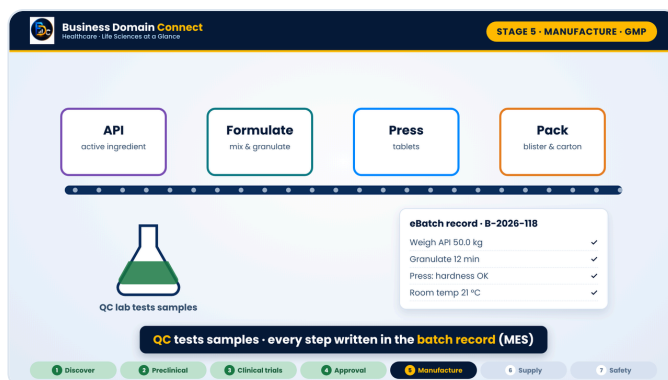
GLP in the lab, GCP in trials. The international GCP guideline is ICH E6, now in its R3 version: quality by design and risk-based monitoring. US: an IND to the FDA before human trials. India: an application to CDSCO under the New Drugs and Clinical Trials Rules, 2019.

Approval, and manufacturing under GMP

Put all the evidence in front of the regulator, then make every batch exactly the same as the one you proved.



Animation: the eCTD dossier, review and approval



Animation: from API to a released batch

A The application and the eCTD

NDA · BLA · ANDA

US applications for a new drug, a biologic, and a generic that proves it is the same as the original.

Five eCTD modules

M1 regional · M2 summaries · M3 quality (CMC) · M4 non-clinical · M5 clinical.

Review

FDA: about 10 months standard, 6 priority, after filing. India: CDSCO with a Subject Expert Committee.

B Manufacturing words you'll hear daily

WORD	WHAT IT MEANS
GMP	Good Manufacturing Practice. US: 21 CFR Parts 210 & 211. India: revised Schedule M, now for all manufacturers
API → formulate → pack	The active ingredient is made, formulated into tablets or injections, then packed; QC tests samples at every stage
Batch record (eBR)	Every step recorded, usually in the MES
QA release	QA reviews the full record and releases the batch. No release, no shipment
Deviation → CAPA	Anything unplanned is investigated and fixed with a corrective and preventive action
Change control	Every planned change is assessed, approved and tested before it happens

After approval, it never stops

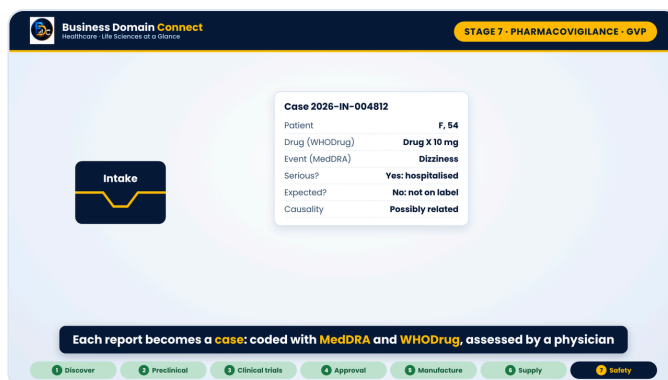
Every later change to the label, the site or the process needs its own submission. The system that tracks them is RIM, regulatory information management.

Supply, and pharmacovigilance

Get the right pack to the right patient safely, and keep watching the medicine's safety for as long as it is sold.



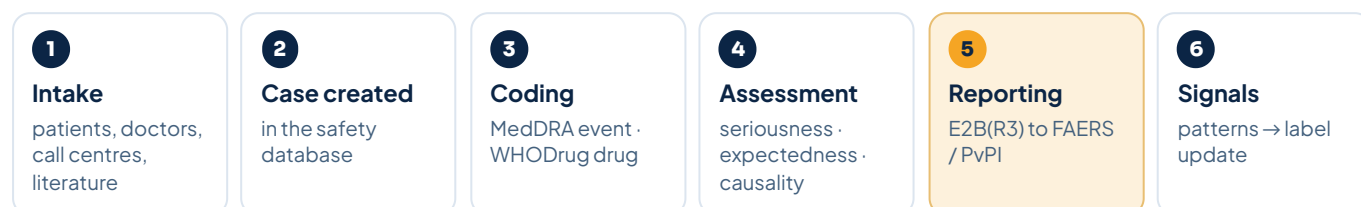
Animation: serialised packs, cold chain, verified at the pharmacy



