

Benchmarking Measures for Scottish Pharma Services

Biosafety Testing

Biosafety Testing Types of Services

Biopharmaceutical Services (Biosafety Testing)

- Cell Line Characterization
- Virus Bank Characterization
- Raw Material Testing
- Immunoassay & Cell Based Assay Services
- Bulk Lot Release Testing
- Final Product Release Testing
- Viral Clearance Studies

Process

- Identification of players within the European Pharma Biosafety Landscape
- Sourcing of financial data associated with each organisation, in cases where results are to 2019 only, actual values have been inputted. These will be updated when 2020 data is available.
- Financial data sources included: Bundesanzeiger Verlagsgesellschaft mbH, Euronext Paris, Infogreffe, Orbus, UK Companies House and SEC 10K reports
- All value quoted in UK£, (exchange rates applied; \$:£ = 0.75; €:£ = 0.85)
- Assumption based modelling to estimate market share based on market experience in the sector

European Pharma Biosafety Landscape

Player	Commentary
BioReliance (BRL)	BRL entered the European market in 2000 via acquisition of Q-One Biotech, BRL now part of Merck Kgaa, acknowledged Market Leader in Europe
Sartorius Stedim BioOutsource Ltd	Founded in 2007 by a team which included ex Q-One Biotech personnel, acquired by Sartorius Stedim
SGS United Kingdom Ltd	Also founded in 2007 by a team which included ex Q-One Biotech personnel, acquired by SGS originally known as Vitrology
Charles River Laboratories	Although CRL has a base in Trarant, most of its Biosafety services are carried out in Ekrath/Cologne and in the Newlab Bioquality sites acquired in 2008
Covance	One of the largest CROs globally, Biosafety work is conducted in Harrogate
Virusure	Founded in 2005, based in Vienna & Singapore, CEO ex Q-One Biotech. Acquired by Asahi Kasei Medical in Oct 2019.
Eurofins/Sinensis	Acquired by Eurofins in Jan 2016, Netherlands based Sinensis had been steadily growing in the area of viral biosafety testing. The organisation is now known as Eurofins Biopharma Safety Testing NL
Clean Cells	Established in 2000, based in Boufféré, France. Largely focussed on France but are initiating expansion into UK and US.
TexCell	Texcell, a spin-off of the Pasteur Institute founded in 1987, providing viral safety (manufacturing process) and Immunology (during clinical trials) services for pharmaceutical industries
Vironova	Spinout founded in 2005 from the Karolinska Institute in Sweden

