

Executive summary

Invitation to Partnership

Small to medium sized life sciences companies are now at the forefront of innovation in the search for new cures and hope for patients. However, medtech and biotech companies face significant challenges related to navigating the business life cycle, including securing IP, managing R&D, raising funds (including IPO), launching product/portfolio and expanding geographically. Next generation therapies (such as gene and cell therapies) also add another layer of complexity in managing regulatory, supply chain and patient journey.

Deloitte's Biotech-in-a-box™ aims to provide a 'one-stop shop' to support the growth of small to mid-cap life sciences companies by leveraging Deloitte's whole portfolio of capabilities. Our global footprint of over 9,000 practitioners in over 90 countries and work with leading companies across the life sciences industry spans across a diverse range of cross-functional capabilities (including Strategy, Research, Commercialisation, Tax, Finance, Legal, Supply Chain, Regulatory, Technology and Human Resource). We have expertise in delivery (the design, build and run of research/commercial operations), partnership (assessing partnership options, finding the right partner and delivering the right risk/reward relationship), and launch products or services (supported >100 launch-related efforts in the last 12 months), and have experience supporting the unique needs of small and mid-cap companies specifically.

To ensure successful build and scale-up of the enterprise, defining the capability requirements for successful launch is key. We support biotech and medtech companies in understanding what maturity level is optimal, which capabilities need to be fully operational and by when? How to overcome key challenges in acquiring specific capabilities and which to build in-house vs. outsource, based on their launch strategies, priorities and goals. We would like to partner with biotech and medtech companies and de-risk the scaling-up journey. The level of Deloitte's involvement as a strategic partner can take a variety of forms, ranging from Deloitte being on-site and leading the execution to full autonomy for the partners, with Deloitte providing assistance as and when necessary as a strategic advisor.

We provide a 'one-stop shop' for biotech/medtech companies leveraging Deloitte's whole portfolio of capabilities

Cross-functional capabilities

Diverse range of capabilities and have the latest thinking on the design new organisations including *Strategy, Tax, Legal, Supply Chain, Regulatory, Technology and HR*

Global footprint

Global footprint (*over 9,000 practitioners in LSHC industry in over 90 countries*) and experience with leading companies across the life sciences industry

Delivery expertise

Skills in the design, build and run of commercial operations, all under one roof (*top ranked in both Strategy and Operations consulting*)



Partnership expertise

Experience in assessing partnership options, finding the right partner and delivering the right risk/reward

Launch expertise

Expertise in supporting product launch efforts (*>100 launch-related projects in the last 12 months and numerous ongoing*)

Partnership Model



We have extensive experience helping small and mid-cap life sciences clients across key business areas

We have experience supporting the unique needs of small and mid-cap companies across a range of key topics...



...and have published a range of thought pieces that demonstrate the breadth of our expertise and knowledge



