Focus on End-to-end Innovation and Efficiency Drives Life Sciences Service Provider Consolidation

The world has changed in Life Sciences and innovation and efficiency have become key to survival. Pharma manufacturers and marketing authorisation holders in the Life Sciences sector are under relentless pressure to adapt to changing strategic priorities against a backdrop of globalisation and increasing regulatory complexity across the whole value chain. Xavier Duburcq, Chairman & CEO of ProductLife Group, and Denis Gross, CSO, highlight the impact this is having on regulatory service companies as they, too, race to reinvent themselves to help their pharma and medtech clients navigate increasing regulatory complexity.

In Life Sciences, the world order has changed forever now, as the golden years of traditional small-molecule drugs draw to a close and the expiry of associated patents renews the call for innovation. All of the momentum now, even among regulators and pricing and reimbursement authorities, is towards promoting new technologies and therapies that address unmet needs; biologics; health-tech and medical technology (medtech). Traditional pharma companies, which up to now have led on their legacy products, must now focus their strategies and resources on high-expertise, high-value activities, and infuse their more routine operational activities with new economies and efficiencies.

From the surge in global drug consumption and increased research and development (R&D) activity, with greater clinical trial complexity, to continuously evolving regulatory requirements globally, and a growing need for global transparency and standardisation, the Life Sciences industry is under enormous pressure to reinvent itself. This is not least as pharmaceutical companies start to develop more complex products and deliver in more countries, in an era that is seeing growing regulatory complexity across the whole value chain – from pre-clinical to commercialisation stages.

Shift to Global Partners

All of this is having an impact on the Life Sciences service provider market, which must now support pharma, biotech and medical device companies with a different blend of services and delivery models. Large pharma companies, under new price and profit pressure, must find new ways to source the support they need at lower cost, while innovative startups need specific expertise without necessarily having the budget for tailored solutions. That required support could extend from an early development phase right through to post-launch lifecycle maintenance, with differing priorities across that spectrum.

Where large pharma companies once favoured local boutique services to fulfil specific requirements, these companies are now looking for global partners that can combine the right blend of specialist expertise with international capability and right-shoring options to keep pricing competitive, where the kind of support required is more routine and/or more readily industrialised/automated. Realising they cannot fulfil that spectrum of needs, many boutique service providers are joining forces with or being subsumed into international consultancies and regulatory/compliance providers, to become a vital part of a wider offering that can be managed end to end for the client.

Agility is Key

So what is it that Life Sciences companies are looking for in the 2020s?

Strategically, traditional players are branching out into biotech and more personalised patient treatments, where demand and future profitability will be concentrated. Other priorities include becoming more agile and responsive to global market opportunities (including improved speed to market), enhancing patient safety, and eliminating supply chain delays and product shortages.

All of these evolving scenarios require an evolving blend of service-based support, because of the difficulties of meeting these diverse needs internally, and because of the impact on agility if manufacturers and MAHs try to spread themselves too thinly by trying to control everything themselves.

Ideally, they want to source everything from one supplier – but knowing that they will have access to the right blend of expertise, experience and capacity, with the right geographical coverage, and an optimised delivery model according to the type of service/stage of the product lifecycle.

Broadening Regulatory and Quality Related Support

At the product development/pre-marketing authorisation stage, the emphasis for regulatory and quality related support is relevant expertise (e.g. in the context of biotech/medtech) via world-class experts in the target countries, and the promise of reduced time to market. Requirements are likely to span pure regulatory support to more strategic advice around building optimal development plans, from clinical and non-clinical strategy (including early market access considerations to best position the product in terms of indication and target patient population) to actual pharmaceutical development/CMC activity (via the optimal pathway for both the active substance and the finished product), and full consideration of all aspects of quality assurance across the supply chain.

At a post approval lifecycle maintenance level, meanwhile, the requirement is for an end-to-end service delivered with maximum efficiency and at a competitive price. A global capability with the flexibility to draw on 'right-shore' resources as appropriate, along with technology to automate routine, labour-intensive work (e.g. use of AI in some activities), becomes important here, to deliver the right support cost-efficiently.

Service Provider Consolidation

Over the next five years we can expect to see service provider consolidation continue, as manufacturer and marketing authorisation holder requirements grow and as the broadening impact of new development technologies and process digitalisation become more embedded. Merger and acquisition activity is expected to continue across the broader life sciences industry, as buyers compete for innovative assets. PwC expects that as major

pharma companies look for merger and acquisition opportunities to achieve their growth plans, midsize biotech companies that can fill in pipeline gaps in the back half of the decade will receive significant attention throughout the rest of this year.