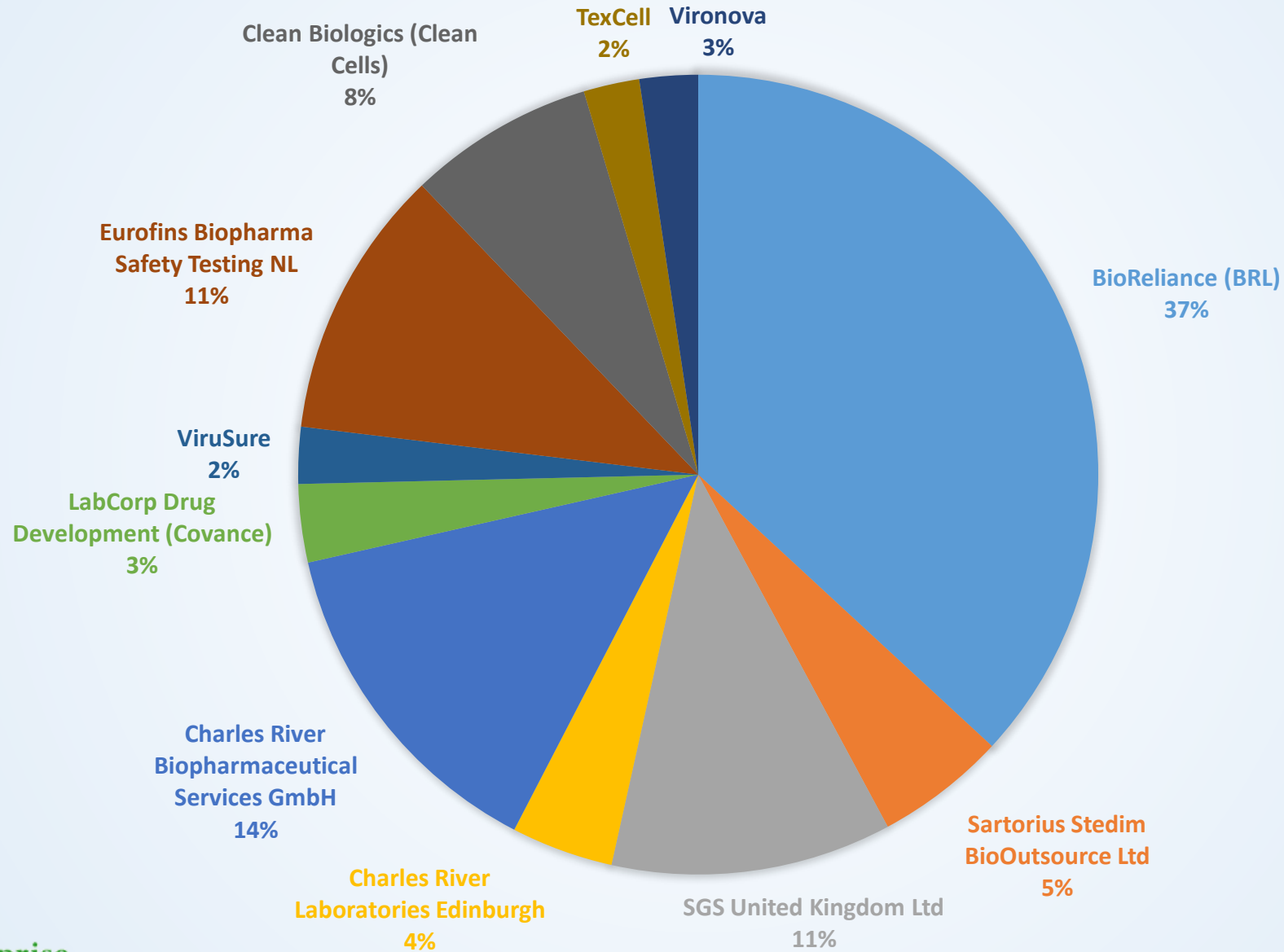
Financials

Player	Commentary
BioReliance (BRL)	In 2020, recorded turnover of £104.8M (19.5% Growth) broken down as follows: North America (£20.0M, 8.7% Growth); Europe (£55.8M, 18.2% Growth) , Asia Pacific (£27.8M, 29.6% Growth), Middle East and Africa (£1.2M, 76.2% Growth),
Sartorius Stedim BioOutsource	In 2020, recorded turnover of £11.96M (47.7% growth) broken down as follows: UK (£1.27M, 40.3% growth); EU (£6.61M, 71.5% growth); North America (£2.04M, 41% growth); Rest of World (£2.04M, growth 8%).
SGS United Kingdom Ltd	In 2020, recorded turnover of £20.48M (60.6% Growth) broken down as follows: UK (£6.37M, 270% Growth); Rest of the World (£14.12M, 127.9% growth). The analysis assumes sales to Europe are 75% of the rest of the world.
Charles River Labs	In 2020, posted revenue of £98.74M (13.7 % Growth) for the Trannent site, and £20.74M for Cologne (-11.6% Growth) in 2019. We have assumed a small portion of 5% for Trannent activities and 80% for Ekrath/Cologne.
LabCorp Drug Development (Covance)	Biosafety work is conducted in Harrogate as a small part of many activities in the site. In 2019 posted revenue of £126M (0.63% Growth), 66% was associated with Europe. Covance rebranded to LabCorp Drug Development in Dec 2020.
Virusure	In 2019, recorded turnover of £3.43M (43.1% Growth), 100% Europe
Eurofins Biopharma Safety Testing NL	In 2020, recorded turnover of £32.75M (31.1% Growth), 100% Europe
Clean Biologics (Clean Cells)	In 2020, recorded turnover of £11.25M, (28.3% Growth), 100% Europe
TexCell	In 2020, recorded turnover of £6.75M (18.5% Growth), 100% Europe
Vironova	In 2020, recorded turnover of £3.53M (24.2% Growth), 100% Europe