European Expansion



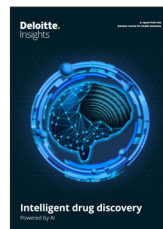
Life Sciences Outlook



Intelligent Biopharma



R&D Return On Innovation: ten years on



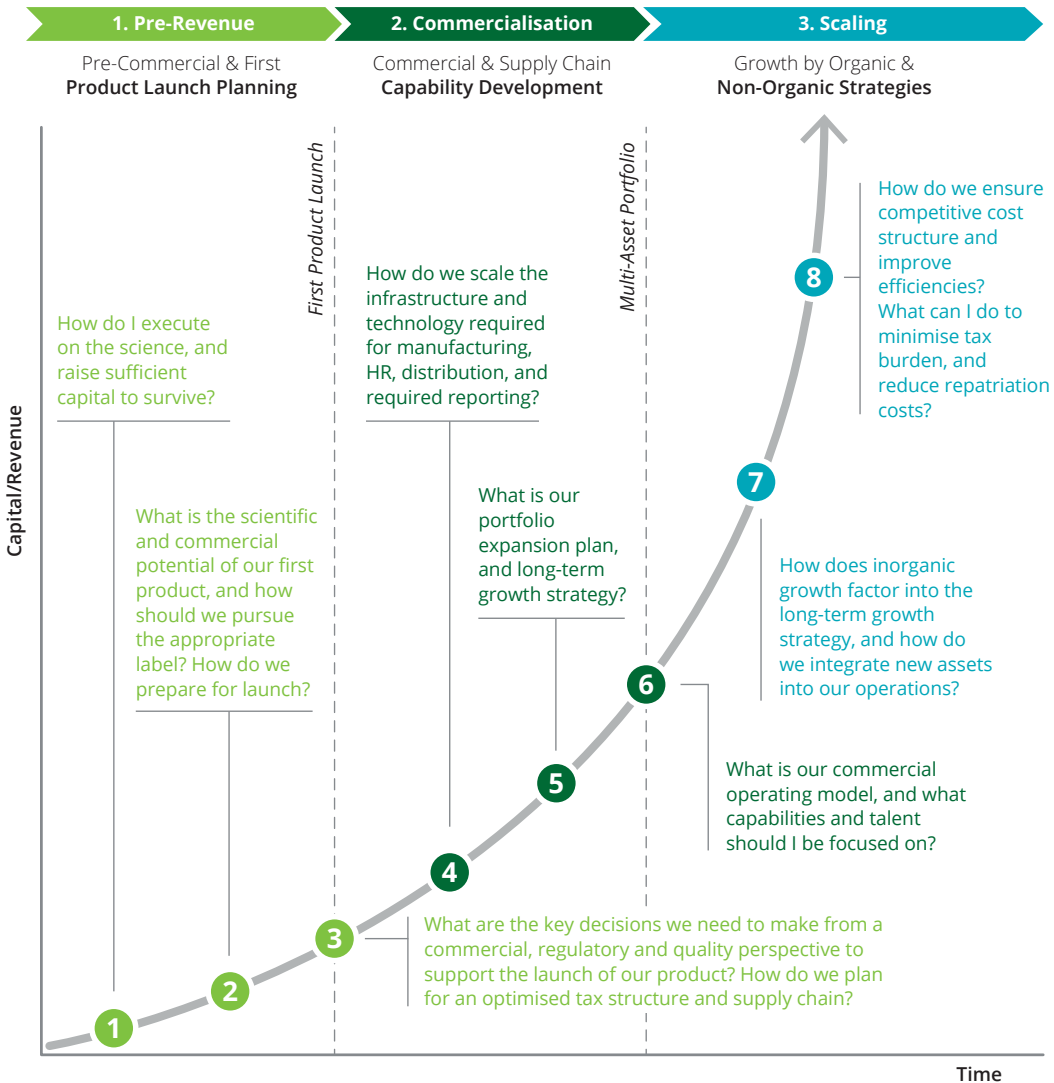
Intelligent Drug Discovery



Human Capital Trends

In our experience, emerging company CxOs face a unique set of challenges...

Evolutionary Stages for a Life Sciences Company



...that we, with our deep expertise and broad set of offerings, is uniquely qualified to address

Evolutionary Stages for a Life Sciences Company

		1. Pre-Revenue	2. Commercialisation	3. Scaling
		Pre-Commercial & First Product Launch Planning	Commercial & Supply Chain Capability Development	Growth by Organic & Non-Organic Strategies
Select Offerings & Services	CFO	<ul style="list-style-type: none"> Partnership strategy and execution (clinical development and commercialisation) Asset Target Screening 	<ul style="list-style-type: none"> Enterprise and Growth Strategy HR Planning & Outsourcing Global Legal Assistance (DT Legal – Ex-US) 	<ul style="list-style-type: none"> Portfolio Growth Digital Strategy HR – Culture, Change, Employee Engagement, Comp, Benefits Talent
	CFO	<ul style="list-style-type: none"> IPO Readiness Capital Efficiency IP Valuation Litigation support R&D Tax Credit NOL Utilisation and Limitations Intellectual Property Planning Fundraising & Public Offering 	<ul style="list-style-type: none"> IP Migration, Monetisation & Valuation Tax Location Strategy Global Tax Compliance & Documentation Operationalising Tax Strategy (e.g., supply chain) Financial Performance & Impact Analysis Commercial Contracting & Government Pricing Managed Services 	<ul style="list-style-type: none"> M&A Strategy, Target Screening & Execution Transaction Diligence & Integration Support Licensing & Partnership Support IP Migration, Monetisation & Valuation Repatriation Planning Specific Event Planning (e.g., acquisition, dispositions, collaborations, etc.) Financial Performance & Impact Analysis
	COO / CSCO	<ul style="list-style-type: none"> Alliance & CRO Management Compliance Program Establishment Regulatory Consulting GCP Compliance 	<ul style="list-style-type: none"> Operating Model Design (e.g., Flexible Supply Chain, Distribution and Manufacturing planning) Product Launch Supply Chain 	<ul style="list-style-type: none"> Commercial Contracting & Government Pricing Managed Services Maintenance & Analytics Compliance Program Maintenance Manufacturing and Network Expansion
	CCO	<ul style="list-style-type: none"> Product Launch Commercial & Marketing Strategy Scientific/Market Due Diligence 	<ul style="list-style-type: none"> Capability Development/Buy or Build Planning Commercial Model Planning 	<ul style="list-style-type: none"> Customer Experience Innovation Gross to Net Services Commercial Contracting & Government Pricing
	CIO	<ul style="list-style-type: none"> IT Outsourcing Strategy IT enablement strategy for Product Launch Manufacturing scale up & efficiency Core R&D operations enablement Foundational IT: (SDLC, Quality, Staff Aug. Infra & Network) 	<ul style="list-style-type: none"> IT Operating Model Information Management Foundation (Product & Customer Master Data, Data Store Strategy, etc.) Commercial Capabilities: Cloud CRM, SFA Early Cyber and Risk policy & standards 	<ul style="list-style-type: none"> Commercial operations and analytics Digital Experience & Engagement Solutions Finance Ops: Performance Management HR and Cloud Learning Management Systems Security & Cyber