"While macroeconomic conditions may remain challenging in 2023, a resetting of valuations and the need for health industries companies to innovate and transform their businesses to achieve their growth goals and stay ahead of competitors will create a compelling case for M&A." says Christian Moldt, Global Health Industries Deals Leader, Partner, PwC Germany.

PwC also notes: "However, only a limited number of truly innovative assets are available, and valuations and competition for these businesses will remain high. We expect more small to midrange deals and the formation of joint ventures, rather than takeovers of larger companies, to continue to dominate M&A activity."

There is no doubt that the Life Sciences service provider community is rising to the challenge of providing the support that both traditional pharma and younger biotech and medtech companies need. There are a number of routes to achieving this – including easing supply chain issues and focusing on patient outcomes and value creation. Reinvention of services, provider consolidation and new models of service delivery will continue to be major trends into the mid-2020s. Agility will be key to service providers adapting to new market realities, surviving and flourishing. Service providers who fail to rise to the challenge may find themselves targets for takeover.

Just some of the recent consolidation activity in Life Sciences – in the industry itself and among the service provider community

Industry tie-ups

- Germany-based Ariceum's purchase of British biotech Theragnostics, for THG-008, a radio-labelled, cancer-imaging PARP inhibitor currently in a phase 1 trial at Memorial Sloan Kettering Hospital in New York; as well as the FDA-approved Nephroscan, used to identify kidney disorders; and a Ga-68 kit technology IP currently licensed to Novartis.

- Ironwood's purchase of VectivBio, for rights to phase 3 drug apraglutide, currently in development to treat short bowel syndrome with intestinal failure.
- Oncology company Biodexa's planned purchase of Varian Biopharmaceuticals, a private U.S. precision oncology company, targeting three rare brain cancers.
- GSK's acquisition of Bellus Health for its phase 3 chronic cough treatment, camlipixant, a rival to Merck's anticipated gefapixant.
- Sun Pharma's acquisition of Concert Pharmaceuticals for the latter's JAK inhibitor/alopecia treatment.
- Leap Therapeutics' acquisition of Flame Biosciences for the latter's clinical-stage anti-Claudine18.2 antibody, FL-301, and two pre-clinical candidates, targeting cancers.
- The merger of hC Bioscience and 4SR Biosciences, towards identifying a preliminary tRNA-based therapy, based on 4SR's sequencing technology. (The acquisition of 4SR comes just more than a year after the company launched.)
- Elicio Therpeutics' merger with Angion Biomedica. Cancer-focused Elicio expects to launch a phase 1–2 trial of its cancer vaccine therapy in the coming months.

PriceWaterhouseCoopers (PwC) predicts buoyant M&A activity in expected areas for future pharma/biotech growth throughout 2023, with a particular focus on oncology and immunology, as well as treatments linked to central nervous system and cardiovascular diseases, plus vaccines, as the market continues to place a premium on therapeutic area leadership.

Examples of recent Life Sciences service providers consolidation

- Healthcare company AmerisourceBergen's acquisition of PharmaLex
- A raft of strategic acquisitions by ProductLife Group, including DS InPharmatics (DSI), Zwiers Regulatory Consultancy in 2022, then Cilatus and Pharma D&S Group in 2023, to build a comprehensive, fully integrated set of global biopharmaceutical development and regulatory consulting activities.
- ProPharma Group's acquisition of OneSource Regulatory to boost its regulatory consultancy services.

Despite global macroeconomic challenges, PwC has seen companies with capital flexibility become more willing to deploy the resources needed to acquire assets with significant upside potential. PwC expects the pharma services sector to see continued healthy consolidation activity throughout 2023, as achieving scale becomes critical in the various subsectors – from differentiated contract development management organisations (CDMOs) to contract research organisations (CROs).

Xavier Duburcq

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Denis Gross

Denis Gross is a global R&D leader and regulatory affairs expert with over 30 years of experience in Life Sciences. He has a proven track record of successful medical solutions development, and worldwide regulatory approvals. Denis joined ProductLife Group in September 2018, initially implementing the group's business development strategy, managing the global delivery operations for Regulatory Affairs, Pharmacovigilance & Safety, and Quality Compliance businesses. In 2022, he became Chief Solutions Officer, with global oversight of all services and competencies offered by ProductLife Group.