Indian Pharma And Life Science Industry Legal And Tax Framework

#Indian Pharma Legal Framework #Life Science Industry Tax India #Pharmaceutical Regulations India #India Bio-Tech Legal Compliance #Indian Healthcare Taxation

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What is an NDA/BLA?

What is an sNDA/sBLA?

Over the Counter Application

What is the 505(b)(1) Regulatory pathway?

What is the 505(b)(2) Regulatory pathway?

What is the 505(j) pathway?

The importance of Regualtory Strategy

10:24 - Conclusion

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Introduction

Agenda

Getting a drug on the market

Contracts

Manufacturing

Innovation

Daniel Bletzler

Innovation and Manufacturing

Business Models

Legal Landscape and Processes

Collaboration is key

Market access

Legal considerations

Comarketing

Licensing

Promotional agreements

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Typical causes of disputes

The importance of arbitration

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Change

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Indira Gandhi 3rd Prime Minister of India

The Patent Act of 1970

Industry Overview

Drug Development

Growth

Getting Better

Overcapacity and Exports

TRIPS

Conversion

Other Ways of Strengthening

Biocon

The Dependence on China

Conclusion

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Basics of the agreement

Appointment, order and delivery

Quality

Indemnification

Limitation of liability

Post-termination

Poll

PharmaLex R&L Compliance

Approach and useful tips for negotiating a quality agreement

Importance of defining responsibilities

Quality contractual requirements - UK regulatory inspection expectations

Indemnity - Caution in assigning liability limitations

Breaches in the agreement - Potential consequences

Post-termination - What happens next?

Poll

Questions/Get in touch

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