

Global Landscape of GLP Tox Outsourcing

A booming frontier for CROs

September 2024

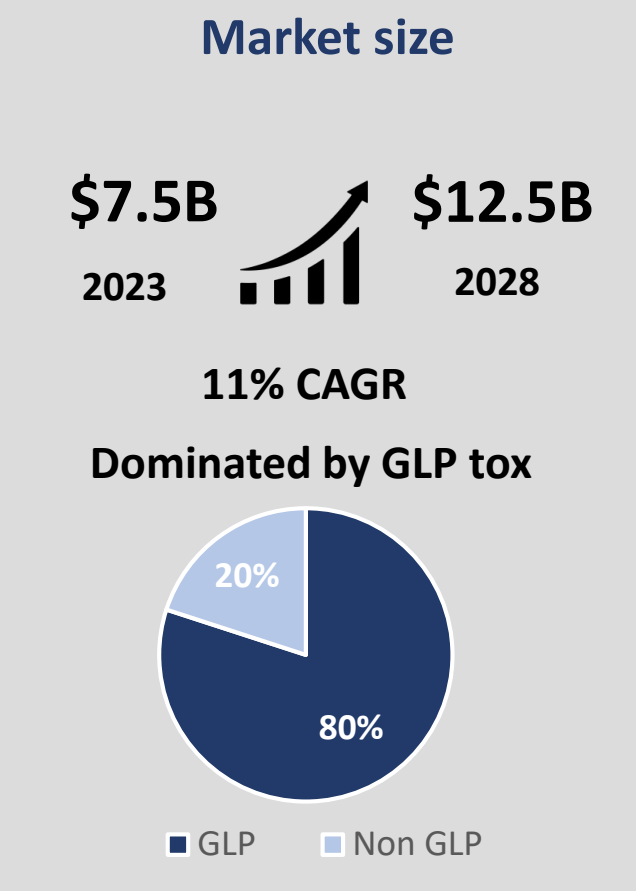


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- GLP toxicity (tox) CRO industry growth is fueled by increasing R&D pipeline, pharma outsourcing, and the rise in complex therapies
- While most CROs are adept at managing small and large molecules, fewer than <10% possess the specialized expertise needed for the complex modalities like as cell/gene therapies
- Consolidation of the Tox CRO space to offer diversify specialized services (like organ specific/advanced bioanalytical testing), adopt disease-specific models, and expand their tox infrastructure
- CROs moving towards a 'one-stop shops' offering comprehensive preclinical drug testing solutions
- MP, with over three decades of experience in the Biopharma space and deep understanding of the global CRO landscape can help catalyze your growth initiatives

Globally expanding R&D and outsourcing activity are fueling the growth of Tox outsourcing

Tox CRO industry is evolving to meet the needs of increased R&D activity, emerging drug modalities and complex targets



Increased R&D activity

- R&D pipeline doubled in 2024 from last 10 years
- ~12,000 assets in the 2024 preclinical pipeline

Rise in complex therapies

- Number of complex modalities in preclinical stage are increasing

ADCs	Oligonucleotide	Peptides	Cell therapies	Gene therapies
~300	~450	~650	~1500	~1200

Demand for specialized offerings

- Service providers are bolstering their offerings in complex therapies, leveraging expertise in specialized tox, differentiated animal models, and advanced bioanalytical skills

Regulatory compliance and tox expertise

- Pharma companies often outsource GLP compliant animal tox studies due to the associated cost and complexity
- ~75% of biopharma outsource their tox testing

ADC - antibody drug conjugates; Source: Secondary research, MP analysis

GLP-Tox CRO market overview

~200 GLP-tox CROs can be segmented by geographic distribution, modalities, or specialized tox offerings



By geography

US dominates the market due to strong IP protection laws, a robust regulatory framework, and cutting-edge technology and infrastructure

Distribution of CROs

US	80%	Canada	2%
China	5%	EU	5%
India	3%	Others	5%



By modality

Most of the CROs cater to GLP tox studies for small or large molecules like mAbs, but only a few cater to Cell & Gene Therapies (CGT) owing to their complex nature

- <10% of CROs cater to CGTs
- All CGT CROs are US-based



By tox offerings

While general tox remains the core expertise of CROs, various companies are standing out by offering specialized tox*






% of CROs offering specialized tox

DART	50-60%		
Ocular tox	20-30%		
Oto tox	<1%		

DART: development and reproductive tox; specialized tox includes any organ specific toxicity like reproductive, juvenile, neuro, ear, eye, genetic etc. Source: Secondary research, MP analysis

