Life Sciences Regulatory and Medical Affairs Operations PEAK Matrix® Assessment 2024

June 2024

PEAK MATRIX®

Life Sciences Business Process

Everest Group®

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Life Sciences Business Process

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- Asset and Wealth Management
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- Contingent Staffing
- Contingent Workforce Management
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- CXM Technology
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- Cyber Threat Detection and Response
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- Digital Workplace
- Employee Experience Management (EXM) Platforms
- Employer of Record (EOR)
- Engineering Research and Development
- Enterprise Platform Services
- Exponential Technologies
- Finance and Accounting
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- Forces & Foresight
- GBS Talent Excellence
- Global Business Services
- Google Cloud
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- Human Resources
- Insurance Business Process
- Insurance Information Technology
- Insurance Technology (InsurTech)
- Insurance Third-Party Administration (TPA) Services
- Intelligent Document Processing
- Interactive Experience (IX) Services
- IT Services Excellence
- IT Talent Excellence
- Life Sciences Business Process
- Life Sciences Commercial Technologies
- Life Sciences Information Technology
- Locations Insider™
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- Market Vista™
- Microsoft Azure
- Microsoft Business Application Services
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- Process Intelligence
- Process Orchestration
- Procurement and Supply Chain
- Recruitment
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- Revenue Cycle Management
- Rewards and Recognition
- SAP Services
- Service Optimization Technologies
- Software Product Engineering Services
- Supply Chain Management (SCM) Services
- Sustainability Technology and Services
- Talent Genius™
- Technology Skills and Talent
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Introduction and overview

Research methodology

Key information on the report

Introduction

Regulatory and medical affairs value chain

Summary of key messages

Our research methodology is based on four pillars of strength to produce actionable and insightful research for the industry

01 Robust definitions and frameworks

Function-specific pyramid, Total Value Equation (TVE), PEAK Matrix®, and market maturity

02 Primary sources of information

Annual contractual and operational RFIs, provider briefings and buyer interviews, web-based surveys

03 Diverse set of market touchpoints

Ongoing interactions across key stakeholders, input from a mix of perspectives and interests

04 Fact-based research

Data-driven analysis with expert perspectives, trend-analysis across market adoption, contracting, and providers

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Proprietary contractual database of over 500 life sciences contracts (updated annually)

Year-round tracking of 45+ life sciences providers

Large repository of existing research in life sciences

Over 30 years of experience advising clients on strategic IT, business services, engineering services, and sourcing

Executive-level relationships with buyers, providers, technology providers, and industry associations

This report is based on two key sources of proprietary information

- Proprietary contract-based database, which tracks the following elements of each contract:
  - Buyer details including size and signing region
  - Contract details including provider, contract type, TCV and ACV, provider FTEs, start and end dates, duration, and delivery locations
  - Scope details including share of individual buyer locations being served in each contract, Line of Business (LOB) served, and pricing model employed

- Proprietary provider database, which tracks the following elements of each provider:
  - Revenue and number of FTEs
  - Number of clients
  - FTE split by line of business
  - Revenue split by region
  - Location and size of delivery centers
  - Technology solutions developed

- Provider briefings
  - Vision and strategy
  - Annual performance and future outlook
  - Key strengths and improvement areas
  - Emerging areas of investment

- Buyer reference interviews, ongoing buyer surveys, and interactions
  - Drivers of and challenges to adopting services
  - Assessment of provider performance
  - Emerging priorities
  - Lessons learned and best practices

Providers assessed[1]

accenture, CliniRx, cencora PharmaLex, DXC Technology, freyr, genpact, HCLTech, ICON, indegene, IQVIA, Medpace, Navitas Life Sciences, parexel, PPD, propharma, ProTrials, Quanticate, Syneos Health, Tech Mahindra, wipro

1 Assessment for CliniRx, Cencora PharmaLex ICON, Medpace, Navitas Life Sciences, Parexel, PPD, ProTrials, Quanticate and Syneos Health excludes service provider inputs and is based on Everest Group's proprietary Transaction Intelligence (TI) database, service provider public disclosures, and Everest Group's interaction with buyers. For these companies, Everest Group's data for assessment may be less complete
The source of all content is Everest Group unless otherwise specified
Confidentiality: Everest Group takes its confidentiality pledge very seriously. Any information we collect that is contract-specific will be presented only in an aggregated fashion

Introduction

The landscape of regulatory requirements is undergoing drastic changes, presenting enterprises with an array of challenges. Challenges such as navigating complex compliance frameworks, staying abreast of emerging regulations, and managing diverse geographical requirements have become formidable obstacles for enterprises striving for regulatory compliance and market access. Consequently, an increasing number of enterprises are turning to external service providers equipped with specialized knowledge and technological expertise to navigate these intricate regulatory landscapes efficiently.

To meet the escalating demand for regulatory and medical affairs support, service providers are proactively fortifying their capabilities and offerings. Recognizing the critical need for adaptable solutions, providers are investing substantially in technological advancements expanding their portfolio to encompass cutting-edge tools and platforms tailored to streamline regulatory processes. Moreover, to offer enhanced value and accessibility, providers are augmenting their global footprint establishing localized support networks to fulfill the nuanced requirements of diverse markets.

In this report, we present an assessment and detailed profiles of 20 service providers featured on the Regulatory and Medical Affairs Operations PEAK Matrix®. The assessment is based on Everest Group's annual RFI process for calendar year 2024, interactions with leading regulatory and medical affairs providers, client reference checks, and an ongoing analysis of the regulatory and medical affairs BPS market.