Animation: from an adverse event report to a safety signal

SUPPLY WORD	WHAT IT MEANS
Serialisation	A unique serial number on every pack in a 2D barcode. US: DSCSA traceability. India: QR or barcode on APIs and top-selling brands
Aggregation	Unit → case → pallet: scan one code and know every pack inside
GDP & cold chain	Good Distribution Practice; many biologics travel at 2–8 °C with temperature loggers
Commercial	Sales and medical affairs inform doctors; market access agrees price and coverage with payers

A Pharmacovigilance, step by step



The 15-day clock

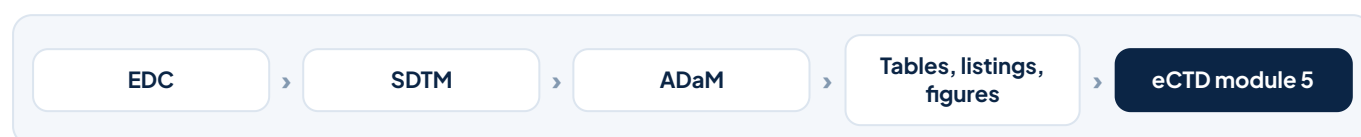
A serious and unexpected reaction must reach the regulator within 15 calendar days of day zero, the day the company first learns of it. A late report isn't just slow: it is a compliance finding.

The systems, and how the data moves

On any project, ask one question first: **is this system GxP?** If it is, validation, Part 11 and change control all apply.

AREA	SYSTEMS	WHAT THEY OWN
Research	ELN · LIMS	Experiments, samples, results
Clinical	CTMS · EDC · IRT/RTSM · eCOA · eTMF	Trial operations, patient data, randomisation and supply, documents
Regulatory	RIM · eCTD publishing	Submissions, approvals, commitments
Quality	QMS · document management · LMS	Deviations, CAPA, change control, SOPs, training records
Manufacturing	MES / eBR · LIMS · ERP (SAP)	Batch execution, QC results, inventory and release
Safety	Safety database (e.g. Argus, LifeSphere)	Adverse event cases, reporting, signals
Commercial	CRM · master data · serialisation	Field teams, product and customer data, serial numbers

A Clinical data, from the site to the regulator



B Manufacturing and supply



Two reconciliations auditors love

SAE reconciliation: every serious adverse event in the EDC must match the case in the safety database. **IRT vs EDC:** which patient got which kit. If either disagrees, you have a finding, or worse, a patient on the wrong treatment.

Standards, GxP, Part 11 and validation

The words people use as nouns, and the rules that make life sciences IT different from any other domain.

CDISC Clinical data
CDASH · SDTM · ADaM ·
define.xml

MedDRA Events dictionary
headache, liver injury...

WHODrug Drug dictionary
codes medicines

E2B(R3) Safety message
individual case reports

eCTD Submission
five-module dossier

GS1 Serialisation
barcodes & EPCIS events

A GxP and 21 CFR Part 11

GxP
GLP · GCP · GMP · GDP ·
GVP. A system that
supports any of them is a
GxP system.

Audit trail
Secure and computer-
generated: who, what,
when, why. Users can't
edit or disable it.

Access control
Unique logins, role-based
permissions, no shared
accounts.

E-signatures
Name, date, time and
meaning. EU equivalent:
Annex 11.

ALCOA+

Data must be Attributable, Legible, Contemporaneous, Original and Accurate, plus Complete, Consistent, Enduring and Available. In plain words: **if it isn't documented, it didn't happen.**

B Validation: proving the system works

1
URS
user requirements

2
Risk assessment
harm to patient or
product?

3
IQ
installed
correctly?

4
OQ
each function
works?

5
PQ
works for our
process?

6
Trace + VSR
every
requirement
tested

From CSV to CSA

The FDA finalised its Computer Software Assurance guidance in 2025: put test effort where the risk to patients and product is highest, use unscripted and exploratory testing for low-risk features, and cut paperwork for its own sake. Framework: GAMP 5.

What to test, and the numbers to watch

Ask these questions stage by stage, on top of normal functional testing. Life sciences values testing more than almost any other industry.

