Regulatory Pathways for Vaccines & Biologics — Hands-on

Build an intuitive, non legal view of how vaccines and biologics move through regulatory pathways. This module focuses on big picture concepts: product lifecycles, evidence expectations, safety oversight and how cross functional teams can frame development and data plans to align with regulatory thinking, without going into jurisdiction specific legal detail.

Regulatory Pathways for Vaccines & Biologics

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Session Index

Session 1

Fee: Rs 8800 Apply Now

Regulatory Landscape & Product Lifecycles

High level view of agencies and pathways (non jurisdiction specific)

role of national and international regulators in concept **why vaccines and biologics are treated as complex products** **harmonisation and guidelines idea in simple language**

Product lifecycle stages from idea to post marketing overview

early research and preclinical concept phase **clinical development, review and launch orientation** **post marketing follow up and lifecycle management ideas**

How vaccines and biologics differ from small molecules in principle

complex structure and manufacturing sensitivity variability, comparability and consistency themes implications for data and documentation expectations

Session 2

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Quality, Nonclinical & Clinical Evidence (Concepts)

Quality and manufacturing information at a high level (no GMP detail)

what regulators look for in product and process descriptions **consistency, control strategy and comparability ideas** **stability and shelf life narratives connecting to previous modules**

Nonclinical and clinical evidence pillars in simple language

safety and immunogenicity themes in nonclinical work **phased clinical development and endpoints in concept** **special aspects of vaccines such as population level benefit thinking**

How data, analyses and modelling support a benefit risk narrative

role of statistics, modelling and bioinformatics outputs **integrating immunogenicity, safety and efficacy information** **importance of clear, reproducible evidence packages**

Session 3

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Safety, Pharmacovigilance & Risk Management Ideas

High level safety and pharmacovigilance concepts for vaccines

pre and post launch safety data flows in story form **spontaneous reports, active follow up and registries overview** **signal detection and investigation ideas (non methodological)**

Risk management planning in simple, cross functional terms

identifying key risks and uncertainties in concept **mitigation ideas such as warnings and monitoring plans** **connecting autoimmunity and safety concepts from earlier modules**

How informatics and analytics support safety oversight narratives

curating and analysing safety datasets conceptually **simple dashboards and reports aligned with regulatory thinking** **importance of traceable, auditable pipelines and outputs**

Session 4

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Pathway Mapping: From Concept to Submission Plan

Drawing a simple pathway map for a hypothetical vaccine project

key stages, decision points and major evidence packages **where immunoinformatics, systems and omics work plug in** **links to manufacturing, clinical and safety streams conceptually**

Structuring documentation and communication at a high level

clear story from product concept to benefit risk summary **tables and figures that help reviewers navigate data** **capturing assumptions, limitations and**

open questions plainly

Cross functional collaboration and handoffs for regulatory success

roles of R&D, clinical, safety, CMC and regulatory teams **meeting preparation and question management concepts** **maintaining alignment between scientific plans and regulatory expectations**