CROs are differentiating themselves to stay competitive


















CROs are diversifying their capabilities to offer comprehensive drug development solutions

Trend	Rationale
Expanding into specialized tox	 <ul style="list-style-type: none">• CROs are diversifying beyond core tox services to provide specialized tox such as DART, genotox, juvenile tox, and neurotox testing, meeting the demand for targeted organ safety assessments
Differentiated animal models	 <ul style="list-style-type: none">• CROs are incorporating specialized in vivo models to cater to the need for highly pharmacologically relevant animal models in challenging therapeutic areas like oncology, neurology or rare diseases
One-stop-shop for preclinical testing	 <ul style="list-style-type: none">• Preclinical CROs are adding GLP tox services to become single points of contact from discovery to preclinical development
Bioanalytical (BA) services	 <ul style="list-style-type: none">• Handling complex biologics (like CGTs or peptides) demands expertise in advanced bioanalytical techniques such as FACS, in vivo imaging, LC-MS, q-PCR, etc.• Tailor-made bioanalytical services enable Tox CROs to adapt to evolving industry demands
Expanding infrastructure /geographic presence	 <ul style="list-style-type: none">• CROs are expanding their tox testing facilities to meet demand

Source: Secondary research, MP analysis

CROs are unlocking values through strategic initiatives (1/2)



















Over the last 5 years, CROs have bolstered their offerings by adding specialized tox, differentiated animal models, and GLP-tox services

Focus area	Company	Size	HQ	Target	Size	HQ	Rationale
Specialized tox	 GBA GROUP	2500	Germany	 ICCR ROBDORF	100	Germany	Acquisition, 2023: Adds genetic tox
	 FRONTAGE	1800	US	 Experimur	60	US	Acquisition, 2022: Adds DART and carcinogenicity services
	 inotiv	2000	US	 BioReliance	-	Germany	Acquisition, 2021: Adds genetic tox
	 inotiv	2000	US	 SMITHERS AVANZA	65	US	Acquisition, 2019: Adds expertise in DART
Differentiated animal models	 scantox	300	Denmark	 QPS	80	Austria	Acquisition, 2023: Adds transgenic in-vivo models in neurology
	 ERBC	350	France	 oncologyfactory	<50	France	Acquisition, 2023: Adds specialized in vivo testing for oncology
	 inotiv	2000	US	 ENVIGO	1200	US	Acquisition, 2021: Adds genetically engineered models
One-stop-shop	 HLB bioStep	180	Korea	 CROEN	-	Korea	Acquisition, 2024: Adds GLP tox services
	 aragen	4500	India	 intox	80	India	Acquisition, 2021: Adds GLP safety assessment capabilities
	 GD Genesis	250	US	 COMPARATIVE BIOSCIENCES INC.	25	US	Acquisition, 2020: Adds GLP tox and safety pharmacology

Source: Secondary research, MP analysis

CROs are unlocking values through strategic initiatives (2/2)

Some of consolidations by CROs have been aimed towards adding bioanalytical services or expanding geographic footprint

Focus area	Company	Size	HQ	Target	Size	HQ	Rationale
BA services	 scantox	300	Denmark		10	Sweden	Acquisition, 2023: Strengthens BA vertical
	 inotiv	2000	US		10	US	Acquisition, 2022: Adds high-tech BA capabilities
	 FRONTAGE	1800	US		25	US	Acquisition, 2021: Adds high-quality BA services
		250	US		<50	US	Acquisition, 2021: Adds GLP-BA
Infrastructure /geographic presence	 FRONTAGE	1800	US		100	Italy	Acquisition, 2024: Adds BA services in EU
	 FRONTAGE	1800	US		180	Canada	Acquisition, 2023: Strengthens GLP tox services in Canada
		70	UK	-	-	-	2023: Expanded GLP tox facility
		1500	US		-	US	Acquisition, 2022: Adds GLP tox facility in Midwest US
		100	Australia	-	-	-	2022: Expanded in in-vivo testing facility
		150	US		15	Germany	Acquisition, 2020: Adds GLP tox footprint in EU

Source: Secondary research, MP analysis

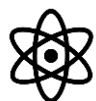
Future outlook of the tox industry

GLP tox market is poised for significant growth in the next five years



One-stop solution

- With the rise of complex therapies, CROs with genetically modified/disease animal models, are likely to become central to the industry's focus
- Major industry players will continue to consolidate to address any gaps in their offerings
- Partnerships between discovery startups and GLP tox services are poised to surge in the next five years



Complex therapies

- CROs with prior experience and handling expertise in advanced therapies like CGTs, mRNA are poised for growth in the future
- Regulatory guidelines are likely to evolve over the next few years to define individualized CGT or nucleic acid product development



Geographic consideration

- Due to the complexities of advanced therapies, having a geographically proximate partner offers a strategic advantage by mitigating logistics challenges



Bioanalytical assays as vital adjunct

- Demand for advanced bioanalytical skills will rise with the shift to complex therapies, prompting CROs to expand capabilities through strategic initiative



Alternative approaches

- Companies reliance on in silico and in vitro methods to refine animal testing is likely to grow, aiming to cut costs and speed up Go/No-go decision making
 - Charles River recently partnered with Deciphex to add digital toxicologic pathology

Source: MP analysis

How MP Group can help?