AREA	ASK THIS
Part 11 (every GxP system)	Is every create, change and delete in the audit trail with old value, new value, user, time and reason? Can anyone edit or disable it? Do e-signatures show name, date, time and meaning? Do roles stop people doing what they shouldn't?
Clinical	Do edit checks fire on bad values? Is randomisation correct and blinding protected on every report and export? Do visit windows calculate correctly across time zones?
Safety	Are day zero and the 15-day clock right? Does the E2B message pass validation and get an acknowledgement?
Manufacturing & supply	Are batch record calculations and limits right? Can a batch ship without QA release? Is aggregation correct after a case is opened and repacked?
Data migration	Can you prove, record by record, that nothing was lost or changed?

A The numbers life sciences watches

Clinical

Cycle times (protocol → first patient in; last patient out → database lock) · enrolment vs plan · screen failure rate · protocol deviations · query ageing

Regulatory

Submission timelines · number of regulator questions

Manufacturing & supply

Right first time · batch release time · CAPA closed on time · OTIF · temperature excursions

Safety

Cases processed on time · 15-day expedited reports on time, target 100%

Time and compliance are measured together

A late safety report or an overdue CAPA isn't only a delay. Inspectors read it as a quality system that isn't in control.

Three scenarios, biotech & devices, your first week

Layer 9 of the framework: what really happens on a live project. These scenarios are illustrative, based on the kind of thing that happens in practice.

The report that unblinded a study

WHAT HAPPENED

A new site report showed kit numbers next to patient IDs.

Test every report and export for blinding.

The late safety reports

WHAT HAPPENED

Day zero used the server's time zone; some expedited reports went on day 16.

Dates and time zones are a GxP risk.

The audit trail that wasn't

WHAT HAPPENED

Lab software allowed delete and re-run with the audit trail off: an FDA warning letter.

Validate and lock audit trail settings.

A Biotech and medical devices: what's different

	BIOTECH (BIOLOGICS)	MEDICAL DEVICES
Made from	Living cells: the process is the product	Engineering, materials, software
US route	BLA · biosimilars	510(k) clearance · PMA for high risk
Quality	GMP plus tight process control, cold chain	QMSR, aligned with ISO 13485 · UDI
Safety · India	Pharmacovigilance · CDSCO, NDCT Rules 2019	Vigilance, MAUDE · Medical Device Rules, 2017

B Your first week on a life sciences project

- Complete your GxP training: no training record, no access
- Read the SOPs for your area and the validation plan
- Find out which systems are GxP, and their change control
- Learn the vocabulary: start from the glossary overleaf
- Draw the data flow for your system, start to end
- Ask for the last audit or inspection findings

The words you'll hear in your first month

Keep this page open in your first meetings. Every term here came up in the session.

ADaM	Analysis datasets built from SDTM	EDC	Electronic data capture
ALCOA+	Data-integrity principles regulators apply	eTMF	Electronic trial master file
ANDA	US application for a generic	FAERS	FDA Adverse Event Reporting System
API	Active pharmaceutical ingredient	GxP	GLP, GCP, GMP, GDP, GVP
BLA	US application for a biologic	IND	US Investigational New Drug application
CAPA	Corrective and preventive action	IQ / OQ / PQ	Installation / operational / performance qualification
CDMO organisation	Contract development & manufacturing	IRT / RTSM	Randomisation and trial supply system
CDSCO	India's drug regulator, led by the DCGI	LIMS	Laboratory information management system
CRA	Clinical research associate: monitors sites	MedDRA	Medical dictionary for events
CRF	Case report form: what a visit collects	MES	Manufacturing execution system
CRO	Contract research organisation	NDA	US New Drug Application
CSR	Clinical study report	Part 11	US rule for e-records & e-signatures
CSV / CSA assurance	Computer system validation / software	PvPI	Pharmacovigilance Programme of India
CTMS	Clinical trial management system	QMS	Quality management system
DSCSA	US Drug Supply Chain Security Act	RIM	Regulatory information management
E2B(R3)	Safety case message format	SAE	Serious adverse event
eCOA / ePRO	Patient-reported outcomes, electronically	SDTM	Standard format for submitted trial data
eCTD	Electronic Common Technical Document	WHODrug	Dictionary for medicines

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Sources: ICH E6(R3) Good Clinical Practice (2025) · FDA, Computer Software Assurance for Production and Quality System Software (final guidance, 2025) · 21 CFR Parts 11, 210 and 211 · US Drug Supply Chain Security Act · India: New Drugs and Clinical Trials Rules 2019, revised Schedule M, Medical Device Rules 2017.

Important: regulation changes often. Check current FDA and CDSCO guidance.