We work with biotech and medtech companies to

Commercial Functions				Medical Affairs	Clinical	Regulatory	CMC Supply Chain
Marketing	Sales	Market Access	Commercial Ops				
Launch/Brand Strategy	Sales Force Deployment	Pricing Strategy Development	Marketing Analysis	MSL Customer Engagement	Clinical Trial Management	Regulatory Strategy	Clinical/ Commercial Manufacturing
Multi-channel/ Digital Marketing	Sales Force Training	Payer Engagement Strategy	Business Intelligence	KOL Engagement	Biostatics	Regulatory Project Management	Packaging & Labelling
Marketing Tactics Execution	Key Account Management	Channel Engagement	Information Management	Scientific Publications	Clinical Data Management	Product Label Management	CMO Management
Market Development		HTA Submissions	Sales Operations	HEOR/RWE Development	Protocol Development	Regulatory Intelligence	Demand Forecasting
Business Insights		Reimbursement	Sales Forecasting & Planning	Medical Communications	Clinical Program Management	Submission Management	Capacity Planning
		Budget impact modelling		Grants Management	Clinical Monitoring	Registration Management	Distribution
		Cost-effectiveness modelling		Speaker Program Development	Medical Writing	Licence Maintenance	Planning and Managing Inventory
		Tendering		Expanded Access Program (EAP) Design		Safety/PV	Inspection Readiness

Key questions

Which capabilities do you find most **challenging to acquire**?

What **capability maturity level** do you require by launch?

The capabilities need to be **fully operational by when**?

Which capabilities should you **build in-house or outsource**?

Quality Management System (QMS) Process

Quality Assurance

Quality Control

build and scale the enterprise

Enabling Functions					
Technology	Finance	HR	Legal/Compliance	Other	Corporate Development
IT Foundation	Credit, Invoicing and Collections	Talent Acquisitions	Government Policy	Business Development	Fundraising
Enterprise Collaboration & Productivity	Procurements and Disbursements	Compensation & Benefits Design	Compliance Auditing and Monitoring	Corporate Communications	Business Development
Document Management	Payroll & Expense Management	New Hire Onboarding & Training	Contract Review (Approvals)	Government Affairs	Licensing and Collaboration
Enterprise Capabilities	Revenue and Cost Accounting	HR Policy Development	Compliance Policy Development	Patient Advocacy	Merger & Acquisition
Domain Operational Capabilities	Financial Reporting	Performance Management	Aggregate Spend/ Sunshine Act Compliance	Vendor Management/ Procurement	IP Protection and Management
Op. Reporting and Information Management	Budgeting and Forecasting	Payroll Management	Compliance Training	Knowledge Management	Licensing and Collaboration
Analytics & Visualisation	Performance Management			Project Management	
Data Strategy & Management	Risk and Compliance			Corporate Governance	
	Treasury				
	Gross-to-net				
	Tax				

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