This report includes the profiles of the following 20 leading service providers featured on the Regulatory and Medical Affairs Operations PEAK Matrix:

- **Leaders:** Accenture, Cencora PharmaLex, Freyr, Genpact, ICON, IQVIA, and Parexel
- **Major Contenders:** DXC Technology, HCLTech, Indegene, Medpace, Navitas life Sciences, PPD, ProPharma Group, Syneos Health, Tech Mahindra, and Wipro
- **Aspirants:** CliniRx, ProTrials, and Quanticate

Scope of this report

Geography: Global

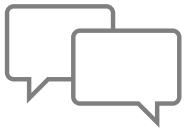
Industry: Life sciences

Services: Life sciences regulatory and medical affairs operations

This report deep dives into the regulatory and medical affairs operations value chain, which is depicted here





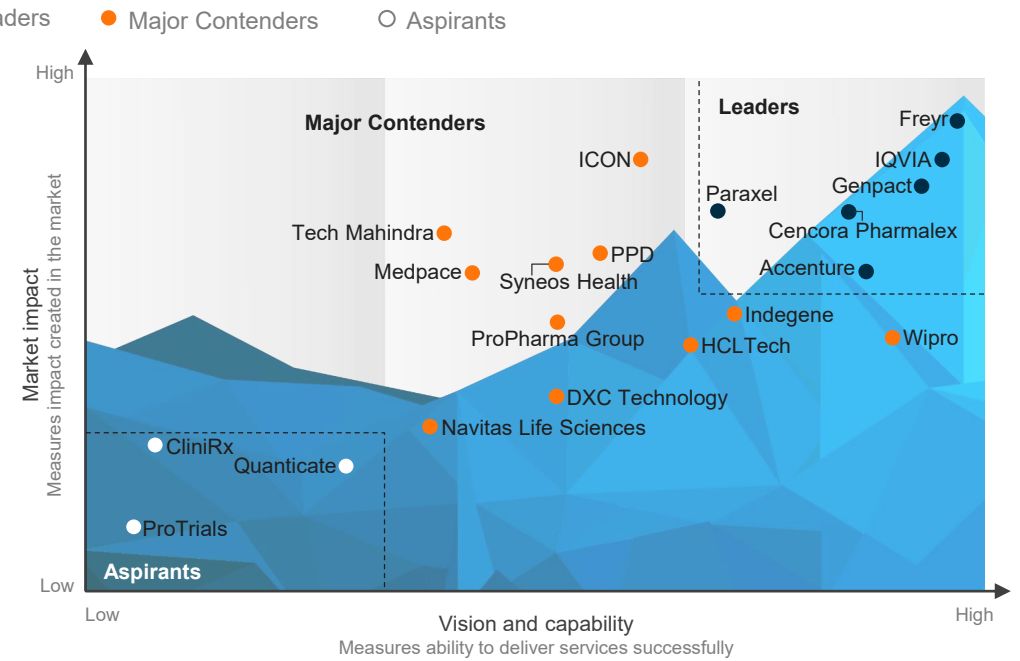
Labeling and artwork management	Regulatory writing and submission management	Regulatory support services	MLR Review and commercial compliance	Medical affairs content generation	Medical affairs engagement
Label authoring, artwork/labeling lifecycle management, review and quality checks, etc.	Regulatory and technical writing and review, Chemistry, Manufacturing, and Control (CMC), product registration and clinical trials application services, submission and approval management including health authority liaison and pre-submission meetings, etc.	Regulatory intelligence, regulatory information management, etc.	Medical review, editorial review and compliance, MLR operations support – coordination and submission management, regulatory ad promo review, etc.	Evidence generation including Real World Evidence (RWE) and HEOR, scientific writing and literature screening, etc.	Medical and scientific publication and communication, Key Opinion Leader (KOL) engagement, field medical excellence including Medical Science Liaison (MSL) support, etc.
Analytics/Automation/Platforms					

Summary of key messages

Everest Group PEAK Matrix® for Regulatory and Medical Affairs Operations

- The PEAK Matrix® is a framework to assess the overall vision, capability, and market impact of service providers
- Everest Group classified 20 regulatory and medical affairs BPS providers on the Everest Group PEAK Matrix® into the three categories of Leaders, Major Contenders, and Aspirants
  - Leaders: Accenture, Cencora PharmaLex, Freyr, Genpact, ICON, IQVIA, and Parexel
  - Major Contenders: DXC Technology, HCLTech, Indegene, Medpace, Navitas Life Sciences, PPD, ProPharma Group, Syneos Health, Tech Mahindra, and Wipro
  - Aspirants: CliniRx, ProTrials, and Quanticate

Everest Group Life Sciences Regulatory and Medical Affairs Operations PEAK Matrix® Assessment 2024[1,2]



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2 The assessments for IQVIA and ProPharma were assisted by the respective service providers through briefing calls
Source: Everest Group (2024)

