The Institute of Chartered Accountants of India

Set up by an Act of Parliament

Industry Sector-Wise Training Series

PHARMAXplore

Decoding the Pharmaceutical Industry for Chartered Accountants

Integrated 24-Hour Online Programme

Jointly organised by :

Members in Industry and Business Committee

&

Members in Practice Committee

From **Molecules** to Markets

From **Compliance** to Controls

From Sector Awareness to **CA Opportunity**

Mode	Duration	Format	Focus
Online / Virtual	24 Learning Hours	8 Days x 3 Hours	Industry + Practice

The Vision Behind Pharma Explore

India's pharmaceutical sector is not merely a manufacturing story; it is a regulated, research-linked, quality-driven and globally connected business ecosystem. For Chartered Accountants, meaningful contribution in this sector requires more than generic knowledge of accounting, taxation and audit. It requires the ability to understand how products are approved, how plants are inspected, how inventory expires, how R&D decisions shape financial statements, how exports and pricing controls influence margins, and how regulatory events can alter business value.

Pharma Explore has been designed to build this sectoral fluency in a structured and practical manner. The programme brings together the industry lens, regulatory lens and CA opportunity lens so that members can understand, interpret, audit, advise, join and build specialised capability in the pharmaceutical sector.

Industry Lens

Understand pharma as a business ecosystem - not merely as a compliance subject.

Regulatory Lens

Decode approvals, pricing, quality, inspections and market access as business drivers.

CA Opportunity Lens

Identify where CAs can create value in finance, audit, risk, controls, tax, ESG and advisory.

Why Pharma? Why Now?

Regulatory intensity

Every approval, manufacturing standard, pricing decision and inspection outcome may carry financial, audit and compliance consequences.

R&D-driven economics

Research, development, clinical trials, ANDA filings, patent cycles and failed molecules directly influence accounting, valuation, budgeting and risk assessment.

Global integration

Export markets, US/EU expectations, international supply chains, currency exposure and global reporting make the sector highly interconnected.

Complex manufacturing and quality systems

Batch production, GMP documentation, quality assurance, quality control, expiry-sensitive inventory and inspection readiness create specialised control needs.

High-value CA opportunities

CAs can contribute meaningfully in regulatory finance, costing, internal audit, compliance, risk management, transaction advisory, ESG, budgeting and strategic advisory.

Relevance for India

India's role in generics, APIs, formulations and healthcare access makes pharma a strategically important domain for industry and practice professionals.

Programme at a Glance

The following quote drafts may be adapted or approved by the respective dignitaries before publication. Names may be inserted after confirmation.

Programme Name	Pharma Explore
Programme Theme	Decoding the Pharmaceutical Industry for Chartered Accountants
Programme Format	Integrated single-level sector-focused online programme
Total Duration	24 learning hours
Delivery Flexibility	8 days x 3 hours each
Target Participants	CAs in industry and practice, newly qualified CAs, members handling pharma clients, internal auditors, consultants, finance professionals and members interested in pharma opportunities
Programme Focus	Pharma business model, regulation, value chain, R&D economics, manufacturing, quality systems, financial reporting, controls, taxation, audit, advisory, ESG and career/ practice opportunities
Core Objective	To build practical domain understanding of the pharmaceutical sector for CAs in India so that they can contribute meaningfully in industry roles, audit, advisory, taxation, compliance, risk, finance and consultancy services

Key Learning Outcomes

1

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2

Decode the pharma value chain from R&D, clinical trials and manufacturing to quality, distribution, exports, sales and post-market obligations.

3

Appreciate how regulatory authorities, pricing frameworks and inspection outcomes affect finance, audit, risk, valuation and business decisions.

4

Understand key financial reporting, R&D accounting, inventory, costing, revenue recognition and taxation issues relevant to pharma companies.

5

Identify pharma-specific internal control, risk management and audit focus areas.

6

Recognise advisory and consultancy opportunities for CAs in the pharmaceutical sector.

7

Build sectoral vocabulary and confidence for roles in industry, practice, internal audit, consulting, finance, compliance and strategic advisory.

8

Develop a roadmap for deeper specialisation or niche practice development in pharma.

Detailed Programme Structure
8 Modules of 3 Hours Each

MODULE

01

Pharma Sector Landscape and Business Ecosystem

Objective:

To provide a clear understanding of how the pharma industry is structured in India and globally.

Indicative Coverage:

Pharma as a regulated and knowledge-intensive sector; India's role in global pharma; formulations, APIs, generics, branded generics, patented drugs, biosimilars; CROs, CMOs, CDMOs; domestic and export-oriented models; how pharma companies generate revenue; value drivers such as approvals, quality record, exports, pricing and market access.

MODULE

02

Regulatory Architecture and Compliance Environment

Objective:

To explain how regulation forms the backbone of pharma and impacts business and finance.

Indicative Coverage:

CDSCO, DCGI, USFDA, EMA, MHRA; drug approvals; manufacturing licences; clinical trials; market authorisation; post-market surveillance; NPPA and DPCO; regulated pricing; warning letters, import alerts, product recalls, plant shutdowns and approval delays.

Detailed Programme Structure
8 Modules of 3 Hours Each

MODULE

03

Pharma Value Chain, Manufacturing, Quality Systems and Safety concerns

Objective:

To understand the pharma value chain and manufacturing-quality ecosystem.

Indicative Coverage:

R&D, clinical trials, sourcing, API manufacturing, formulation manufacturing, packaging, warehousing, distribution, exports and sales; own/loan/contract manufacturing; GMP; batch records; SOPs; validation; QA vs QC; batch release; stability studies; deviations; complaints; recalls; expiry-sensitive inventory and traceability.