2020 Market Share Model

Organisation	European Revenue (Total)	Estimated Portion of European Revenue associated with Biosafety Services	Europe (Market Share Model)	Europe (Market Share Model %)	Scottish Market Share
BioReliance (BRL)	£55,167,000	80%	£44,133,600	37%	58%
Sartorius Stedim BioOutsource Ltd	£7,878,375	80%	£6,302,700	5%	
SGS United Kingdom Ltd	£16,960,000	80%	£13,568,000	11%	
Charles River Laboratories Edinburgh	£98,738,000	5%	£4,936,900	4%	
Charles River Biopharmaceutical Services GmbH	£20,736,123	80%	£16,588,898	14%	
LabCorp Drug Development (Covance)	£75,600,000	5%	£3,780,000	3%	
Virusure	£3,429,355	80%	£2,743,484	2%	
Eurofins Biopharma Safety Testing NL	£32,750,000	40%	£13,100,000	11%	
Clean Biologics (Clean Cells)	£11,250,000	80%	£9,000,000	8%	
TexCell	£6,750,000	40%	£2,700,000	2%	
Vironova	£3,530,651	80%	£2,824,521	2%	
Totals	£332,789,504		£119,678,103		

2020 Market Share Model



Brexit effect

- No issues have been reported in the financial accounts of Scottish based organisations with regards to Brexit.
- The BioReliance Strategic review which is included in their annual report submission on the 31st of December 2020 states the following:

‘Being outside the EU currently have no impact on our ability to trade freely. Even though Biopharma products produced of the EU are subject to safety testing taking place within the EU also, the company wasn’t affected by any negative impact on the growth of sales’

European Pharma Biosafety Recent Announcements

Player	Recent Announcements
BioReliance (BRL)	In Sept 2020, announced the expansion of their biosafety testing laboratory services, including the viral clearance offering, in Singapore. This increased viral capacity at the Singapore lab is 50% which is intended to meet demand from biopharmaceutical, cell and gene therapy developers and manufacturers in Asia-Pacific.
Sartorius Stedim BioOutsource Ltd	No recent announcements, however currently recruiting 24 personnel for the Glasgow site.
SGS United Kingdom Ltd	In May 2019, announced the official opening of the Biologics, Viral Vaccine, Gene and Cell Therapy Testing facility expansion in Glasgow.
Charles River Laboratories	In Jan 2019, announced expanded biologics operations and facility square footage in Tranent. In Feb 2021, announced the expansion of Viral Clearance facilities and capabilities in Cologne.
Covance	No recent announcements on Biosafety testing
Virusure	No recent announcements on Biosafety testing
Eurofins Biopharma Safety Testing	No recent announcements on Biosafety testing
Clean Cells	In Sept 2021, announced a new facility which will quadruple analysis capacity
TexCell	No recent announcements on Biosafety testing
Vironova	No recent announcements on Biosafety testing

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Match to Brief

Brief requirements, commentary and results

Client Needs/Scope of Services	Commentary
<p>Analysis of the bio-safety testing landscape to identify key Scottish and European companies providing this service to pharma/biotech customers (including any new entrants into the field from 2017)</p>	<p>Data to 2020 was found for the majority of companies, no new entrants identified.</p>
<p>Based on the updated landscape analysis, recalculate the 2017 estimation of the following measure:</p> <ul style="list-style-type: none">• Scottish based organisations hold dominant market positions in the provision of Biosafety Testing within Europe (53%)• To allow a direct comparison between the assessment in 2017, it is anticipated that the same methodology as used previously will be applied.	<p>The exact same method was applied, the share has increased to 58%. Furthermore strong double digit growth was noted for BioReliance (BRL), Sartorius Stedim BioOutsource and SGS United Kingdom Ltd</p>
<p>If there has been a change in the value, provide additional detail on where the market share has moved to and any likely drivers behind this (eg EU-transition, price sensitivity, investment in key European sites by competitors)?</p>	<p>No issues noted with regards to Brexit or revenue loss due to competition. Investment was noted in Germany (Charles River) and France (Clean Cells).</p>

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Marketing Messages (SDI)

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‘Scottish based organisations hold dominant market positions in the provision of Biosafety Testing (58%)’