Regulatory and Medical Affairs Operations PEAK Matrix® characteristics

PEAK Matrix framework

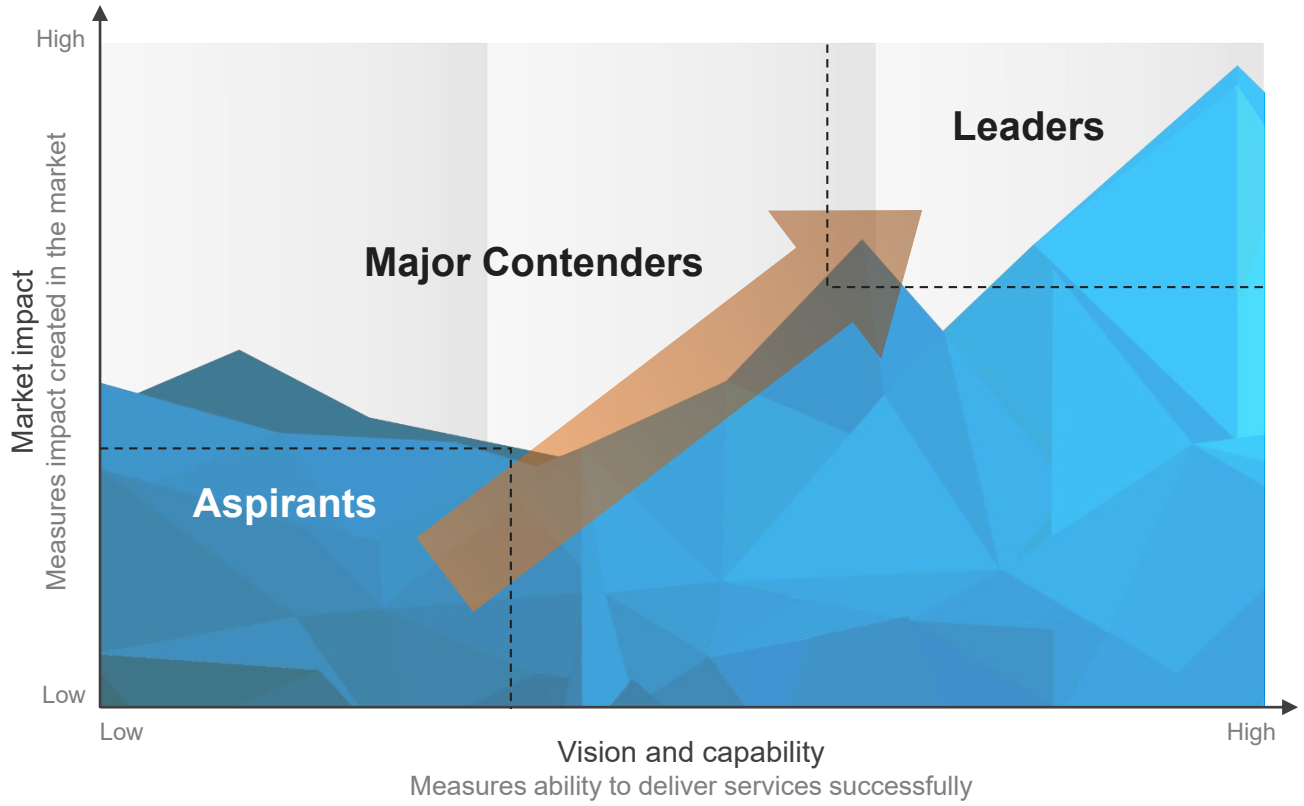
Everest Group PEAK Matrix for Regulatory and Medical Affairs Operations

Characteristics of Leaders, Major Contenders, and Aspirants

Provider capability summary dashboard

Everest Group PEAK Matrix® is a proprietary framework for assessment of market impact and vision and capability

Everest Group PEAK Matrix



Please click Everest Group PEAK Matrix® for more information

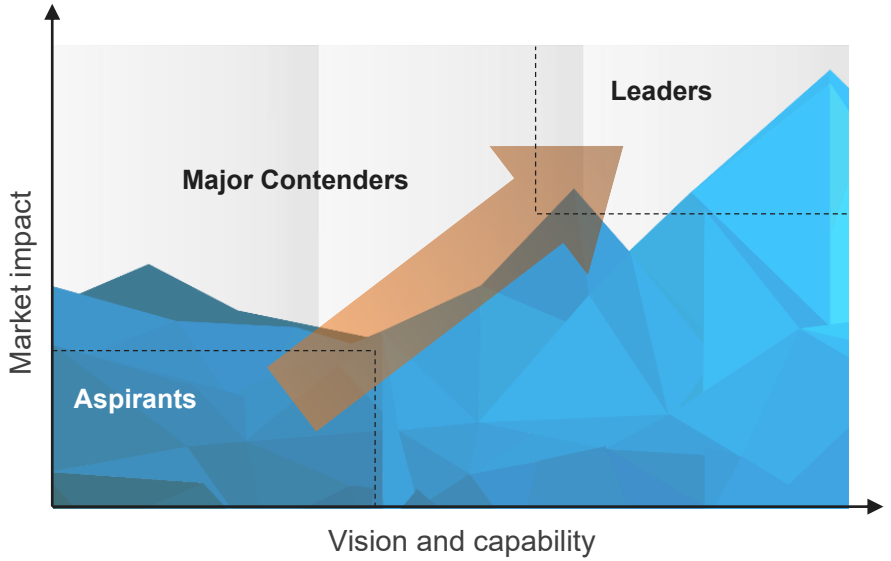
Services PEAK Matrix® evaluation dimensions

Measures impact created in the market – captured through three subdimensions

Market adoption
Number of clients, revenue base, YoY growth, and deal value/volume

Portfolio mix
Diversity of client/revenue base across geographies and type of engagements

Value delivered
Value delivered to the client based on customer feedback and transformational impact



Measures ability to deliver services successfully. This is captured through four subdimensions

Vision and strategy
Vision for the client and itself; future roadmap and strategy

Scope of services offered
Depth and breadth of services portfolio across service subsegments/processes