MODULE

04

R&D Economics, Innovation and Pharma Business Strategy

Objective:

To explain how R&D, patents, filings and pipelines influence pharma economics.

Indicative Coverage:

Drug discovery lifecycle; clinical trial phases; high investment and failure risk; ANDA filings; patent cliffs; generic opportunities; exclusivity; licensing and collaboration; CRO/CMO/CDMO models; domestic/export strategy; regulated and semi-regulated markets; product mix; market entry; digital health and e-pharmacy.

Detailed Programme Structure
8 Modules of 3 Hours Each

MODULE

05

Financial Reporting, Accounting and Costing Issues in Pharma

Objective:

To interpret pharma financial statements through a sector lens.

Indicative Coverage:

Revenue recognition under Ind AS 115; domestic/export/institutional sales; tenders; returns; discounts and rebates; research vs development expenditure; capitalisation and impairment; failed molecules; clinical trial expenditure; inventory of APIs/intermediates/finished goods; expiry and obsolescence; batch costing, process costing and product profitability.

MODULE

06

R&D Economics, Innovation and Pharma Business Strategy

Objective:

To understand pharma-specific controls, risks, tax and compliance challenges.

Indicative Coverage:

Controls over procurement, production records, quality documentation, inventory, expiry, sales returns, credit notes, approvals and R&D spend; regulatory risk, product liability, quality failure, API dependency, currency and IP risk; GST classification, samples, ITC, exports/refunds, customs duty, R&D tax, transfer pricing, royalties and related-party arrangements.

Detailed Programme Structure
8 Modules of 3 Hours Each

MODULE

07

Pharma Audit, Assurance and Due Diligence Focus Areas

Objective:

To equip participants with audit and assurance perspectives for pharma companies.

Indicative Coverage:

Risk-based audit planning; key audit matters; R&D capitalisation; inventory valuation and expiry provisioning; revenue recognition; export sales; regulatory provisions and contingencies; impairment of intangibles/product rights; batch records; third-party locations; contract manufacturing; GMP documentation; inspection readiness; product recalls; due diligence of portfolios, approvals, IP, quality record and liabilities.

MODULE

08

Advisory Opportunities, ESG, Career Pathways and Practice Development

Objective:

To map professional opportunities and career/practice pathways in pharma.

Indicative Coverage:

Regulatory finance advisory; cost optimisation; working capital; internal control design; SOP development; R&D cost review; inventory advisory; export/incentive advisory; ESG and BRSR; waste management; pharma M&A; product portfolio, IP and brand valuation; licensing; career roles in R&D finance, business finance, costing, internal audit, compliance, risk, treasury, exports and global reporting; niche practice development.

Delivery Plans

Day	Hours	Module / Theme
Day 1	3 Hours	Pharma Sector Landscape and Business Ecosystem
Day 2	3 Hours	Regulatory Architecture and Compliance Environment
Day 3	3 Hours	Pharma Value Chain, Manufacturing, Quality System and Safety concerns
Day 4	3 Hours	R&D Economics, Innovation and Pharma Business Strategy
Day 5	3 Hours	Financial Reporting, Accounting and Costing Issues in Pharma
Day 6	3 Hours	Internal Controls, Risk Management, Taxation and Compliance
Day 7	3 Hours	Pharma Audit, Assurance and Due Diligence Focus Areas
Day 8	3 Hours	Advisory Opportunities, ESG, Career Pathways and Practice Development

Who Should Attend?

- Chartered Accountants in practice who wish to explore pharma as a sector-specific audit, advisory, compliance, tax, risk or consultancy domain.
- Chartered Accountants working in industry who wish to enter or grow in pharma, healthcare, life sciences, manufacturing or export-oriented organisations.
- Newly qualified Chartered Accountants seeking sector readiness for career decisions, interviews and professional positioning.
- Members handling clients in pharma, healthcare, API manufacturing, formulations, exports, distribution, hospitals, clinical research or allied sectors.
- Internal auditors, consultants, CFO office professionals, finance teams and members interested in building domain-led capability.

What Participants Take Away

Takeaway	Practical Value
A working mental model of pharma	Understanding of segments, regulators, value chain and economics that define the sector.
Regulatory fluency	Confidence to connect CDSCO, DCGI, USFDA, EMA, MHRA, NPPA and DPCO with finance and risk.
Commercial insight	Understanding of R&D economics, manufacturing, quality, exports, sales and pricing realities.
Finance and audit readiness	Ability to identify sector-specific accounting, costing, controls, audit and due diligence focus areas.
Advisory opportunity map	Clarity on how CAs can create value through controls, tax, ESG, transaction advisory, valuation and niche practice.

Learning Experience

Learning Design Element	How It Adds Value
Sector-first orientation	Participants first understand the business model before moving into technical interpretation.
Regulatory-context learning	Regulation is treated as a business driver, not merely as a compliance list.
Value-chain mapping	The learning follows the pharma lifecycle from R&D to manufacturing, distribution, exports, sales and post-market obligations.
Case-based discussions	Participants apply concepts to regulatory events, failed R&D, inventory expiry, product recall and transfer pricing scenarios.
CA role mapping	Each major industry process is connected to possible CA roles in industry and practice.
Online knowledge checks	Short polls/quizzes can reinforce understanding in virtual delivery.

Registration Information

Programme	Pharma Explore - Integrated 24-Hour Online Programme
Mode	Online / Virtual, live instructor-led sessions
Days	8 Days
Total Learning Hours	24 Hours
Eligibility	ICAI members (Industry and Practice)
Fee	₹1000/- Plus applicable GST
CPE	Non-CPE Event

Scan for Registration

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