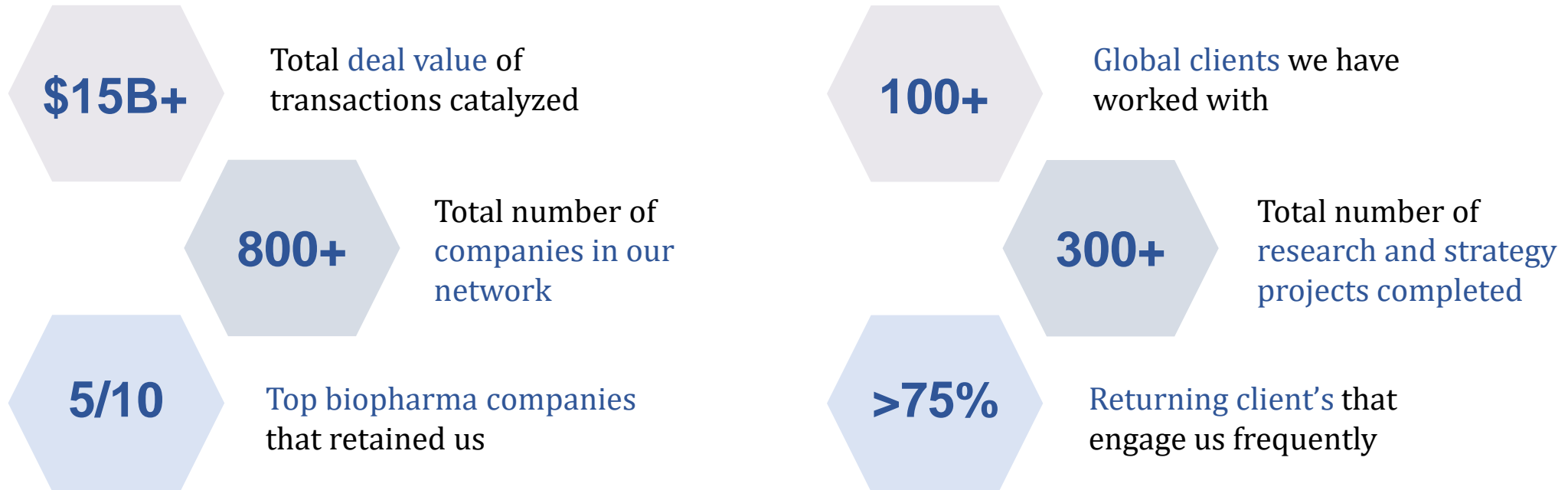
With 35 years of global biopharma expertise and a profound understanding of the outsourced services sector, the MP team is ready to catalyze your global expansion journey

MP Team will be happy to be an extension of the management team and support the following:

- Catalyze the growth and expansion strategy of your organization for long-term success
- Provide comprehensive and customized landscaping to identify specific potential opportunities
- Leverage MP's global network to uncover below-the-radar opportunities for partnering or investment that align with your company's vision
- Support due diligence efforts for targets being considered for investment or acquisition

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Select projects in the CRO space

Drug Discovery	Biologics Discovery	Bioinformatics	Cell/Gene Tx
Joint Venture (buy-side) Takeda partnership with Advinus	Acquisition (buy-side) GVK Bio acquires Aragen	Acquisition (buy-side) Excelra acquires BISC Global	Techno-Commercial Due Diligence for One of largest investor groups in India
\$45m	Undisclosed	Undisclosed	NA
2012	2014	2023	2024

Deep understanding of the landscape and markets translated into reports (hyperlinked):



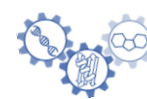
[An Outlook on Specialized Chemistry Outsourcing](#)



[CROs for the new-age biopharma](#)



[Trends in Bio-IT Outsourcing Industry](#)



[Next generation CROs - Differentiated technologies today that will pay-off tomorrow](#)

THANK YOU.

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