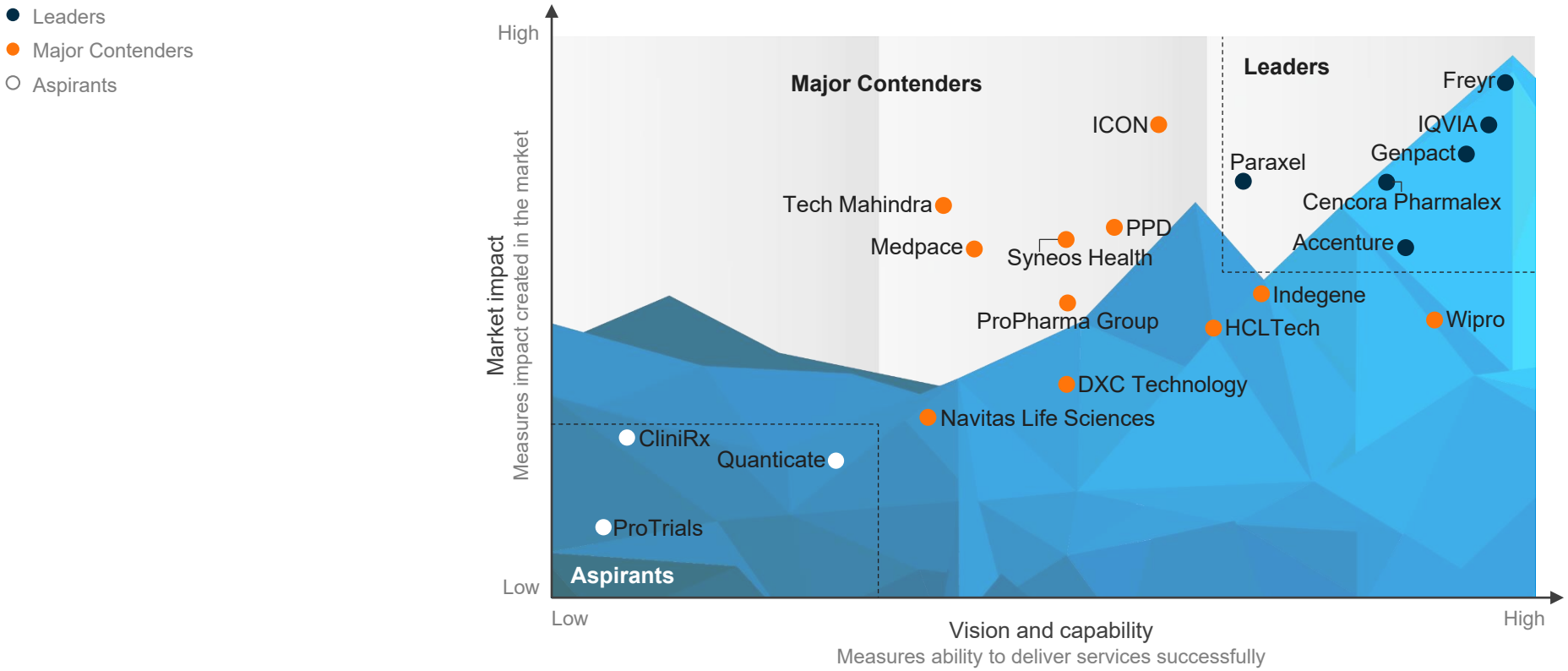
Innovation and investments
Innovation and investment in the enabling areas, e.g., technology IP, industry/domain knowledge, innovative commercial constructs, alliances, M&A, etc.

Delivery footprint
Delivery footprint and global sourcing mix

Everest Group PEAK Matrix®

Life Sciences Regulatory and Medical Affairs Operations PEAK Matrix® Assessment 2024

Everest Group Life Sciences Regulatory and Medical Affairs Operations PEAK Matrix® Assessment 2024[1,2]



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Source: Everest Group (2024)

Regulatory and Medical Affairs Operations – services PEAK Matrix® characteristics

Leaders

Accenture, Cencora PharmaLex, Freyr, Genpact, ICON, IQVIA, and Parexel

- Leaders have a global delivery footprint, and they exhibit capabilities to serve clients from all tiers – ranging from emerging biotechs to large established pharma and MedTech enterprises
- Along with driving superior client engagement, they have showcased high levels of proactiveness in taking their innovations and next-generation service offerings to clients, thereby positioning themselves as strategic partners. Their offerings, coupled with consulting-based solutions, are appreciated by clients
- The majority of Leaders have broad coverage across the regulatory and medical affairs value chain and can offer one-stop solutions to enterprises

Major Contenders

DXC Technology, HCLTech, Indegene, Medpace, Navitas life Sciences, PPD, ProPharma Group, Syneos Health, Tech Mahindra, and Wipro

- While Major Contenders may not have an integrated and comprehensive coverage of the regulatory and medical affairs operations value chain, they have been able to deliver value by strengthening their capabilities through investments
- Few Major Contenders have also made small acquisitions to expand their breadth and coverage
- To bridge the gap with Leaders, Major Contenders are investing in cutting-edge technologies and AI/ML solutions, while simultaneously increasing their scale of operations

Aspirants

CliniRx, ProTrials, and Quanticate

- The majority of Aspirants are focused on selective areas, be it in terms of value chain segments, buyer type, or geographies
- Aspirants in the regulatory and medical affairs operations arena seek to carve out their niche by strategically directing investments toward unique capabilities and specialized use cases, positioning themselves for future growth and innovation in the market
- They have relatively limited domain and technology capabilities compared to the Leaders and Major Contenders

Summary dashboard | market impact and vision and capability assessment of providers for regulatory and medical affairs operations 2024 (page 1 of 4)

Leaders

Measure of capability: Low High

	Market impact				Vision and capability				
Providers	Market adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Scope of services offered	Innovation and investments	Delivery footprint	Overall
Accenture									
Cencora PharmaLex									
Freyr									
Genpact									
IQVIA									
Paraxel									

Summary dashboard | market impact and vision and capability assessment of providers for regulatory and medical affairs operations 2024 (page 2 of 4)

Major Contenders

Measure of capability: Low High

	Market impact				Vision and capability				
Providers	Market adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Scope of services offered	Innovation and investments	Delivery footprint	Overall
DXC Technology									
HCLTech									
ICON plc									
Indegene									
Medpace									
Navitas Life Sciences									

Summary dashboard | market impact and vision and capability assessment of providers for regulatory and medical affairs operations 2024 (page 3 of 4)

Major Contenders

Measure of capability: Low High

	Market impact				Vision and capability				
Providers	Market adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Scope of services offered	Innovation and investments	Delivery footprint	Overall
PPD									
ProPharma Group									
Syneos Health									
Tech Mahindra									
Wipro									

Summary dashboard | market impact and vision and capability assessment of providers for regulatory and medical affairs operations 2024 (page 4 of 4)

Aspirants

Measure of capability: Low High

	Market impact				Vision and capability				
Providers	Market adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Scope of services offered	Innovation and investments	Delivery footprint	Overall
CliniRx									
ProTrials									
Quanticate									

Enterprise sourcing considerations

Leaders

- Accenture
- Cencora PharmaLex
- Freyr
- Genpact
- IQVIA
- Parexel

Accenture

Everest Group assessment – Leader

Measure of capability: Low High

Market impact				Vision and capability				
Market adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Scope of services offered	Innovation and investments	Delivery footprint	Overall
								

