

Compliance Readiness & Dossier Preparation in Safety — Hands-on

Learn how to organise safety and ADMET evidence into clear, structured dossiers that support internal compliance readiness and communication with regulatory teams. You will practice building tables, summaries and traceable data trails around toxicity, exposure and risk concepts. This module is for educational purposes only and does not constitute legal or regulatory advice.

Compliance Readiness & Dossier Preparation in Safety

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Session 1

Fee: Rs 8800 [Apply Now](#)

Safety & Regulatory Evidence Landscape

Safety and regulatory evidence at a high level

toxicology and ADME evidence (conceptual)

exposure and risk notions **internal vs external audiences**

Dossier types and components (overview, non advisory)

core sections and annex style thinking **study lists**

and summary tables idea | narrative summaries vs data blocks

Concept of compliance readiness vs formal submission

internal gap awareness | traceability and documentation | collaboration with regulatory experts

Session 2

Fee: Rs 11800 | Apply Now

Structuring Safety Data & Endpoints

Organising studies and endpoints into logical blocks

study inventory tables concept | key toxicology and safety endpoints (idea) | linking endpoints to sections

Traceability from raw data to dossier level summaries

unique IDs and cross references | simple data lineage records | version and change notes (conceptual)

Capturing assumptions, limitations and uncertainty clearly

explicit caveats and data gaps | range of applicability style notes | flags for expert regulatory review

Session 3

Fee: Rs 14800 | Apply Now

Tables, Summaries & Narrative Dossiers

Design of safety and ADMET summary tables (conceptual)

study overview and key findings | endpoint and species fields (idea) | traffic light style flags

Writing non prescriptive safety narratives from data

descriptive rather than advisory tone | clear separation of fact and interpretation | signposting to

expert review needs

Structuring a dossier style document for internal review

contents, section order and annexes **linking tables, figures and text** **checklist oriented quality review**

Session 4

Fee: Rs 18800 Apply Now

Mini Capstone: Safety Dossier Readiness Pack

Assemble a mock safety study and endpoint inventory

Theory + Practical

Create summary tables and non prescriptive narratives

study overview and endpoint tables **short safety and ADMET summary text** **highlighted gaps and caveats**

Deliverables: safety dossier readiness pack (educational)

mock dossier style document **tables, figures and checklists** **PDF/HTML narrative for training use**