Strengths

- Accenture combines its operations, consulting, and technology capability across multiple therapeutic areas through in-house proprietary solutions and strategic partnerships (Veeva, Trackwise, Adobe, etc.) to deliver robust regulatory offerings, especially labeling, artwork, and regulatory submission services
- Accenture has a strong technology portfolio including solutions such as iACTIVATE (labeling and artwork), Viewpoint (regulatory submissions), StartingPoint (authoring), and RISE (regulatory intelligence), with continued investment in generative AI tools such as iCRAFT (regulatory submissions) and regulatory document authoring solution
- Referenced clients have complimented its skilled talent pool, strong regulatory network, and flexibility

Limitations

- While it has strong regulatory offerings, its penetration in the MedTech space stands limited vis-à-vis peers
- Accenture's limited capabilities in medical affairs engagements by utilizing MSLs and KOLs may hinder its ability to fully address the strategic needs of clients seeking to build scientific credibility and relationships with key experts
- Clients would appreciate more proactive account management along with faster onboarding of resources

Cencora PharmaLex

Everest Group assessment – Leader

Measure of capability: Low High

Market impact				Vision and capability				
Market adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Scope of services offered	Innovation and investments	Delivery footprint	Overall
								

Strengths

- PharmaLex offers a wide spectrum of services across the regulatory affairs value chain (labeling and artwork, CMC services, regulatory and technical writing, and agency interactions) as well as medical writing services
- PharmaLex's wide-reaching presence across emerging geographies such as MEA, LATAM, and APAC along with the nuanced understanding of local markets delivered by its in-market experts and on-ground teams position it as a glocalized domain expert
- Its diversified client portfolio consisting of biotech, medical devices, and pharmaceuticals demonstrates its prowess in serving multiple client needs
- PharmaLex's recent acquisition by Cencora has allowed it to expand its scale in delivery and technological capabilities

Limitations

- PharmaLex's breadth of offerings in the medical affairs segment is restricted, with it being primarily focused around medical writing
- While it has rich experience in serving biopharmaceutical clients, its penetration in the medical devices segment remains limited

Freyr

Everest Group assessment – Leader

Measure of capability: Low High

Market impact				Vision and capability				
Market adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Scope of services offered	Innovation and investments	Delivery footprint	Overall
								

Strengths

- Freyr combines its deep domain expertise, consultative offerings, and dedicated Centers of Excellence (CoEs) to offer an end-to end coverage across the regulatory value chain
- Freyr's extensive market footprint and strong affiliate network, coupled with its localized expertise and language capabilities, solidifies its strength in navigating diverse regulatory environments effectively
- Its extensive and robust technological solutions such as Freya.Submit, Freya.Register, Freya.Intelligence, Freya.Artwork and Freya.Label have seen good traction in the market
- Referenced buyers have lauded Freyr for its cost optimization, skilled talent pool, and proactiveness

Limitations

- Freyr's comparatively limited MSL and KOL engagement capabilities could restrict its ability to maximize opportunities for clients seeking to build scientific credibility and relationships with key experts
- Client feedback has highlighted occasional challenges during the implementation phases of high-volume projects. Freyr could refine its implementation process to further enhance a seamless client experience

Genpact

Everest Group assessment – Leader

Measure of capability: Low High

Market impact				Vision and capability				
Market adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Scope of services offered	Innovation and investments	Delivery footprint	Overall
								

Strengths

- Genpact offers a comprehensive suite of digital solutions, including in-house tools (Cora Reg Assure, Core Reg Intel, RIM BI Hub, etc.), strategic partnerships (AWS, Veeva, etc.), and cutting-edge AI capabilities such as the HAQA tool that uses generative AI and NLP to automate responses to health authority inquiries
- Genpact's Regulatory-as-a-Service (GRaaS) integrates the domain knowledge of regulatory specialists with Genpact's robust digital solutions while providing the flexibility to select a modular or a full-service package as per client requirements
- This service provider specializes in medical affairs engagement, offering expertise in KOL engagement and MSL support
- Genpact has strengthened its presence in the MedTech space by winning new deals, including deals that serve carve-outs of medical device companies

Limitations

- Buyers have cited that although Genpact has demonstrated expertise in handling volume-intensive tasks such as CMC, its prowess in addressing regional level domain-intensive services and market authorization holder (MAH) services remains relatively limited compared to specialists
- While small enterprises are actively seeking digital transformation support to compete with larger enterprises, Genpact’s limited penetration amongst the small client segment, may result in it missing out on this opportunity

IQVIA

Everest Group assessment – Leader

Measure of capability: Low High

Market impact				Vision and capability				
Market adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Scope of services offered	Innovation and investments	Delivery footprint	Overall
								

Strengths

- IQVIA has a robust suite of technological offerings, including RIM Smart (end-to-end regulatory information management system), IQVIA productivity tools (for electronic submissions), and IQVIA Smart Labeling solutions
- Its extensive global footprint and expertise in collaborating with multiple health authorities allows it to navigate the complexities of diverse regulatory environments and effectively serve clients
- IQVIA leverages its strong domain expertise and network connects to offer services such as KOL engagement and health authority liaison support
- IQVIA has established separate business units for MedTech and biotech clients, thereby serving mostly all client domains

Limitations

- Buyer perceive IQVIA as a premium-priced provider. This might limit its ability to service firms that have a strong requirement for cost reduction via outsourcing
- While there is an increasing market demand for outcome-based pricing models, there is limited evidence of IQVIA engaging in such constructs

Parexel

Everest Group assessment – Leader

Measure of capability: Low High

Market impact				Vision and capability				
Market adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Scope of services offered	Innovation and investments	Delivery footprint	Overall
								

Strengths

- Parexel harnesses its deep therapeutic expertise and large team of regulatory professionals to deliver comprehensive services across the value chain, including regulatory intelligence, regulatory writing, submissions, and medical affairs engagement
- Its team of ex-regulators offers in-depth knowledge of regulatory expectations and requirements, facilitating effective communication and strategic engagement with authorities
- It leverages Parexel Medical Communications, a full-service agency dedicated to providing medical affairs solutions, to offer robust medical writing and MSL support services
- Its optimum delivery mix enables it to serve clients from onshore, offshore, and nearshore locations

Limitations

- While there's a growing demand from enterprise clients for digital capabilities in labeling and artwork services, its investments in that space remain limited
- It largely focuses on biopharmaceutical clients, with limited penetration in the medical devices segment
- Its client portfolio is skewed toward large buyers, while its ability to serve small to midsize clients remains relatively untested

Enterprise sourcing considerations

Major Contenders

- DXC Technology
- HCLTech
- ICON plc
- Indegene
- Medpace
- Navitas Life Sciences
- PPD
- ProPharma Group
- Syneos Health
- Tech Mahindra
- Wipro

DXC Technology

Everest Group assessment – Major Contender

Measure of capability: Low High

Market impact				Vision and capability				
Market adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Scope of services offered	Innovation and investments	Delivery footprint	Overall
								

Strengths

- DXC Technology provides its clients with robust services and software capabilities with its digital portfolio comprising solutions such as DXC RIM Platform, DXC FirstDoc (document management), DXC Writer (medical writing), and DXC RegTracker (regulatory intelligence), among others
- The service provider is actively investing in generative AI to enhance its capabilities in document generation and assembly and regulatory intelligence
- DXC Technology offers flexibility to its clients to adopt different commercial models such as transaction-based, T&M, and outcome-based. Its ability to tie outcome-based constructs with rewards is viewed positively by mature clients as it incentivizes high performance and motivates teams
- Clients have complimented DXC Technology on its relationship management and strong innovation capabilities

Limitations

- While peers have a heavy focus on labeling and artwork services, DXC Technology has limited breadth in this space
- Its limited foray into the medical affairs space might hinder its ability to attract enterprises seeking end-to-end regulatory and medical affairs support
- Its client portfolio for regulatory affairs is skewed toward biopharmaceuticals, with limited penetration in the medical device segment
- Clients have highlighted adaptability and expertise in data migration in supporting clients' preferred cloud platforms as key areas of improvement for DXC Technology

HCLTech

Everest Group assessment – Major Contender

Measure of capability: Low High

Market impact				Vision and capability				
Market adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Scope of services offered	Innovation and investments	Delivery footprint	Overall
								

Strengths

- HCL's specialized CoEs for regulatory, labeling, and medical affairs, combined with its extensive coverage across multiple devices and therapeutic areas, allow it to deliver both global and local regulatory compliance support to clients
- HCL has leveraged its strong upstream capabilities for product design and engineering to expand into downstream opportunities in regulatory affairs, resulting in a strong MedTech client portfolio
- Its robust technological portfolio is augmented by its proactive investments in generative AI, leveraging the technology to deliver labeling, document submission, and regulatory intelligence services to clients

Limitations

- While it has penetrated well into the emerging APAC market, other markets such as LATAM and MEA remain relatively untapped
- Compared to other IT/BPO providers and CROs, HCL's scale of operations in regulatory and medical affairs is lower both in terms of revenue and clients

ICON plc

Everest Group assessment – Major Contender

Low High

Market impact				Vision and capability				
Market adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Scope of services offered	Innovation and investments	Delivery footprint	Overall
								

Strengths

- ICON's large resource base consists of regulatory experts with prior experience across FDA, EMA, Health Canada, and other international regulatory authorities. This allows it to deliver an extensive range of regulatory services including labeling support, regulatory submission, and clinical report preparation and review
- Its dedicated medical writing teams offer a full range of services for individual documentation as well as extensive medical writing programs
- ICON's regulatory intelligence team, with its expertise in interpreting complex regulations and guidelines, augments the capabilities of its regulatory experts and empowers them to deliver highly customized and compliant solutions for clients
- ICON's deep expertise in the biosimilar market positions it as an experienced provider for biopharmas looking to navigate the complex biosimilars regulatory landscape

Limitations

- Its onshore-heavy delivery model affects the cost-effectiveness of its services and might impact engagement, especially among first-time outsourcing buyers
- While it offers robust technological capabilities for clinical trials, its investments in technological platforms and solutions for regulatory and medical affairs remain limited when compared with other CRO peers
- Compared to other large CROs, buyers view ICON as an expert in clinical research. Its brand recognition in the regulatory and medical affairs segment, remains lower vis-à-vis peers

Indegene

Everest Group assessment – Major Contender

Market impact				Vision and capability				
Market adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Scope of services offered	Innovation and investments	Delivery footprint	Overall
								

Strengths

- Indegene’s NEXT suite of technology platforms offers solutions across the regulatory and medical affairs value chain, including MLR review, medical writing, literature surveillance, labeling and artwork, regulatory submissions, and health authority query management
- Indegene leverages its medical affairs CoE to offer services such as evidence generation, medical publication and communication, MSL support, and KOL engagement, while augmenting its capabilities with generative AI-powered medical writing and NLP-based literature screening tools
- Referenced clients have lauded its domain expertise and implementation and transition capabilities

Limitations

- Indegene's lack of MedTech-focused case studies limits its impact compared to peers that are actively leveraging their upstream capabilities to expand into downstream opportunities in regulatory affairs within the MedTech space
- While clients value their relationship with its upper management, they expect more proactive on-ground teams for faster implementation and leaner processes
- Clients expect Indegene to proactively showcase its broader range of capabilities, even those outside the immediate contract scope. This approach would help clients visualize the potential for deeper engagement and expanded partnership

Medpace

Everest Group assessment – Major Contender

Market impact				Vision and capability				
Market adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Scope of services offered	Innovation and investments	Delivery footprint	Overall
								

Strengths

- Medpace is a global full-service CRO that offers different services across the value chain including document preparation and submission, regulatory agency interactions, and medical writing
- Medpace bolsters its offerings with a team of Advanced Clinical Practitioners (ACPs) who support its operations and medical experts with their extensive knowledge and experience
- Its scale of operations and seasoned therapeutic expertise in serving pharmaceuticals, biotech, and medical device enterprises allow it to address diverse client needs

Limitations

- It has a limited range of offerings within high-growth segments such as MLR review, KOL engagement, and MSL support
- The service provider has limited offerings in labeling and artwork services, which may not fully meet the growing needs of enterprises seeking robust solutions in this area
- Its technology offerings for regulatory and medical affairs are not mature enough to attract enterprises looking for comprehensive digitization solutions
- Its client base primarily consists of small enterprises with limited penetration in midsize to large enterprises

Navitas Life Sciences

Everest Group assessment – Major Contender

Market impact				Vision and capability				
Market adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Scope of services offered	Innovation and investments	Delivery footprint	Overall
								

Strengths

- Navitas' regulatoryREADY suite of technology offers targeted solutions such as rimREADY (regulatory information data management), labelREADY (labeling management, and idmpREADY (IDMP management)
- Its strong focus on building advanced technology capabilities such as AI/ML is further amplified by strategic partnerships, such as the integration of Navitas' regulatoryREADY suite with Glemser Technologies' ComplianceAuthor suite
- Navitas' robust regulatory network community includes tailored forums empowering life sciences professionals to address sector-specific regulatory hurdles, share insights, and stay updated on the latest niche developments

Limitations

- Enterprises looking for a one-stop shop in outsourcing medical affairs operations might find its breath of offerings less attractive due to limited medical affairs capabilities
- Its client portfolio is skewed toward midsize to large biopharmaceuticals, with limited penetration in the small as well as medical devices buyer category

PPD

Everest Group assessment – Major Contender

Market impact				Vision and capability				
Market adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Scope of services offered	Innovation and investments	Delivery footprint	Overall
◔	◔	◑	◕	◔	◑	◑	◔	◕

Strengths

- PPD offers deep domain expertise in regulatory affairs with its team consisting of regulatory affairs leads, country managers, CMC specialists, and publishing specialists with extensive experience across the pharmaceutical and medical device industries
- It leverages technological solutions (both in-house and partnerships) such as RegView intelligence platform, Veeva Vault regulatory information management system, and a dedicated publishing solution to augment its domain expertise
- Its prominent presence in China and Japan, supported by strong relationships with local regulatory bodies, might appeal to enterprises looking for APAC-based service providers

Limitations

- The company's current capabilities in automation, analytics, and design tools for labeling and artwork services are limited, an area experiencing increasing demand from enterprise clients
- It has limited penetration into the medical affairs market when compared to peers

ProPharma Group

Everest Group assessment – Major Contender

Market impact				Vision and capability				
Market adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Scope of services offered	Innovation and investments	Delivery footprint	Overall
								

Strengths

- The acquisition of OneSource Regulatory has significantly bolstered ProPharma Group’s regulatory and medical affairs portfolio, enabling it to provide comprehensive regulatory offerings across all product lifecycle stages
- ProPharma stands out for its extensive support in regulatory authority meetings, providing expert guidance, thorough preparation, and diligent post-meeting follow-up. Additionally, it specializes in local regulatory submissions
- Its team of specialized experts across various therapeutic areas and experience of serving diverse pharmaceutical, biotechnology, and medical device clients enable it to tailor solutions to each client's specific needs
- Referenced buyers have cited ProPharma’s domain expertise and proactiveness as its key strength areas

Limitations

- Compared to peers, it has limited penetration into medical affairs including segments such as KOL engagement and MSL support
- ProPharma has limited digital expertise and technological capabilities, thereby lagging behind peers in the ability to enhance process efficiency
- Clients pointed out the need for ProPharma to offer more cost-effective and innovative solutions

Syneos Health

Everest Group assessment – Major Contender

Low High

Market impact				Vision and capability				
Market adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Scope of services offered	Innovation and investments	Delivery footprint	Overall
								

Strengths

- Syneos Health provides a full spectrum of solutions spanning both regulatory and medical affairs, ensuring comprehensive support throughout the product life cycle. Its Global Regulatory Affairs Solution (GRAS) harnesses technology to deliver tailored offerings for a diverse set of clients
- With a strong focus on upskilling its talent pool, it offers comprehensive training programs for its global MSLs and clinical educators along with MyCourse Medical Affairs, Syneos Heath's learning and development program focused on training medical affairs professionals
- Its optimum onshore-offshore delivery mix is bolstered by its broad therapeutic area knowledge and CoE-led approach

Limitations

- Its technology portfolio in the regulatory and medical affairs domain is not as strong as that of peers to lure enterprises looking to digitize their operations
- While it has a strong foothold in the biopharma segment, it has relatively limited penetration in the medical device client segment

Tech Mahindra

Everest Group assessment – Major Contender

Market impact				Vision and capability				
Market adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Scope of services offered	Innovation and investments	Delivery footprint	Overall
								

Strengths

- Within its regulatory portfolio, Tech Mahindra specializes in providing labeling and artwork services, boasting a dedicated artwork studio. Its recent acquisition of Perigord Life Sciences further strengthens its offerings with an integrated platform and expanded service offerings
- Tech Mahindra has shown prowess in serving a diverse set of clients including small, midsize, and large biopharma and medical device clients
- It has expanded its market footprint by penetrating emerging markets such as Asia Pacific (APAC) and Middle East and Africa (MEA)

Limitations

- While it has robust labeling and artwork capabilities, it has a limited breadth of offerings in other segments such as CMC submissions
- While peers are proactively developing their own RIM platforms and medical authoring tools while investing in generative AI capabilities, Tech Mahindra's investment in these areas remains limited
- Compared to IT/BPO peers, Tech Mahindra has limited penetration in the North American market

Wipro

Everest Group assessment – Major Contender

Market impact				Vision and capability				
Market adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Scope of services offered	Innovation and investments	Delivery footprint	Overall
								

Strengths

- Wipro leverages its strong digital portfolio (IntelliDoc – regulatory submissions, NeuroSafe – regulatory support services, TaloSafe – content generation, artwork PLM tool) to offer a wide variety of capabilities including regulatory submissions, medical writing, labeling and artwork, and regulatory information management
- It continues to deepen its service offerings through strategic partnerships (Navitas Life Sciences – developing automation tools for regulatory services, Biomapas for local PV and regulatory responsible person, etc.)
- It has expanded beyond its strong foothold in North America and Europe to venture into the emerging markets of LATAM and APAC
- Its client portfolio comprises a balanced mix of biopharma and MedTech enterprises

Limitations

- While medical affairs engagement services such as MSL support and KOL engagement are experiencing high demand from enterprises, Wipro's capabilities in this space remain limited when compared to peers
- Wipro's client portfolio leans toward midsize to large enterprises with limited penetration in the small client segment

Enterprise sourcing considerations

Aspirants

- CliniRx
- ProTrials
- Quanticate

CliniRx

Everest Group assessment – Aspirant

Market impact				Vision and capability				
Market adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Scope of services offered	Innovation and investments	Delivery footprint	Overall
								

Strengths

- CliniRx is a specialized CRO focused on regulatory and medical affairs including pre-study document review, feasibility planning, site selection, protocol training, patient eligibility assessment, on-site medical monitoring, patient data medical review, coding, and safety management
- It provides both Functional Service Provider (FSP) and Full-Service Outsourcing (FSO) models
- Its experienced employee base consists of former health authority leaders and FDA members boosting their credentials in the medical affairs space

Limitations

- CliniRx is limited to biopharma clients and does not operate in the medical devices segment
- Compared to peers, it has limited centers worldwide thereby limiting its scale of operations
- Its breadth of services is limited to medical affairs and it does not offer a one-stop solution for regulatory functions
- CliniRx has made limited investments in technology compared to peers

ProTrials

Everest Group assessment – Aspirant

Low High

Market impact				Vision and capability				
Market adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Scope of services offered	Innovation and investments	Delivery footprint	Overall
								

Strengths

- ProTrials is a full-service CRO that specializes in providing regulatory writing review, tracking, and maintenance services
- Its diverse clientele including pharmaceuticals, biotech, and medical device enterprises demonstrates its prowess in serving multiple client needs

Limitations

- Enterprises looking for end-to-end support in outsourcing regulatory affairs will find its breadth of offerings limited
- While enterprises are looking for service providers for medical affairs support, its capabilities in this segment are limited
- Its technology-related investments are relatively on the lower side when compared to other peers in the market
- ProTrials' delivery mix is largely onshore-centric, while peers are rapidly expanding to offshore and nearshore locations to deliver cost-effective services

Quanticate

Everest Group assessment – Aspirant

Low High

Market impact				Vision and capability				
Market adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Scope of services offered	Innovation and investments	Delivery footprint	Overall
								

Strengths

- Quanticate is a global data-focused CRO that possesses strong capabilities in medical writing and regulatory submission management services across a variety of therapeutic areas
- It leverages technological solutions including CluePoints, SAS JMP, Medidata Edge, and its proprietary IQ visualization and collaboration portal, in combination with clinical data managers and biostatisticians to provide data quality oversight services, ensuring that the data submitted is as per the correct data standards

Limitations

- It has limited capabilities in the high-growth areas of MLR review and labeling and artwork services
- The company's limited foray into medical affairs engagement services hinders its ability to capitalize on a growing market opportunity, as enterprises actively seek service providers in this area
- Its client portfolio is primarily inclined toward pharmaceuticals, while the medical devices space remains relatively untapped

Appendix

Glossary

Research calendar

Glossary of key terms used in this report

AI	Artificial Intelligence is the simulation of human intelligence and decision-making capabilities by machines
Buyer	The company/entity that purchases outsourcing services from a provider of such services
CMC	Chemistry, Manufacturing, and Controls encompasses the scientific and technical details of a drug's composition, production, and quality control, ensuring safety, efficacy, and consistency for regulatory approval
CoE	A Center of Excellence refers to a team that provides support on a particular focus area
CRO	A Contact Research Organization is a company that provides research and development services to firms in the life sciences industry
EMA	The European Medicines Agency is the European Union's central authority responsible for authorizing and supervising medicines to ensure they are safe, effective, and of high quality
FDA	The Food and Drug Administration is the United States' regulatory agency responsible for safeguarding public health through the control and supervision of food, drugs, medical devices, and other related products
FTEs	Full-time Employees on the rolls of the company
KOL	Key Opinion Leaders are influential experts, typically healthcare professionals (doctors, researchers, etc.) or patient advocates, who possess deep knowledge and experience in a specific therapeutic area or regulatory process
MSL	Medical Science Liaisons are specialized professionals who act as intermediaries between pharmaceutical companies and healthcare providers, offering expertise on clinical data and scientific information
NLP	Natural Language Processing is a field of AI that helps computers understand and process human language
RIM	Regulatory Information Management is a software solution that centralizes, streamlines, and tracks all the regulatory data and processes needed to bring products to market in regulated industries

Research calendar

Life Sciences Business Process

Published Current release Planned

Reports title	Release date
Navigating Economic, Geopolitical, and Regulatory Uncertainty in the Life Sciences Industry	April 2023
Life Sciences Sales and Marketing Operations – Provider Compendium 2023	June 2023
Life Sciences Operations PEAK Matrix® Assessment 2023	September 2023
Adapting Commercial Models for Success in the Life Sciences Industry	October 2023
MedTech Operations PEAK Matrix® Assessment 2023	November 2023
Life Sciences Operations – Provider Compendium 2024	February 2024
MedTech Operations – Provider Compendium 2024	March 2024
Life Sciences Enterprise Sourcing Considerations	May 2024
Regulatory and Medical Affairs Operations PEAK Matrix® Assessment 2024	June 2024
Patient Recruitment Services – Market Report 2024	June 2024
Generative AI in Life Sciences: Moving from Ideas to Operationalization	July 2024
Data and Analytics in Life Sciences Commercial PEAK Matrix® Assessment 2024	September 2024
Pharmacovigilance Operations PEAK Matrix® Assessment 2024	November 2024
Pharmacovigilance: State of the Market	December 2024
Pharmacovigilance Operations Provider Compendium 2024	December 2024

Note: Click to see a list of all of our published Life Sciences Business Process reports

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